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Navilyst Medical

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February 12, 2015

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (W066-0609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: BioFlo Midline Catheter Abbreviated 510(k) Premarket Notification

Dear Sir/Madam:

In accordance to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR §807 Subpart E, Navilyst Medical, Inc. (NMI) hereby submits three copies (one original copy and two eCopies) of this Special 510(k) Premarket Notification for the proposed BioFlo Midline Catheter. Please note: both eCopies provided are identical to the paper copy.

The purpose of this Abbreviated 510(k) is to introduce into commercial distribution the option of a BioFlo Midline Catheter. The catheter shaft of the proposed device will employ the same BioFlo Endexo material currently used on a variety of cleared NMI devices (including PICCs, ports, and dialysis catheters). The BioFlo Endexo material is a polymer incorporated into the catheter shaft that reduces thrombus accumulation throughout the catheter shaft. The primary predicate for the proposed BioFlo Midline catheter is CR Bard's Poly Midline Catheter (**K001901**). The proposed device is a Class II device per 21 CFR 880.5200, ProCode: FOZ.

The Abbreviated 510(k) was selected based upon the conclusions of FDA's Guidance Document "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." The device is subject to FDA's device-specific guidance document "Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters."

There was no pre-submission correspondence (i.e. Pre-Submission Requests, emails or telephone calls, etc.) between Navilyst Medical, Inc. and the Agency related to this submission.

Navilyst Medical, Inc. considers its intent to manufacture this device for distribution under its own label to be confidential commercial information and exempt from public disclosure; and therefore, requests that FDA does not disclose the existence or content of this 510(k) submission, or this letter. If you have any questions regarding this submission please contact me directly at 508-658-7984, or Wanda M. Carpinella, Director of Global Regulatory Affairs, at 508-658-7929.

Sincerely,

Brandon M. Brackett
Specialist II, Global Regulatory Affairs
Navilyst Medical, Inc.
brandon.brackett@navilyst.com
Fax: 508-658-7984

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ABBREVIATED 510(K) PREMARKET NOTIFICATION

BIOFLO MIDLINE CATHETER

FEBRUARY 12, 2015

NAVILYST MEDICAL, INC.
26 FOREST STREET
MARLBOROUGH, MA 01752

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INTRODUCTORY INFORMATION/510(K) SCREENING CHECKLIST

Premarket Notification 510(k) Checklist for Acceptance Decision and Required Information

I. Critical Elements

The proposed BioFlo Midline Catheter, as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act, as Amended (the Act), is not exempt from the 510(k) requirements, by regulation or by policy, and is subject to review by CDRH.

a. Has the device been the subject of a previous NSE decision? Yes ☐ No ☒

II. Required Information (under Sections 510(k), 513(f), and 512(i) of the Act, and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations)

a.	Device Trade or Proprietary Name:	BioFlo Midline Catheter
b.	Device Common Usual Name, or Classification:	Catheter, Intravascular, Therapeutic, Short-Term, Less Than 30 Days.
c.	Establishment Registration Number: Owner/Operator Number:	3006716497 10024617
d.	Class Into Which the Device is Classified (21 CFR Parts 862 to 892):	Class II; 21 CFR 880.5200 ProCode: FOZ
e.	Classification Panel:	General Hospital Device Panel
f.	Action taken to comply with Section 514 of the Act:	Navilyst Medical, Inc. is not aware of any specific performance standards addressing this device for compliance with Section 514 of The Act.
g.	Proposed labels, instructions for use: (which describes the device, its intended use, and directions for use):	**Section 13**
h.	510(k) Summary:	**Section 5**
i.	For Class III Devices only, a Class III Certification and a Class III Summary:	**Section 7**
j.	Photographs of the Device:	**Section 11**
k.	Engineering Drawings for the Device with Dimensions and Tolerances:	**Section 11**
l.	Marketed Device(s) to which Substantial Equivalence is claimed including Labeling and Description of Device:	**Section 12** and **13**
m.	Statement of Similarities and/or Differences from the Marketed Device(s):	**Section 12**
n.	Data to show consequences and effects of modified Device:	**Section 18**

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III. Additional Information that is Necessary under 21 CFR 807.87(h)

a.	Submitter's name and address:	Navilyst Medical, Inc. 26 Forest Street Marlborough, MA 01752
	Owner Operator Number:	10024617
b.	Contact Person(s), telephone, fax:	Brandon M. Brackett Specialist II, Global Regulatory Affairs Navilyst Medical, Inc. Phone: 508-658-7984 Email: brandon.brackett@navilyst.com OR Wanda M. Carpinella Director, Global Regulatory Affairs Navilyst Medical, Inc. Phone: 508-658-7929 Email: wanda.carpinella@navilyst.com
c.	Representative/Consultant, if applicable:	Not Applicable
d.	Table of Contents with Pagination:	Table of Contents
e.	Manufacturing Facility/Facilities Name and Address:	Navilyst Medical, Inc 10 Glens Falls Technical Park Glens Falls, NY 12801 USA
f.	Establishment Registration Number:	1317056
g.	Sterilization Site(s) Name and Address:	(b)(4)

III. Additional Information that may be Necessary under 21 CFR 807.87(h)

a.	Comparison table of the new device to the marketed device(s):	**Section 12**
b.	Action Taken to comply with voluntary standards:	**Section 9**
c.	Performance data: Marketed Device Bench Testing: Animal Testing: Clinical Testing: New Device Bench Testing: Animal Testing: Clinical Testing:	 **Section 18** Not Applicable Not Applicable **Section 18** Not Applicable Not Applicable
d.	Sterilization Information:	**Section 14**
e.	Software Information:	**Section 16** (Not Applicable to Device)
f.	Energy/Hardware Information:	**Section 17** (Not Applicable to Device)
g.	Is the device subject to an issue that has been addressed in a specific guide documents?	Yes; FDA's "Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters."

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Abbreviated 510(k) Screening Checklist

Based on CDRH "*Refuse to Accept Policy for 510(k)s – Guidance for Industry and Food and Drug Administration Staff*", December 31, 2012.

		Y	N/A	N
	Preliminary Questions			
1.	Is the product a device (per section 201(h) of the FD&S Act) or a combination product (per 21 CFR 3.2 (e)) with a device constituent part subject to review in a 510(k)?	X		
	Comment: Yes.			
2.	Is the application with the appropriate Center?	X		
	Comment: Yes.			
3.	If a Request for Designation (RFD) was a submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD# and confirm the following: a) Is the device or combination the same (e.g., design, formulation) as the predicate in the RFD submission? b) Are there indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?		X	
	Comment: Not Applicable.			
4.(1)	Is the device type eligible for a 510(k) submission?	X		
	Comment: Yes.			
4. (2)	Is there a pending PMA for the same device with the same indications for use?		X	
	Comment: Not Applicable.			
5.	If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?		X	
	Comment: Not Applicable.			
		Y	**N/A**	**N**
	Abbreviated 510(k) Criteria			
1.	Submission relies on a device-specific guidance document, other than a special controls guidance document, and a summary report is provided that:	X		
	a. Includes a description of adherence to the relevant guidance document to support substantial equivalence	X		
	b. Includes a description of how the guidance document was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations	X		
	Comment: A Summary report identifying compliance to the guidance document is provided in Section 9.			
2.	Submission relies on a special control(s), either in a device-specific regulation or special controls document, as defined in Section 513(a)(1)(B) of the FD&C Act, to demonstrate substantial equivalence and a summary report is provided that:		X	
	a. Includes a description of adherence to the special control(s) to support substantial equivalence			
	b. Includes a description of how the special control(s) was used to satisfy the requirements of 21 CFR 807.87 (e.g., data to support substantial equivalence) and lists any deviations			

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		Y	N/A	N
	Comment: Not Applicable.			
3.	Submission relies on device-specific standard(s) (See section 514(c)).	X		
	For each cited standard:			
	a. Submission includes: - the device specific conformity statement as specified in device-specific guidance document (e.g., latex condoms) or - a declaration for conformity to the device specific standard OR the items below for use of FDA-recognized consensus standards	X		
	i. An identification of the applicable FDA-recognized consensus standards (full citation including version number)	X		
	ii. An identification, for each consensus standard, of any adaptations of the standard for evaluation of the device under review (e.g., an identification of an alternative series of tests that were performed)	X		
	iii. An identification, for each consensus standard, of any items (e.g., normative requirements of the standard) applicable to your device	X		
	iv. A specification of any deviations from each applicable standard (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70))	X		
	v. A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification for the applicability of the test results in these areas of differences.	X		
	Comment: Declarations of Conformity and 510(k) Standards Data Report forms provided in Section 9.			
		Y	**N/A**	**N**
	Organizational Elements			
	a. Submission contains Table of Contents	X		
	b. Each section is labeled	X		
	c. All pages of the submission are numbered	X		
	d. Type of 510(k) is identified– traditional, abbreviated, or special	X		
	Comment: Type of 510(k) is Abbreviated (see Section 3).			

	Elements of a Complete Submission (21 CFR 807.87 unless otherwise indicated)			
A.	**Administrative**			
1.	All content used to support the submission is written in English	X		
	Comment: All contents in English.			
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or in 510(k) cover letter):	X		
	a. Device trade name or proprietary name	X		
	b. Device common name	X		
	c. Device class and panel or	X		

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		Y	N/A	N
	Classification regulation or Statement that device has not been classified with rationale for that conclusion			
	Comment: See Section 5.			
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also and 801.109)	X		
	Comment: See Section 4.			
4.	Submission contains 510(k) Summary or 510(k) Statement	X		
	a. Summary contains all elements per 21 CFR 807.92	X		
	b. Statement contains all elements per 21 CFR 807.93		X	
	Comment: See Section 5.			
5.	Submission contains signed Truthful and Accuracy Statement per 21 CFR 807.87(k)	X		
	Comment: See Section 6.			
6.	Submission contains signed Class III Summary and Certification		X	
	Comment: Not Applicable – Device is Class II.			
7.	Submission contains clinical data		X	
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each clinical study included in the submission.		X	
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.		X	
	Comment: Not Applicable			
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X		
	Comment: See Section 9.			
9.	The submission identifies related submissions for the same device which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X		
	a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.		X	
	Comment: See Section 2.			
B.	**Device Description**			
10.	a. If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the	X		

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		Y	N/A	N
	recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			
	Comment: See Section 10.			
11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:	X		
	a. A description of the principle of operation and mechanism of action for achieving the intended effect.	X		
	b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other interface compatible devices; and/or how the device interacts with the patient.	X		
	c. A list and description of each device for which clearance is requested.	X		
	Comment: See Section 11.			
12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X		
	Comment: See Section 11.			
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system			
	a. Submission includes a list of all components and accessories to be marketed with the subject device.	X		
	b. Submission includes a description (as detailed in item #11.a. and b. and 12 above) of each component or accessory.	X		
	c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.	X		
	Comment: See Sections 11 and 23.			
C.	**Substantial Equivalence Discussion**			
14.	Submitter has identified a predicate(s) device	X		
	a. Predicate's 510(k) number, trade name, and model number (if applicable) provided.	X		
	b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X		
	Comment: See Section 12.			
15.	Submission includes a comparison of the following for the predicate(s) and subject device	X		
	a. Indications for use	X		
	b. Technology, including features, materials, and principles of operation	X		
	Comment: See Section 12.			
16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate) affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(l)(A) of the FD&C	X		

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		Y	N/A	N
	Act)			
	Comment: See Section 12.			
D.	**Proposed Labeling (see also 21 CFR part 801)**			
	If a vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted		X	
17.	Submission includes proposed package labels and labeling (e.g., instructions for sue, package insert, operator's manual) that include a description of the device, its intended use, and directions for use.	X		
	a. Indications for use are stated in the labeling and are identical to Indications for Use form and 510(k) summary (if 510(k) Summary provided.)	X		
	b. Submission includes directions for use that - Include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21CFR 801.5) OR submission states that the device qualifies for exemption 21 21 CFR 801 Subpart D	X		
	Comment: See Section 13.			
18.	If indicated for prescription us, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol	X		
	Comment: See Section 13.			
19.	General labeling provisions			
	a. Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		
	b. Labeling includes device common or usual name (21 CFR 801.61)	X		
	Comment: See Section 13.			
20.	a. If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	X		
	c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set for in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		X	
	Comment: See Section 13.			
21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.		X	
E.	**Sterilization**			
	If in vitro diagnostic (IVD) device, select N/A. The criteria in the section will be omitted from the checklist if N/A is selected.			
	Submission states that the device and/or accessories are (one of the below must be checked) ☒ provided sterile	X		

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		Y	N/A	N
	☐ provided non-sterile but sterilized by the end user ☐ non-sterile when used			
	Comment: See Section 14.			
22.	Assessment of the need for sterilization information			
	a. Identification of device, and/or accessories, and/or components that are provided sterile.	X		
	b. Identification of device, and/or accessories, and/or components that are end user sterilized.		X	
	c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.		X	
	Comment: See Section 14.			
23.	If the device, and/or accessory, and/or component is provided sterile:			
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		
	b. A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.	X		
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X		
	d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X		
	e. Sterility Assurance Level (SAL) stated	X		
	Comment: See Sections 11 and 14.			
24.	If the device, and/or accessory, and/or component is end user sterilized:		X	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)			
	b. A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.			
	c. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)			
	d. Submission includes sterilization instructions for end user			
	Comment: Device is not sterilized by end user.			
25.	a. If there are requirements regarding sterility controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance other than a special controls guidance document applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the		X	

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		Y	N/A	N
	applicable statutory or regulatory criteria through an alternative approach.			
	c. If there is a special controls guidance document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document uses alternative mitigation measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		X	
	Comments: No specific sterility or special controls apply.			
F.	**Shelf Life**			
26.	Proposed shelf life/expiration date stated	X		
	Comment: See Section 14.			
27.	For sterile device, submission included summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.	X		
	Comment: See Section 14.			
28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X		
	Comment: See Sections 14 and 18.			
G.	**Biocompatibility**			
	If a vitro diagnostic (IVD) device, select N/A. The criteria in the section will be omitted from the checklist if N/A is selected.		X	
	Submission states that there: ☒ are ☐ are not direct or indirect (e.g., through infusion) patient-contacting components.			
	Comment: See Section 15			
29.	Submission includes a list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X		
	Comment: See Section 15			
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	X		
	Comment: See Section 15			
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria. And results provided for each completed test, OR A statement that the biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X		
	Comment: See Section 15.			
H.	**Software**			
	Submission states that the device:	X		

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		Y	N/A	N
	☐ does ☒ does not contain software/firmware.			
	Comment: See Section 16			
32.	Submission includes a statement of software level of concern and rationale for the software level of concern.		X	
	Comment: Not Applicable			
33.	All applicable software documentation provided based on the level of concern identified by the submitter, as described in Guidance for the Content of premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).		X	
	Comment: Not Applicable			
I.	**EMC and Electrical Safety**			
	Submission states that the device: ☐ does ☒ does not require EMC and Electrical Safety evaluation	X		
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		X	
	Comment: Not Applicable (See Section 17)			
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			
	Comment: Not Applicable (See Section 17)			
J.	**Performance Data – General** **If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.**			
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results	X		

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		Y	N/A	N
	summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.			
	Comment: See Section 18			
37.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.		X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach	X		
	c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.		X	
	Comment: See Section 18			
38.	If literature is referenced in the submission, submission includes:			
	a. Legible reprints or a summary table of each article		X	
	b. Discussion of how each article is applicable to support substantial equivalence of the subject device to the predicate.		X	
	Comment: Not Applicable			
39.	For each completed nonclinical (i.e., animal) study conducted		X	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120			
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185			
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.			
	Comment: Not Applicable			
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**			
	Submission states that the device: ☐ is ☒ is not an in vitro diagnostic device (IVD)			
	Comment: Not Applicable			
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:		X	
	a. Precision/reproducibility			
	b. Accuracy (includes as appropriate linearity; calibrator or assay			

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		Y	N/A	N
	traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.			
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			
	d. Analytical specificity			
	Comment: Not Applicable			
41.	1. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			
	2. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			
	3. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			

Applicable Device Specific Guidance

BioFlo Midline Catheter

Content and Organization of Information in a 510(k)
"Guidance on the Content of Premarket Notification 510(k) Submissions for Short and Long-Term Intravascular Catheters" – March 1995

The following items, as listed in the above guidance, can be found in the following 510(k) sections:

- Cover Letter: See **Section 3**
- Labels and Labeling: See **Section 13**
- Standards: See **Section 9**
- Device Description: See **Section 11**
- Descriptive Comparison to a Legally Marketed Device: See **Section 12**
- Sterilization Information: See **Section 14**
- Safe Medical Devices Act (SMDA) Information: See **Section 5**
- Sample: **N/A – None Available**
- Anti-Needle Stick Requirements: **N/A – This device does not incorporate anti-needle stick mechanism.**

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SECTION 1
MDUFMA (USER FEES) COVER SHEET

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

NAVILYST MEDICAL INC
26 Forest St
Marlborough
MA 0175
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****4286

2. CONTACT NAME
Lori Fitton
2.1 E-MAIL ADDRESS
lfitton@angiodynamics.com
2.2 TELEPHONE NUMBER (include Area code)
508-6587938
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 22-Jan-2015

orm FDA 3601 (05/13)

"Close Window" Print Cover sheet

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Online Payment

Step 3: Confirm Payment 1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees
Pay.gov Tracking I (b)(4)
Agency Tracking I
Transaction Date and Time: 01/22/2015 07:55 EST

Payment Summary

Address Information		Account Information		Payment Information	
Account Holder Name:	LORI A FITTON	Card Type	(b)(4)	Payment Amount:	(b)(4)
Billing Address:	26 FOREST ST	Card Number		Transaction Date and Time:	01/22/2015 07:55 EST
Billing Address 2:					
City:	MARLBOROUGH				
State / Province:	MA				
Zip / Postal Code:	01752				
Country:	USA				

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SECTION 2
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
	(b)(4)	Unknown

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☒ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Navilyst Medical, Inc.	3006716497		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Not Applicable	508-658-7984		
Street Address	**FAX Number *(including area code)***		
26 Forest Street	508-658-7976		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Marlborough	Massachusetts	01752	USA
Contact Name			
Brandon M. Brackett			
Contact Title	**Contact E-mail Address**		
Specialist II, Global Regulatory Affairs	brandon.brackett@navilyst.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Modification to materials and sizes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1		2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K001901	Poly Per-Q-Cath Midline Catheter	C.R. Bard
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Intravascular Catheter

	Trade or Proprietary or Model Name for This Device	Model Number
1	BioFlo Midline Catheter	H965460100 - H965464901
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	K001901	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FOZ

C.F.R. Section *(if applicable)*: 880.5200

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Classification Panel: General Hospital

Indications *(from labeling)*

The BioFlo Midline is indicated for short term access (<30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.

Maximum Power Injection Flow Rate: 3F Single Lumen, 20 cm: 2 mL/sec; 4F Single Lumen, 20 cm: 6 mL/sec; 5F Single Lumen, 20 cm: 6 mL/sec; 5F Dual Lumen, 20 cm: 6 mL/sec.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*: Unknown

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 1317056	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Navilyst Medical, Inc.		Establishment Registration Number: 1317056	
Division Name *(if applicable)*: Not Applicable		Phone Number *(including area code)*: 508-658-7984	
Street Address: 26 Forest Street		FAX Number *(including area code)*: 508-658-7976	
City: Marlborough	State / Province: Massachusetts	ZIP Code: 01752	Country: USA
Contact Name: Brandon M. Brackett	Contact Title: Specialist II, Global Regulatory Affairs	Contact E-mail Address: brandon.brackett@navilyst.com	

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: (b)(4)	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(b)(4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number:	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name:		Establishment Registration Number:	
Division Name *(if applicable)*:		Phone Number *(including area code)*:	
Street Address:		FAX Number *(including area code)*:	
City:	State / Province:	ZIP Code:	Country:
Contact Name:	Contact Title:	Contact E-mail Address:	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	10555-1	EN ISO	Intravascular Catheters - Sterile and Single-Use Catheters - Part 1: General Requirements	2013	N/A
	Standards No.	Standards Organization	Standards Title	Version	Date
2	10555-3	EN ISO	Intravascular Catheters - Sterile and Single-Use Catheters - Part 3: Central Venous Catheters	2013	N/A
	Standards No.	Standards Organization	Standards Title	Version	Date
3	594-2	ISO	Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment - Part 2: Lock Fittings	1998	N/A
	Standards No.	Standards Organization	Standards Title	Version	Date
4	10993-1	EN ISO	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process	2009	N/A
	Standards No.	Standards Organization	Standards Title	Version	Date
5	10993-4	EN ISO	Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood	2009	N/A
	Standards No.	Standards Organization	Standards Title	Version	Date
6	10993-5	EN ISO	Biological Evaluation of Medical Devices - Part 5: Tests for In-Vitro Cytotoxicity	2009	N/A
	Standards No.	Standards Organization	Standards Title	Version	Date
7	10993-6	EN ISO	Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation	2009	N/A
Please include any additional standards to be cited on a separate page.					

This section applies only to requirements of the Paperwork Reduction Act of 1995.

^DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.^

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section I – Utilization of Standards (Continued)

	Standards Number	Standards Organization	Standards Title	Version	Date
8.	10993-10	EN ISO	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	2013	N/A
9.	10993-11	EN ISO	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity	2009	N/A
10.	10993-12	EN ISO	Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials	2012	N/A
11.	11737-1	EN ISO	Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products	2006	N/A
12.	10993-7	EN ISO	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	2008	N/A
13.	11135-1	EN ISO	Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	2007	N/A
14.	556-1	EN	Sterilization of Medical Devices – Requirements for Medical Devices to be Designated "STERILE" – Part 1: Requirements for Terminally Sterilized Medical Devices	2001	N/A
15.	ST72	AAMI	Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	2011	N/A
16.	11138-1	EN ISO	Sterilization of Health Care Products – Biological Indicators – General Requirements	2006	N/A
17.	11138-2	EN ISO	Sterilization of Health Care Products – Biological Indicators – Biological Indicators for Ethylene Oxide Sterilization Processes	2009	N/A
18.	11607-1	EN ISO	Packaging for Terminally Sterilized Medical Devices – Requirements for Materials, Sterile Barrier Systems, and Packaging Systems	2009	N/A
19.	11607-2	EN ISO	Packaging for Terminally Sterilized Medical Devices – Validation Requirements for Forming, Sealing, and Assembly Processes	2006	N/A
20.	F1980	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2007	N/A
21.	F88/F88M	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials	2009	N/A
22.	F1929	ASTM	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	2012	N/A
23.	F1886/F188M	ASTM	Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	2009	N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 3
COVER LETTER

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Navilyst Medical

February 12, 2015

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (W066-0609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: BioFlo Midline Catheter Abbreviated 510(k) Premarket Notification

Dear Sir/Madam:

In accordance to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR §807 Subpart E, Navilyst Medical, Inc. (NMI) hereby submits three copies (one original copy and two eCopies) of this Special 510(k) Premarket Notification for the proposed BioFlo Midline Catheter. Please note: both eCopies provided are identical to the paper copy.

The purpose of this Abbreviated 510(k) is to introduce into commercial distribution the option of a BioFlo Midline Catheter. The catheter shaft of the proposed device will employ the same BioFlo Endexo material currently used on a variety of cleared NMI devices (including PICCs, ports, and dialysis catheters). The BioFlo Endexo material is a polymer incorporated into the catheter shaft that reduces thrombus accumulation throughout the catheter shaft. The primary predicate for the proposed BioFlo Midline catheter is CR Bard's Poly Midline Catheter (**K001901**). The proposed device is a Class II device per 21 CFR 880.5200, ProCode: FOZ.

The Abbreviated 510(k) was selected based upon the conclusions of FDA's Guidance Document "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." The device is subject to FDA's device-specific guidance document "Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters."

There was no pre-submission correspondence (i.e. Pre-Submission Requests, emails or telephone calls, etc.) between Navilyst Medical, Inc. and the Agency related to this submission.

Navilyst Medical, Inc. considers its intent to manufacture this device for distribution under its own label to be confidential commercial information and exempt from public disclosure; and therefore, requests that FDA does not disclose the existence or content of this 510(k) submission, or this letter. If you have any questions regarding this submission please contact me directly at 508-658-7984, or Wanda M. Carpinella, Director of Global Regulatory Affairs, at 508-658-7929.

