

APR 29 1993
h 930622

Summary of Safety and Effectiveness

Owner: Meadox Medicals, Inc.
112 Bauer Drive
Oakland, NJ 07436

Contact: Nancy Koffman
Associate Regulatory Affairs Specialist

Submission Date: February 4, 1993

Device Name: Amplatz Guidewires

The Amplatz Guidewires are substantially equivalent in design and function to the Meadox Surgimed Teflon Coated Guidewires, Teflon Guidewires manufactured by Cook, Inc. and the Amplatz Guidewires 510(k) 912789.

The Amplatz Guidewires are radiopaque, stainless steel, teflon coated guidewires which are designed for the intravascular introduction of a percutaneous catheter.

The following tests were performed to show the safety, efficacy and performance of the product:

<u>Test</u>	<u>Results</u>
Tensile Strength Test	Equivalent to Marketed Product
Cytotoxicity	Passed
Sensitization	Passed
USP Class VI	Passed
Hemolysis testing	Passed
EtO Residual Analysis	

RG623

061



APR 29 1993

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Ms. Nancy C. Koffman
Regulatory Affairs Assistant
Meadox Medicals, Inc.
112 Bauer Drive
Oakland, New Jersey 07436

Re: K910622
Amplatz Guidewire
Regulatory Class: II
Dated: February 4, 1993
Received: February 8, 1993

Dear Ms. Koffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1342. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Memorandum

Date

REVIEWER(S) - NAME(S)

Chen Byrd

Subject

510(k) NOTIFICATION

K 930622

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- ☒ (A) Is substantially equivalent to marketed devices.
- ☐ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- ☐ (C) Requires more data.
- ☐ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☒

This 510(k) contains: (check appropriate box(es))

- ☒ A 510(k) summary of safety and effectiveness, or
- ☐ A 510(k) statement that safety and effectiveness information will be made available
- ☐ The required certification and summary for class III devices

The submitter requests under
21 CFR 807.95:*

- ☐ No Confidentiality
- ☐ Confidentiality for 90 days
- ☐ Continued Confidentiality
exceeding 90 days

Predicate Product Code w/panel
and class:

DDX 74 II

Additional Product Code(s)
w/Panel (optional):

REVIEW:

Palmer for Tague
(BRANCH CHIEF)

ICD3
BRANCH CODE

4/29/93
(DATE)

FINAL REVIEW:

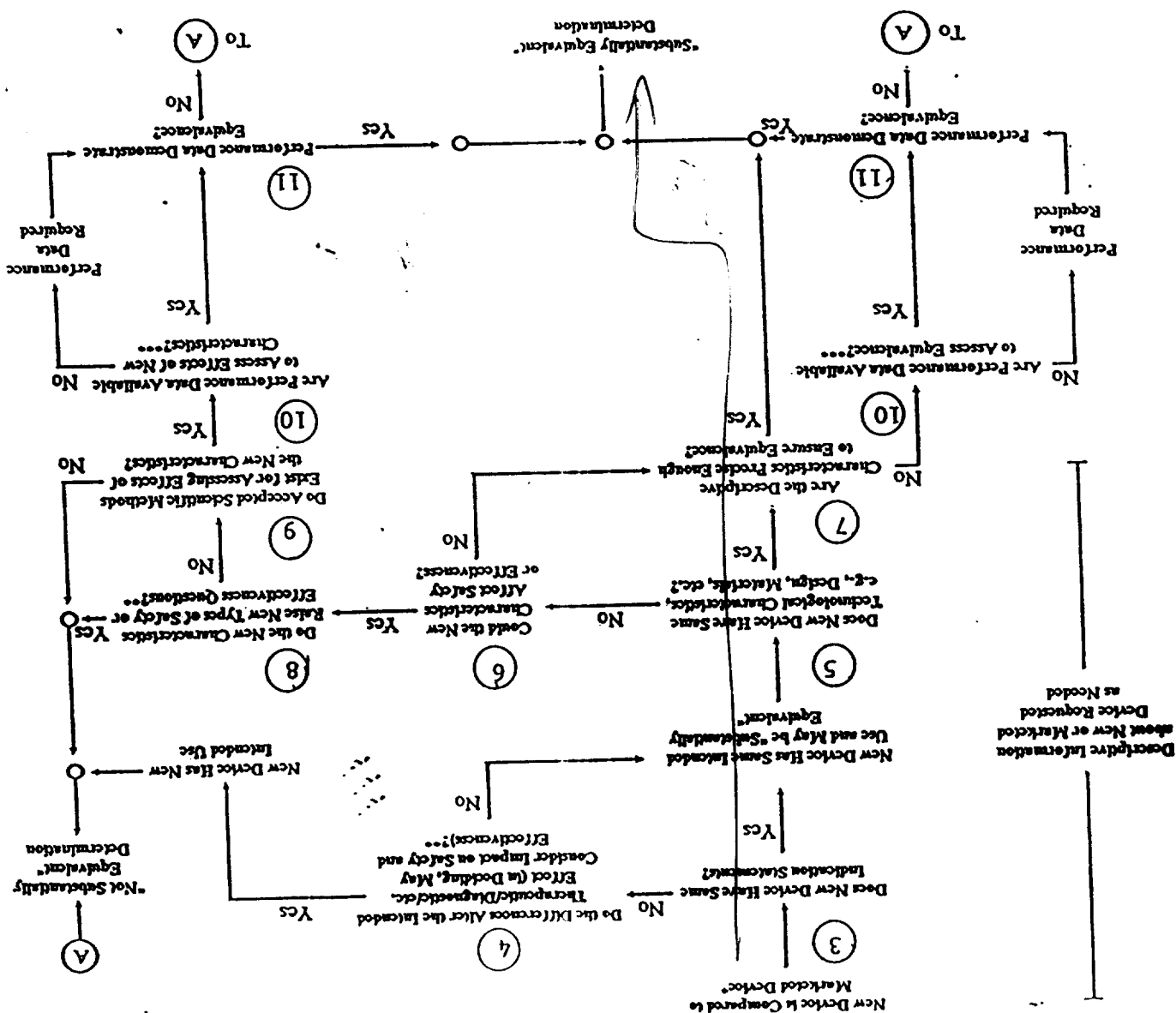
Kenneth B. Palmer
(DIVISION DIRECTOR)

4/29/93
(DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.



K 930622 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: Glenn Byrd DIVISION/BRANCH: DCRND/ICDB

TRADE NAME: AMPLATE GUIDEWIRE COMMON NAME: GUIDEWIRE

PRODUCT TO WHICH COMPARED: K912798
(510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?	☒	☐	- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	☒	☐	- IF NO STOP
3. SAME INDICATION STATEMENT?	☒	☐	- IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	☐	☐	- IF YES STOP 
5. SAME TECHNOLOGICAL CHARACTERISTICS?	☒	☐	- IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	☐	☐	- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	☒	☐	- IF NO GO TO 10 - IF YES STOP 
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	☐	☐	- IF YES STOP 
9. ACCEPTED SCIENTIFIC METHODS EXIST?	☐	☐	- IF NO STOP 
10. PERFORMANCE DATA AVAILABLE?	☐	☐	- IF NO REQUEST DAT
11. DATA DEMONSTRATE EQUIVALENCE?	☐	☐	

 **NOTE:** IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: Percutaneous introduction of an
intravascular catheter - peripheral use.