Sincerely,

Brandon M. Brackett
Specialist II, Global Regulatory Affairs
Navilyst Medical, Inc.
brandon.brackett@navilyst.com
Fax: 508-658-7984

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

SECTION 4
INDICATIONS FOR USE STATEMENT

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown

Device Name
BioFlo Midline Catheter

Indications for Use *(Describe)*

The BioFlo Midline is indicated for short term access (<30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.

Maximum Power Injection Flow Rate:
-3F Single Lumen, 20 cm: 2 mL/sec
-4F Single Lumen, 20 cm: 6 mL/sec
-5F Single Lumen, 20 cm: 6 mL/sec
-5F Dual Lumen, 20 cm: 6 mL/sec

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

SECTION 5
510(K) SUMMARY

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

510(k) Summary – BioFlo Midline Catheter

Date Prepared: February 12, 2015

A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Brandon M. Brackett
Specialist II, Global Regulatory Affairs
508-658-7984

OR

Wanda Carpinella
Director, Global Regulatory Affairs
508-658-7929

C. Device Name

Trade Name:	BioFlo Midline Catheter
Common/Usual Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term, Less than 30 days.
Classification Panel:	General Hospital

D. Predicate Device(s)

Trade Name:	Bard Poly Per-Q-Cath Midline Catheter (K001901)
Common/Usual Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Long-Term, Greater than 30 days.
Classification Panel:	General Hospital

E. Device Description

The BioFlo Midline Catheter is a short term (< 30 days) peripheral venous access devices between 3 to 10 inches in length (8 to 25 cm). Midlines are usually placed in an arm vein such as the basilic, brachial or cephalic and the tip ends below the level of the axillary line. Midline catheters are longer than peripheral IV catheters which are generally 1 to 3 inches long and shorter than peripherally inserted central catheters (PICC) which extend into the superior vena cava. This device provides an alternative to short peripheral IVs and PICCs for certain treatments.

F. Intended Use/Indications for Use

The BioFlo Midline Catheter is indicated for short term access (< 30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and the sampling of blood and blood products. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L. Maximum Power Injection Flow Rates:

- 3F Single Lumen, 20cm: 2 mL/sec
- 4F Single Lumen, 20cm: 6 mL/sec
- 5F Single Lumen, 20cm: 6 mL/sec
- 5F Dual Lumen, 20cm: 6 mL/sec

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed BioFlo Midline Catheter is substantially equivalent to the Bard Poly Midline Catheter, previously reviewed and cleared by the Agency via **K001901**. When compared to the predicate, the proposed BioFlo Midline Catheter has equivalent materials, design, components, and technological characteristics as well as a comparable "Indications for Use" statement. Both the proposed device and the predicate device are:

- primarily constructed of a polyurethane shaft;
- available in a variety of size and length configurations including 3F-5F diameters with 10-20cm lengths;
- clearly labeled as a midline catheter to aid with catheter identification;
- able to be placed without the confirmation of an X-ray (or other imaging methods);
- compatible with the StatLock® Stabilization device; and
- indicated for short-term (<30 days) peripheral access for selective intravenous therapies.

Additionally, the proposed BioFlo Midline Catheter contains Endexo; a polymer blended into the Carbothane (polyurethane) catheter shaft of the device that reduces the accumulation of thrombus. The same Endexo polymer material is used in a variety of cleared NMI devices including BioFlo PICCs, BioFlo Ports, and BioFlo DuraMax Chronic Hemodialysis catheters. Reduction of thrombus accumulation was evaluated using in-vitro and in-vivo models; however, pre-clinical in-vitro and in-vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation. The catheter also has an addition of teal colorant.

H. Performance Data

The performance evaluation of the proposed BioFlo Midline Catheter included testing conducted in accordance to the following FDA Guidance Documents, and international standards:

- FDA's "Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters";
- EN ISO 10555-1:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements"
- EN ISO 10555-3:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 3: Central Venous Catheters"
- ISO 594-2:1998 – "Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings"
- EN ISO 10993-1:2009 – "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"

Furthermore, the proposed BioFlo Midline Catheter has demonstrated successful results based upon the conclusions of non-clinical bench testing per the above guidance and standards, including:

- Internal Product Specification Requirements
- Tensile Testing
- Priming Volume
- Power Injection
- Catheter Interface Compatibility
- In-Vitro and In-Vivo Thromboresistance Testing

I. Conclusion

Based upon successful results of testing and responses to questions posed within FDA's 510(k) Decision-Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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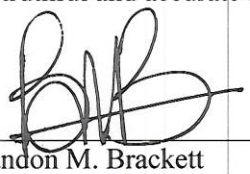
SECTION 6
TRUTHFUL AND ACCURACY STATEMENT

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TRUTHFUL AND ACCURACY STATEMENT
As Required by 21 CFR 807.87(k)

I certify that, in my capacity as a Specialist II of Global Regulatory Affairs at Navilyst Medical, Inc., I believe to the best of my knowledge, that the data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Brandon M. Brackett
Specialist II, Global Regulatory Affairs
Navilyst Medical, Inc.

12-FEBRUARY-2015
Date

Premarket Notification Number [510(k)] Number: _____

*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

SECTION 7
CLASS III SUMMARY AND CERTIFICATION

The proposed device has been previously classified by the FDA as:

- **Class II** per 21CFR §880.5200, Pro-Code FOZ.

Therefore, no Class III Certification & Summary Statement is required in support of this submission.

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

SECTION 8
FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

There were no clinical trials conducted in support of this submission. Therefore, no financial certification/disclosure statement is required.

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 9
DECLARATIONS OF CONFORMITY AND STANDARDS DATA REPORT FORMS

Part 1: Declarations of Conformity

A. Performance

B. Biocompatibility

C. Sterilization/Microbiological

D. Packaging

Part 2: Standards Data Report Forms

A. Performance

- EN ISO 10555-1:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements"
- EN ISO 10555-3:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 3: Central Venous Catheters"
- ISO 594-2:1998 – "Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings"

B. Biocompatibility

- EN ISO 10993-1:2009 – "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"
- EN ISO 10993-4:2009 – "Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood"
- EN ISO 10993-5:2009 – "Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity"
- EN ISO 10993-6:2009 – "Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation"
- EN ISO 10993-10:2013 – "Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization"
- EN ISO 10993-11:2009 – "Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity"
- EN ISO 10993-12:2012 – "Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials"

C. Sterilization

- EN ISO 11737-1:2006 – "Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products"
- EN ISO 10993-7:2008 – "Biological Evaluation of Medical Devices – Part 7- Ethylene Oxide Sterilization Residuals"
- EN ISO 11135-1:2007 – "Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices"
- EN 556-1:2001 – "Sterilization of Medical Devices – Requirements for Medical Devices to be Designated "Sterile" – Part 1 – Requirements for Terminally Sterilized Medical Devices"

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- AAMI ST72:2011 – "Bacterial Endotoxins - Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing"
- EN ISO 11138-1:2006 – "Sterilization of Health Care Products – Biological Indicators – General Requirements"
- EN ISO 11138-2:2009 – "Sterilization of Health Care Products – Biological Indicators – Biological Indicators for Ethylene Oxide Sterilization Processes"

D. Packaging

- EN ISO 11607-1:2009 – "Packaging for Terminally Sterilized Medical Devices – Requirements for Materials, Sterile Barrier Systems and Packaging Systems"
- EN ISO 11607-2:2006 – "Packaging for Terminally Sterilized Medical Devices – Validation Requirements for Forming, Sealing and Assembly Processes"
- ASTM F1980-07:2011 – "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device"
- ASTM F88/F88M-09 – "Standard Test Method for Seal Strength of Flexible Barrier Materials"
- ASTM F1929-12 – "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"
- ASTM F1886/F188M-09:2013 – "Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection"

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Navilyst Medical

26 Forest Street
Marlborough, MA 01752
Tel 508.658.7990

www.navilystmedical.com

A. Performance

The proposed BioFlo Midline Catheter conforms to the following FDA recognized standards:

- EN ISO 10555-1:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements"
- EN ISO 10555-3:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 3: Central Venous Catheters
- ISO 594-2:1998 – "Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment – Part 2: Lock Fittings"

I certify that, in my capacity as Engineer II, Research and Development of Navilyst Medical Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no information has been omitted.

In addition, to the best of my knowledge, this device complies as indicated with the FDA recognized and voluntary standards identified above.

Tim Deso
Engineer II, Research and Development

1/30/15
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Navilyst Medical

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Marlborough, MA 01752
Tel 508.658.7990

www.navilystmedical.com

B. Biocompatibility

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- EN ISO 10993-5:2009 – "Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity"
- EN ISO 10993-6:2009 – "Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation"
- EN ISO 10993-10:2013 – "Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization"
- EN ISO 10993-11:2009 – "Biological Evaluation of Medical Devices- Part 11: Tests for Systemic Toxicity"
- EN ISO 10993-12:2012 – "Biological Evaluation of Medical Devices- Part 12: Sample Preparation and Reference Materials"

The proposed BioFlo Midline Catheter conforms to the following voluntary standards:

- EN ISO 10993-4:2009 – "Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood"

I certify that, in my capacity as Director of Design Assurance of Navilyst Medical Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no information has been omitted.

In addition, to the best of my knowledge, this device complies as indicated with the FDA recognized and voluntary standards identified above.

Brett Nowlin
Director, Design Assurance

23-JAN-2015
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tel 508.658.7990

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C. Sterilization and Microbiological

The proposed BioFlo Midline Catheter conforms to the following FDA recognized standards:

- EN ISO 11737-1:2006 – "Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products"
- EN ISO 10993-7:2008 – "Biological Evaluation of Medical Devices – Part 7- Ethylene Oxide Sterilization Residuals"
- EN ISO 11135-1:2007 – "Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices"
- AAMI ST72:2011 – "Bacterial Endotoxins - Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing"
- EN ISO 11138-1:2006 – "Sterilization of Health Care Products – Biological Indicators – General Requirements"

The proposed BioFlo Midline Catheter conforms to the following voluntary standards:

- EN ISO 11138-2:2009 – "Sterilization of Health Care Products – Biological Indicators – Biological Indicators for Ethylene Oxide Sterilization Processes"
- EN 556-1:2001 – "Sterilization of Medical Devices – Requirements for Medical Devices to be Designated "Sterile" – Part 1 – Requirements for Terminally Sterilized Medical Devices"

I certify that, in my capacity as Director of Design Assurance of Navilyst Medical Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no information has been omitted.

In addition, to the best of my knowledge, this device complies as indicated with the FDA recognized and voluntary standards identified above.

Brett Nowlin
Director, Design Assurance

30-JAN-2015
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Navilyst Medical

26 Forest Street
Marlborough, MA 01752
Tel 508.658.7990

www.navilystmedical.com

D. Packaging

The proposed BioFlo Midline Catheter conforms to the following FDA recognized standards:

- EN ISO 11607-1:2009 – "Packaging for Terminally Sterilized Medical Devices – Requirements for Materials, Sterile Barrier Systems and Packaging Systems"
- EN ISO 11607-2:2006 – "Packaging for Terminally Sterilized Medical Devices – Validation Requirements for Forming, Sealing and Assembly Processes"
- ASTM F1980-07:2011 – "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device"
- ASTM F88/F88M-09 – "Standard Test Method for Seal Strength of Flexible Barrier Materials'
- ASTM F1929-12 – "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"
- ASTM F1886/F188M-09:2013 – "Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection"

I certify that, in my capacity as Senior Packaging Engineer, Research and Development of Navilyst Medical Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no information has been omitted.

In addition, to the best of my knowledge, this device complies as indicated with the FDA recognized and voluntary standards identified above.

Jerald Jaggers
Senior Packaging Engineer, Research and Development

23 JAN 2015
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10555-1:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 6-301	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☒	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☒	☐

Title of guidance: Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, Issued March 16, 1995

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10555-1:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Corrosion Resistance	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

Device does not contain metal components

JUSTIFICATION

Device does not contain metal components, therefore no testing is required.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.6	Freedom from Leakage	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10555-3:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 3: Central Venous Catheters"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 6-305	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☒	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☒	☐

Title of guidance: Guidance of Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, Issued March 16, 1995

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10555-3:2013 – "Intravascular Catheters – Sterile and Single-Use Catheters – Part 3: Central Venous Catheters"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.6	Flow Rate	☐ Yes ☒ No ☐ N/A
(b)(4)		
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ISO 594-2:1998 – "Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain other Medical Equipment – Part 2: Lock Fittings"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 6-129	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☒	☐
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☒	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☒	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☒

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 594-2:1998 – "Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain other Medical Equipment – Part 2: Lock Fittings"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.7	Stress Cracking	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-1:2009 – "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510(k)?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'."

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-1:2009 – "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

(b)(4)

		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-4:2009 – "Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-4:2009 – "Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

Testing was conducted in compliance with US FDA Good Laboratory Practices (GLP) regulations set forth in 21CFR Part 58.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2	Categories of Tests and Blood Interactions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-5:2009 – "Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-5:2009 – "Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

The MEM elution assay was performed. Testing was conducted in compliance with US FDA Good Laboratory Practices (GLP) regulations set forth in 21CFR Part 58.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-6:2009 – "Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-120	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-6:2009 – "Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects after Implantation"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-10:2013 – "Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-173	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-10:2013 – "Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

Testing was conducted in compliance with US FDA Good Laboratory Practices (GLP) regulations set forth in 21CFR Part 58.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.4	Animal Intracutaneous (Intradermal) Reactivity Tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-11:2009 – "Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐
Title of guidance:		

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-11:2009 – "Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-12:2012 – "Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 2-198	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-12:2012 – "Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

Testing was conducted in compliance with US FDA Good Laboratory Practices (GLP) regulations set forth in 21CFR Part 58.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

AAMI ST72:2011 – "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-360	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance:_____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ST72:2011 – "Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
B.7	Selection of Techniques	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN 556-1:2001 – "Sterilization of Medical Devices – Requirements for Medical Devices to be Designated "STERILE" – Part 1 – Requirements for Terminally Sterilized Medical Devices"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN 556-1:2001 – "Sterilization of Medical Devices – Requirements for Medical Devices to be Designated "STERILE" – Part 1 – Requirements for Terminally Sterilized Medical Devices"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 10993-7:2008 – "Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-278	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 10993-7:2008 – "Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 11135-1:2007 – "Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 11135-1:2007 – "Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B	Determination of Lethal Rate of the Sterilization Process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 11138-1:2006 – "Sterilization of Health Care Products – Biological Indicators – "Part 1: General Requirements"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-296	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 11138-1:2006 – "Sterilization of Health Care Products – Biological Indicators – "Part 1: General Requirements"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.4	Resistance Characteristics	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 11138-2:2009 – "Sterilization of Health Care Products – Biological Indicators – Biological Indicators for Ethylene Oxide Sterilization Processes"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 11138-2:2009 – "Sterilization of Health Care Products – Biological Indicators – Biological Indicators for Ethylene Oxide Sterilization Processes"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Population and Resistance	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 11737-1:2006 – "Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 11737-1:2006 – "Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of a Population of Microorganisms on Products"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
A.7	Validation of Method for Determining Bioburden	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

(b)(4)

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F88/F88M:2009 – "Standard Test Method for Seal Strength of Flexible Barrier Materials"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-283	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☒	☐
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F88/F88M:2009 – "Standard Test Method for Seal Strength of Flexible Barrier Materials"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4-2	Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

Option Selection: Technique C: Supported 180 degrees

DESCRIPTION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F1886/F188M-09:2013 – "Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-288	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1886/F188M-09:2013 – "Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F1929:2012 – "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-378	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1929:2012 – "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F1980-07:2011 – "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1980-07:2011 – "Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Sections	All Sections	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION

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STANDARD TITLE [1]

EN ISO 11607-1:2009 – "Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-193	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☒	☐
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 11607-1:2009 – "Packaging for Terminally Sterilized Medical Devices – Requirements for Materials, Sterile Barrier Systems and Packaging Systems"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	General Requirements	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

Compliance with section 4 of ISO 11607 may be demonstrated by using one or more parts of the series EN 868-2 to EN 868-10.

JUSTIFICATION

Per the scope of individual parts, EN 868 Parts 2 - 10 are voluntary, and add no other req's to the general req's of Part 1. Thus, Navilyst Medical does not specifically assess conformance to parts 2 – 10.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	General Requirements	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

EN 868-2 Sterilization Wrap

JUSTIFICATION

This product does not use sterilization wraps. Part 2 is voluntary.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	General Requirements	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

EN 868-3, -4, -5, -6, -7 Papers

JUSTIFICATION

This product does not use paper for sterile barrier pkg.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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EN ISO 11607-1:2009 – "Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Material, Sterile Barrier Systems, and Packaging Systems"
Continued from Standard Form

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	General Requirements	□ Yes □ No √ N/A

(b)(4)

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Form Approved OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

EN ISO 11607-2:2006 – "Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 14-194	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)?	☐	☒
If no, complete a summary report table.		
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria?		
If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests?	☐	☒
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)[5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS?	☐	☒
If yes, report these deviations or adaptations in the summary report table.		
Were there exclusions from the standard?	☒	☐
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510(k)?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 11607-2:2006 – "Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.3.2	Operational Qualification (OQ)	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED◊

N/A

DESCRIPTION

C) For other closure systems

JUSTIFICATION

NMI does not use closure systems.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Use of Reusable Sterile Barrier Systems	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

Instructions and restrictions for use as specified in 5.1.10/11 of ISO 11607-1 shall be followed.

JUSTIFICATION

NMI does not use reusable sterile packages.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Sterile Fluid Path Packaging	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

N/A

DESCRIPTION

Sterile fluid-path components and closures.

JUSTIFICATION

NMI does not use sterile fluid-path closure assemblies.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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SECTION 10
EXECUTIVE SUMMARY

This Abbreviated 510(k) Premarket Notification is being submitted to obtain FDA clearance to introduce a line of short-term intravascular catheters, namely the BioFlo Midline Catheter, into US commercial distribution.

Based upon the conclusions found in Attachment 1: The New 510(k) Paradigm within FDA's Guidance document "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the Abbreviated 510(k) pathway was most appropriate, since there is a recognized standard in place for the device that the results of non-clinical bench testing have demonstrated conformance to.

The proposed BioFlo Midline Catheter is substantially equivalent to the Bard Poly Midline Catheter, previously reviewed and cleared by the Agency via **K001901**. When compared to the predicate, the proposed BioFlo Midline Catheter has equivalent materials, design, components, and technological characteristics as well as a comparable "Indications for Use" statement. Both the proposed device and the predicate device are:

- primarily constructed of a polyurethane shaft;
- available in a variety of size and length configurations including 3F-5F diameters with 10-20cm lengths;
- clearly labeled as a midline catheter to aid with catheter identification;
- able to be placed without the confirmation of an X-ray (or other imaging methods);
- compatible with the StatLock® Stabilization device; and
- indicated for short-term (<30 days) peripheral access for selective intravenous therapies.

The proposed BioFlo Midline Catheter has the following Indications for Use:

"*The BioFlo Midline Catheter is indicated for short-term access (<30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.*

Maximum power injection flow rate:

- *3F Single-Lumen, 20cm = 2 mL/sec*
- *4F Single-Lumen, 20cm = 6 mL/sec*
- *5F Single-Lumen, 20cm = 6 mL/sec*
- *5F Dual-Lumen, 20cm = 6 mL/sec"*

A more detailed description of the device including drawings, photographs/computer renderings, FDA procode, and other information can be found in **Section 11, Device Description**. A summary of Substantial Equivalence and a completed Decision Tree can be found in **Section 12, Substantial Equivalence Discussion**. Lastly, results of bench testing that support conformance to FDA recognized standards can be found in **Section 18, Performance Testing (Bench)**.

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SECTION 11
DEVICE DESCRIPTION

General Device Description / Principle of Operation

A midline functions as a short-term (<30 days) peripheral venous access device that is most often between 3 to 10 inches (8 to 25 cm) in length. Designated as FDA Procode FOZ, these devices are usually placed in an arm vein, such as the basilica, brachial, or cephalic and the distal tip resides below the level of the axillary line; as compared to a PICC device, which is typically longer and extends into the superior vena cava. Based upon the anatomical location of placement, the midline is limited in the types of therapies it is able to administer compared to other devices (such as a PICC); however, the benefit of a midline is that it can be placed without a chest X-ray to confirm placement since the distal (patient) end does not reach the central veins.

Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600mOsm/L; primarily because these medications are likely to be damaging to the peripheral veins. However, midline catheters are appropriate for all intravenous fluids that would normally be administered through a short peripheral IV; as well as for certain medications, the sampling of blood/blood products, and infusates with a pH and osmolarity within the constraints of the IFU statement.

Proposed BioFlo Midline Catheter Description

The proposed BioFlo Midline Catheter consists of a non-valved 10 or 20 cm long catheter shaft, suture wing, extension leg, oversleeve, and clamps that are all made of polyurethane. The catheter comes in single or dual lumen configurations, which are compatible with a 0.018" guidewire for over the wire delivery method, and is loaded with Barium Sulfate (BaSO4) for visualization under fluoroscopy. The catheter is offered in 3F, 4F, and 5F diameters in the sizes.

The proposed BioFlo Midline Catheter is substantially equivalent to the Bard Poly Midline Catheter, previously reviewed and cleared by the Agency via **K001901**. When compared to the predicate, the proposed BioFlo Midline Catheter has equivalent materials, design, components, and technological characteristics as well as a comparable "Indications for Use" statement. Both the proposed device and the predicate device are:

- primarily constructed of a polyurethane shaft;
- available in a variety of size and length configurations including 3F-5F diameters with 10-20cm lengths;
- clearly labeled as a midline catheter to aid with catheter identification;
- able to be placed without the confirmation of an X-ray (or other imaging methods);
- compatible with the StatLock® Stabilization device; and
- indicated for short-term (<30 days) peripheral access for selective intravenous therapies.

Additionally, the proposed BioFlo Midline Catheter contains Endexo; a polymer blended into the catheter shaft of the device that reduces the accumulation of thrombus. The same Endexo polymer material is used in a variety of cleared NMI devices including BioFlo PICCs, BioFlo Ports, and BioFlo DuraMax Chronic Hemodialysis catheters. Reduction of thrombus accumulation was previously evaluated using in-vitro (Blood Loop) and in-vivo (Sheep Implantation Study) models via reports provided in K121089, reviewed and cleared by the FDA. Please note: pre-clinical in-vitro and in-vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation. Lastly, the catheter also has an addition of teal colorant.

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The proposed BioFlo Midline Catheter has the following Indications for Use:

"*The BioFlo Midline Catheter is indicated for short-term access (<30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.*

Maximum power injection flow rate:

- *3F Single-Lumen, 20cm = 2 mL/sec*
- *4F Single-Lumen, 20cm = 6 mL/sec*
- *5F Single-Lumen, 20cm = 6 mL/sec*
- *5F Dual-Lumen, 20cm = 6 mL/sec"*

Key characteristics and features of the proposed BioFlo Midline Catheter are described in detail within **Table #1** below:

Table #1 – Key Characteristics of the Proposed BioFlo Midline Catheter	
Catheter Shaft Number of Lumens	Single Lumen (SL) Dual Lumen (DL)
Lumen Shape	Round (SL) D-Shaped (DL)
Outside Diameter French Size	3F, 4F, and 5F
Usable/Effective Length	10cm, 20cm
Catheter Shaft Design	Reverse Tapered
Maximum Power Injector Setting	325 psi
Maximum Power Injection Flow Rate	3F Single-Lumen, 20cm = 2 mL/sec 4F Single-Lumen, 20cm = 6 mL/sec 5F Single-Lumen, 20cm = 6 mL/sec 5F Dual-Lumen, 20cm = 6 mL/sec
Clamp ID Tags	Printed with "**POWER INJECT**"; Flow-Rate "**2 mL/sec**" or "**6 mL/sec**"
Lumens Differentiated by Color	Purple (SL) Purple, White (DL)
Suture Wing	2 Holes (to accommodate posts on catheter securement device OR fixation with skin to sutures); Printed with Product Name
"MIDLINE" Identification Locations	Hubs, Oversleeve, Clamp, and Suture Wing
Incremental Markings Printed on Catheter Shaft	Marked every 1 cm; Numbered every 5 cm
Sterilization Method	Ethylene Oxide

Note: All dimensions provided are nominal.