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: see memo

Glenn N. Byrd

FDA/CDRH/ODE/DCRND/ICDB

April 23, 1993

Comments on K930622 for the Meadox Surgimed
Amplatz Guidewire dated February 4, 1993

This submission notifies FDA of an intended modification to the device previously cleared under K912798. The modification consists of (b)(4)

(b)(4)

(b)(4)

(b)(4)

This change is intended to enhance the structural integrity of this device. The only other change is the (b)(4) of this same design. No other changes (design, manufacturing, materials, sterilization, etc.) were made to this device.

This device is intended for the percutaneous introduction of an intravascular catheter. It is supplied sterile (EtO) and is for single use only. A 510k summary is provided.

Tensile strength testing was conducted to validate the change and the new diameter wire and the results indicate that these devices are safe for the intended use and compare favorably to other marketed guidewires

No question arose during my review; therefore, I recommend that this device be found SE to the claimed predicate devices.

Glenn N. Byrd
4/28/93

Concurrence
KAP
4/29/93

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: _____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE: _____

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: _____

7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH: _____

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW: _____

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED: _____

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED: _____

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT: _____

ATTACH ADDITIONAL SUPPORTING INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

FEBRUARY 22, 1993

MEADOX MEDICALS, INC.
ATTN: NANCY C. KOFFMAN
112 BAUER DRIVE
OAKLAND, NJ 07436

510(k) Number: K930622
Received: 02-08-93
Product: AMPLATZ GUIDEWIRES

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law

requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Furthermore, the new legislation, section 522(a)(1), of the Act, states that if your device is a permanent implant the failure of which may cause death, you may be subject to required postmarket surveillance. If the premarket notification for your device was originally received on or after November 8, 1991, is subsequently found to be substantially equivalent to an Aneurysm Clip, Annuloplasty Ring, Artificial Embolization Device, Automatic Implanted Cardioverter Defibrillator System, Cardiovascular Intravascular Filter, Cardiovascular Permanent Pacemaker Electrode (Lead), Central Nervous System Fluid Shunt, Coronary Vascular Stent, Implantable Pacemaker Pulse Generator, Implanted Diaphragmatic/Phrenic Nerve Stimulator, Intracardiac Patch or Pledget, Intravascular Occluding Catheter, Replacement Heart Valve, Total Artificial Heart, Tracheal Prosthesis, Vascular Graft Prosthesis (less than 6 mm diameter), Vascular Graft Prosthesis (6 mm or greater diameter), Vena Cava Clip, or Ventricular Assist Device - Implant, you will be subject to the required postmarket surveillance and so notified of this determination in your substantially equivalent letter. (Some of the above listed types of devices may require a premarket approval application). This list is subject to change without notification. If you have any questions as to whether or not your device may be subject to postmarket surveillance or about this program, please contact the Postmarket Surveillance Studies Branch at (301) 227-8006.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

MeadoxMedicals, Inc.

112 BAUER DRIVE
OAKLAND, N.J. 07436
201-337-6126
1-800-526-0356
FAX 201-337-5797

K930622

February 4, 1993

Office of Device Evaluation
510(K) Notification
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Re: 510(k) Premarket Notification
Product: Amplatz Guidewire

Gentlemen:

By means of this letter, Meadox Surgimed, a division of Meadox Medicals, Inc., hereby notifies FDA of the intent to market the Meadox Surgimed Amplatz Guidewires. These guidewires are made of the identical materials used in our Premarket Notification for Amplatz Guidewire K912798.

This 510(k) is being submitted because a modification has been made to the design of the Amplatz Guidewire. The required information for this 510(k) Premarket Notification is provided in the following attachments.

Meadox Medicals, Inc., considers the intent to market these devices to be confidential commercial information and requests that FDA maintain confidentiality of the submission. In addition, Meadox Medicals, Inc., certifies that, to the best of our knowledge, requirements concerning confidentiality as outlined in CFR 21 Section 807.95 have been met. The product description given in Attachment III is considered to be trade secret and it is requested that FDA not release this under Freedom of Information requests.

Please feel free to contact me at (201) 337-6126 Ext. 340, if you have any questions.

Sincerely,

MEADOX MEDICALS, INC.

Nancy C. Koffman

Nancy C. Koffman
Regulatory Affairs Assistant

NK:en

Attachments

Submitted in Duplicate

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

STATEMENT OF CONFIDENTIALITY

Meadox Medicals, Inc., has invested significant resources in the research and development of this device. Information presented in this document is proprietary and should be considered confidential and not to be released without the expressed written permission of an authorized Officer of Meadox Medicals, Inc.

RG621

TABLE OF CONTENTS

510(k) Notification

Attachment I Proposed Labeling

Attachment II Literature on Currently Marketed Products

Attachment III Device Description

Attachment IV Product Testing

Attachment V Biocompatibility Testing

Attachment VI Summary of Safety and Effectiveness

RG623

Notification

510 (K) PREMARKET NOTIFICATION

1. CLASSIFICATION NAME: Cardiovascular Devices - Catheter Guidewire
COMMON/USUAL NAME: Teflon® Coated Guidewires
PROPRIETARY NAME: Amplatz Guidewires
2. ESTABLISHED REGISTRATION NUMBERS:
 - A. Owner/Operator Number: 2242352
Meadox Medicals, Inc.
112 Bauer Drive
Oakland, N.J. 07436
 - B. Establishment Number - Importer/Distributor: 1045549
Meadox Surgimed, a division of Meadox Medicals, Inc.
112 Bauer Drive
Oakland, NJ 07436
 - C. Establishment Number - Manufacturer: 8020501
Meadox Surgimed A/S
Gymansievej 5
DK-3650 Stenlose, Denmark
3. CLASSIFICATION: Cardiovascular Device - Catheter Guidewire,
Class II CFR 21, 870.1330
4. PERFORMANCE STANDARD: No applicable performance standards have
been published in the Federal Register to
date.
5. LABELING: The proposed labels and labeling are
provided in ATTACHMENT I.

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RG623

6. STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The Amplatz Guidewires are substantially equivalent in design and function to:

- 1) Meadox Surgimed Teflon® Coated Guidewires - (Pre-Amendment Devices) - marketed prior to 1976.
- 2) Teflon Coated Guidewires marketed by Cook Incorporated.
- 3) Amplatz and Bentson Guidewires K912789 which received notification of substantial equivalency on Sept. 23, 1991.

The currently marketed design for the 0.035" and 0.038" Amplatz Guidewires has a [REDACTED] B(4) connecting the [REDACTED] B(4) [REDACTED] [REDACTED] [REDACTED]. The new Design Amplatz Guidewires [REDACTED] (b)(4) [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]; this modification was made to enhance the structural safety of the device.

ATTACHMENT II contains comparative product literature.

A description of the guidewires, their packaging, device drawings and sterilization validation can be found in Attachment III.

In Vitro product testing is located in Attachment IV.

The biocompatibility testing presented in Attachment V was performed on the currently marketed Amplatz Guidewires, but applies to the new Amplatz Guidewires, as the materials used in both guidewires are identical.

The Summary of Safety and Effectiveness may be found in Attachment VI.

*Teflon is a registered trademark of E. I. Du Pont de Nemours & Co., Inc.