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The components and materials used in the manufacture of the proposed BioFlo Midline Catheter are described below within **Table #2**. Please note: the materials of the proposed device are identical to that of the BioFlo PICC cleared via **K140266**.

Table #2 – Components and Materials of the Proposed BioFlo Midline Catheter

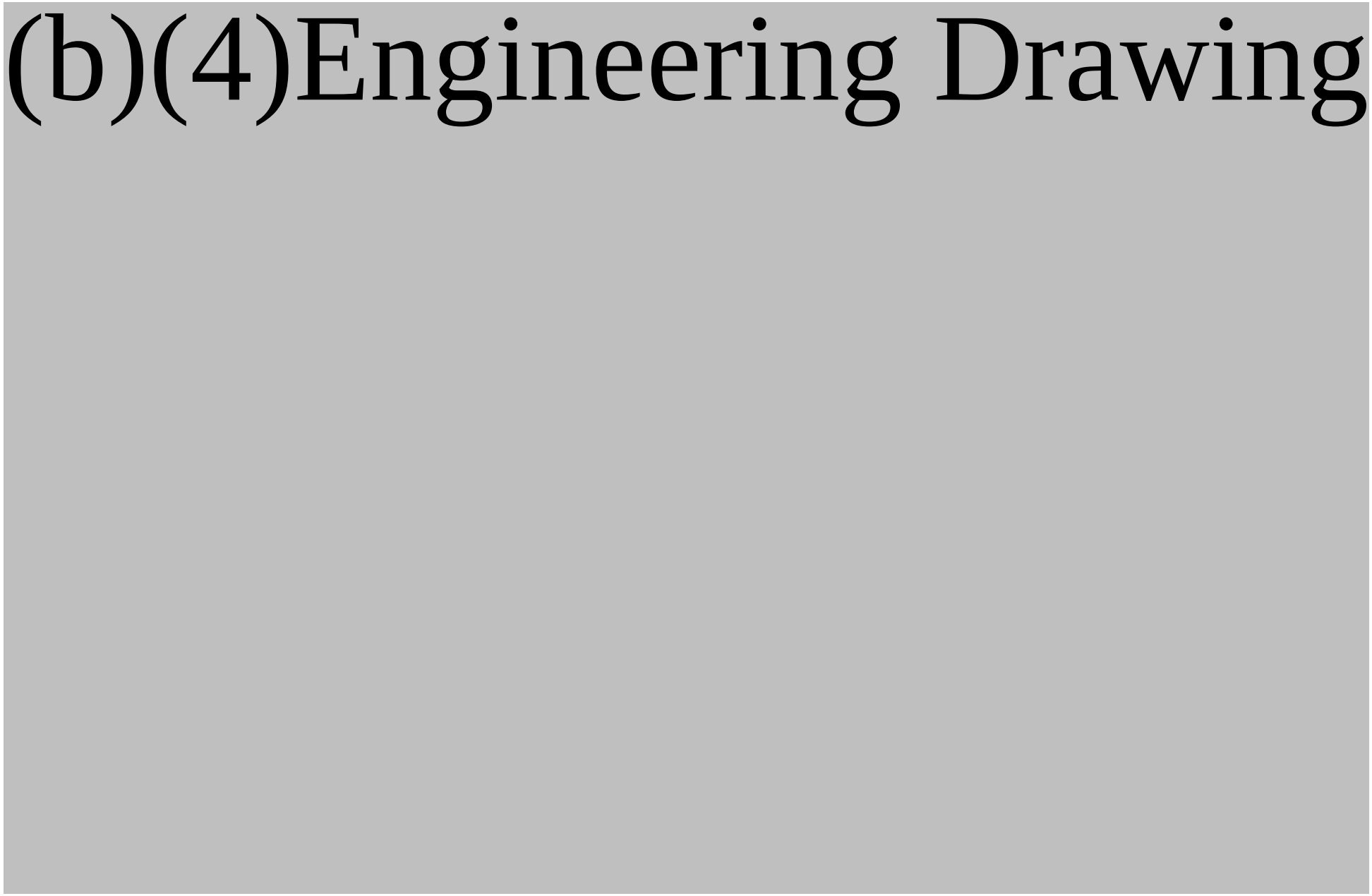
Device Component	Material
Catheter Tubing	(b)(4)
Suture Wing	
Extension Tubing	
Oversleeve	
Purple Luer	
White Luer	
Ink	
Clamp	

(b)(4)

The proposed BioFlo Midline Catheter is available in a variety of configurations including 3F Single Lumen, 4F Single Lumen, 5F Single Lumen, and 5F Dual Lumen diameters, all in either 10cm or 20cm lengths. **Figures #1** thru **#8** beginning on the following page include drawings and final renderings of the proposed configurations.

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(b)(4)Engineering Drawing

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(b)(4)Engineering Drawing

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(b)(4)Engineering Drawing

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Figure #5 – Proposed BioFlo Midline Rendering, 3F SL Configuration

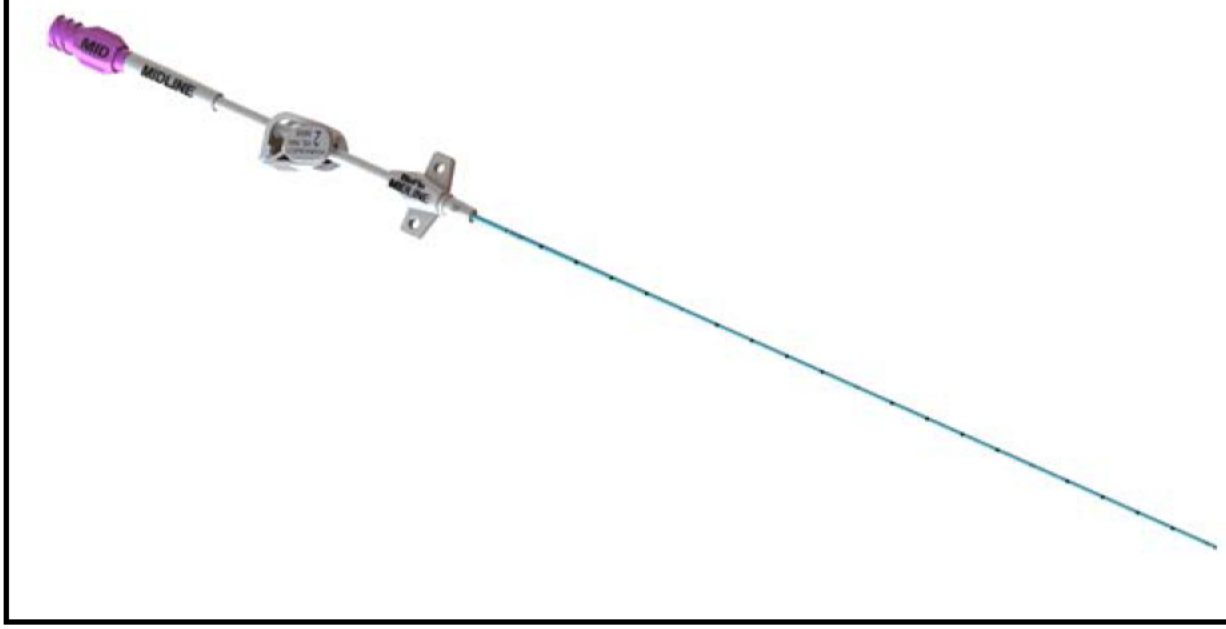


Figure #6 – Proposed BioFlo Midline Rendering, 4F SL Configuration



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Figure #7 – Proposed BioFlo Midline Rendering, 5F SL Configuration

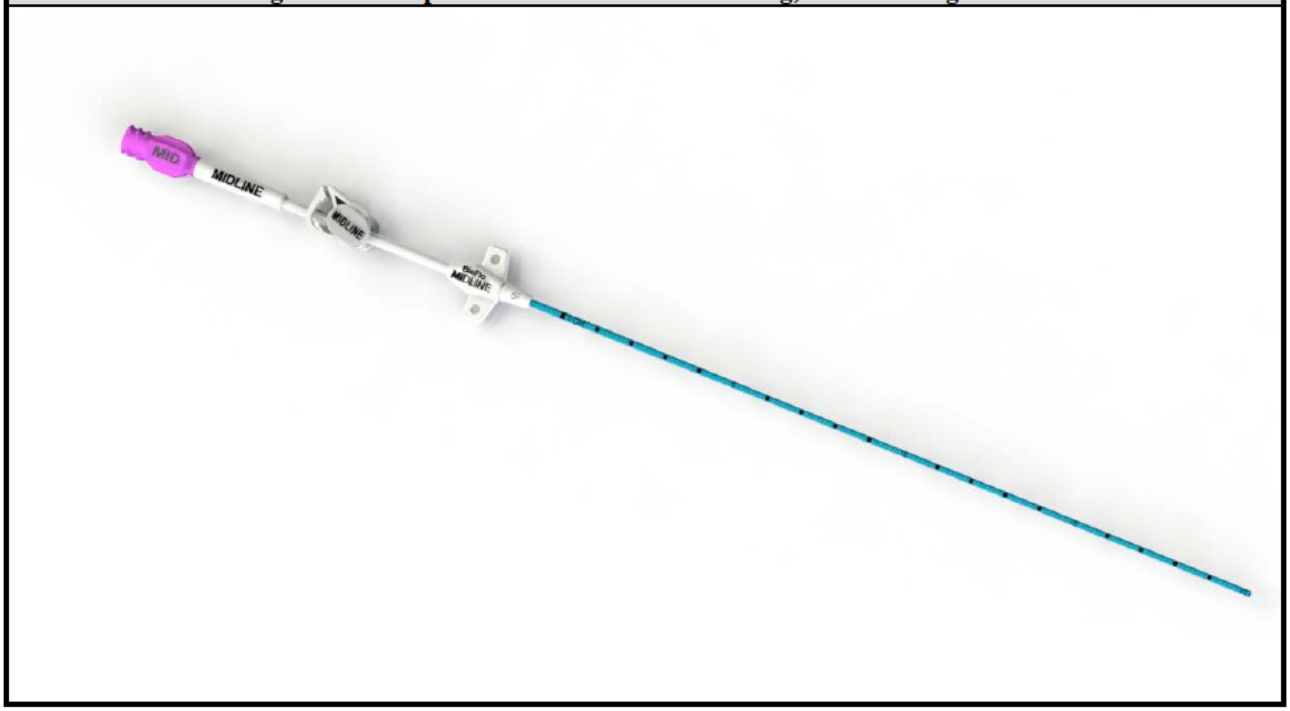
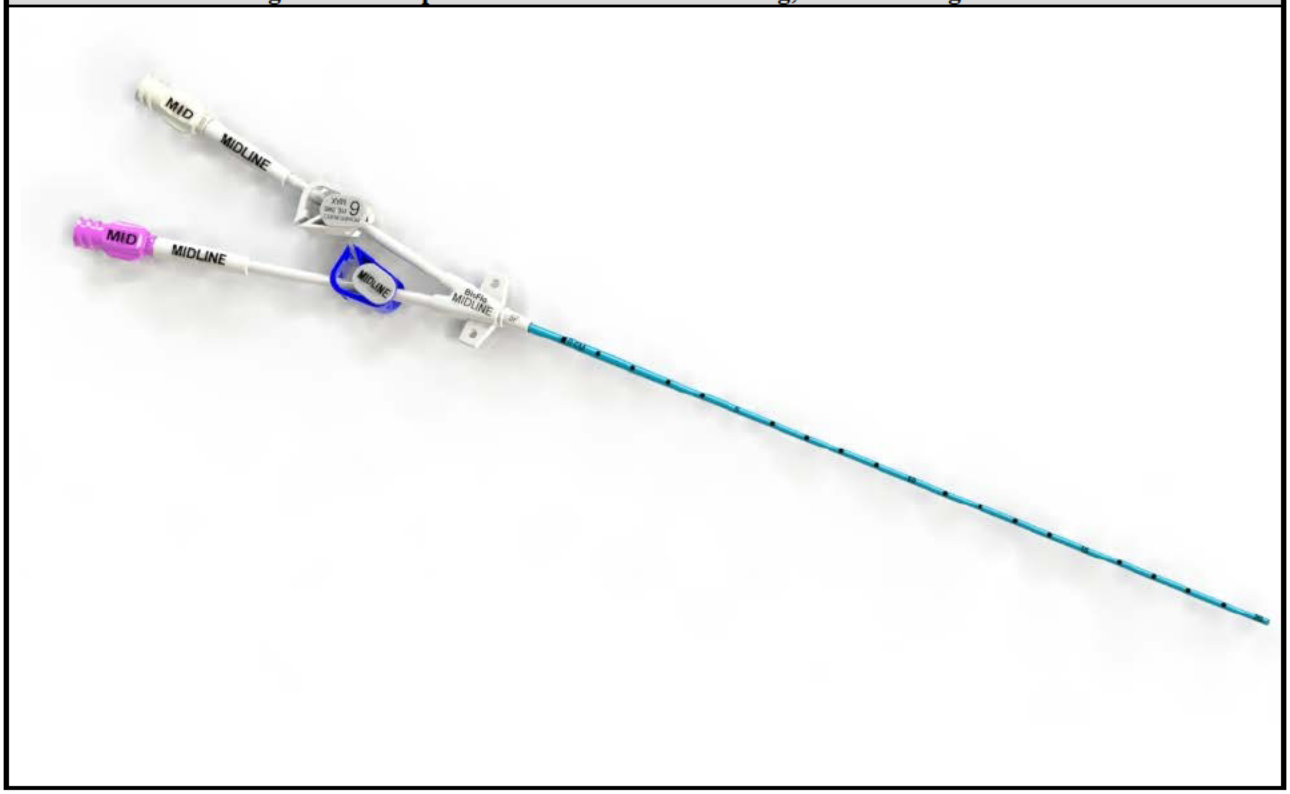


Figure #8 – Proposed BioFlo Midline Rendering, 5F DL Configuration



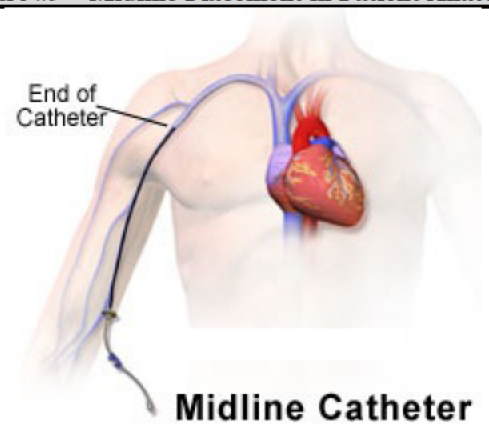
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Midline Placement Techniques

Midlines are usually placed in an arm vein, such as the basilica, brachial, or cephalic and the distal tip resides below the level of the axillary line (see **Figure #9**). The combination of an introducer needle, guidewire, and peelable sheath/dilator or peelable sheath introducer needle allow for percutaneous insertion of the catheter.

Figure #9 – Midline Placement in Patient Anatomy



Midlines may be used by physicians and nurses in numerous settings such as operating rooms, at patient bedside, outpatient clinics, and radiology departments. The insertion techniques utilized for midlines include the Seldinger Technique and the Modified Seldinger Technique.

By using the Seldinger Technique, one accesses a vein percutaneously using a small-gauge needle. The user then inserts a guidewire through the needle lumen and into the vessel. The guidewire is inserted until its tip terminates at or just below the level of the axillary line. Once this has been accomplished the needle is removed, and a scalpel is used to nick the skin at the insertion site. This allows for a sheath/dilator to be placed over the wire and into the vessel, widening the opening of the skin and vessel. The dilator is then removed with the wire left in the vessel, and the prepared catheter is advanced over the wire, through the sheath and into the vessel. The catheter is then inserted to the tip of the guidewire in a small, incremental fashion; while doing this the user also separates and peels the sheath until it is fully removed. Once in place, the wire is removed and the catheter is flushed and secured.

The Modified Seldinger Technique (MST) is similar to the Seldinger Technique, however the tip of the guidewire does not terminate at or below the axillary line; it is simply used to gain access to the vessel, and is removed along with the dilator. In order for the catheter to maintain body, a stiffening wire is inserted into the catheter during preparation. This assembly is fed directly into the vessel via the sheath and "floated" through the vessel until reaching its termination point. The catheter is then flushed and secured.

How Supplied

The proposed BioFlo Midline Catheter will be packaged with a variety of legally marketed procedural accessories (see **Section 23, Kit Certification Statement**) as a convenience for the user, and is packaged in a handful of different kit configurations as detailed on the next page.

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Catheter Only Kit

- 1 BioFlo Midline Catheter
- 1 Stiffening Wire/Stylet
- 1 End Cap (or multiple, depending on number of catheter lumens)

Catheter Only Kit w/ Nitinol Guidewire

- 1 BioFlo Midline Catheter
- 1 45cm Nitinol Guidewire
- 1 End Cap (or multiple, depending on number of catheter lumens)

MST Kit (offered in 1 or 2 guidewire configurations)

- 1 BioFlo Midline Catheter
- 1 Flush Assembly
- 1 or 2 45cm Hydrophilic Stainless Steel Guidewires
- 1 Stiffening Wire/Stylet
- 1 Peelable Sheath Dilator
- 1 Catheter Securement Device
- 1 Safety Scalpel
- 1 10 cc or 12 cc Luer Lock syringe
- 1 Paper Tape Measure
- 1 End Cap (or multiple, depending on number of catheter lumens)
- 1 Safety and Standard Introducer Needle
- 1 Scissors

Maximal Barrier Nursing Kit (offered in 1 or 2 guidewire configurations)

- 1 BioFlo Midline Catheter
- 1 Flush Assembly
- 1 45cm Stiffening Wire
- 1 Safety Introducer Needle
- 1 or 2 45cm Guidewire
- 1 Safety Scalpel
- 1 Peel-away Sheath
- 1 Catheter Securement Device
- 2 10 mL Pre-Filled Saline Syringes
- 1 Tape Measure
- 1 End Cap (or multiple, depending on number of catheter lumens)
- 2 Antiseptic Skin Prep
- 1 2.75" Standard Introducer Needle
- 1 Patient Drape
- 1 Window Dressing
- 1 Lidocaine Syringe Label
- 1 Hairnet
- 1 Sharps Container
- 2 10cc Luer Lock Syringe
- 1 Surgical Gown
- 5 4x4" Gauze Pads
- 1 Surgical Tape
- 1 Scissors
- 1 Tourniquet
- 1 Skin Protectant Swabstick
- 1 3cc Luer Lock Syringes
- 1 Safety Hypodermic Needle
- 1 Transducer Cover
- 1 Safety Ampule Cracker
- 1 Face Mask
- 1 Filter Straw
- 2 CSR Wraps
- 1 Fenestrated Drape
- 1 Lidocaine Ampule
- 1 Full Body Drape
- 2 Towels
- 1 MIDLINE Stop Sign
- 2 MIDLINE Sticker Labels

All of the packaging configurations and device materials are comparable to those of the predicate Bard Poly Midline (**K001901**), and are provided with the same (but not identical) accessories as those used for the BioFlo PICCs, cleared by the FDA via **K121089** (which contains the Catheter Kit and MST Kit configurations) and **K131038** (which contains the Maximal Barrier Nursing Kit configurations). Drawings for the packaging components have been previously provided within those 510(k)'s.

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SECTION 12
SUBSTANTIAL EQUIVALENCE DISCUSSION

Summary of Similarities and Differences

The proposed BioFlo Midline Catheter is substantially equivalent to the Bard Poly Midline Catheter, previously reviewed and cleared by the Agency via **K001901**. When compared to the predicate, the proposed BioFlo Midline Catheter has equivalent materials, design, device components, and technological characteristics as well as a comparable "Indications for Use" statement. Both the proposed device and the predicate device are:

- primarily constructed of a polyurethane shaft;
- available in a variety of size and length configurations including 3F-5F diameters with 10-20cm lengths;
- clearly labeled as a midline catheter to aid with catheter identification;
- able to be placed without the confirmation of an X-ray (or other imaging methods);
- compatible with the StatLock® Stabilization device; and
- indicated for short-term (<30 days) peripheral access for selective intravenous therapies.

Additionally, the proposed BioFlo Midline Catheter contains Endexo; a polymer used throughout the catheter shaft of the device that reduces the accumulation of thrombus. The same Endexo polymer material is used in a variety of cleared NMI devices including BioFlo PICCs, BioFlo Ports, and BioFlo DuraMax Chronic Hemodialysis catheters. Reduction of thrombus accumulation was evaluated using in-vitro and in-vivo models; however, pre-clinical in-vitro and in-vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation. The catheter also has an addition of teal colorant. A comparison of the proposed BioFlo Midline Catheter and the predicate Bard Poly Midline is presented in **Table #3** below.

Table #3 – Comparison of Key Characteristics
Proposed BioFlo Midline Catheter and Predicate Bard Poly Midline

Characteristic	Proposed BioFlo Midline Catheter	Predicate Bard Poly Midline
Catheter Shaft Material	Polyurethane	Polyurethane
Key Device Components	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Oversleeve, Clamp	Catheter Shaft, Suture Wing, Extension Tube, Luer Hub, Clamp
Indications for Use Statement	The BioFlo Midline Catheter is indicated for short-term access (<30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications, and the sampling of blood and blood products. Therapies not appropriate for midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.	The Bard Poly Midline Catheters are indicated for short-term (<30 days) peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling (See Contraindications). For blood therapy, it is recommended that a 4F or larger catheter be used.
Outside Diameter French Size	3F, 4F, and 5F	3F and 4F
Usable/Effective Length	10 cm and 20 cm	20 cm
Number of Lumens	Single Lumen (SL) and Dual Lumen (DL)	Single Lumen (SL)
X-Ray Confirmation Required	No	No
Identified as "Midline"	Yes	Yes
Catheter Shaft Design	Reverse Tapered	Reverse Tapered
Available Kit Configurations	Catheter Kit, MST Kit, Max. Barrier	MST Kit and Max. Barrier

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Substantial Equivalence Tree

The 510(k) "Substantial Equivalence" Decision-Making Flowchart, as outlined in FDA's Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)'s]" dated July 28, 2014, was used to confirm substantial equivalence of the proposed device to the predicate devices described. The completed Decision-Making Flowchart from FDA's Guidance Document is presented in **Figure #10**, and was utilized to determine that the proposed BioFlo Midline Catheter is substantially equivalent to the predicate device. The answers to the Decision Questions are provided in **Table #4**, below:

Table #4 – Answer to Decision-Making Flowchart Questions

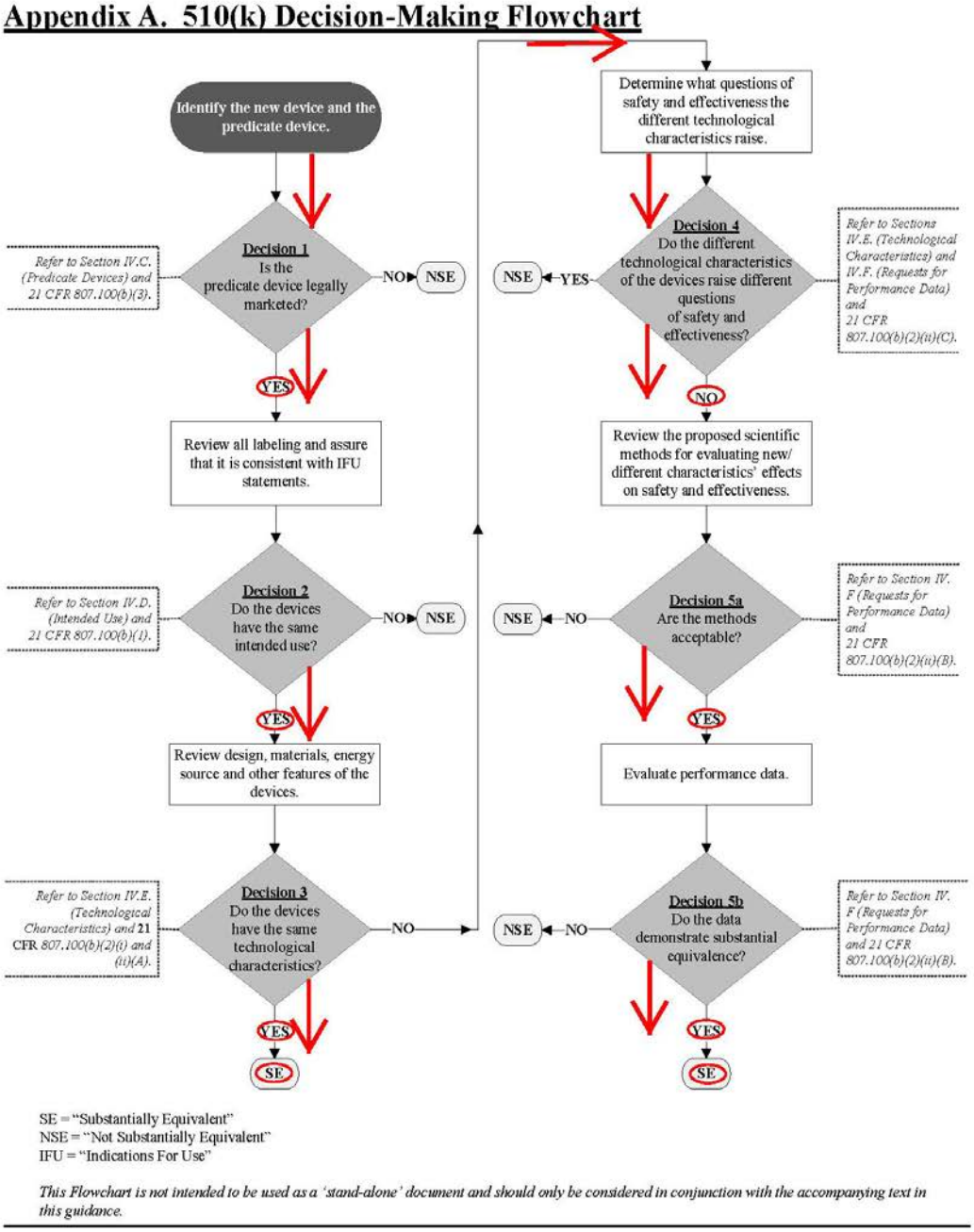
Decision-Making Flowchart Question	Summary Response
1. Is the predicate device legally marketed?	Yes: The Bard Poly Midline has been cleared by the FDA via K001901.
2. Do the devices have the same intended use?	Yes: The proposed BioFlo Midline Catheter and the Bard Poly Midline have the same intended uses.
3. Do the devices have the same technological characteristics?	Yes: The proposed and predicate devices do have the same technological characteristics. The fundamental operating principles and overall design of the proposed BioFlo Midline are the same as those of the predicate. However, due to slight differences in material and configurations, consideration has been given to Decision Question 4 in FDA's Decision Making Flowchart.
4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	No: The different technological characteristics of the proposed device do not raise different questions of safety and effectiveness. A review of the performance verification testing demonstrates that the proposed device performs and operates in a similar manner to that of predicate device.
5A. Are the methods acceptable?	Yes: The methods used for evaluation of device performance are based upon FDA-accepted consensus standards.
5B. Do the data demonstrate substantial equivalence?	Yes: The data provided in this submission and data provided via reference 510(k)'s demonstrate substantial equivalence.

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Figure #10 – Decision-Making Flowchart

Contains Nonbinding Recommendations



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SECTION 13
PROPOSED LABELING

Proposed Labeling:

- Proposed BioFlo Midline Catheter Directions for Use
- Proposed BioFlo Midline Catheter Labels:
    - Catheter Kit (Pouch and Carton)
    - MST-45 Kit (Pouch and Carton)
    - MST-45 Kit with 2 Guidewires (Pouch and Carton)
    - Maximal Barrier Nursing Kit (Pouch, Carton, and Patient Chart Sticker)
    - Maximal Barrier Nursing Kit with 2 Guidewires (Pouch, Carton, and Patient Chart Sticker)
- Proposed BioFlo Midline Catheter Brochure

Predicate Labeling:

- Bard Poly Midline Directions for Use

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angiodynamics

BioFlo Midline

with ENDEXO Technology

Directions For Use..... 4

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BioFlo Midline

with ENDEXO Technology

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The *BioFlo** Midline catheter with *ENDEXO** Technology is a radiopaque, polyurethane catheter with luer lock hub(s), polyurethane extension tube(s) and suture wing. The catheter is available in single and dual lumen configurations. The BioFlo Midline is clearly labeled on all available catheter surfaces to identify as a MIDLINE versus a traditional PICC. Maximum power injection flow rates are indicated on the clamp(s) (Figure 1 and Table 2).

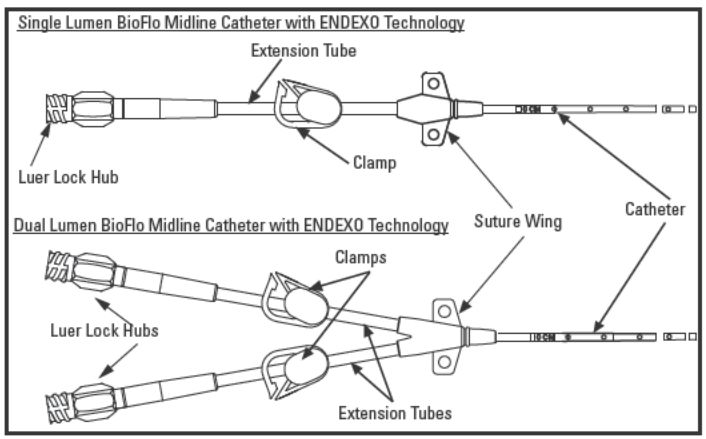


Figure 1. Catheter Configurations

When determining patient selection and catheter diameter, clinicians must consider variations in individual's anatomy and physiology due to size and age (i.e. adult, child, or infant). Appropriate guidance, vein assessment and insertion techniques for BioFlo Midline placement should be employed.

The BioFlo Midline with ENDEXO Technology is provided in multiple packaging configurations, including:

- Maximal Barrier Nursing Kit
- Catheter Kit
- MST Kit with 45 cm Wire

NOTE: MST=Modified Seldinger Technique

ENDEXO technology has been shown to be effective in reducing thrombus accumulation (based on platelet count). Reduction of thrombus accumulation was evaluated using acute in-vitro models. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation.

INTENDED USE/ INDICATIONS FOR USE

The BioFlo Midline is indicated for short term access (< 30 days) to the peripheral venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and the sampling of blood and blood products. Therapies not appropriate for BioFlo Midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.

Maximum Power Injection Flow Rate*

- 3F Single Lumen/20 cm -2 mL/sec
- 4F Single Lumen/20 cm - 6 mL/sec
- 5F Single Lumen/20 cm – 6 mL/sec
- 5F Dual Lumen/20 cm - 6 mL/sec

*Refer to table 2

CONTRAINDICATIONS

- Venous thrombosis in any portion of the vein to be catheterized.
- Conditions that impede venous return from the extremity such as paralysis or lymphedema after mastectomy.
- Orthopedic or neurological conditions affecting the extremity.
- Anticipation or presence of dialysis grafts or other intraluminal devices, including pacemakers.
- Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy.
- Pre-existing skin surface or subsurface infection at or near the proposed catheter insertion site.
- Anatomical distortion of the veins from surgery, injury or trauma.
- Inadequate antecubital veins.
- Anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures.

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WARNINGS

Refer to procedural steps for additional warnings. Due to the risk of exposure to blood borne pathogens, care providers must adhere to guidelines for universal blood and body fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.

- Do not use if package is opened or damaged.
- If using bacteriostatic saline, do not exceed 30 mL in a 24-hour period.
- Do not fully insert catheter up to suture wing.
- Do not use the catheter with chemicals that are incompatible with any of its accessories, as catheter damage may occur.
- Do not re-sheath any needles. Place needles in puncture resistant, leak proof, sharps containers per institutional protocol.
- Do not attempt to trim the catheter with the guidewire or stylet loaded as catheter, stylet, or guidewire may become damaged resulting in patient injury.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter.
- Exceeding the maximum allowable flow rate (Table 2) may result in catheter failure and/or catheter tip displacement.
- Catheter indication for power injection of contrast media implies the catheter's ability to withstand this procedure, but does not imply appropriateness of this procedure for a particular patient. A trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- The maximum pressure of power injectors used with the power injectable BioFlo Midline must not exceed 325 psi (2,240 kPa).
- Prior to loading stylet or guidewire cut catheter to desired length. Do not cut catheter while stylet or guidewire is loaded into catheter as device damage or patient injury may occur.
- Therapies NOT appropriate for BioFlo Midline catheters include:
    - continuous vesicants
    - parenteral nutrition
    - solutions with pH < 5 and > 9
    - solutions > 600 mOsm/L

PRECAUTIONS

Refer to procedural steps for additional precautions.

- Do not advance a guidewire past the level of the axilla.
- Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and re-attempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into desired position (zero mark).
- If guidewire must be withdrawn, remove the needle and guidewire as a single unit.
- Carefully read all instructions prior to insertion, care or use.
- Do not use sharp objects to open package as damage to the device may occur.
- Catheter insertion should be performed only by a licensed and qualified healthcare practitioner.
- If catheter and accessories show any sign of damage (crimped, crushed, cut, etc.), do not use.
- If using an introducer sheath other than the one provided (as in Modified Seldinger and Max Barrier kits), verify that the catheter fits easily through the sheath.
- Do not insert the stiff end of the floppy-tipped guidewire into the vein.
- Exercise care when advancing the catheter or guidewire to avoid trauma to the vessel intima. Do not use clamps, toothed or ribbed forceps. Do not use clamps or other instruments with teeth or sharp edges on the catheter or other instruments to advance or position catheter as catheter damage may occur.
- Avoid sharp or acute angles during insertion which may compromise catheter functionality.
- Acetone and polyethylene glycol-containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
- Catheter replacement may be required if catheter is cut too short.
- Do not use sharp instruments near the extension tubes or catheter shaft.
- Do not suture through any part of the catheter. If using sutures to secure catheter, make sure they do not occlude, puncture, or cut the catheter.
- Following institutional policy, secure catheter externally to prevent catheter movement, migration, damage, kinking or occlusion.
- It is recommended that only Luer lock accessories be used with the BioFlo Midline Catheter with ENDEXO Technology. Repeated over-tightening may reduce hub connector life. Do not use hemostats to secure or remove devices with Luer lock hub connections.
- If resistance is met while attempting to flush catheter, follow institutional protocol for occluded catheters.
- When discarding used accessories, follow institutional protocol.
- Incompatible drug delivery within the same lumen may cause precipitation. Flush catheter lumen following each infusion.
- It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. The BioFlo Midline Catheter with ENDEXO Technology catheter bench testing included ten (10) power injection cycles.
- Failure to retract the stylet into the catheter prior to catheter insertion may cause vessel damage during insertion procedure.
- Do not use scissors to remove the dressing, as this may possibly cut or damage the catheter.

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- Prior to dressing the catheter and access site, inspect both to assure that they are completely dry of isopropyl alcohol or acetone based cleansing agents. To avoid pooling of an agent, do not fully insert catheter up to suture wing.
- Apply a sterile end cap on the catheter hub to prevent contamination when not in use.
- Patient movement may cause catheter tip displacement.
- Do not attempt to repair the catheter. If breaks or leaks are apparent in the catheter, remove the catheter immediately.
- Catheter use, care or removal is to be undertaken only by trained, qualified healthcare provider.
- Use of force to remove the catheter may lead to catheter separation. Hold the catheter distal to the suture wing during removal.
- Patients must be educated regarding the care and maintenance of their BioFlo Midline. The healthcare provider is responsible for this patient instruction.
- Avoid blood pressure measurement or the application of a tourniquet to an arm with an implanted device, since occlusion or other damage to the device may occur.
- Avoid pressure on the inner surface area or axilla of the cannulated arm while using crutches.
- Use of a needle to access the catheter is not recommended. However, if a needle is used, do not use a needle longer than 1.9 cm.

POTENTIAL COMPLICATIONS / ADVERSE EVENTS

- Air Embolism
- Bleeding
- Brachial Plexus or other Nerve Injury
- Catheter Dislodgement
- Catheter Embolism
- Catheter Erosion through Skin/Vessel
- Catheter Fragmentation
- Catheter Malfunction
- Catheter Malposition
- Catheter Migration
- Catheter Occlusion
- Catheter Retraction
- Catheter Rupture
- Death
- Drug or Contrast Medium Precipitate
- Extravasation/Infiltration of Infusate
- Embolism
- Hemothorax
- Infection
- Inflammation/Phlebitis
- Intolerance Reaction to Contrast Media
- Intolerance Reaction to Implanted Device
- Malposition
- Nerve Damage
- Pain
- Pleural Effusion
- Pneumothorax
- Pulmonary Embolism
- Renal Compromise
- Sensitivity or Allergy
- Sepsis
- Subintimal Venous or Myocardial Injection
- Thoracic Duct Injury
- Thromboembolism
- Endocarditis
- Exit Site Necrosis
- Fibrin Sheath Formation
- Foreign Body Rejection
- Hematoma
- Hemorrhage
- Thrombophlebitis
- Vascular Thrombosis
- Vessel Damage
- Vessel Stenosis
- Vessel Tamponade

HOW SUPPLIED

Contents supplied STERILE using an ethylene oxide (EO) process. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Please see package label for additional storage conditions.

OPERATIONAL INSTRUCTIONS

The BioFlo Midline with ENDEXO Technology is to be inserted, manipulated, and removed only by a qualified, licensed healthcare practitioner. The techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for a physician's experience and judgment in treating any specific patient. Please refer to the appropriate section based upon configuration selected.

NOTE: Strict aseptic technique must be used during insertion, maintenance and removal procedures. Prior to use, carefully examine the product to verify that it has not expired and the sterile package has not been damaged in shipment.

PRECAUTION: Do not use sharp objects to open package.

Table 1. Catheter Specifications

French Size (mm) (Outer Diameter)	Lumens	Lumen Gauge[1]	Catheter Length (cm)	Minimum Gravity Flow Rate (Water) (mL/hr)	Lumen Size (mm)	Priming Volume (mL)
3F (1.02)	1	20.0	20	512	0.6	0.43
4F (1.40)	1	17.0	20	1928	0.9	0.52
5F (1.68)	1	15.5	20	2280	1.1	0.57
5F (1.73)	2	17.5[2]	20	1524	0.8/0.8	0.60

1 Maximum guidewire compatibility is 0.018 in. (0.46 mm).
2 Both lumens.

INSTRUCTIONS FOR USE
CATHETER INSERTION DIRECTIONS

Patient Preparation

1. If placing catheter at patient bedside, apply tourniquet to upper arm. Select a vein based on patient assessment. Common veins used for insertion include the Basilic, Brachials and Cephalic. Release tourniquet.
2. Prepare sterile field and supplies.
3. Prepare insertion site and surrounding area with an acceptable topical antimicrobial cleansing agent according to institutional protocol, policies and procedures.

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Venous Access

4. Access vein using the appropriate method below.

Using Guidewire

a. Insert introducer needle, bevel up, into selected vein and confirm vessel entry.

b. Insert soft or guiding tip of the guidewire through the needle and into the vein to the desired position based on clinical practice guidelines and standards or institutional policy and procedure.

NOTE: If using hydrophilic guidewire, fill the wire holder (hoop) or bathe the guidewire with sterile normal saline for injection to ensure activation of the hydrophilic coating prior to the procedure. This may need to be repeated during the procedure by gently flushing the catheter with sterile normal saline solution for injection through the supplied flush assembly with the guidewire in place.

c. Recommended tip location is at or below the axillary line.

PRECAUTION: If guidewire must be withdrawn, remove the needle and guidewire as a single unit.

d. Gently withdraw safety needle from guidewire while holding guidewire in place.

Safety Needle Use

i. To activate safety mechanism, hold safety handle in one hand and rotate flashback chamber counter-clockwise.

ii. Pull back on flashback chamber until needle tip disappears into safety handle and locks securely into needle handle (indicated by audible click and feel).

iii. Verify needle tip is securely locked inside safety handle by pushing flashback chamber forward while holding safety handle. Repeat prior step, if necessary.

e. Discard needle per institutional protocol

Access without using guidewire

a. Select peelable sheath safety introducer needle.

b. Insert peelable sheath safety introducer needle per manufacturer's instructions for use.

NOTE: Ensure sheath lies within vessel.

c. Release tourniquet.

d. Retract needle half way out of peelable sheath, maintaining sheath position.

e. Hold peelable sheath in place, and remove safety needle per manufacturer's instructions for use. Discard according to institutional protocol.

NOTE: Do not reinsert introducer needle into peelable sheath, as this may cause damage to sheath.

Catheter Preparation

NOTE: Catheter preparation may occur prior to venous access, if catheter is being placed at patient bedside.

5. Determine catheter length.

NOTE: The BioFlo Midline catheter tip location should be at or below the axillary line.

a. Bedside Placement: Position patient with arm extended outward from body at a 90-degree angle, or as tolerated. Measure distance along vein track between selected insertion site and the desired catheter tip location.

6. Cut catheter to length, using previous measurement.

NOTE: Cut catheter tip square. Inspect cut surfaces to ensure there is no loose material or rough edges.

7. Attach flush assembly to catheter hub. Ensure locking collar is in open position (Figure 2).

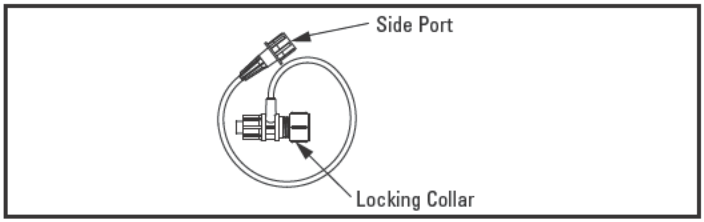


Figure 2. Flush Assemblies

NOTE: When inserting a dual lumen catheter either lumen may be used for stylet placement.

8. Draw 10 mL sterile normal saline into syringe (unless already supplied pre-filled), remove cap on side port of flush assembly, and attach syringe.

9. While covering locking collar opening with finger to prevent fluid loss, prime flush assembly and catheter.

NOTE: For multi lumen catheters, be sure to prime each lumen prior to insertion, clamping unused lumen(s) after it is primed.

10. If stylet is used (recommended for all techniques except for Seldinger technique), advance stylet slowly through flush assembly locking collar into catheter until tip of stylet extends beyond end of catheter. Continue to inject sterile normal saline, as needed, to assist in advancement.

11. Retract stylet back to a position at least one cm within the catheter (Figure 3).

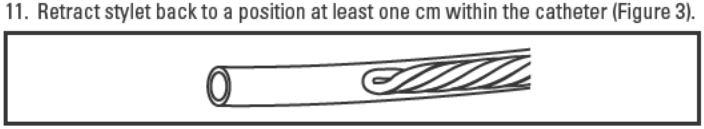


Figure 3. Stylet Position within Catheter

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PRECAUTION: Failure to retract stylet into catheter prior to catheter insertion may cause vessel damage during insertion procedure.

12. Turn flush assembly locking collar clockwise to secure stylet in place.

WARNING: Do not cut stylet or guidewire.

PRECAUTION: Do not reinsert stylet into catheter, as damage to catheter and vein may result.

PRECAUTION: Do not apply any type of clamp on catheter or extension tube while stylet is inside catheter. Stylet may become kinked and damage catheter, resulting in leakage or fracture of catheter.

13. Remove syringe from flush assembly and place cap on side port.

Catheter Placement Using Guidewire

a. Alongside guidewire, nick insertion site with safety scalpel. To use safety scalpel, depress top button on protective shield, and retract to rear locked position. Once nick is made, depress top button again and advance to forward locked position at lock indicator line.

b. Advance peelable sheath/dilator assembly over guidewire. Using a slight twisting motion, advance assembly into the vein.

c. Seldinger technique: Withdraw the dilator, leaving the sheath and guidewire in place.

   Modified technique: Withdraw dilator and guidewire together, leaving peelable sheath in place. Cover opening to prevent blood loss and/or air embolism.

14. If placing catheter at patient bedside turn patient's head toward insertion side with chin to shoulder.

15. Slowly and incrementally, insert catheter assembly through the peelable sheath to desired tip location.

NOTE: If inserting multi lumen catheter, ensure that extension tube(s) not being used is clamped.

NOTE: If practicing Seldinger technique, wet the exposed segment of the guidewire with saline and thread catheter over guidewire first.

16. Holding catheter steady, slowly withdraw peelable sheath from insertion site.

17. Grasp wings of sheath firmly, and pull apart applying equal pressure to both wings - peel the sheath away from the catheter using a forward motion. Discard according to institutional protocol.

18. Slowly advance remaining catheter into vein until "0" mark on catheter is at insertion site. Do not fully insert catheter to suture wing.

19. Loosen flush assembly from catheter hub and withdraw, with stylet or guidewire, while holding suture wing in place. Discard according to institutional protocol.

20. Once catheter is inserted, aspirate gently with syringe attached to flush assembly side port and observe for blood return. Detach and discard according to institutional protocol.

PRECAUTION: Do not reinsert stylet into catheter, as damage to catheter or vein may occur.

21. Close catheter clamp.

22. See FLUSHING AND HEPARINIZATION and CATHETER STABILIZATION sections for next steps.

FLUSHING AND HEPARINIZATION

1. Attach syringe to hub, open clamp, and aspirate blood.
2. Close clamp, detach syringe and discard according to institutional protocol.
3. Attach syringe filled with 10 mL sterile normal saline, open clamp, and flush lumen, using a "pulse" or "stop/start" technique.

NOTE: If flushing after a power injection, use 20 mL sterile normal saline.

4. Close clamp, detach syringe and discard according to institutional protocol.
5. Draw heparinized saline into syringe, and attach to hub.
6. Open clamp, and inject amount equal to or greater than priming volume into lumen (see Table 1).
7. Maintaining positive pressure on syringe, close clamp, detach syringe and discard.
8. Repeat for second lumen, if necessary.

NOTE: Never leave catheter uncapped.

NOTE: Flush catheter after every use. When not in use, flush at least every 12 hours, or according to institutional protocol to maintain patency.

CATHETER STABILIZATION

1. Prepare stabilization site with alcohol and remove betadine, if present.
2. Apply skin prep solution for enhanced adherence and skin protection. Allow skin prep solution to completely dry.
3. Slide device under suture wing. Slide one suture hole over a post, then slide that post and suture wing toward opposite side until second suture hole easily fits over second post.
4. Close lids over posts to secure catheter.
5. Peel away paper backing and place on skin.
6. Apply adhesive strip at or near insertion site.

CONTRAINDICATION: Patients with known tape or adhesive allergies.

PRECAUTION: Do not use where loss of adherence could occur, such as with a confused patient, unattended access device, diaphoretic or non-adherent skin.

PRECAUTION: Minimize catheter manipulation during application and removal.

NOTE: Monitor stabilization device daily. Replace at least every seven days.

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POWER INJECTION

Table 2. Power Injection Specifications

French Size (mm) (Outer Diameter)	Lumens	Catheter Length (cm)	Maximum Flow Rate for 11.8 cP CT Contrast (ml/sec) [1]	Maximum Catheter Pressure at Maximum Flow Rate (psi[1,2] (kPa))	Maximum Static Burst Pressure Post Injection (psi[3] (kPa))
3F (1.02)	1	20	2	168 (1158)	299 (2062)
4F (1.40)	1	20	6	181 (1248)	309 (2128)
5F (1.68)	1	20	6	153 (1055)	302 (2085)
5F (1.73)	2	20	6	172 (1186)	251 (1733)

1 Testing was conducted using contrast with viscosity of 11.8 centipoise (cP), measured at body temperature (37°C) with injector set at 325 psi (2,240 kPa). Data represent approximate flow capabilities of power injection of contrast media.
2 Internal catheter pressure data point observed during power injection testing.
3 Burst pressure is the static burst pressure failure point of the catheter after completion of 10 power injection cycles.

WARNING: During power injection testing catheter pressures did not exceed those outlined in Table 2.

WARNING: During static burst pressure testing, catheter failure was recorded as detailed in Table 2.

WARNING: Exceeding maximum allowable flow rate (Table 2) may result in catheter failure and/or catheter tip displacement.