ATTACH 1

CONFIDENTIAL

TEFLON COATED AMPLATZ GUIDEWIRE

Catalogue No.		
Diameter	" /	mm
Length	cm	
Fixed core	x	

STERILE DATE YYMMDD: XXXXXX
 EXPIRY DATE YYMMDD: XXXXXX
 STERILE LOT NUMBER: XXXX
 BATCH NUMBER: XXXXXX

For Single Patient Use Only - Do Not Resterilize
Sterile unless opened or damaged.
Sterilized by ethylene oxide
Store in a cool, dry place.

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

Distributed by:

MEADOX SURGIMED,
 a division of
 MEADOX MEDICALS, INC.
 112 BAUER DRIVE
 OAKLAND, NJ 07436
 PHONE 201-337-6126
 FAX 201-337-5797

Made in Denmark by:

MEADOX SURGIMED A/S
 GYMNASIEVEJ 5 3660 STENLOSE
 DENMARK
 PHONE 42173800 - FAX 42177955

RG623

003

Instructions for Use
Bentson and Amplatz Guide Wires

CONFIDENTIAL

Indication: For the percutaneous introduction of an intravascular catheter.

Description: Radiopaque, stainless steel, Teflon coated guide wire.

Instructions:

When inserting the guide wire:

Make a puncture hole with a needle and insert the guide wire through the cannula (The Seldinger Technique).

When withdrawing the guide wire:

In order to avoid damage to the surface, do not withdraw the guide wire through a metal cannula.

During use:

1. If the guide wire is stained with blood, it can be cleaned by simply wiping it once or twice with a gauze moistened with physiological saline. DO NOT USE DRY GAUZE, as this might damage the wire surface, resulting in increased resistance when the wire is inserted into the catheter.
2. After cleaning the guide wire, replace it in the holder, starting with the proximal end. This guide wire may only be used during the same catheterization procedure on the same patient.

Warnings & Cautions:

1. Federal (USA) law restricts this device to sale by, or on the order, of a physician.
2. Do not resterilize or reuse the guide wire for any other procedure.
3. Single use only.
4. Sterile unless opened or damaged.

RG670

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ATTACH II

A

THIS SECTION CONTAINS LITERATURE ON CURRENTLY MARKETED PRODUCTS,
AS WELL AS INFORMATION FROM A 1975 CATALOGUE WHICH DEMONSTRATES
THAT THE MEADOX SURGIMED TEFLON COATED GUIDEWIRES WERE MARKETED
PRIOR TO 1976.

005



SURGIMED

Manufacturers of surgical & medical products

1-3 Havremarken

3650 Ølstykke

Denmark

Telephone: (03) 17 78 00

Cables: SURGIMED ØLSTYKKE

Telex: 42545 surgi dk

Associated companies:

SURGIMED INC.

Charleston S.C.

U.S.A.

SURGIMED Pty. Limited

Frankston, Australia

PRODUCTS FOR RADIOLOGY

Surgimed's considerable experience and expertise in medical product manufacturing has, over the years, been devoted exclusively to the application of advanced technology to diagnostic radiology. Close collaboration with leading radiological centres enables Surgimed to offer one of the most sophisticated and comprehensive product ranges to radiologists.

GENERAL INFORMATION ON GUIDE WIRES

SURGIMED Guide Wires are manufactured from the best quality stainless steel and are produced to the highest specifications. Each Guide Wire is tested and examined individually before despatch from the factory.

All Guide Wires should be used once only. It is impossible to remove all traces of protein material from inside the windings of Guide Wires by any method, and re-use is hazardous.

All standard fixed core Surgimed Guide Wires incorporate a 3.5 cm long soft tip. Guide Wires CS and TS 160 have a 15 cm long soft tip.

Shorter or longer soft tips can be supplied: minimum order 100.

GUIDE WIRE DIMENSIONS

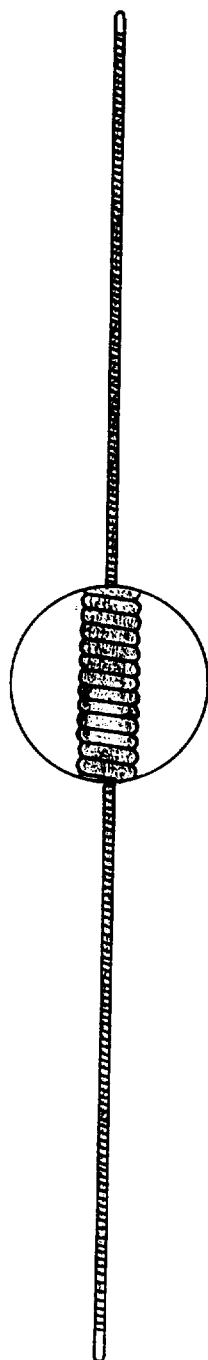
Surgimed Type No. 40	0.457 mm	.018 inch	US No. 18	Surgimed	Catalogue No. 0
Surgimed Type No. 50	0.533 mm	.021 inch	US No. 21	Surgimed	Catalogue No. 1
Surgimed Type No. 60	0.635 mm	.025 inch	US No. 25	Surgimed	Catalogue No. 2
Surgimed Type No. 90	0.711 mm	.028 inch	US No. 28	Surgimed	Catalogue No. 3
Surgimed Type No. 100	0.812 mm	.032 inch	US No. 32	Surgimed	Catalogue No. 4
Surgimed Type No. 160	0.889 mm	.035 inch	US No. 35	Surgimed	Catalogue No. 5
Surgimed Type No. 190	0.965 mm	.038 inch	US No. 38	Surgimed	Catalogue No. 6
Surgimed Type No. 200	1.14 mm	.045 inch	US No. 45	Surgimed	Catalogue No. 7
Surgimed Type No. 205	1.19 mm	.047 inch	US No. 47	Surgimed	Catalogue No. 8
Surgimed Type No. 240	1.32 mm	.052 inch	US No. 52	Surgimed	Catalogue No. 9

When Surgimed first started to manufacture Guide Wires they received their type number according to which PE tubing they could pass through and this type number is still being used.

However, in order to shorten the catalogue number as much as possible a simplified system has been adopted and we give you below a few examples which will explain how the catalogue numbers on the following pages have been compiled.

Catalogue No. C581	=	Cat. No. C	5	8	1
		Type No. C	160,	80 cm	fixed core
- TA4122	=	Cat. No. TA	4	12	2
		Type No. TA	100,	120 cm,	movable core
- TS5155	=	Cat. No. TS	5	15	5
		Type No. TS	160,	150 cm,	15 cm soft tip
- J810212	=	Cat. No. J	8	10	2 12
		Type No. J	205	100 cm,	movable core, 12 mm curve

If other lengths in soft tip should become popular this will result in a change of the figure representing the length of the soft tip.

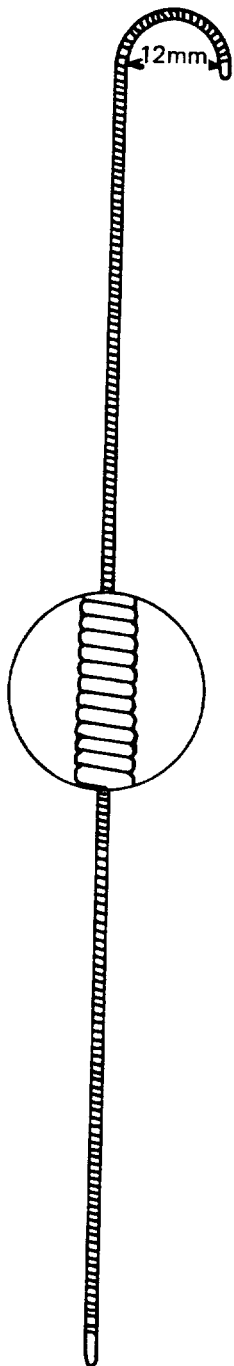
STERILE SAFETY GUIDE WIRE TA**TEFLON COATED**

Type No.:	Diameter		U.S. No.:	Length cm	Catalogue No.:	
	mm	inch			Fixed core	Movable core
TA 50	0.533	.021	21	40	TA141	TA142
				60	TA161	TA162
				80	TA181	TA182
				100	TA1101	TA1102
				120	TA1121	TA1122
				150	TA1151	TA1152
TA 60	0.635	.025	25	40	TA241	TA242
				60	TA261	TA262
				80	TA281	TA282
				100	TA2101	TA2102
				120	TA2121	TA2122
				150	TA2151	TA2152
TA 90	0.711	.028	28	40	TA341	TA342
				60	TA361	TA362
				80	TA381	TA382
				100	TA3101	TA3102
				120	TA3121	TA3122
				150	TA3151	TA3152
TA 100	0.812	.032	32	40	TA441	TA442
				60	TA461	TA462
				80	TA481	TA482
				100	TA4101	TA4102
				120	TA4121	TA4122
				150	TA4151	TA4152
TA 160	0.889	.035	35	40	TA541	TA542
				60	TA561	TA562
				80	TA581	TA582
				100	TA5101	TA5102
				120	TA5121	TA5122
				150	TA5151	TA5152
TA 190	0.965	.038	38	40	TA641	TA642
				60	TA661	TA662
				80	TA681	TA682
				100	TA6101	TA6102
				120	TA6121	TA6122
				150	TA6151	TA6152
TA 200	1.14	.045	45	40	TA741	TA742
				60	TA761	TA762
				80	TA781	TA782
				100	TA7101	TA7102
				120	TA7121	TA7122
				150	TA7151	TA7152
TA 205	1.19	.047	47	40	TA841	TA842
				60	TA861	TA862
				80	TA881	TA882
				100	TA8101	TA8102
				120	TA8121	TA8122
				150	TA8151	TA8152

008

Caution: Never re-sterilize teflon coated guide wires by irradiation.
Complete destruction of teflon results.

0.1224mm CURVE DIAMETER - TEFLON COATED



Type No.:	Diameter		U.S. No.:	Length cm	Catalogue No.:	
	mm	inch			Fixed core	Movable core
TJ 50	0.533	.021	21	80	TJ181 +CURVE	TJ182 +CURVE
				100	TJ1101	TJ1102
				120	TJ1121	TJ1122
				150	TJ1151	TJ1152
TJ 60	0.635	.025	25	80	TJ281 +CURVE	TJ282 +CURVE
				100	TJ2101	TJ2102
				120	TJ2121	TJ2122
				150	TJ2151	TJ2152
TJ 90	0.711	.028	28	80	TJ381 +CURVE	TJ382 +CURVE
				100	TJ3101	TJ3102
				120	TJ3121	TJ3122
				150	TJ3151	TJ3152
TJ 100	0.812	.032	32	80	TJ481 +CURVE	TJ482 +CURVE
				100	TJ4101	TJ4102
				120	TJ4121	TJ4122
				150	TJ4151	TJ4152
TJ 160	0.889	.035	35	80	TJ581 +CURVE	TJ582 +CURVE
				100	TJ5101	TJ5102
				120	TJ5121	TJ5122
				150	TJ5151	TJ5152
TJ 190	0.965	.038	38	80	TJ681 +CURVE	TJ682 +CURVE
				100	TJ6101	TJ6102
				120	TJ6121	TJ6122
				150	TJ6151	TJ6152
TJ 200	1.14	.045	45	80	TJ781 +CURVE	TJ782 +CURVE
				100	TJ7101	TJ7102
				120	TJ7121	TJ7122
				150	TJ7151	TJ7152
TJ 205	1.19	.047	47	80	TJ881 +CURVE	TJ882 +CURVE
				100	TJ8101	TJ8102
				120	TJ8121	TJ8122
				150	TJ8151	TJ8152

Caution: Never re-sterilize teflon coated guide wires by irradiation.
Complete destruction of teflon results.

009

Non-standard lengths available — minimum quantity 100 — maximum length 150 cm.

MEADOX SURGIMED

Meadox Surgimed A/S

**TEFLON[®] COATED GUIDE WIRES SUPERIOR
QUALITY AND PERFORMANCE TO
MEET YOUR NEEDS**

CONFIDENTIAL

TEFLON[®] COATED GUIDE WIRES



01021

MEADOX SURGIMED GUIDE WIRES

TEFLON® COATED

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NO COMPROMISE IN QUALITY AND PERFORMANCE

The Meadox Surgimed, movable core guide wire incorporates a Teflon® coated inner core. The low friction core facilitates tip control during guide wire manipulation. Teflon coated outer surface reduces thrombogenicity and eases insertion and catheter manipulation.

Guide wire diameters

Inches	.018"	.021"	.025"	.028"	.032"	.035"	.038"	.045"	.047"
mm	0.46	0.53	0.64	0.71	0.81	0.89	0.97	1.14	1.19

SPECIFICATIONS:

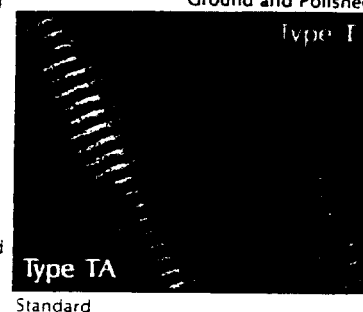
- Core – Smoothly tapered stainless steel
- Movable Core – Teflon® coated stainless steel
- Sterilization – Ethylene Oxide
- Packaging – Tyvek® and Mylar® peel pack pouch
10 unit dispenser box

SUPERIOR CHARACTERISTICS WITH A SPECIAL DESIGN:

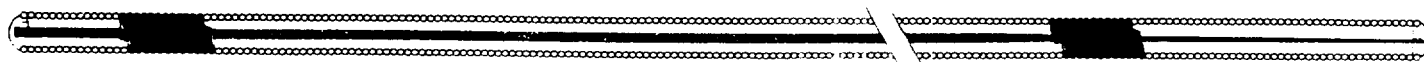
The smooth Teflon® coated surface of the Meadox Surgimed T-guide wire is the result of a special polishing technique. This design eases insertion and manipulation.

CAUTION: Federal (USA) law restricts this device to sale only on the order of a physician.

Teflon®, Tyvek® and Mylar® are registered trademarks of E. I. DuPont de Nemours and Co., Inc.