1. Verify power injector is appropriately programmed and does not exceed catheter flow rate limit (see Table 2).
2. Warm contrast to body temperature (37°C).

   WARNING: Failure to warm contrast media to body temperature prior to power injection study may result in catheter failure.

3. Inspect catheter for damage.
4. Attach syringe, open clamp, and aspirate amount greater than priming volume of catheter, or until blood return (Table 1). Close clamp, and remove and discard used syringe according to institutional protocol.
5. Attach syringe filled with 10 mL sterile normal saline, open clamp, and vigorously flush lumen.
6. Close clamp, and detach syringe and discard according to institutional protocol.

   WARNING: Failure to ensure catheter patency prior to power injection studies may result in catheter failure.

   PRECAUTION: If a needleless connector is attached to catheter hub, first ensure that it will sustain power injection.

7. Attach power injector to selected lumen hub per manufacturer's recommendations, and open clamp.
8. Complete power injection study taking care not to exceed maximum flow rate limit (Table 2), and close clamp.

   PRECAUTION: It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. The BioFlo Midline with ENDEXO Technology catheter testing included ten (10) power injection cycles.

9. Disconnect the power injector.
10. Refer to FLUSHING AND HEPARINIZATION section.

CATHETER MAINTENANCE

It is recommended that institutional protocols be followed for all aspects of catheter care, use and maintenance. The following care, use and maintenance information is not intended as a substitute for institutional protocol, but rather, to describe guidelines and recommendations that can be used successfully with the BioFlo Midline with ENDEXO Technology.

GENERAL CATHETER CARE AND USE

- Use aseptic technique during catheter care and use.
- Use Standard and Universal Precautions during catheter care procedures.
- Never leave catheter uncapped.
- Do not use clamps, or instruments with teeth or sharp edges on the catheter, as catheter damage may occur.

CARE OF INSERTION SITE AND DRESSING

- Examine insertion site, including catheter stabilization device, routinely and with each dressing change, for complications.
- Follow institutional protocol for dressing change. It is recommended that dressings be changed weekly and as necessary.
- To maintain unobstructed flow, make sure there are no kinks in catheter or IV tubing.

  WARNING: Prior to dressing catheter and access site, inspect both to assure they are completely dry of isopropyl alcohol-based cleansing agents.

- A sterile, occlusive dressing covering the entire insertion site, suture wing and at least 2.5 cm of the extension tube is recommended.
- All efforts are to be made to keep insertion site and dressing clean, dry and intact.

DRESSING REMOVAL

- Stabilize catheter and Luer lock hub during dressing removal to prevent accidental dislodgment.
- Separate dressing away from Luer lock hub and toward insertion site. As you separate, keep any tape and dressing close to patient's arm to avoid dislodging catheter or sutures.

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ASSESSING CATHETER INTEGRITY

Assess catheter integrity before any injection/infusion by completing the following steps:

- Examine and palpate catheter tract and insertion site for complications.
- Using a 10 mL syringe, aspirate slowly for blood return. Difficulty in withdrawing blood may indicate catheter compression, malposition, and/or obstruction. Discard syringe according to institutional protocol.
- Using second 10 mL syringe, flush catheter with 10 mL of sterile normal saline to clear catheter.

NOTE: If catheter integrity is questioned as a result of any of the above steps, do not use catheter without further inquiry and resolution of the problem.

BLOOD SAMPLING

1. Stop administration of infusates.
2. Using aseptic technique, swab catheter hub and allow to air dry.
3. Flush the selected lumen with 10 mL of sterile normal saline.
4. Use syringe to aspirate small amount of blood and fluid (3-5 mL minimum) to verify patency. Discard syringe according to institutional protocol.
5. Using second syringe, slowly withdraw specimen, and close clamp.
6. Refer to FLUSHING AND HEPARINIZATION section.
7. Transfer specimens as per institutional protocol.

MANAGEMENT OF LUMEN OCCLUSION

The lumens of BioFlo Midlines may infrequently become obstructed. Lumen obstruction is usually evident by failure to aspirate or infuse through the lumen or inadequate flow and/or high resistance pressures during aspiration and/or infusion. The causes may include but not limited to catheter tip malposition, catheter kink, or clot. One of the following may resolve the obstruction:

- Verify there is no kinked tubing in the catheter section external to the body.
- Reposition the patient.
- Have the patient cough.
- Provided there is no resistance with aspiration, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall. Use a 10 mL or larger syringe.

PRECAUTION: Never forcibly flush an obstructed lumen. If any lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, consult institutional protocol for management of thrombosis.

CATHETER REPAIR

In the event that the catheter is accidentally torn or broken, it is recommended that the catheter be replaced.

CATHETER REMOVAL

Catheter removal is per the discretion of the physician in regards to the patient's therapy regimen.

1. Position patient upright with arm at 45-degree angle outward from body. Maintain insertion site below level of heart.
2. See DRESSING REMOVAL section.
3. Open catheter stabilization device retainer lids and remove catheter from retainer.

NOTE: It is preferred to use aseptic technique for the following steps.

4. To remove catheter, grasp catheter between suture wing and insertion site and remove slowly, in small increments, keeping catheter parallel to skin surface. Do not grasp Luer lock hub to remove catheter, as catheter damage may occur.
5. If resistance is still met, follow institutional protocol for the management of difficult-to-remove catheters.
6. To verify that entire catheter has been removed, measure and compare catheter length with initial length recorded at time of insertion.
7. Apply generous amount of alcohol to loosen edges of catheter stabilization device. While lifting adhesive pad, gently stroke undersurface of pad with alcohol to dissolve adhesive.
8. Following removal of catheter, cover insertion site with occlusive dressing for at least 24 hours.

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Single Lumen Dual Lumen

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26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973



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BioFlo Midline

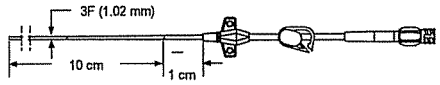
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Maximum Flow Rate 2 mL/sec	Maximal flödeshastighet 2 mL/sek	Didžiausias tėkmės greitis: 2 ml/sek.
Índice de flujo máximo 2 mL/sec	最大流量 2 mL/秒	Maksimaalne vooluklirens 2 ml/s
Débit maximum 2 ml/s	Maximální áramlási rychlost 2 mL/s	Frecvența maximă a fluxului 2 ml/sec
Maximale Flussrate 2 ml/s	Maximální průtok 2 ml/sec	Maximálny prietok 2 ml/s
Portata di flusso massima 2 mL/sec	Maksymalna prędkość przepływu 2 ml/s	Maksimalna brzina protoka 2 ml/sek
Maximaal debiet 2 ml/sec	Maksimum strømfrekvens 2 ml/sek.	Макс. стапка на проток 2 mL/sec
Maksimal gennemstrømningshastighed 2 ml/sek.	最大流速 2 mL/s	Maksimalna brzina protoka 2 ml/s
Μέγιστος ρυθμός ροής 2 mL/δευτ.	최대 유속 2 mL/초	Максимальная скорость потока 2 мл/сек
Taxa de fluxo máxima 2 ml/seg	Maksimum Akış Hızı 2 mL/sn	

Contents
1





0.014 in X 45 cm
(0.36 mm X 45 cm)

REF Catalog No. **46-010** Catheter Kit LOT 55515551Q

UPN Product No. H965460100 **3F-10 cm** Use By 2014-03

Catheter Kit / Kit del catéter / Kit de cathéter / Katheterkit / Kit catetere / Katheterset / Katetersæt / Κιτ καθετήρα / Kit de cateter / Katetersats / カテーテル・キット / Katéterkészlet / Souprava katetru / Zestaw cewnika / Katetersett / 导管套件 / 카테터 키트 / Kateter Kiti / Kateterių rinkinys / Kateetri komplekt / Set de cateterizare / Súprava katétra / Komplet opreme katetera / Комплект катетера / Komplet katetera / Комплект катетера

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BioFlo Midline Catheter Kit REF 46-010
with ENDEXO Technology 3F-10 cm 2014-03

BioFlo Midline Catheter REF 46-010
with ENDEXO Technology 3F-10 cm 2014-03

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BioFlo Midline

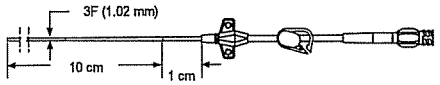
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Contents
1





0.014 in X 45 cm
(0.36 mm X 45 cm)

REF Catalog No. **46-010** **Catheter Kit** LOT 555155551555Q

UPN Product No. H965460100 **3F-10 cm** Use By 2014-03

Catheter Kit / Kit del catéter / Kit de cathéter / Katheterkit / Kit catetere / Katheterset / Kateterseti / Κιτ καθετήρα / Kit de cateter / Kateterats / カテーテル・キット / Katéterkészlet / Souprava katetru / Zestaw cewnika / Katetersett / 导管套件 / 카테터 키트 / Kateter Kiti / Kateterių rinkinys / Kateetri komplekt / Set de cateterizare / Súprava katétra / Komplet katétra / Комплект катетер / Komplet katetera / Комплект катетера



BioFlo Midline 3F
with ENDEXO Technology
REF 46-010 LOT 555155551555Q

BioFlo Midline 3F
with ENDEXO Technology
REF 46-010 LOT 555155551555Q

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Patient Chart Sticker / Adhesivo de historia clínica del paciente / Autocollant Graphique du patient / Aufkleber für Patientenakte / Adesivo cartella clinica paziente / Sticker voor status patiënt / Klistermærke til patientkort / Αυτοκόλλητο διαγράμματος ασθενή / Etiqueta da ficha do paciente / Patientjournaldekal / 患者カルテ・ステッカー / A beteg kórlaptára való matrica / Nálepka do chorobopisu pacienta / Nalepka karty pacjenta / Paskeitjournalo lipdukas / 患者病历标签 / 환자 차트 스티커 / Hasta Çizelgesi Etiketi / Paciente tarjetas lipdukas / Pārsienlīmēšanās lēkgs / Autocolant pentru fișa pacientului / Nálepka pacienta / Nalepnica za bolesnikov zdravstveni karton / Налепница за здравственот картон на пациентот / Nalepnica za karton pacijenta / Наклейка диаграммы пациента

BioFlo Midline REF 46-010 LOT 555155551555Q
with ENDEXO Technology

Patient Name / Nombre del paciente / Nom du patient / Name des Patienten / Nome paziente / Naam patiënt / Patientnavn / Ovqua ασθενή / Nome do paciente / Patientnamn / 患者名 / Ime bolesnika / Jméno pacienta / Imię i nazwisko pacjenta / Patientnavn / 患者姓名 / 환자 이름 / Hasta Adı / Paciente nombre y parentesco / Patsiendi nimi / Numele pacientului / Meno pacienta / Ime bolesnika / Име и презиме на пациентот / Ime pacijenta / Нэм пациента

Insertion Date / Fecha de inserción / Date d'insertion / Datum der Einführung / Data introduzione / Inbrengdatum / Indføringsdato / Ημερομηνία εισαγωγής / Data da inserção / Införingsdatum / 留置年月日 / A behelyezés dátuma / Datum zavedení / Data wprowadzenia / Innføringsdato / 插管日期 / 삽입 날짜 / Giriş Tarihi / Įvedimo data / Sisestamiskuupäev / Data inserției / Dátum vloženia / Datum uvođenja / Датум на вметнување / Datum umetanja / Data introducerii

French Size / Calibre francés / Taille fr / French-Größe / Dimensioni French / French-maat / Størrelse i French / Μέγεθος French / Tamanho fr / French-storlek / フレンチサイズ / Méret F-ben / Velikost v jednotkách French / Rozmiar w skali French / French-størrelse / 法国尺码 / 프렌치 크기 / Fransız Boyutu / Fr dydis / Prantsuse skaala / Dimensiune pe scala franceză / Francúzska veľkosť / Veľkosť v jednotkách French / Razmernaya prilagalnaya na katetera / F veličina prečnika / Калибр катетера, fr **3F**

Single Lumen / Luz simple / Simple lumière / Einzelnes Lumen / Lume singolo / Enkel lumen / Enkellumen / Μονός αυλός / Lúmen único / Enkel lumen / シングル・ルーメン / Egy lumen / Jednocestný / Jednokanałowy / Enkellumen / 外腔 / 단일관 / Tekli Lümen / Vienas spindis / Une valendikuga / Un singur lumen / Jeden kimen / Jednotrubí lumen / Co egzem rymen / Jedan lumen / Одноканальный

Catheter Trim Length / Longitud de recorte del catéter / Longueur de découpe du cathéter / Schnittlänge Katheter / Lunghezza taglio catetere / Katheter afgesneden op lengte / Kateterets afskårede længde / Μήκος κοπής καθετήρα / Comprimento de corte do cateter / Kateterns längd / カテーテル切断長 / A katéter levágási hossza / Délka zkrácení katetru / Długość cewnika po obcięciu / Kateteris kärpimispikkus / 导管修剪长度 / 카테터 잘린 길이 / Kateter Kesme Uzunluğu / Nupjautos kateterio dalies ilgis / Kateetri kärbitud pikkus / Lungimea tăiturii cateterului / Dĺžka skrátenia katétra / Dužina podrezivanja katetera / Должина на скратен дел на катетер / Dužina za skraćivanje katetera / Длина обрезки катетера

Consult instructions for use.

Do not use if package is damaged.

Country of Origin

STERILE EO Sterilized using ethylene oxide.

+HS654601003

+SS801031455551555155503/

Made in USA:
10 Glens Falls Technical Park
Glens Falls, NY 12801 USA

Legal Manufacturer
Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

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EU Authorized Representative
Donewa Lifescience Consulting Srl
Piazza Albania, 10
00153 Rome, Italy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BioFlo Midline

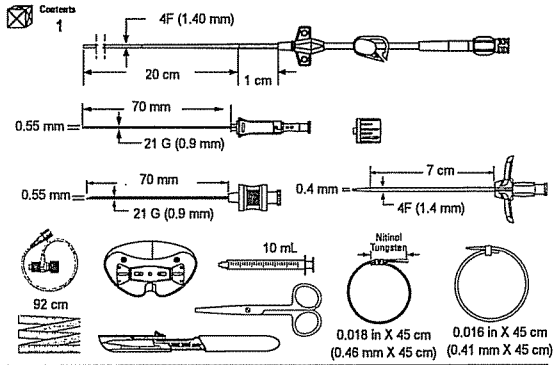
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with ENDEXO Technology

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Maximum Flow Rate 6 mL/sec	Maximal flödeshastighet 6 mL/sek	Didžiausias tėkmės greitis: 6 ml/sek.
Índice de flujo máximo 6 mL/sec	最大流量 6 mL/秒	Maksimaalne voolukiirus 6 ml/s
Débit maximum 6 ml/s	Maximális áramlási sebesség: 6 ml/s	Frecvența maximă a fluxului 6 ml/sec
Maximale Flussrate 6 ml/s	Maximální průtok 6 ml/sec	Maximálny prietok 6 ml/s
Portata di flusso massima 6 mL/sec	Maksymalna prędkość przepływu 6 ml/s	Maksimalna brzina protoka 6 ml/sek
Maximaal debiet 6 ml/sec	Maksimum strømfrekvens 6 ml/sek.	Макс. стапка на проток 6 mL/sec
Maksimal gennemstrømningshastighed 6 ml/sek.	最大流速 6 mL/s	Maksimalna brzina protoka 6 mL/s
Μέγιστος ρυθμός ροής 6 mL/δευτ.	최대 유속 6 mL/초	Максимальная скорость потока 6 мл/сек
Taxa de fluxo máxima 6 ml/seg	Maksimum Akış Hızı 6 mL/sn	

Contents
1



REF Catalog No. **46-012** **MST-45 Kit** LOT 55515551Q

UPN Product No. H965460120 **4F-20 cm** Use By 2012-03

MST-45 Kit / Kit MST-45 / Kit MST-45 / MST-45-Kit / Kit MST-45 / MST-45-set / MST-45-szet / Kit MST-45 / Kit de MST-45 / MST-45-sats / MST-45 キット / MST-45 készlet / Souprava MST-45 / Zestaw MST-45 / MST-45-sett / MST-45 套件 / MST-45 키트 / MST-45 Kiti / MST-45 rinkinys / MST-45 komplekt / Set MST-45 / Súprava MST-45 / Komplet MST-45 / Комплект ST-45 / Komplet MST-45 / Комплект MST-45

Nitinol Tungsten / Nitinol y tungsteno / Nitinol Tungstène / Nitinol Wolfram / Nitinol-tungsteno / Nitinol wolfraam / Nitinol Wolfram / Nitinol Volfram / Nitinol Tungstênio / Νιτινόλη Βολφράμιο / Nitinol volfrám / Nitinol Wolframu / Nitinol z dodatkiem wolframu / Nitinol Tungsten / Nitinol Volfram / Nitinolis, volframas / Nitinool volfram / Nitinol-tungsten / Nitinol Wolfrám / Nitinol tungsten / Нитинол Волфрам / Nitinol volfram / ナイチノール タングステン / 镍钛合金 钨 / 나티놀 텅스텐

Consult instructions for use.

Do not use if package is damaged.

STERILE EO Sterilized using ethylene oxide.

Do Not Restorilize

For single use only. Do not reuse.

℞ ONLY

VS1CH01 01
12/2014

Made in USA:
10 Glens Falls Technical Park
Glens Falls, NY 12801 USA

+H9654601205

+S$801031255515551Q5P

BioFlo

Legal Manufacturer
Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

Guidewire made in Ireland

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BioFlo Midline with ENDEXO Technology — **MST-45 Kit** — **4F-20 cm** — REF **46-012** — **2012-03**

BioFlo Midline with ENDEXO Technology — **MST-45 Kit** — **4F-20 cm** — REF **46-012** — **2012-03**

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BioFlo Midline

with ENDEXO Technology

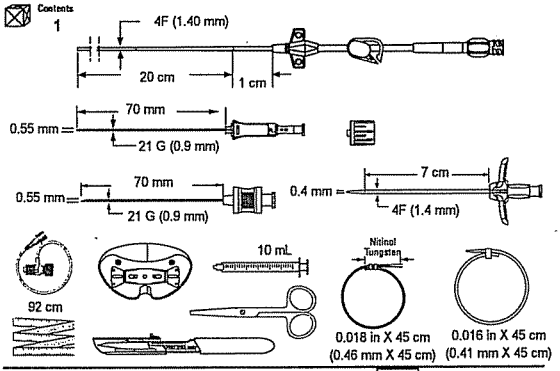
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Maximum Flow Rate 6 mL/sec	Maximal flödeshastighet 6 mL/sek	Didžiausias tėkmės greitis: 6 ml/sek.
Índice de flujo máximo 6 mL/sec	最大流量 6 mL/秒	Maksimaalne voolukiirus 6 ml/s
Débit maximum 6 mL/s	Maximális áramlási sebesség: 6 mL/s	Frecvența maximă a fluxului 6 ml/sec
Massimale Flussrate 6 mL/s	Maximální průtok 6 ml/sec	Maximálny prietok 6 ml/s
Portata di flusso massima 6 mL/sec	Maksymalna przepływność przepływu 6 ml/s	Maksimalna brzina protoka 6 ml/sek
Maximaal debiet 6 ml/sec	Maksimum strømtrykvens 6 ml/sek	Макс. стапка на проток 6 mL/sec
Maksimal gennemstrømningshastighed 6 ml/sek.	最大流速 6 mL/s	Maksimalna brzina protoka 6 mL/s
Μέγιστος ρυθμός ροής 6 mL/δευτ.	최대 유속 6 mL/초	Максимальная скорость потока 6 мл/сек
Taxa de fluxo máxima 6 ml/seg	Maksimum Akış Hızı 6 mL/sn	

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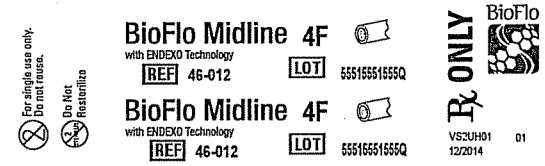


REF Catalog No. **46-012** MST-45 Kit LOT 555155551555Q

UPN Product No. H965460120 **4F-20 cm** Use By 2012-03

MST-45 Kit / Kit MST-45 / Kit MST-45 / MST-45-Kit / Kit MST-45 / MST-45-set / MST-45-szet / Kit MST-45 / Kit de MST-45 / MST-45-sats / MST-45 キット / MST-45 készlet / Souprava MST-45 / Zestaw MST-45 / MST-45-sett / MST-45 套件 / MST-45 키트 / MST-45 Kit / MST-45 tinklos / MST-45 komplekt / Set MST-45 / Súprava MST-45 / Komplet MST-45 / Комплект ST-45 / Komplet MST-45 / Комплект MST-45

Nitinol Tungsten / Nitinol y tungsteno / Nitinol Tungstène / Nitinol Wolfram / Nitinol-tungsteno / Nitinol wolfraam / Nitinol Wolfram / Nitinol Volfram / Nitinol Tungsténio / Νιτινόλη Βολφράμιο / Nitinol volfrám / Nitinol Wolframu / Nitinol z dodatkiem wolframu / Nitinol Tungsten / Nitinol Volfram / Nitinolis, volframas / Nitinool volfram / Nitinol-tungstan / Nitinol Wolfrám / Nitinol tungsten / Нитинол Вольфрам / Nitinol volfram / ナイチノール タングステン / 镍钛合金 钨 / 나티논 텅스텐



Patient Chart Sticker / Adhesivo de historia clínica del paciente / Autocollant Graphique du patient / Aufkleber für Patientenakte / Adesivo cartella clinica paziente / Sticker voor status patiënt / Klistermærke til patientkort / Αυτοκόλλητο διαγράμματος ασθενή / Etiqueta da ficha do paciente / Patientjournaldekal / 患者カルテ-ステッカー / A beteg kórlapjára való matrica / Nálepka do zdravotního pacienta / Kulkyšių karty pacjenta / Pasientjournalklistremerke / 患者病历标签 / 환자 차트 스티커 / Hasta Çizelgesi Etiketi / Pacienta korteles lipdukas / Pasienlimkaardi kleeps / Autocolant pentru fișa pacientului / Nálepka pacienta / Nalepnica za bolesničar zdravstveni karton / Налепница на здравственот картон на пациентот / Nalepka za karton pacijenta / Наклейка диаграммы пациента

BioFlo Midline REF 46-012 LOT 555155551555Q

Patient Name / Nombre del paciente / Nom du patient / Name des Patienten / Nome paziente / Naam patiënt / Patientnavn / Ονομα ασθενή / Nome do paciente / Patientnamn / 患者名 / Ime bolesnika / Jméno pacienta / Imię i nazwisko pacjenta / Pasientnavn / 患者姓名 / 환자 이름 / Hasta Adı / Paciento vardas ir pavardė / Patsiendi nimi / Numele pacientului / Meno pacienta / Ime bolesnika / Име и презиме на пациентот / Ime pacijenta / Име пациента

Insertion Date / Fecha de inserción / Date d'insertion / Datum der Einführung / Data introduzione / Inbrengdatum / Indføringsdato / Ημερομηνία εισαγωγής / Data da inserção / Införingsdatum / 留置年月日 / A behelyezés dátuma / Datum zavedení / Data wprowadzenia / Innføringsdato / 插管日期 / 삽입 날짜 / Galg laikas / Įvedimo data / Sisestamiskuupäev / Data inserției / Dátum vkladania / Datum uvođenja / Датум на вметнување / Datum umetanja / Дата введения

French Size / Calibre francés / Taille Fr / French-Größe / Dimensioni French / French-maat / Størrelse i French / Μέγεθος French / Tamanho Fr / French-storlek / フレンチサイズ / Méret F-ben / Veličost v jednotkách French / Rozmiar w skali French / French-størrelse / 法国尺码 / 프렌치 크기 / Fransız Boyutu / Fr dydis / Prantsuse skaala / Dimensiune pe scala franceză / Francúzska veľkosť / Veličina u jedinicama French / Надворешен дијаметар на катетер / F veličina prečnika / Калибр катетера, Fr **4F**

Single Lumen / Luz simple / Simple lumière / Einzelnes Lumen / Lume singolo / Enkel lumen / Enkelt lumen / Μονός αυλός / Lúmen único / Enkel lumen / シングル・ルーメン / Egy lumen / Jednocestný / Jednokanálový / Enkeltlumen / 单腔 / Ühe valendiku / Vienas spindis / Ühe valendikuga / Un singur lumen / Jeden lúmen / Jednostruki lumen / Со еден лумен / Jedan lumen / Једноканалний

Catheter Trim Length / Longitud de recorte del catéter / Longueur de découpe du cathéter / Schaftlänge Katheter / Lunghezza taglio catetere / Kateter afgesneden op lengte / Kateterets afskårede længde / Μήκος κοπής καθετήρα / Comprimento de corte do cateter / Kateters längd / カテーテル切断長 / A katéter levágási hossza / Délka zkrácení katetru / Długość czewnika po obcięciu / Kateetrets lõppelengde / 导管修剪长度 / 카테터 절단 길이 / Kateter Kesme Uzunluğu / Kupjautos kateterio dalies ilgis / Kateetri kärbitud pikkus / Lungimea tăierii cateterului / Dĺžka skrátenia katétra / Dužina podrezivanja katetera / Должина на скратен дел на катетер / Dužina za skraćivanje katetera / Дължа обрязан катетъра

Consult instructions for use.