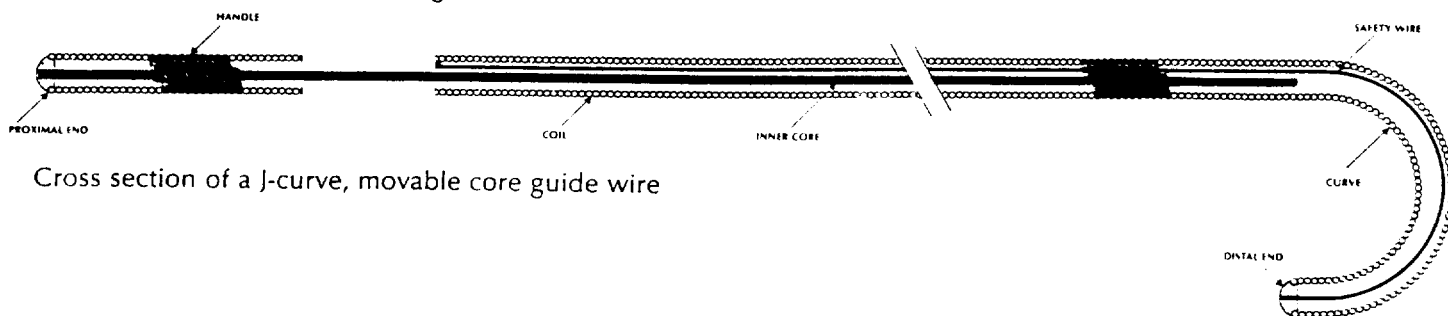
GUIDE WIRE CONSTRUCTION



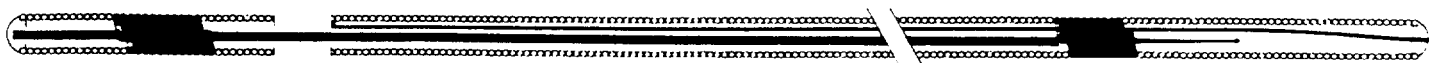
Cross section of a fixed core guide wire



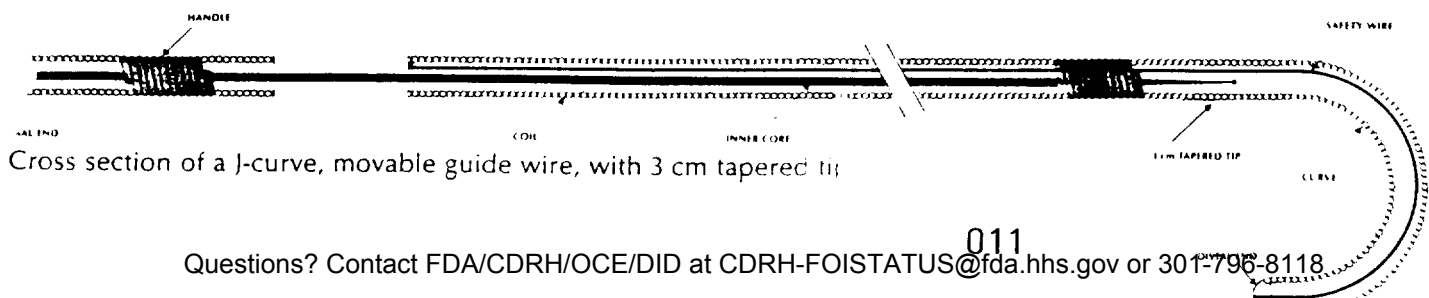
Cross section of a movable core guide wire



Cross section of a J-curve, movable core guide wire



Cross section of a movable core guide wire with 3 cm tapered tip



Cross section of a J-curve, movable guide wire, with 3 cm tapered tip

TEFLON® COATED GUIDE WIRES - J-CURVED**STANDARD GUIDE WIRE PROGRAMME: COLOUR CODED IN RED****CONFIDENTIAL**Teflon® coated type "TJ"-J-curved-FIXED core-3.5 cm flexible tip
1.5 mm J-curved radius

Dimension	Length in cm					
	40	60	80	100	120	150
.032"						
.035"	616510	616520	616530	616540	616550	616460
3 mm J-curved radius						616560
.021"	616111	616121	616131	616141	616151	616161
.025"	616211	616221	616231	616241	616251	616261
.028"	616311	616321	616331	616341	616351	616361
.032"	616411	616421	616431	616441	616451	616461
.035"	616511	616521	616531	616541	616551	616561
.038"	616611	616621	616631	616641	616651	616661
6 mm J-curved radius						
.021"	616112	616122	616132	616142	616152	616162
.025"	616212	616222	616232	616242	616252	616262
.028"	616312	616322	616332	616342	616352	616362
.032"	616412	616422	616432	616442	616452	616462
.035"	616512	616522	616532	616542	616552	616562
.038"	616612	616622	616632	616642	616652	616662
.045"	616712	616722	616732	616742	616752	616762
.047"	616812	616822	616832	616842	616852	616862
12 mm J-curved radius						
.021"	616113	616123	616133	616143	616153	616163
.025"	616213	616223	616233	616243	616253	616263
.028"	616313	616323	616333	616343	616353	616363
.032"	616413	616423	616433	616443	616453	616463
.035"	616513	616523	616533	616543	616553	616563
.038"	616613	616623	616633	616643	616653	616663
.045"	616713	616723	616733	616743	616753	616763
.047"	616813	616823	616833	616843	616853	616863

Teflon® coated type "TJ"-J-curved-MOVABLE core-Teflon® coated inner core
1.5 mm J-curved radius

Dimension	Length in cm					
	40	60	80	100	120	150
.035"	617510	617520	617530	617540	617550	617560
3 mm J-curved radius						
.032"	617411	617421	617431	617441	617451	617461
.035"	617511	617521	617531	617541	617551	617561
.038"	617611	617621	617631	617641	617651	617661
.045"					617751	617761
6 mm J-curved radius						
.032"	617412	617422	617432	617442	617452	617462
.035"	617512	617522	617532	617542	617552	617562
.038"	617612	617622	617632	617642	617652	617662
.045"	617712	617722	617732	617742	617752	617762
.047"	617812	617822	617832	617842	617852	617862
12 mm J-curved radius						
.032"	617413	617423	617433	617443	617453	617463
.035"	617513	617523	617533	617543	617553	617563
.038"	617613	617623	617633	617643	617653	617663
.045"	617713	617723	617733	617743	617753	617763
.047"	617813	617823	617833	617843	617853	617863

Teflon® coated-J-curved-MOVABLE core-Teflon® coated inner core with 3 cm tapered tip
1.5 mm J-curved radius

Dimension	Length in cm			Dimension	Length in cm		
	100	120	150		100	120	150
.035"	617240	617250	617260	.035"	617241	617251	617261
.038"				.038"	617341	617351	617361
.035"	617242	617252	617262	.035"	617243	617253	617263
.038"	617342	617352	617362	.038"	617343	617353	617363

Lunderquist Teflon® coated type "TLJ"-J-curved-FIXED core-3 mm J-curved radius
7 cm flexible tip

Dimension	Length in cm			Length in cm		
	80	90	100		80	120
.035"	618111			.035"	618221	618121
.038"				.038"		618621

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

TEFLON® COATED GUIDE WIRES - STRAIGHT**STANDARD GUIDE WIRE PROGRAMME: COLOUR CODED IN RED****CONFIDENTIAL**

Catalogue number appears at the intersection of the desired dimension and length.