Do not use if package is damaged.

Guidewire made in Ireland

STERILE EO Sterilized using ethylene oxide.

+H9654601205

+$$$01031255515551555505/

Made In USA:
10 Glens Falls Technical Park
Glens Falls, NY 12801 USA

Legal Manufacturer
Navilyst Medical, Inc.
25 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

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Donawa Lifescience Consulting Srl
Piazza Albania, 10
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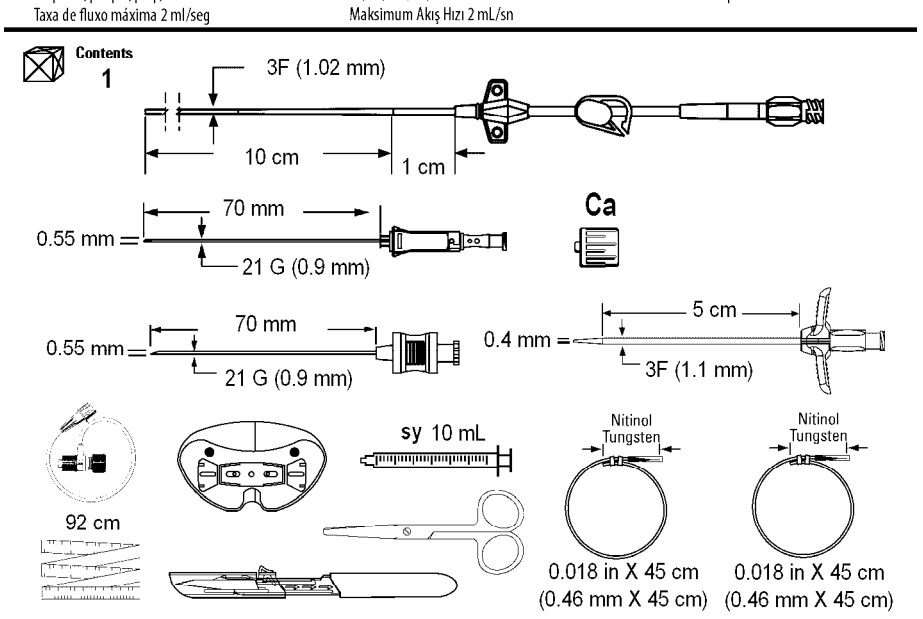
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with ENDEXO Technology

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Maximum Flow Rate 2 mL/sec	Maximal flödeshastighet 2 mL/sek	Didžiausias tėkmės greitis: 2 ml/sek.
Índice de flujo máximo 2 mL/sec	最大流量 2 mL/秒	Maksimaalne voolukiirus 2 ml/s
Débit maximum 2 ml/s	Maximális áramlási sebesség: 2 ml/s	Frecvența maximă a fluxului 2 ml/sec
Maximale Flussrate 2 ml/s	Maximální průtok 2 ml/sec	Maximálny prietok 2 ml/s
Portata di flusso massima 2 mL/sec	Maksymalna prędkość przepływu 2 ml/s	Maksimalna brzina protoka 2 ml/sek
Maximaal debiet 2 ml/sec	Maksimum strømfrekvens 2 ml/sekc	Макс. стапка на проток 2 mL/sec
Maksimal gennemstrømningshastighed 2 ml/sek.	最大流速 2 mL/s	Maksimalna brzina protoka 2 mL/s
Μέγιστος ρυθμός ροής 2 mL/δευτ.	최대 유속 2 ml/초	Максимальная скорость потока 2 мл/сек
Taxa de fluxo máxima 2 ml/seg	Maksimum Akış Hızı 2 mL/sn	



REF Catalog No. **46-150** **MST-45 Kit** LOT 55515551Q

UPN Product No. H965461500 **3F-10 cm** Use By 2012-03

MST-45 Kit / Kit MST-45 / Kit MST-45 / MST-45-Kit / Kit MST-45 / MST-45-set / MST-45-sæt / Κιτ MST-45 / Kit de MST-45 / MST-45-sats / MST-45 キット / MST-45 készlet / Souprava MST-45 / Zestaw MST-45 / MST-45-sett / MST-45 套件 / MST-45 키트 / MST-45 Kiti / MST-45 rinkinys / MST-45 komplekt / Set MST-45 / Súprava MST-45 / Komplet MST-45 / Комплет ST-45 / Komplet MST-45 / Комплект MST-45

Nitinol Tungsten / Nitinol y tungsteno / Nitinol Tungstène / Nitinol Wolfram / Nitinol-tungsteno / Nitinol wolfraam / Nitinol Wolfram / Nitinol Volfram / Nitinol Tungsténio / Νιτινόλη Βολφράμιο / Nitinol volfrám / Nitinol Wolframu / Nitinol z dodatkiem wolframu / Nitinol Tungsten / Nitinol Volfram / Nitinolis, volframas / Nitinool volfram / Nitinol-tungsten / Nitinol Wolfrám / Nitinol tungsten / Нитинол Волфрам / Nitinol volfram / ナイチノール タングステン / 镍钛合金 钨 / 나티놀 텅스텐

Consult instructions for use.

Do not use if package is damaged.

STERILE EO Sterilized using ethylene oxide.

Do Not Resterilize

For single use only. Do not reuse.

℞ ONLY

VS1CH01 01
12/2014

Made In USA:
10 Glens Falls Technical Park
Glens Falls, NY 12801 USA

+H9654615008

+$$801031255515551Q8S

BioFlo

Legal Manufacturer
Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

Guidewire made in Ireland

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with ENDEXO Technology
MST-45 Kit
3F-10 cm
REF 46-150
2012-03

BioFlo Midline
with ENDEXO Technology
MST-45 Kit
3F-10 cm
REF 46-150
2012-03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BioFlo Midline

with ENDEXO Technology

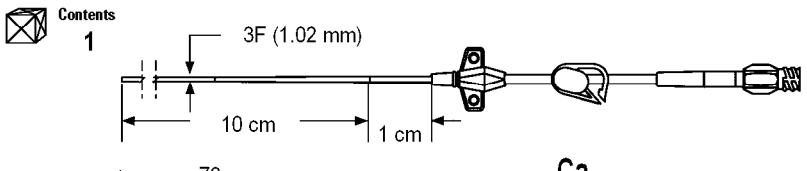
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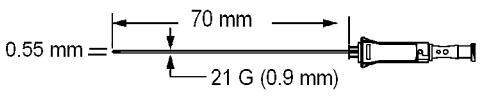
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Maximum Flow Rate 2 mL/sec
Índice de flujo máximo 2 mL/sec
Débit maximum 2 ml/s
Maximale Flussrate 2 ml/s
Portata di flusso massima 2 mL/sec
Maximaal debiet 2 ml/sec
Maksimal gennemstrømningshastighed 2 ml/sek.
Μέγιστος ρυθμός ροής 2 mL/δευτ.
Taxa de fluxo máxima 2 ml/seg
Maximal flödeshastighet 2 mL/sek
最大流量 2 mL/秒
Maximális áramlási sebesség: 2 ml/s
Maximální průtok 2 ml/sec
Maksymalna prędkość przepływu 2 ml/s
Maksimum strømfrekvens 2 ml/sekc
最大流速 2 mL/s
최대 유속 2 mL/초
Maksimum Akış Hızı 2 mL/sn
Didžiausias tėkmės greitis: 2 ml/sek.
Maksimaalne voolukiirus 2 ml/s
Frecvenţa maximă a fluxului 2 ml/sec
Maximálny prietok 2 ml/s
Maksimalna brzina protoka 2 ml/sek
Макс. стапка на проток 2 mL/sec
Maksimalna brzina protoka 2 mL/s
Максимальная скорость потока 2 мл/сек

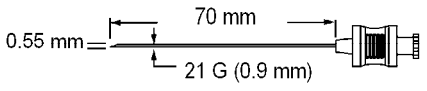
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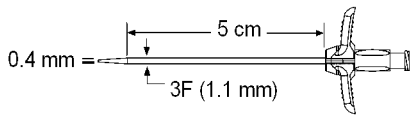
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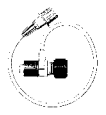


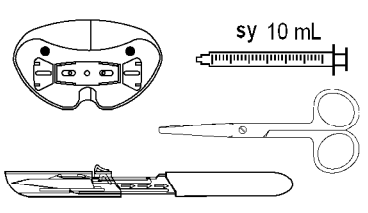


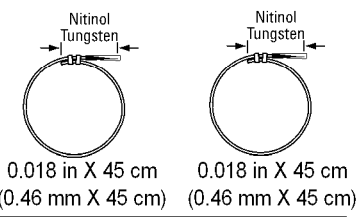
Ca











REF Catalog No. **46-150** **MST-45 Kit** **LOT** 555155551555Q

UPN Product No. H965461500 **3F-10 cm** Use By 2012-03

MST-45 Kit / Kit MST-45 / Kit MST-45 / MST-45-Kit / Kit MST-45 / MST-45-set / MST-45-sæt / Κιτ MST-45 / Kit de MST-45 / MST-45-sats / MST-45 キット / MST-45 készlet / Souprava MST-45 / Zestaw MST-45 / MST-45-sett / MST-45 套件 / MST-45 키트 / MST-45 Kiti / MST-45 rinkinys / MST-45 komplekt / Set MST-45 / Súprava MST-45 / Komplet MST-45 / Комплет ST-45 / Komplet MST-45 / Комплект MST-45

Nitinol Tungsten / Nitinol y tungsteno / Nitinol Tungstène / Nitinol Wolfram / Nitinol-tungsteno / Nitinol wolfraam / Nitinol Wolfram / Nitinol Volfram / Nitinol Tungsténio / Νιτινόλη Βολφράμιο / Nitinol volfrám / Nitinol Wolframu / Nitinol z dodatkiem wolframu / Nitinol Tungsten / Nitinol Volfram / Nitinolis, volframas / Nitinool volfram / Nitinol-tungsten / Nitinol Wolfrám / Nitinol tungsten / Нитинол Волфрам / Nitinol volfram / ナイチノール タングステン / 镍钛合金 钨 / 나티놀 텅스텐

For single use only. Do not reuse.

Do Not Resterilize

BioFlo Midline 3F
with ENDEXO Technology
REF 46-150 **LOT** 55515551555Q

BioFlo Midline 3F
with ENDEXO Technology
REF 46-150 **LOT** 55515551555Q

Rx ONLY

BioFlo

VS2UH01 01
12/2014

Patient Chart Sticker / Adhesivo de historia clínica del paciente / Autocollant Graphique du patient / Aufkleber für Patientenakte / Adesivo cartella clinica paziente / Sticker voor status patiënt / Klistermærke til patientkort / Αυτοκόλλητο διαγράμματος ασθενή / Etiqueta da ficha do paciente / Patientjournaldekal / 患者カルテ・ステッカー / A beteg kórlapjára való matrica / Nálepka do chorobopisu pacienta / Naklejka karty pacjenta / Pasientjournalklistremerke / 患者病历标签 / 환자 차트 스티커 / Hasta Çizelgesi Etiketi / Paciento kortelės lipdukas / Patsiendikaardi kleeps / Autocolant pentru fişa pacientului / Nálepka pacienta / Naljepnica za bolesnikov zdravstveni karton / Налепница на здравствениот картон на пациентот / Nalepnica za karton pacijenta / Наклейка диаграммы пациента

BioFlo Midline with ENDEXO Technology **REF** 46-150 **LOT** 55515551555Q

Patient Name / Nombre del paciente / Nom du patient / Name des Patienten / Nome paziente / Naam patiënt / Patientnavn / Όνομα ασθενή / Nome do paciente / Patientnamn / 患者名 / Ime bolesnika / Jméno pacienta / Imię i nazwisko pacjenta / Pasientnavn / 患者姓名 / 환자 이름 / Hasta Adı / Paciento vardas ir pavardė / Patsiendi nimi / Numele pacientului / Meno pacienta / Ime bolesnika / Име и презиме на пациентот / Ime pacijenta / Имя пациента

Insertion Date / Fecha de inserción / Date d'insertion / Datum der Einführung / Data introduzione / Inbrengdatum / Indføringsdato / Ημερομηνία εισαγωγής / Data da inserção / Införingsdatum / 留置年月日 / A behelyezés dátuma / Datum zavedení / Data wprowadzenia / Innføringsdato / 插管日期 / 삽입 날짜 / Giriş Tarihi / Įvedimo data / Sisestamiskuupäev / Data inserţiei / Dátum vloženia / Datum uvođenja / Датум на вметнување / Datum umetanja / Дата введения

French Size / Calibre francés / Taille Fr / French-Größe / Dimensioni French / French-maat / Størrelse i French / Μέγεθος French / Tamanho Fr / French-storlek / フレンチサイズ / Méret F-ben / Velikost v jednotkách French / Rozmiar w skali French / French-størrelse / 法国尺码 / 프랑스 크기 / Fransız Boyutu / Fr dydis / Prantsuse skaala / Dimensiune pe scala franceză / Francúzska veľkosť / Veličina u jedinicama French / Надворешен дијаметар на катетер / F veličina prečnika / Калибр катетера, Fr **3F**

Single Lumen / Luz simple / Simple lumière / Einzelnes Lumen / Lume singolo / Enkel lumen / Enkeltlumen / Μονός αυλός / Lúmen único / Enkel lumen / シングル・ルーメン / Egy lumen / Jednocestný / Jednokanałowy / Enkellumen / 单腔 / 단일 관 / Tekli Lümen / Vienas spindis / Ühe valendikuga / Un singur lumen / Jeden lúmen / Jednostruki lumen / Со еден лумен / Jedan lumen / Одноканальный

Catheter Trim Length / Longitud de recorte del catéter / Longueur de découpe du cathéter / Schnittlänge Katheter / Lunghezza taglio catetere / Katheter afgesneden op lengte / Kateterets afskårede længde / Μήκος κοπής καθετήρα / Comprimento de corte do cateter / Kateterns längd / カテーテル切断長 / A katéter levágási hossza / Délka zkrácení katetru / Długość cewnika po obcięciu / Kateterets klippelengde / 导管修剪长度 / 카테터 절단 길이 / Kateter Kesme Uzunluğu / Nupjautos kateterio dalies ilgis / Kateetri kärbitud pikkus / Lungimea tăieturii cateterului / Dĺžka skrátenia katétra / Duljina podrezivanja katetera / Должина на скратен дел на катетер / Dužina za skraćivanje katetera / Длина обрезки катетера

Consult instructions for use.

Do not use if package is damaged.

Guidewire made in Ireland

STERILE EO Sterilized using ethylene oxide.

+H9654615008

+$$8010312555155515555Q80

Made In USA:
10 Glens Falls Technical Park
Glens Falls, NY 12801 USA

Legal Manufacturer
Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

This product is protected by one or more of the following United States Patents: 6,127,507.

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EC REP
EU Authorized Representative
Donawa Lifescience Consulting Srl
Piazza Albania, 10
00153 Rome, Italy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

BioFlo Midline

with ENDEXO Technology

Maximal Barrier Nursing Kit

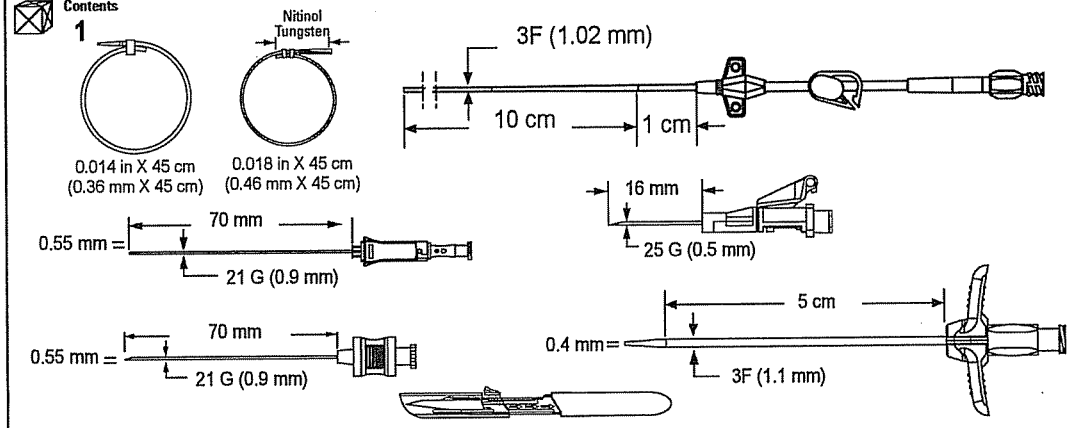
angiodynamics

Maximum Flow Rate 2 mL/sec

3F-10 cm

REF Catalog No. **44046011** LOT 111111Q Use By 2013-03

Contents 1



(1) Safety Ampule Cracker	(1) End Cap	(1) Transparent Dressing	(1) 3 mL Orange Antispetic Skin Prep
(1) Lidocaine Ampule	(1) Flush Assembly	(1) Transducer Cover (4 x 58)	(1) Surgical Tape
(1) Lidocaine Label	(5) 4x4 Gauze Pad	(1) Full Body Drape	(2) CSR Wraps
(1) Filter Straw	(1) Sharps Container	(1) Underarm Drape	(1) Surgical Gown
(1) 3 mL Luer Lock Syringe	(1) 3 mL Antiseptic Skin Prep	(1) Fenestrated Drape	(1) Mask with Earloops
(1) Tape Measures	(1) Skin Protectant Swabstick	(1) Towels	(1) Hairnets
(1) Scissors	(1) Catheter Stabilization Device	(1) Tourniquets	

STERILE EO Sterilized using ethylene oxide.

Consult instructions for use.

Do not use if package is damaged.

For single use only. Do not reuse.

Do Not Resterilize

℞ ONLY

BioFlo

20°C 25°C Temperature limitation.

This product is protected by one or more of the following United States Patents: 6,127,507; U.S. Patent Pending.

+4404601101

+$$801031311111101L

BioFlo Midline 3F-10 cm
with ENDEXO Technology REF 44046011
Maximal Barrier Nursing Kit LOT 111111Q

BioFlo Midline 3F -10 cm
with ENDEXO Technology REF 44046011
Maximal Barrier Nursing Kit LOT 111111Q

Legal Manufacturer

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

Made In USA:
10 Glens Falls Technical Park
Glens Falls, NY 12801 USA

Underarm Drape, Fenestrated Drape, Ruler, Gauze and Hairnet made in China; Scissors made in Pakistan, Thin wall needle and Stabilization Device made in Mexico, Full body Drape, Mask and Towel made in Thailand; Gown made in Honduras.

gwnt006.pcx

VSKLH01 01
12/2014

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

BioFlo Midline
with ENDEXO Technology

Maximal Barrier Nursing Kit

Contents

UPN Product No. **H965460110**

REF Catalog No. **46-011**

Use By **2013-03**

LOT **55515551Q**

1 REF 44046011 **3F-10 cm**
Made in USA

BioFlo Midline
with ENDEXO Technology

2 REF 306553 (single pack)
Made in Ireland

Syringe Pre-filled with 0.9% Sodium Chloride

VSJCH01 01 12/2014

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

BioFlo Midline

with ENDEXO Technology

REF Catalog No. 44046011

LOT 111111Q

Peel and attach to patient chart

Patient Name _____

Inserted by / Date _____

Catheter Trim Length _____ 3F

WARNINGS

- **NOT A PICC:** Therapies not appropriate for Midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Failure to ensure patency of the catheter prior to power injection may result in catheter failure.
- Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter which may cause catheter failure.
- Exceeding the maximum allowable flow rate may result in catheter failure and/or catheter tip displacement.
- Catheter indication for power injection of contrast media implies the catheter's ability to withstand this procedure, but does not imply appropriateness of the procedure for a particular patient. A trained clinician is responsible for evaluating the health and status of a patient as it pertains to a power injection procedure.
- The maximum pressure of power injectors used with the power injectable Midline must not exceed 325 psi (2,240 kPa).

Precaution: It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. The BioFlo Midline with ENDEXO Technology catheter testing included 10 power injection cycles.

angiodynamics

USA Customer Service 800-833-9973

Consult instructions for use.

IN8PH01 01
12/2014

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

BioFlo Midline

with ENDEXO Technology

Maximal Barrier Nursing Kit

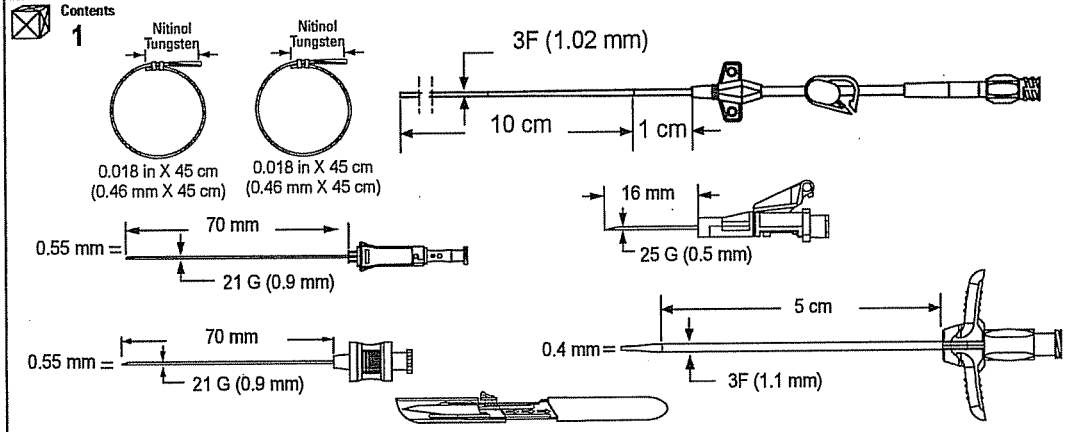
angiodynamics

Maximum Flow Rate 2 mL/sec

3F-10 cm

REF Catalog No. **44046420** LOT 111111Q Use By 2013-03

Contents 1



(1) Safety Ampule Cracker	(1) End Cap	(1) Transparent Dressing	(1) 3 mL Orange Antispetic Skin Prep
(1) Lidocaine Ampule	(1) Flush Assembly	(1) Transducer Cover (4 x 58)	(1) Surgical Tape
(1) Lidocaine Label	(5) 4x4 Gauze Pad	(1) Full Body Drape	(2) CSR Wraps
(1) Filter Straw	(1) Sharps Container	(1) Underarm Drape	(1) Surgical Gown
(1) 3 mL Luer Lock Syringe	(1) 3 mL Antiseptic Skin Prep	(1) Fenestrated Drape	(1) Mask with Earloops
(1) Tape Measures	(1) Skin Protectant Swabstick	(1) Towels	(1) Hairnets
(1) Scissors	(1) Catheter Stabilization Device	(1) Tourniquets	

STERILE EO Sterilized using ethylene oxide.

Consult instructions for use.

Do not use if package is damaged.

For single use only. Do not reuse.

Do Not Resterilize

℞ ONLY

20°C 25°C Temperature limitation.

BioFlo

This product is protected by one or more of the following United States Patents: 6,127,507; U.S. Patent Pending.