Teflon® coated type "TA"-Straight-FIXED core-3.5 cm flexible tip

Dimension	Length in cm						
	40	60	80	100	120	150	260
.018"	611010	611020	611030	611040	611050	611060	-
.021"	611110	611120	611130	611140	611150	611160	-
.025"	611210	611220	611230	611240	611250	611260	-
.028"	611310	611320	611330	611340	611350	611360	-
.032"	611410	611420	611430	611440	611450	611460	-
.035"	611510	611520	611530	611540	611550	611560	611570
.038"	611610	611620	611630	611640	611650	611660	611670
.045"	611710	611720	611730	611740	611750	611760	-
.047"	611810	611820	611830	611840	611850	611860	-

Teflon® coated type "TA"-Straight-MOVABLE core-Teflon® coated inner core

Dimension	Length in cm						
	40	60	80	100	120	150	260
.032"	612410	612420	612430	612440	612450	612460	-
.035"	612510	612520	612530	612540	612550	612560	-
.038"	612610	612620	612630	612640	612650	612660	612670
.045"	612710	612720	612730	612740	612750	612760	-
.047"	612810	612820	612830	612840	612850	612860	-

Teflon® coated straight-MOVABLE core-Teflon® coated inner core with 3 cm tapered tip

Dimension	Length in cm			
	100	120	150	260
.032"	612413	612423	612433	-
.035"	612513	612523	612533	-
.038"	612613	612623	612633	832205

Ground and Teflon® coated type "T"-Straight-FIXED core-3.5 cm flexible tip

Dimension	Length in cm					
	40	60	80	100	120	150
.035"	613510	613520	613530	613540	613550	613560
.038"	613610	613620	613630	613640	613650	613660
.047"	613810	613820	613830	613840	613850	613860

Ground and Teflon® coated type "T"-Straight-MOVABLE core-Teflon® coated inner core

Dimension	Length in cm					
	40	60	80	100	120	150
.035"	614510	614520	614530	614540	614550	614560
.038"	614610	614620	614630	614640	614650	614660
.047"	614810	614820	614830	614840	614850	614860

Newton Teflon® coated type "TAN"-Straight-FIXED core**10 cm flexible tip****15 cm flexible tip**

Dimension	Length in cm		Length in cm	
	120	150	120	150
.035"	619511	619521	619515	619522
.038"	619611	619621	619615	619622

Teflon® coated type-Heavy duty guide wires-FIXED core-straight-3.5 cm flexible tip

Dimension	Length in cm					
	60	80	100	120	150	250
.032"	619423	619433	619443	619453	619463	-
.035"	619523	619533	619543	619553	619563	619583
.038"	619623	619633	619643	619653	619663	-

Lunderquist Teflon® coated guide wire type "TL"-Straight-FIXED core**7 cm flexible tip****15 cm flexible tip**

Dimension	Length in cm				Length in cm			
	80	90	120	150	80	90	120	150
.035"	615511	615521	615531	615541	-	615522	615532	615542
.038"	-	615621	615631	615641	-	615622	615632	615643

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Meadox Surgimed A/S

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or fax to +45 2 17 38 00

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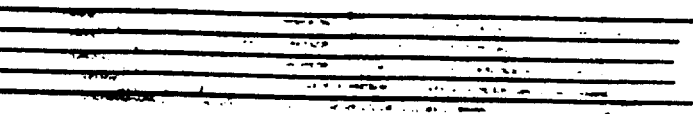
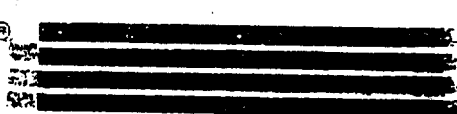
DK-2800 Kongens Lyngby - Denmark

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*Diagnostic and
Interventional Products
for Radiology, Cardiology and Surgery*

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CONTENTS

GENERAL INFORMATION

WIRE GUIDES

(G) (4) (C) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11) (12) (13) (14) (15) (16) (17) (18) (19) (20) (21) (22) (23) (24) (25) (26) (27) (28) (29) (30) (31) (32) (33) (34) (35) (36) (37) (38) (39) (40) (41) (42) (43) (44) (45) (46) (47) (48) (49) (50) (51) (52) (53) (54) (55) (56) (57) (58) (59) (60) (61) (62) (63) (64) (65) (66) (67) (68) (69) (70) (71) (72) (73) (74) (75) (76) (77) (78) (79) (80) (81) (82) (83) (84) (85) (86) (87) (88) (89) (90) (91) (92) (93) (94) (95) (96) (97) (98) (99) (100)

DIGITAL SUBTRACTION

DILATORS

CATHETER INTRODUCERS

NEEDLES

CONNECTING TUBES

BILIARY DRAINAGE

ENDOSCOPIC

GASTROENTEROLOGY

STONE REMOVAL

EMBOLIZATION AND OCCLUSION

LYMPHANGIOGRAPHY AND SIALOGRAPHY

SYRINGES AND INJECTOR

FLARING TOOL AND HOLE PUNCHES

FILMS, VIDEOTAPES, AND REFERENCE GUIDES

015

CONFIDENTIAL
PAGE

PRODUCT

WIRE GUIDES

AMPLATZ STIFF WIRE GUIDES	16
BENTSON CEREBRAL CURVED SAFE-T-J® WIRE GUIDES	7
BENTSON CEREBRAL STRAIGHT SAFETY WIRE GUIDES	6
CATHETER EXCHANGE CURVED SAFE-T-J® WIRE GUIDES	7
CATHETER EXCHANGE STRAIGHT SAFETY WIRE GUIDES	6
COOK DEFLECTING HANDLE	12
COONS INTERVENTIONAL WIRE GUIDES	16
COPE MANDRIL WIRE GUIDES	18
DOUBLE FLEXIBLE TIPPED WIRE GUIDES	11
EXCHANGE TIP DEFLECTING WIRE GUIDE HANDLE	14
HANAFEE CEREBRAL STRAIGHT SAFETY WIRE GUIDE	6
HAWKINS COAXIAL WIRE GUIDES	19
HAWKINS EXCHANGE TIP DEFLECTING WIRE GUIDES	14
HEAVY DUTY STRAIGHT SAFETY WIRE GUIDES	6
HILAL-GROSSMAN CURVED SAFE-T-J® WIRE GUIDES	7
HILAL-GROSSMAN STRAIGHT SAFETY WIRE GUIDES	6
JUDKINS CORONARY ARTERY STRAIGHT SAFETY WIRE GUIDE	6
LONG FLEXIBLE TIP STRAIGHT SAFETY WIRE GUIDES	6
LUNDERQUIST EXCHANGE WIRE GUIDES	15
LUNDERQUIST-RING TORQUE WIRE GUIDES	15
MOSES CURVED SAFE-T-J® WIRE GUIDES	17
MOVABLE CORE CURVED SAFE-T-J® WIRE GUIDES	8
MOVABLE CORE MULTIPLE CURVED SAFE-T-J® WIRE GUIDES	8
MOVABLE CORE STRAIGHT SAFETY WIRE GUIDES	8
MULTIPLE CURVED SAFE-T-J® WIRE GUIDES	7
NEWTON CEREBRAL CURVED SAFE-T-J® WIRE GUIDES	7
NEWTON CEREBRAL STRAIGHT SAFETY WIRE GUIDES	6
RING INTRAVASCULAR TORQUE WIRE GUIDES	18
ROSEN CURVED SAFE-T-J® WIRE GUIDES	17
STANDARD CURVED SAFE-T-J® WIRE GUIDES	7
STANDARD STRAIGHT SAFETY WIRE GUIDES	6
TAPERED MOVABLE CORE CURVED WIRE GUIDES	10
TAPERED MOVABLE CORE STRAIGHT WIRE GUIDES	10
TEFCOR MOVABLE CORE CURVED WIRE GUIDES	9
TEFCOR MOVABLE CORE STRAIGHT WIRE GUIDES	9
TIP DEFLECTING WIRE GUIDES AND CATHETERS	13
VARIABLE STIFFNESS WIRE GUIDES	12
WILLSON TORQUE WIRE GUIDES	19

CATHETERS

AMPLATZ LEFT CORONARY CATHETERS	34
AMPLATZ RIGHT CORONARY CATHETERS	35
ANGLED VENTRICULOGRAPHY PIGTAIL CATHETERS	10
BENTSON-HANAFEE-WILSON CEREBRAL CATHETERS	18
BROCKENBROUGH TRANSSEPTAL LEFT HEART CATHETERS	29
CHUANG VISCERAL CATHETERS	26
COAXIAL INFUSION SETS	37
COBRA VISCERAL CATHETERS	25
COURNAND RIGHT HEART CATHETERS	31
DAVIS CEREBRAL CATHETERS	18
FLOW-DIRECTED BALLOON CATHETERS	38
GROLLMAN PULMONARY PIGTAIL CATHETERS	10
HILAL AORTOGRAM CATHETERS	11
HILAL MODIFIED HEADHUNTER CEREBRAL CATHETERS	15
HINCK HEADHUNTER CEREBRAL CATHETERS	14

016

ATTACH III

39

DESCRIPTION OF COMPONENT MATERIALS

	Springwire	Inner Core	Safety Thread	Solder	Coating
Amplatz K912798	Stainless Steel	Stainless Steel	Stainless Steel	(b)(4)	Teflon
Amplatz (New Design)	Stainless Steel	Stainless Steel	None		Teflon
Lunderquist (pre-amendment)	Stainless Steel	Stainless Steel	Stainless Steel		Teflon

PACKAGING

Guidewire holder -
 Holder clip -
 Guidewire Inserter -
 Holder hub -
 Packaging -

(b)(4) Product Specifications

STERILIZATION

Ethylene Oxide

See Attachment V for EtO residual analysis.

Sterility Assurance Level 10^{-6} .

Method - ETO

(b)(4)

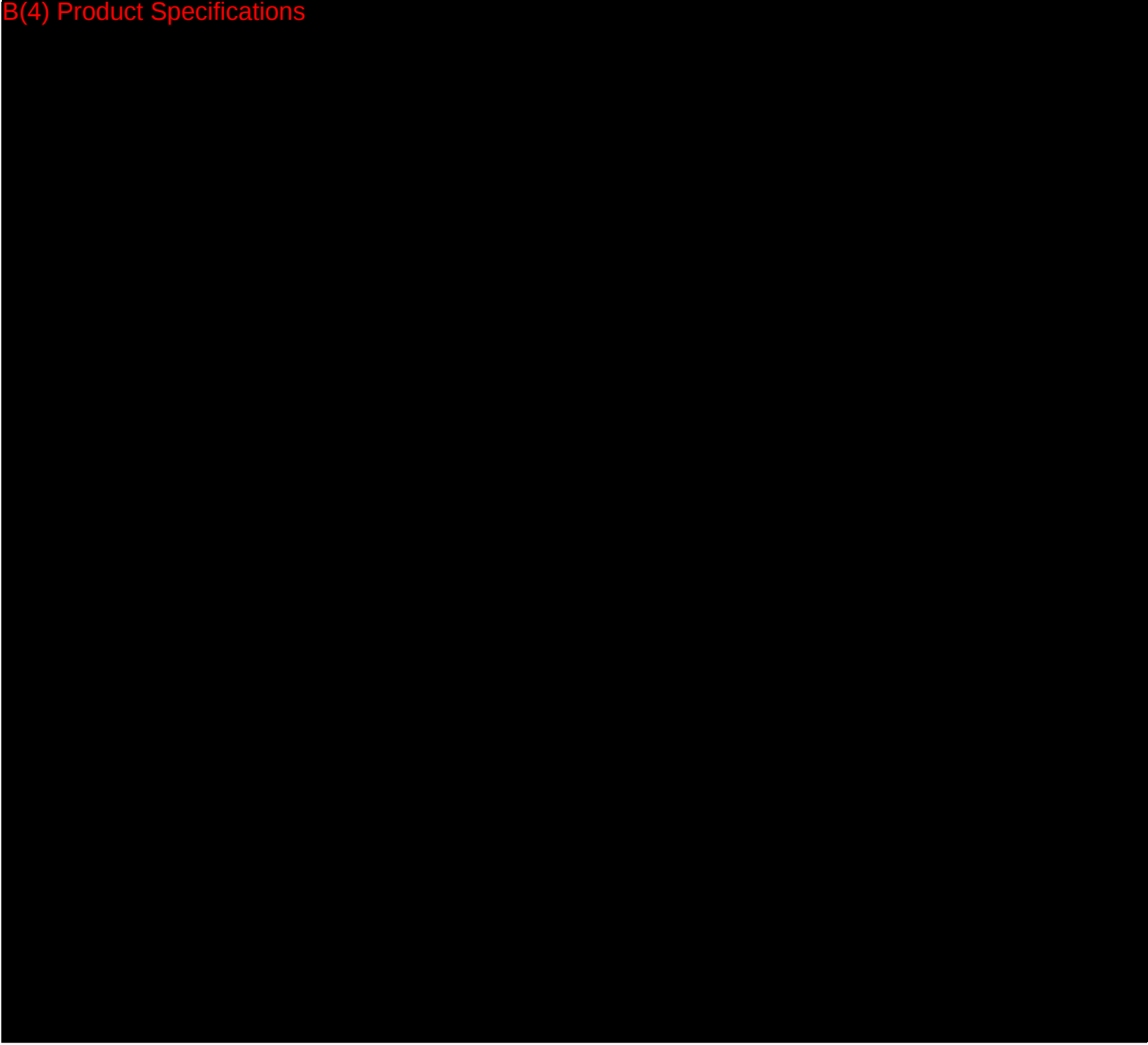
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017

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I. Description of Components