+440464200M

+$$8010313111111QMP

BioFlo Midline 3F-10 cm
with ENDEXO Technology REF 44046420
Maximal Barrier Nursing Kit LOT 111111Q

BioFlo Midline 3F -10 cm
with ENDEXO Technology REF 44046420
Maximal Barrier Nursing Kit LOT 111111Q

Legal Manufacturer

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752 USA
USA Customer Service 800-833-9973

Made In USA:
10 Glens Falls Technical Park
Glens Falls, NY 12801 USA

Underarm Drape, Fenestrated Drape, Ruler, Gauze and Haimet made in China; Scissors made in Pakistan, Thin wall needle and Stabilization Device made in Mexico, Full body Drape, Mask and Towel made in Thailand; Gown made in Honduras.

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VSKLH01 01
12/2014

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BioFlo Midline
with ENDEXO Technology

Maximal Barrier Nursing Kit

Contents

UPN Product No. **H965464200**

REF Catalog No. **46-420**

Use By **2013-03**

LOT **55515551Q**

1 REF 44046420 **3F-10 cm**
Made in USA

BioFlo Midline
with ENDEXO Technology

2 REF 306553 (single pack) **Syringe Pre-filled with 0.9% Sodium Chloride**

VSJCH01 01 12/2014

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request 2016-1384; Released by CDRH on 08/31/2016

BioFlo Midline

with ENDEXO Technology

REF Catalog No. 44046420

LOT 111111Q

Peel and attach to patient chart

Patient Name _____

Inserted by / Date _____

Catheter Trim Length _____ **3F**

WARNINGS

- **NOT A PICC:** Therapies not appropriate for Midline catheters include continuous vesicant therapy, parenteral nutrition, infusates with pH less than 5 or greater than 9, and infusates with an osmolarity greater than 600 mOsm/L.
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- Failure to ensure patency of the catheter prior to power injection may result in catheter failure.
- Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter which may cause catheter failure.
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Precaution: It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. The BioFlo Midline with ENDEXO Technology catheter testing included 10 power injection cycles.

angiodynamics

USA Customer Service 800-833-9973

Consult instructions for use.

IX8PH01 01
12/2014

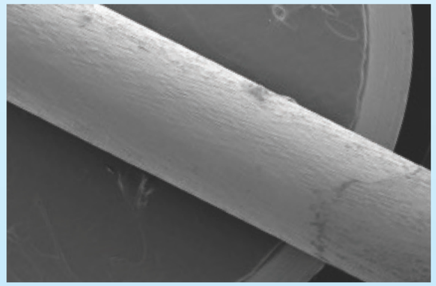
ENDEXO is a trademark of Interface Biologics, Inc.

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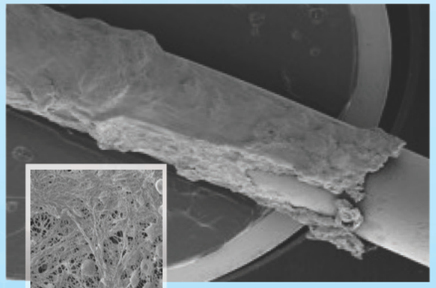
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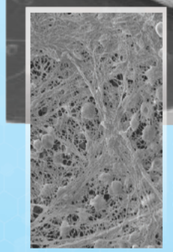
SEM Images
(Scanning Electron Microscopy)

BioFlo Catheter at 18X magnification
Catheter has no visible thrombus, fibrin sheath, or clot.



Competitor B at 15X magnification
Catheter with significant thrombus accumulation.





Competitor B at 1500X magnification
Higher magnification of catheter surface shows a fibrin sheath where distinct fibrin strands are in the process of forming.

87%
Less Thrombus Accumulation

In-vitro, compared to commonly used catheters (based on platelet count)‡

BioFlo Midline Catheter (20 cm)—Ordering Information

	French Size			
Kit Description	3F—SL	4F—SL	5F—SL	5F—DL
Catheter Kit—PG	H965460511	H965460611	H965460711	H965460811
Catheter Kit w/ 1 Nitinol Guidewire	H965461901	H965462101	H965463101	H965464101
Catheter Kit w/ 2 Nitinol Guidewires	H965465101	H965466101	H965467101	H965468101
MST 45 Kit	H965460911	H965460121	H965460131	H965460141
Max Barrier Drape Kit w/ 1 Nitinol Guidewire	H965460155	H965460165	H965460175	H965460185
Max Barrier Drape Kit w/ 2 Nitinol Guidewires	H965464605	H965464705	H965464805	H965464905

SL=Single Lumen
DL=Dual Lumen

IMPORTANT RISK INFORMATION

BIOFLO MIDLINE CATHETERWITH ENDEXO TECHNOLOGY

INTENDED USE/INDICATIONS FOR USE: The BioFlo Midline catheter with Endexo Technology is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

CONTRAINDICATIONS: Venous thrombosis in any portion of the vein to be catheterized. Conditions that impede venous return from the extremity such as paralysis or lymphedema after mastectomy. Orthopedic or neurological conditions affecting the extremity. Anticipation or presence of dialysis grafts or other intraluminal devices. Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy. Pre-existing skin surface or subsurface infection at or near the proposed catheter insertion site. Anatomical distortion of the veins from surgery, injury or trauma. Inadequate antecubital veins. Anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures.

Maximum Power Injection Flow Rates:
- 3F Single Lumen/20 cm—2 mL/sec
- 4F Single Lumen/20 cm—6 mL/sec
- 5F Single Lumen/20 cm—6 mL/sec
- 5F Dual Lumen/20 cm—6 mL/sec

Refer to Directions for Use provided with the product for complete instructions, warnings, precautions and potential complications.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

USA > 14 Plaza Drive, Latham, NY 12110 > tel: 800-772-6446 > fax: 518-798-1360 > Canada tel: 800-268-0184
International > Haaksbergweg 75 (Margriettoren), 1101 BR, Amsterdam Z-O > The Netherlands
tel: +31 (0)20 753 2949 > fax: +31 (0)20 753 2939

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Manufacturer:
Navilyst Medical, Inc.,
26 Forest Street, Marlborough, MA 01752

BioFlo Midline Catheter
with Endexo Technology



BioFlo

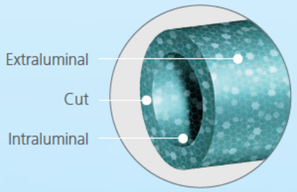
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Proven to Reduce Thrombus Accumulation, In Vitro†

The BioFlo* Midline Catheter is the first, and only, midline catheter with Endexo* Technology, providing a catheter material more resistant to in-vitro thrombus accumulation, compared to commonly used catheters (based on platelet count).[1]

The BioFlo Midline Catheter provides short-term access (< 30 days) to the peripheral venous system for selected intravenous therapies and blood sampling. The BioFlo Midline Catheter is a 10 cm or 20 cm catheter featuring Endexo Technology which is present throughout the catheter shaft including the intraluminal, extraluminal and cut surface of the catheter.



- X-ray confirmation is not required after placement
- Visibly marked as a midline catheter to aid in identification

Power Injectable

Advanced features, such as large lumen diameters allow the BioFlo Midline Catheter to deliver the power injection flow rates required for contrast-enhanced CTs compatible with up to 325 psi CT injectors.

Compatible with up to
325 psi
CT INJECTORS

†The reduction in thrombus accumulation (based on platelet count) is supported by acute in-vitro testing. Pre-clinical in-vitro evaluations do not necessarily predict clinical performance with respect to thrombus formation.

‡Based on benchtop testing performed up to two hours using bovine blood which may not be indicative of clinical results.

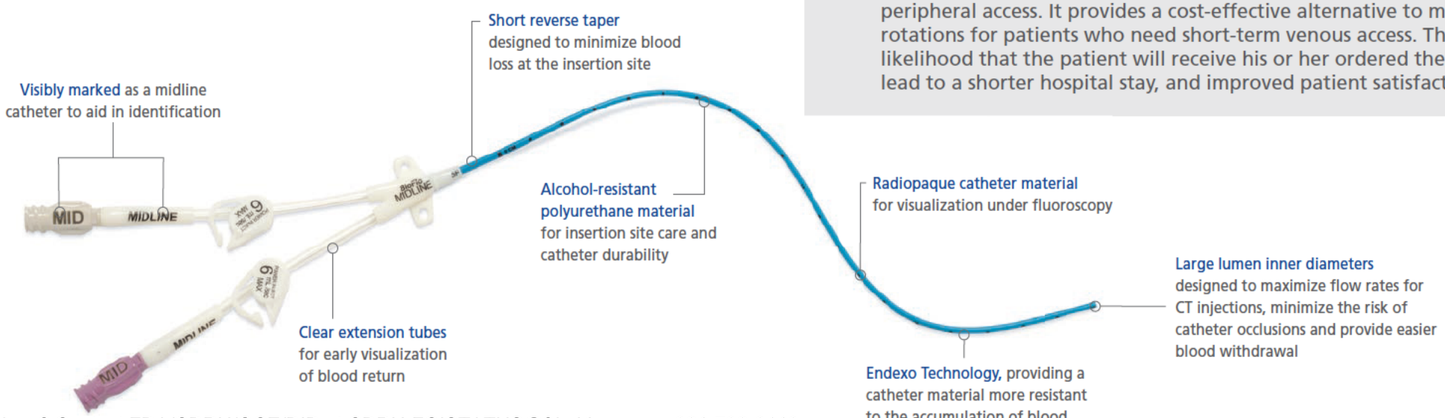
Maximal Protection for Improved Patient Care

BioFlo Midline Catheters are available in a Max Barrier Nursing Kit configuration that includes a comprehensive set of components for safe and reliable bedside placement.



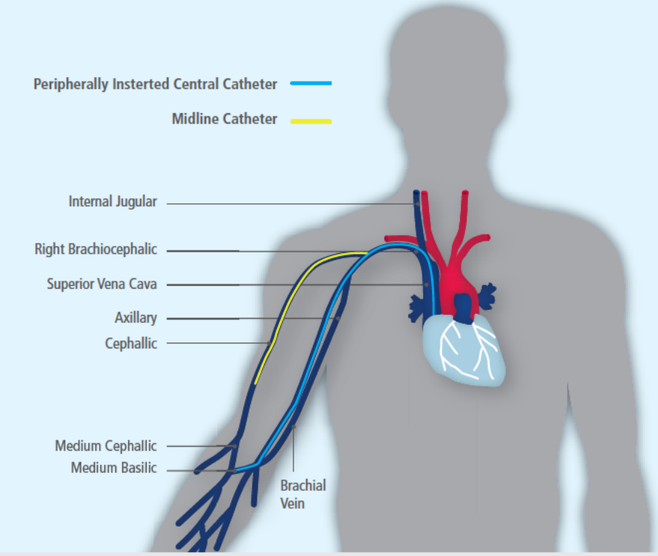
Also available:
- Modified Seldinger Technique Kit
- Catheter Only Kit

BioFlo Midline Catheter —5F Dual Lumen



Site Selection for Midline Catheters

Midline Catheters are inserted into the basilic, cephalic or brachial veins



The BioFlo Midline Catheter is an effective solution to preserving a patient's peripheral access. It provides a cost-effective alternative to multiple IV site rotations for patients who need short-term venous access. This improves the likelihood that the patient will receive his or her ordered therapy, which may lead to a shorter hospital stay, and improved patient satisfaction.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BARD® POLY MIDLINE

Polyurethane Midline

with Microintroducer

BARD

ACCESS SYSTEMS

Instructions For Use

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Bard Access Systems

BARD* Poly Midline with Microintroducer

Instructions For Use

Product Description

A family of single-lumen, peripherally placed catheters made from specially-formulated and processed medical grade polyurethane materials, in a tray with accessories for reliable short-term (less than 30 days) vascular access.

Contents are supplied sterile. Sterilized by ethylene oxide. DO NOT RESTERILIZE.

Indications

The **BARD* Poly Midline** catheters are indicated for short-term (less than 30 days) peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling (See Contraindications). For blood therapy, it is recommended that a 4 French or larger catheter be used.

Contraindications

The device is contraindicated whenever:

- The presence of device-related infection, bacteremia, or septicemia is known or suspected.
- The patient's body size is insufficient to accommodate the size of the implanted device.
- The patient is known or is suspected to be allergic to materials contained in the device.
- Past irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- Local tissue factors will prevent proper device stabilization and/or access.
- **A midline catheter placement is contraindicated for patients requiring any of the following:**
  - **Solutions with final glucose concentrations above 10 percent;**
  - **Solutions with protein concentrations above 5 percent;**
  - **Continuous infusion of vesicants.**

Warnings

- Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and/or risk of patient injury.
- When using alcohol or alcohol-containing antiseptics with polyurethane midlines, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.
- Alcohol should not be used to lock, soak or declot polyurethane midlines because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Acetone-based solutions and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
- (**Pediatric**) This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.
- **(Pediatric)** Insertion techniques and placement locations are often modified according to the size and developmental age of the child. Only clinicians experienced in proper positioning and placement of Midlines in pediatric patients should place this catheter in this patient population.
- Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- After use, this product may be a potential biohazard. Handle and discard in accordance with medical practice and applicable local, state and federal laws and regulations.
- If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
- Place a finger over the orifice of the sheath to minimize the blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.
- Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.
- The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.

Precautions

- Carefully read and follow all instructions prior to use.
- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates, as specified by their manufacturer.
- Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their catheter locked with heparinized saline.
- As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement[1], positioning[1], flushing[2] of catheters or cleaning of catheter exit site[3]. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.
- If CHG allergy is suspected, confirmatory testing is recommended [4,5]
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Only qualified health care practitioners should insert, manipulate and remove these devices.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.

I. To avert device damage and/or patient injury during placement:

- DO NOT USE A SYRINGE SMALLER THAN 10 mL. Prolonged infusion pressure greater than 25 psi may damage blood vessels or viscus.
- To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 ml of saline.
- Do not reinsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.
- Do not cut guidewire to alter length.
- Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
- Keep sufficient guidewire length exposed at hub to allow for proper handling. A non-controlled guidewire can lead to wire embolism.
- Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding.
- If the guidewire must be withdrawn while the needle is inserted, remove both needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
- Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable) after insertion.
- Do not clamp extension leg when stylet or stiffening wire is in catheter to minimize the risk of component or catheter damage.
- Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position (zero mark).

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- Avoid placement or securement of the catheter where kinking may occur to minimize stress on the catheter, patency problems or patient discomfort.
- Placement of BARD* Poly Midline above antecubital fossa is recommended.
- Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating methods.
- The midline catheter tip location should be at or below the axillary line [INS, 2011].
- Catheter stylet must be wetted prior to stylet repositioning or withdrawal.
- The catheter must be secured in place to minimize risk of catheter breakage and embolization.
- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Do not perforate, tear, or fracture the catheter when using a guidewire.
- Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.
- When using peel-apart introducers:
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.
  - Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.
  - Do not withdraw dilator from microintroducer sheath until sheath is within vessel to minimize the risk of damage to sheath tip.
- Do not occlude or cut catheter if using sutures to secure catheter.
- Do not suture through or around any part of the catheter's tubing (shaft or extension legs). If using sutures to secure catheter **USE THE SUTURE WINGS** and make sure they do not occlude, puncture, or cut the catheter.

II. After placement, observe the following precautions to avoid device damage and/or patient injury:

- Do not use scissors to remove dressing to minimize the risk of cutting catheter.
- Accessories and components used in conjunction with this device should incorporate luer lock connections. Do not overtighten the luer connector.
- DO NOT USE A SYRINGE SMALLER THAN 10 mL. Prolonged infusion pressure greater than 25 psi may damage blood vessels or viscus.
- This is not a power injectable catheter. Do not use for CT or other power injectable applications. For further information or questions, please call 800-443-3385 or 801-522-5000 (USA Only)

Possible Complications

The potential exists for serious complications including the following:

- Heparin Induced Thrombocytopenia
- Hypersensitivity, anaphylactic or anaphylactic-like reaction during placement[1], positioning[1], flushing[2] of catheter or cleaning of catheter exit site[3]
- Air Embolism
- Bleeding
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Phlebitis
- Spontaneous Catheter Tip Malposition or Retraction
- Thromboembolism
- Venous Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

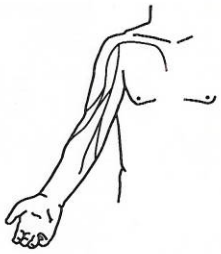
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Insertion Instructions

Prior to beginning placement procedure, do the following:

- Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized by ethylene oxide. Do not resterilize.
- Inspect kit for inclusion of all components.

1. Identify the Vein and Insertion Site



NOTE: (**Pediatric**) Insertion of midlines in pediatric patients may require the use of accessories or components not included in this kit configuration, based on the size and developmental age of the child and facility protocol. Follow manufacturer's recommendations regarding use of any drugs or medications such as chlorhexidine prep solutions, lidocaine injections and heparin lock solutions.

NOTE: (**Pediatric**) "Site selection for vascular access shall include assessment of the patient's condition; age; diagnosis; comorbidities; condition of the vasculature at the insertion site and proximal to the intended insertion site; condition of skin at intended insertion site; history of previous venipunctures and access devices; type and duration of infusion therapy; patient preference." In addition, facility policies, procedures, and/or practice guidelines can be used to access proper site selection. [INS, 2011]

NOTE: (**Pediatric**) Midline catheters are peripheral infusion devices with the tips terminated in either the basilic, cephalic, or brachial vein, distal to the shoulder. The basilic vein is preferred due to vein diameter. The tip does not enter the central vasculature. Midline catheters inserted via a scalp vein in neonates and pediatric patients should have the tip terminating in the external jugular vein (EJV) [INS, 2011].

NOTE: These catheters feature a reverse-taper catheter design. Taper length and size should be taken into account when selecting the appropriate vessel and determining catheter length.

- Apply a tourniquet above the anticipated insertion site.
- Select a vein based on patient assessment. Recommended veins are basilic, cephalic and median cubital veins.

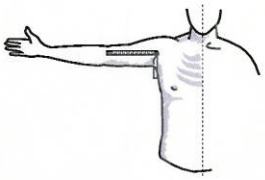
Caution: Placement of BARD* Poly Midline above antecubital fossa is recommended.

Caution: Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.

- Release tourniquet.
- Assess the selected vein to ensure the vessel size is adequate to accommodate the catheter being placed.

NOTE: The vein must be appropriately sized to accommodate the catheter size. Guidelines for catheter placement recommend that the diameter of the vein should be approximately two times the outer diameter of the catheter. [INS, 2010]

2. Patient Position / Catheter Measurement



- Position the arm at a 90° angle.
- For midline placement, measure to the desired tip location in the proximal portion of the extremity just distal of the shoulder and deltoid muscle.

Caution: The midline catheter tip location should be at or below the axillary line [INS, 2011].

Note: External measurement can never exactly duplicate the internal venous anatomy.

3. Skin Preparation

NOTE: (**Pediatric**) Prep the insertion site and surrounding skin per facility policies, procedures, and/or practice guidelines. Chlorhexidine is not recommended for infants under 2 months of age [INS, 2011]. Povidone Iodine should be removed from the skin after the procedure to prevent tissue damage, absorption, and thyroid suppression. [NANN, 2007]

- Don prep gloves.
- Apply underdrape.
- Prepare the site with the ChloraPrep* Antimicrobial Solution One-Step Applicator or according to institutional policy using sterile technique.
- When alcohol is used as a skin prep, it must be allowed to completely air dry before proceeding with insertion.

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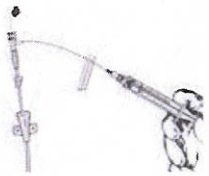
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- Remove and discard gloves.

4. Sterile Field Preparation

- Apply the tourniquet above the intended insertion site to distend the vessel.
- Don sterile gloves.
- Apply fenestrated body drape & complete sterile field preparation.

5. Preflush the Catheter

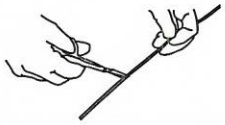


Caution: Do not clamp extension leg when stylet or stiffening wire is in catheter to minimize the risk of component or catheter damage.

Caution: Catheter stylet must be wetted prior to stylet repositioning or withdrawal.

- Attach prefilled syringe to the luer attachment on the T-Lock extension set.
- Preflush the catheter lumen with sterile normal saline to wet hydrophilic stylet.
- Remove the syringe after preflushing.

6. Modification of Catheter Length



Warning: Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolism and surgical removal.

Note: Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion according to hospital protocol. Catheter depth markings are in centimeters.

- Measure the distance from the zero mark to the desired tip location.
- Disconnect the T-Lock from the catheter luer connector.
- Withdraw the entire T-lock connector/stylet assembly as one unit.

Caution: Catheter stylet must be wetted prior to stylet repositioning or withdrawal.

- Retract the stylet to well behind the point the catheter is to be cut.

Caution: Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.

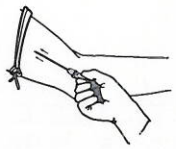
- Using a sterile scalpel or scissors, carefully cut the catheter according to institutional policy, if necessary.

Warning: The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.

- Inspect cut surface to assure there is no loose material.
- Re-advance the T-lock connector/stylet assembly.
- Lock the T-Lock connector to the catheter hub.
- Gently retract the stylet through the locked T-lock connector until the stylet tip is contained
- inside the catheter.

Warning: Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and/or risk of patient injury.

7. Perform Venipuncture



- Anesthetize with local anesthesia as required.
- Insert the safety introducer needle into the desired vein.

Alternate Technique: The safety IV catheter may be used as an alternate to the safety introducer needle. Remove the needle from the catheter after the vein is accessed.



Caution: Do not reinsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.

Warning: If the artery is entered, withdraw the needle and apply manual pressure for several minutes.

- Release tourniquet.
- Remove the guidewire tip protector from the guidewire hoop and insert the flexible end of the guidewire into the introducer needle or catheter and into the vein. Advance the guidewire to the desired depth.

Caution: Do not perforate, tear, or fracture the catheter when using a guidewire.

Caution: Do not cut guidewire to alter length.

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Caution: Do not insert stiff end of guidewire into vessel as this may result in vessel damage.

Caution: Keep sufficient guidewire length exposed at hub to allow for proper handling. A non-controlled guidewire can lead to wire embolism.

Caution: Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding.

Caution: Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating methods.

- Gently withdraw and remove the safety introducer needle or safety IV catheter, while holding the guidewire in position.

Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.

- Advance the small sheath and dilator together as a unit over the guidewire, using a slight rotational motion. If necessary, a small incision may be made adjacent to the guidewire to facilitate insertion of the sheath and dilator. Verify institutional guidelines concerning the use of a safety scalpel prior to making incision.

Caution: Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.

Cautions: Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.

Caution: Do not withdraw dilator from microintroducer sheath until sheath is within vessel to minimize the risk of damage to sheath tip.

- Withdraw the dilator and guidewire, leaving the small sheath in place.

Warning: Place a finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.

8. Insert and Advance the Catheter

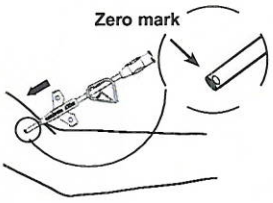
- Insert the catheter into the introducer sheath.
- Advance the catheter slowly.

Warning: (**Pediatric**) Insertion techniques and placement locations are often modified according to the size and developmental age of the child. Only clinicians experienced in proper positioning and placement of midlines in pediatric patients should place this catheter in this patient population.

Note: (**Pediatric**) When infusion volume is a concern in small or pediatric patients, flush with 3 mL per lumen or per facility guidelines.

Note: Resistance may be felt approximately 7 cm distal of catheter hub when introducing the catheter into the sheath due to an increase in outer diameter (O.D.) The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.

9. Complete Catheter Insertion



- Complete catheter advancement into the desired position.

Note: Midlines should be positioned with the catheter tip distal of the shoulder and deltoid muscle.

Caution: The midline catheter tip location should be at or below the axillary line [INS, 2011].

Warning: (**Pediatric**) This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.

10. Retract and Remove the Introducer Sheath

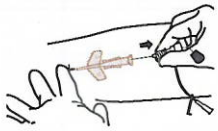
- Stabilize the catheter position by applying pressure to the vein distal to the introducer sheath.
- Withdraw the introducer sheath from the vein and away from the site.
- Split the introducer sheath and peel it away from the catheter.