B(4) Product Specifications



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018

34

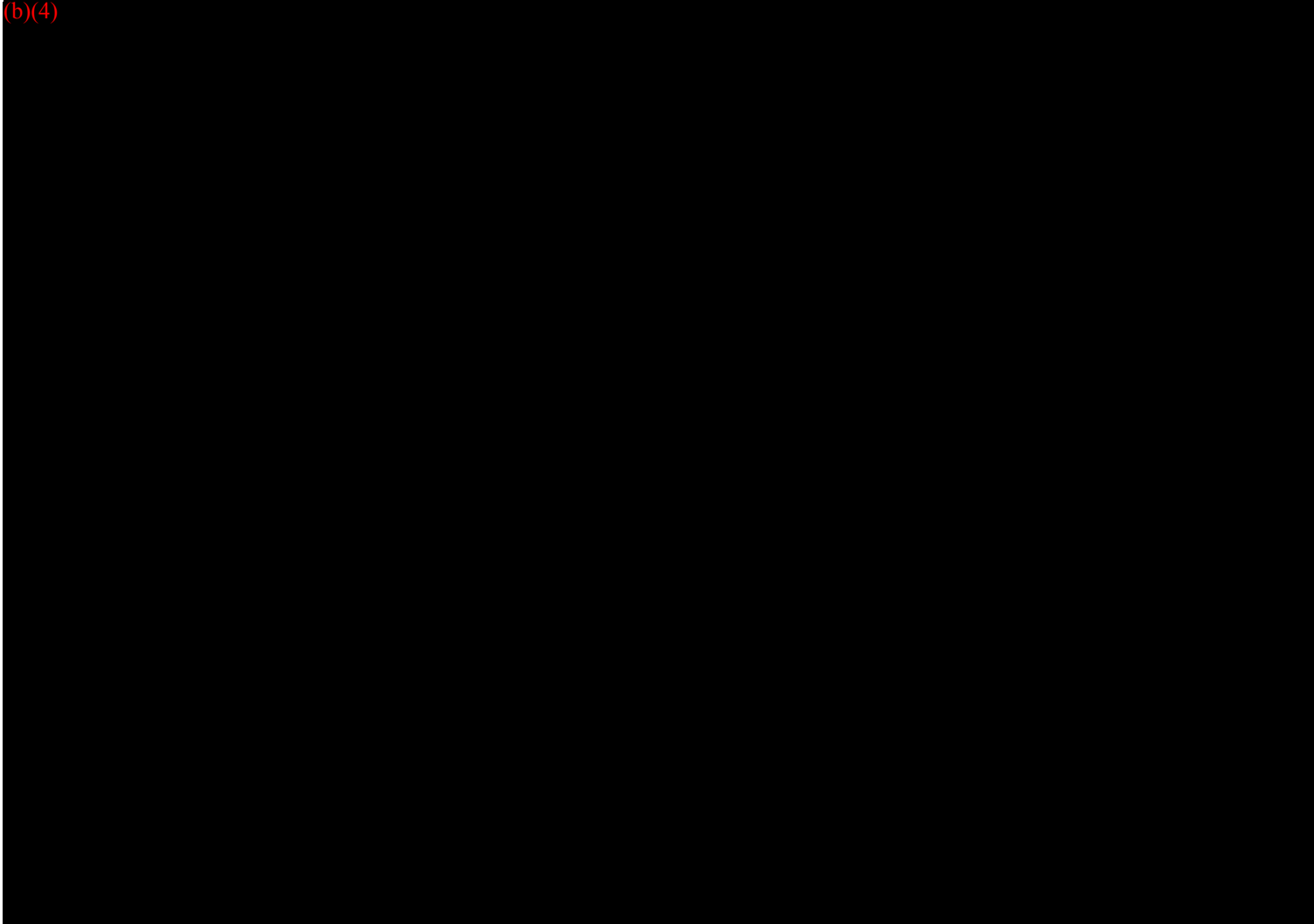
ATTACH IV

58

AMPLATZ PRODUCT TESTING

Bench Testing

(b)(4)



RG623

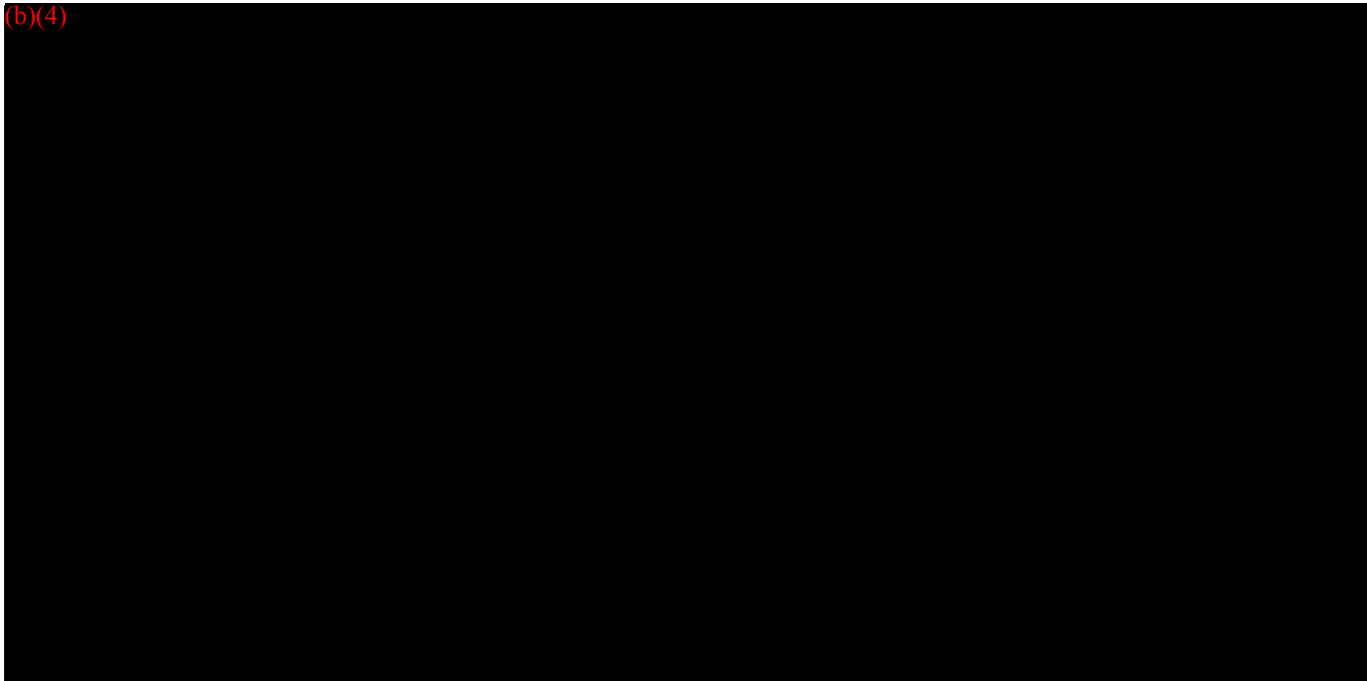
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25

Attachment V

BIOCOMPATIBILITY TESTING

(b)(4)

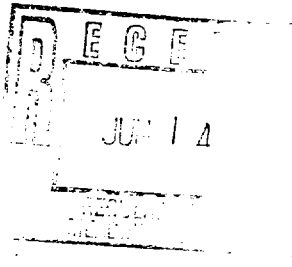


RG623

021

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B(4) Product Test Results



Lab No.

P.O. No.

B(4) Product Test Results

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STUDY TITLE:

B(4) Product Test Results

TEST ARTICLE:

B(4) Product Test Results

IDENTIFICATION #:

B(4) Product Test Results

SPONSOR:

B(4) Product Test Results

B(4) Product Test Results

Attach VI

81

Summary of Safety and Effectiveness

Owner: Meadox Medicals, Inc.
112 Bauer Drive
Oakland, NJ 07436

Contact: Nancy Koffman
Associate Regulatory Affairs Specialist

Submission Date: February 4, 1993

Device Name: Amplatz Guidewires

The Amplatz Guidewires are substantially equivalent in design and function to the Meadox Surgimed Teflon Coated Guidewires, Teflon Guidewires manufactured by Cook, Inc. and the Amplatz Guidewires 510(k) 912789.

The Amplatz Guidewires are radiopaque, stainless steel, teflon coated guidewires which are designed for the intravascular introduction of a percutaneous catheter.

The following tests were performed to show the safety, efficacy and performance of the product:

<u>Test</u>	<u>Results</u>
Tensile Strength Test	Equivalent to Marketed Product
Cytotoxicity	Passed
Sensitization	Passed
USP Class VI	Passed
Hemolysis testing	Passed
EtO Residual Analysis	

RG623

061