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

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11. Remove the Stylet / T-Lock Assembly

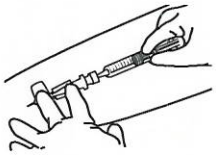


- Disconnect the T-Lock from the catheter luer connector.
- Stabilize the catheter position by applying light pressure to the vein distal to the insertion site.
- Slowly remove the T-Lock and stylet.

Caution: Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position (zero mark).

Caution: Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable) after insertion.

12. Aspirate and Flush



- Attach primed extension set and/or saline-filled syringe.
- Aspirate for adequate blood return and flush the lumen of the catheter with at least 10 mL of saline to ensure patency. In addition, lock the lumen of the catheter with heparinized saline. Usually one ml per lumen is adequate.

Caution: To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of saline.

- Cap catheter.

Warning: The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.

13. Securing the BARD* Poly Midline Catheter

The StatLock® catheter stabilization device is included in BARD* Poly Midline catheter kits. Please refer to Instructions For Use on the proper use and removal. The StatLock® catheter stabilization device should be monitored daily and replaced at least every seven days.

Caution: The catheter must be secured in place to minimize risk of catheter breakage and embolization.

Warning: When using alcohol or alcohol containing antiseptics with polyurethane midlines, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

Warning: Alcohol should not be used to lock, soak or declot polyurethane midlines because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Warning: Acetone-based solutions and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.

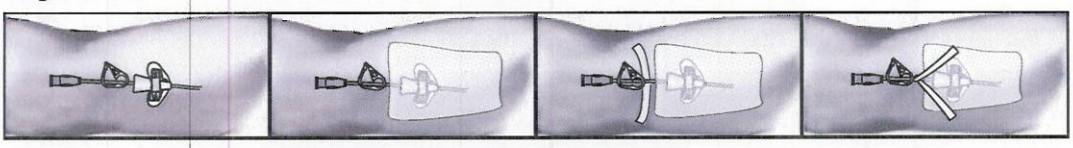
Caution: Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.

Caution: Do not occlude or cut catheter when using sutures to secure catheter.

Caution: Do not suture through or around any part of the catheter's tubing (shaft or extension legs). If using sutures to secure catheter **USE THE SUTURE WINGS** and make sure they do not occlude, puncture, or cut the catheter.

The StatLock® Catheter Stabilization Device Procedure

Single Lumen



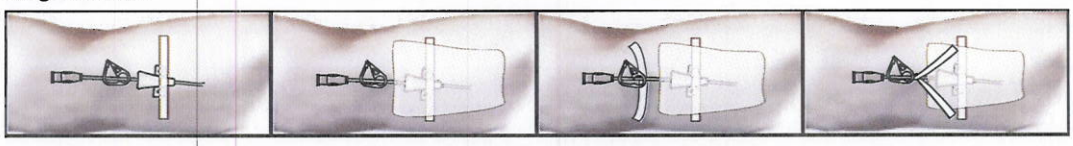
1. Secure catheter with StatLock® catheter stabilization device.
2. Cover site and StatLock® catheter stabilization device with transparent dressing.
3. Place anchor tape sticky side up, under hub. Wedge tape between hub and wings.
4. Chevron anchor tape on top of transparent dressing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tape Strip Securement Procedure

Single Lumen



1. Place 1st anchor tape over wings or bifurcation.
2. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.
3. Place 2nd anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings.
4. Chevron 2nd anchor tape on top of transparent dressing and place 3rd anchor tape over hub.

14. Suggested Catheter Maintenance

The catheter should be maintained in accordance with standard hospital protocols. Suggested catheter maintenance is as follows:

A. Dressing Changes

Caution: Do not use scissors to remove dressing to minimize the risk of cutting catheter.

Caution: Accessories and components used in conjunction with this device should incorporate luer lock connections. Do not overtighten the luer connector.

- Assess the dressing in the first 24 hours for accumulation of blood, fluid or moisture beneath the dressing. During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred. Periodically confirm catheter placement, tip location, patency and security of dressing.

B. Flushing

- Flush the lumen of the catheter with 10 mL of saline every 12 hours or after each use. In addition, lock the lumen of the catheter with heparinized saline. Usually one mL per lumen is adequate.

Note: Flush with 20 mL of saline after blood therapy.

Caution: DO NOT USE A SYRINGE SMALLER THAN 10 mL. Prolonged infusion pressure greater than 25 psi may damage blood vessels or viscus.

Caution: This is not a power injectable catheter. Do not use for CT or other power injectable applications.

Warning: If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.

C. Occluded or Partially Occluded Catheter

- Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against resistance. If the lumen will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, a declotting procedure per institution protocol may be appropriate.

D. When Cleaning the exit site

Warning: Acetone-based solutions and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.

- Maintain according to hospital protocol. Avoid using acetone based solutions, or polyethylene glycol containing ointments. These substances are known to degrade polyurethane.
- Use chlorhexidine gluconate or povidone iodine to clean the exit site around the catheter.
- Allow all cleaning agents / antiseptics to dry completely before applying dressing.

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15. Catheter Removal

Warning: After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Warning: Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.

Caution: Do not use scissors to remove dressing to minimize the risk of cutting catheter.

- Remove dressing, and StatLock® catheter stabilization device or tape securement strips.
- Grasp catheter near insertion site.
- Remove slowly. Do not use excessive force.
- If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
- Resume removal procedure.
- Inspect the end of the catheter and the catheter length to ensure complete removal.

References

1. Halpern M.D., Georges. "Allergic and Toxic Reactions." Adverse Events During Infusion Therapy Symposium, University of California, Davis School of Medicine. (1993)
2. Findlay, Steven R. et al,. "Hyperosmolar Triggering of Histamine Release from Human Basophils." Journal of Clinical Investigation. (1981)
3. Benjamin, Richard J. et al,. "Skin disinfection with single-step 2% chlorhexidine swab is more effective than a two-step povidoneiodine method in preventing bacterial contamination of apheresis platelets." Transfusion. (2010)
4. "FDA Public Health Notice: Potential Hypersensitivity to chlorhexidine-Impregnated Medical Devices." FDA U.S. Food and Drug Administration. <http://www.fda.gov>. (accessed March, 1998).
5. Beaudouin, E. et al,. "Immediate Hypersensitivity to chlorhexidine: literature review." European Annals of Allergy and Clinical Immunology. 36, no. 4 (2004)

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.

Revised date: April 2012

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Introduction

Your Health Care Provider is giving you a BARD* Poly Midline catheter so that you can easily get the intravenous medicines you need without repeated needle sticks in your arms. Please talk to your Health Care Provider about how to care for your BARD* Poly Midline catheter and how the catheter may change your daily activities.

The BARD* Poly Midline catheter is made of polyurethane. Polyurethane material can be damaged when some products are used to clean around them. See the following warning:

WARNING! When cleaning or changing the bandage (dressing) around your catheter, do not clean the catheter with ointment or with solutions that contain acetone or polyethylene glycol (check the label for these ingredients). These can damage the polyurethane material if used over time.

Caring for Your Catheter

- Always wash your hands thoroughly using warm, soapy water before touching your catheter, changing the dressing, or changing caps or tubing attached to your catheter.
- Always make sure that caps or tubing attached to your catheter remain secure.
  - o Flush the lumen of the catheter with 10 mL of saline every 12 hours or after each use. In addition, lock the lumen of the catheter with heparinized saline. Usually one mL per lumen is adequate.
  - o Do not use smaller than a 10 mL syringe for flushing.
  - o Do not flush against resistance.
- Always handle your catheter carefully.
  - o Do not over-twist the adapter when changing the injection caps or tubing.
  - o Never have scissors or sharp objects near the catheter.
  - o Never pull on the catheter tubing.
- Be sure the catheter does not move in or out of its place in your arm.

Bandage (Dressing) Change:

Your bandage has two important jobs -

1. It provides a germ-free (sterile) environment for the catheter.
2. It helps keep the catheter from moving or breaking.

If you or your family have been told how to change the bandage, please follow your Health Care Provider's instructions carefully. Properly changing your bandage using germ-free (sterile) methods will help reduce the chance of catheter problems.

Important

- Allow cleaning materials and antiseptics to dry completely before putting on a clean bandage.
- If bandage becomes loose, dirty, wet or if spotting can be seen through the bandage, change it right away.
- Use chlorhexidine gluconate or povidone iodine to clean around the catheter.

CAUTION! To minimize risk of the catheter being pulled out or broken, the catheter must be secured in place.

Catheter Problems

Call your Health Care Provider right away if you notice:

1. A lot of bleeding or drainage where the catheter comes out of your arm.
2. Redness or swelling where the catheter comes out of your arm.
3. Pain, soreness or swelling of the arm, shoulder or neck.
4. Pain or discomfort when IV solution fluids are put into your catheter.
5. Chest pain, shortness of breath or discomfort while your catheter is in place. This may be a medical emergency.
6. Catheter movement either in or out of its place in your arm.
7. If you have a catheter leak or accidentally break or damage the catheter, fold and tape the catheter between the break or leak and where the catheter comes out of your arm.
8. Fever or chills, swelling or oozing from the insertion site may be signs of infection. General fatigue or decrease in activity in a child, even without fever, may be signs of a problem.

NOTE! Any of these changes in or around your catheter could be very serious. You should contact your Health Care Provider as soon as you see any problems like those described above.

This fact sheet is for information purposes only. It is not meant to take place of medical advice, diagnosis or treatment. Always talk to a health care professional about any health questions or concerns you have.

For additional information, please visit **www.bardaccess.com**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BARD® POLY MIDLINE

Polyurethane Midline

with Microintroducer

Manufacturer:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
Clinical Information Hotline: 1-800-443-3385
Ordering Information: 1-800-545-0890
www.bardaccess.com

0733736 1204R

Please fill this card out and keep on your person at all times

Patient's Name _____

Doctor _____

Doctor's Phone No. ( ) _____

Date of Insertion _____

Trimmed Length _____

Home Healthcare Agency _____

Agency Phone No. ( ) _____

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
1-800-545-0890 1-801-522-5000
www.bardaccess.com

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BARD ACCESS SYSTEMS

BARD® Poly Midline
with Micro Introducer

Place product identification sticker from the unit label here.

Patient Guide

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 14
STERILIZATION AND SHELF LIFE

Sterilization

The proposed BioFlo Midline Catheter will be sterilized using the same validated 100% ethylene oxide cycle as the predicate. The validation process conforms to the following standard: AAMI/ANSI/ISO 11135-1:2007 "Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices", using the overkill – Half Cycle approach. The sterility assurance level (SAL) for the proposed device is 1 X 10^{-6}.

Contract Sterilizer

(b)(4)

Method

Sterilization Method: Ethylene Oxide (EO)

Sterility Assurance Level

1x 10^{-6}

Residuals:

The proposed BioFlo Midline Catheter meets the maximum requirements for a permanent contact device per AAMI/ANSI/ISO 10993-7:2008 Biological Evaluation of Medical Devices – Part 7 Ethylene Oxide Sterilization Residuals for residual level of ethylene oxide (EO) and ethylene chlorohydrin (ECH) (**Table #5**). Actual EO Residuals data for the proposed BioFlo Midline Catheter is presented in **Table #6**.

Table #5 - Residue Limits				
Device Category	Allowable Limits (mg)			
	Avg. Daily Dose (ADD) (mg/d)	24 hour Period (mg)	30 day Period (mg)	Lifetime (mg)
Permanent Contact Device	(b)(4)			

Table #6 – Actual EtO Residuals Results					
Test Article	Extraction Time	Avg. Daily Dose (mg/d)	24 hour Period (mg)	30 day Period (mg)	Lifetime (mg)
Proposed BioFlo Midline Catheter	(b)(4)				

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Sterilization Validation and Monitoring

The validation and routine sterilization monitoring processes conform to the following standard: AAMI/ANSI/ISO 11135-1:2007, "Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices". Navilyst Medical utilizes the Overkill – Half Cycle approach for sterilization validations as described in the Association for the Advancement of Medical Instrumentation (AAMI) Recommended Practice ST27 "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices: Process Design, Validation, routine sterilization, and Contract Sterilization" (3/88).

Pyrogenicity

(b)(4)

Shelf Life

The proposed BioFlo Midline Catheter has a claimed shelf-life of 6 months. Although bench testing supports up to a 2-year shelf life (based upon the results of 2-year accelerated age test results), packaging testing of the proposed device was only done at 6 month accelerated age rates. However, Navilyst Medical, Inc. intends to conduct further accelerated age testing on the packaging in the future; at which point, the data will be put on file and the shelf-life of the product will be increased accordingly.

Arrhenius Equation

(b)(4)

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SECTION 15
BIOCOMPATIBILITY

The proposed BioFlo Midline Catheter is classified per ISO 10993-1 as follows:

- Category: Externally Communicating
- Contact Duration: Prolonged (>24 to 30 days)
- Device Body Contact: Blood Path, Direct

The following tests were considered and conducted for this device classification per ISO 10993-1:

Category	Test
Cytotoxicity	• ISO MEM Elution
Irritation	• ISO Intracutaenous Reactivity (NS & CSO Extracts)
Sensitization	• ISO Guinea Pig Maximization Sensitization Test (NS & CSO Extracts)
Systemic Toxicity (Acute)	• ISO Acute Systemic Injection Test (NS & CSO Extracts) • Material Mediated Rabbit Pyrogen Test
Subchronic Toxicity	• Subchronic (14-Day) Intravenous Toxicity Study in Non-Swiss Webster Mice with Histopathology and Subacute (14-Day) Intraperitoneal Toxicity Study with Mice
Genotoxicity	• Bacterial Mutagenicity (Ames Assay) Using Four Salmonella Strains and One E. Coli Strain • In-Vivo Mouse Micronucleus Assay • In-Vitro Mouse Lymphoma Assay
Implantation	• Intramuscular Implantation Test – 2 Week and 13 Week
Hemocompatibility	• Hemolysis (Direct and Indirect) • Partial Thromboplastic Time (PTT) • In-Vitro Hemocompatibility Assay • In-Vivo Thromboresistance 2-Dog Study (72 Hour Contract) • Complement Activation
Chemical Characterization	• USP Physiochemical Tests for Plastics

The following tests were recommended per ISO 10993-1 but were not conducted, and the rationales for exclusion are provided below:

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(b)(4)

All of the components and materials of the proposed BioFlo Midline Catheter are identical to that of the BioFlo PICC with PASV (**K131942**) with the exception of the PASV Valve componentry, as the proposed device is non-valved. **Table #7** below contains a side-by-side comparison of each component and material of the proposed BioFlo Midline Catheter and the BioFlo PICC with PASV Valve cleared via **K131942**.

Table #7 – Components and Materials Comparison
Proposed BioFlo Midline Catheter vs. BioFlo PICC with PASV

Device Component	Material Proposed BioFlo Midline Catheter	Material BioFlo PICC with PASV (K131942)
Catheter Tubing	(b)(4)	
Suture Wing		
Extension Tubing		
Oversleeve		
Purple Luer		
White Luer		
Ink		
Clamp		
Valve Disk		
Valve Adhesive		

As all of the materials of the proposed device are also within the BioFlo PICC with PASV, it is Navilyst's position that the biocompatibility data representative of the BioFlo PICC with PASV also covers the proposed BioFlo Midline Catheter; as such, no new biocompatibility testing has been conducted on the proposed device. All previously conducted biocompatibility testing is summarized in the cleared **K121089**, and is again below for ease of review.

Table #8 – Results of Biocompatibility Testing

Test Performed & ISO 10993 Part #	Test Lab & Report Number	Extract / Conditions*	Results
MEM Elution Cytotoxicity ISO 10993, Part 5	(b)(4)		
Guinea Pig Maximization Sensitization ISO 10993, Part 10			
Intracutaneous Reactivity ISO 10993, Part 10			

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Table #8 – Results of Biocompatibility Testing			
Test Performed & ISO 10993 Part #	**Test Lab & Report Number**	**Extract / Conditions***	**Results**
Acute Systemic Injection ISO 10993, Part 11	(b)(4)		
Materials Mediated Rabbit Pyrogen ISO 10993, Part 11			
Subchronic Toxicity ISO 10993, Part 11			
Hemolysis Indirect Contact ISO 10993, Part 4			
Hemolysis Direct Contact			
Partial Thromboplastin Time ISO 10993, Part 4			
In Vitro Hemocompatibility Assay ISO 10993, Part 4			
Complement Activation			
Ames Mutagenicity ISO 10993, Part 3			
Mouse Lymphoma ISO 10993, Part 3			
In Vivo Mouse Micronucleus Assay			
2-Week Implantation			
13-Week Implantation			
USP Physicochemical <661>			

(b)(4)

Conclusion: The results of biocompatibility tests and assessments per ISO 10993-1 confirm that the proposed BioFlo Midline Catheter is biocompatible for its intended use.

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SECTION 16
SOFTWARE

The proposed BioFlo Midline Catheter does not contain software; therefore, this section is not applicable to the proposed device.

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SECTION 17
ELECTROMAGNETIC COMPATIBILITY, INTERFERENCE TESTING, AND ELECTRICAL SAFETY

The proposed BioFlo Midline Catheter does not contain electronic components; therefore, this section is not applicable to the proposed device.

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SECTION 18
PERFORMANCE TESTING (BENCH)

Performance Testing, Table of Contents:

Test #1 – Power Injection Flow Rate
Test #2 – Static Burst Strength
Test #3 – Multiple Power Injections
Test #4 – Gravity Flow Rate
Test #5 – Catheter Length
Test #6 – Priming Volume
Test #7 – Midline Identification
Test #8 – Catheter Profile (Reverse Taper)
Test #9 – Lumen Size (ID)
Test #10 – Tapered Shaft Length
Test #11 – Shaft Extrusion Flex Life
Test #12 – Shaft Tip Tensile Strength
Test #13 – Catheter Assembly Elongation
Test #14 – Catheter Stiffness
Test #15 – Catheter Flex Life Strength
Test #16 – Extension Tube Alcohol Compatibility Strength
Test #17 – Catheter Kink Resistance
Test #18 – Catheter Radiopacity
Test #19 – Catheter Shaft Markings
Test #20 – Catheter Trimmability
Test #21 – Identification of Maximum Flow Rate
Test #22 – Identification of Power Injectability
Test #23 – Extension Tube Kink Resistance
Test #24 – Extension Tube to Oversleeve Tensile Strength
Test #25 – Oversleeve to Luer Tensile Strength
Test #26 – Extension Tube to Suture Wing Tensile Strength
Test #27 – Extension Tube Length
Test #28 – Translucent Extension Tube
Test #29 – Long-Term Extension Tube and Clamp Life Compatibility

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SECTION 19
PERFORMANCE TESTING (ANIMAL STUDIES)

No animal studies were conducted on the proposed BioFlo Midline Catheter; therefore, this section is not applicable.

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SECTION 20
PERFORMANCE TESTING (CLINICAL)

There were no clinical trials conducted in support of the proposed BioFlo Midline Catheter. Therefore, this section is not applicable.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 21
CERTIFICATE OF COMPLIANCE WITH REQUIREMENTS OF CLINICAL TRIALS

There were no clinical trials conducted in support of the proposed BioFlo Midline Catheter.

Certification that the requirements of 42 U.S.C. §282(j)(5)(B) do not apply to this submission is provided in the attached Form FDA 3674.

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2015. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Navilyst Medical, Inc.

2. Date of the Application/Submission Which This Certification Accompanies
February 2015

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
26 Forest Street

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Marlborough

State/Province/Region
Massachusetts

Country
USA

ZIP or Postal Code
01752

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 508-658-7984

(Fax): 508-658-7976

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

BioFlo Midline Catheter, Class II per 21 CFR 880.5200.

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number *(If number previously assigned)*

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(J)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. *(Add continuation page as necessary.)*

NCT Number(s): _____ _____ _____ _____ _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Brandon M. Brackett	Specialist II, Global Regulatory Affairs

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	26 Forest Street
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	
City	Marlborough
State/Province/Region	Massachusetts
Country	USA
ZIP or Postal Code	01752

13. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): 508-658-7984

(Fax): 508-658-7976

14. Date of Certification

30. JANUARY. 2015

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative *(Sign)*

Sign

Brandon M. Brackett, Specialist II

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 22
PRE-SUBMISSION CORRESPONDENCE

There was no pre-submission correspondence (i.e. Pre-Submission Requests) regarding the proposed BioFlo Midline Catheter; therefore, this section is not applicable to the proposed device.

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION 23
KIT CERTIFICATION STATEMENT

Confidential and Proprietary to Navilyst Medical, Inc.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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KIT CERTIFICATIONS:

a.) I certify that the following devices in the proposed BioFlo Midline Catheter kits are either:
1) legally marketed preamendment devices,
2) exempt from pre-market notification, or
3) have been found to be substantially equivalent through the pre-market notification process for the use(s) for which they are intended

The following devices are owned and manufactured by Navilyst Medical, Inc.:

Description	Current Manufacturer	FDA Class	FDA Status	21 CFR
Port Protector, Male, N/V, Threaded (End cap)	Navilyst Medical, Inc	II	K842829	870.4290
Touhy Borst with Side Port	Navilyst Medical. Inc.	II	K0901634	870.4290
Tape Measure	Navilyst Medical, Inc.	I	Exempt	878.4800

The following devices are purchased bulk-non sterile and sterilized in a manner consistent with their pre-market notification:

Description	Current Manufacturer	FDA Class	FDA Status	21 CFR
Scalpel, #11, Safety	(b)(4)	I	Exempt	878.4800
Cannula, 1-3/4", Filtered Straw		1	Exempt	878.4800
Gauze, 4"X 4", 4-Ply		I	Exempt	878.4450
Tourniquet, 18" X 1", Latex Free		I	Exempt	878.5900
Scissors, Blunt		I	Exempt	878.4800
Statlock SL PICC Plus, Crescent Slidings Ports		I	Exempt	880.5210
LAL Introducer Needle, Safety, 21G X 2.75"		I	Exempt	870.4500
Tape, 3/4" X 24", Surgical Irradiated		I	Exempt	880.5240
Hairnet, 24"		I	Exempt	878.4040
Introducer, Peelable, 3F X 5cm		II	K000313	870.1340
Introducer, Peelable, 4F X 7cm		II	K000313	870.1340
Introducer, Peelable, 5F X 7cm		II	K000313	870.1340
Guidewire, Nitinol, .018" X 45cm		II	K043398	870.1330
Drape, Fenestrated		II	K964142	878.4370
Drape, Full Body, 70" X 100"		II	K964142	878.4370
Drape, Underarm, 24" X 32"		II	K964142	878.4370
Wrap, CSR, 36"X36", Heavy-Duty		II	K881471	880.6850
Syringe, 3CC/ML		II	K980987	880.5860
Needle, 21G X 2.75", Thin Wall Echo Tip, Sharp		II	K082580	870.1340
Sharps Container, Single		II	K954015	868.1100
Towel, 14" X 25", Absorbant		II	K962205	876.4370
Gown, Surgical, Extra Large		II	K842115	878.4370
Mask with Earloops		II	K911334	878.4040
LAL Stiffening Stylet, .014" X 45cm		II	K890959	870.1330

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Description	Current Manufacturer	FDA Class	FDA Status	21 CFR
LAL Stiffening Stylet, .016" X 45cm	(b)(4)	II	K890959	870.1330
Ampule, Safety Breaker		Does not meet the definition of medical device. Assists to facilitate cracking of the saline ampule.		

b.) I further certify that the devices listed below are purchased in their finished form (i.e. they are packaged, labeled, etc., consistent with their pre-amendment, exemption, or premarket notification criteria and status.

Description	Current Manufacturer	FDA Class	FDA Status	21 CFR
Skin Protectant, Swabstick	(b)(4)	I	Exempt	880.5090
Dressing, Tegaderm		I	Exempt	878.4020
Needle, 25G X 5/8", Safety		II	K951294	880.5570
Saline, 10 mL, Syringe x1 per pack		II	K042061	880.5200
Cover, Transducer, 4" X 58"		II	K970513	892.1570

All purchased drug and biologics below are also packaged and labeled consistent with their approval licensing.

Description	Current Manufacturer	FDA Status
Drug, Chloraprep, 3ml	(b)(4)	NDA 20-832
Drug, Lidocaine		NDC 0409-4713-65

12 FEBRUARY 2015

Brandon M. Brackett
Specialist II, Global Regulatory Affairs
Navilyst Medical, Inc.

Date

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118