Medtronic

Abre™

Venous Self-expanding Stent System

Instructions for Use

Symbol definitions

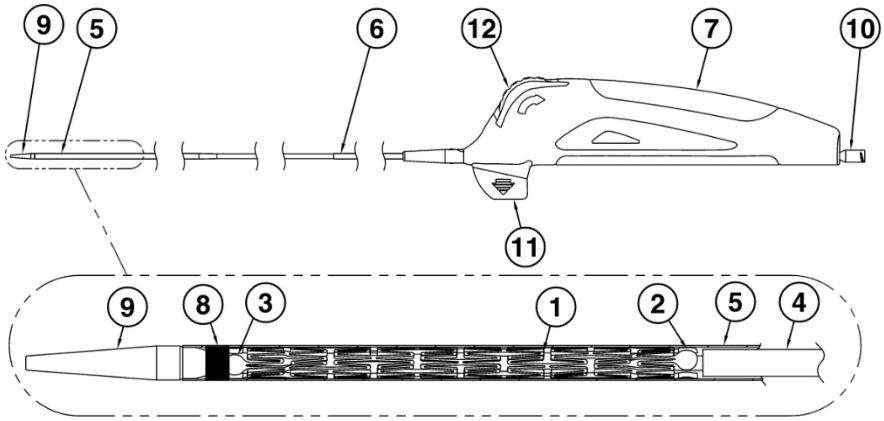
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalog number
	Sterilized using ethylene oxide
	Do not reuse
	Do not use if package is damaged
	MR Conditional
	Quantity
	Keep away from sunlight
	Keep dry
	Compatible guidewire
	Minimum sheath inner diameter
	Lumen diameter
	Consult instructions for use at this website
! USA	For US audiences only
Rx only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

1 Device description

The Abre venous self-expanding stent system (Abre system) is a vascular self-expanding nitinol stent system. The Abre stent is intended for permanent implant and comes premounted on a 9 Fr delivery system inserted over a 0.89 mm (0.035 in) wire.

- The Abre self-expanding stent, as shown in *Figure 1*, is cut from a nickel titanium alloy (nitinol) tube in an open lattice design (1), with integral nitinol markers at the trailing end (2) and the leading end (3) of the stent. Upon deployment, the Abre stent exerts an outward force to establish patency.
- The Abre delivery system, as shown in *Figure 1*, has a triaxial shaft design, comprised of an inner shaft assembly (4), a retractable sheath (silver, 5), an isolation sheath (blue, 6), and an ergonomic handle (7). The inner shaft assembly terminates with a flexible catheter tip (9) and originates at the luer hub (10). The deployment handle (7) has a removable locking pin (11), thumbwheel (12), and luer hub (10).
- The radiopaque markers, at the trailing end and the leading end of the stent, guide stent positioning at the target lesion before Abre stent deployment. There is a single luer hub on the deployment handle. A thumbwheel on the deployment handle rotates to pull back the retractable sheath (silver). A locking pin prevents the stent from being deployed before use and must be removed to actuate the thumbwheel. The Abre stent is fully deployed when the radiopaque marker (8) in the retractable sheath (silver) reaches beyond the integral nitinol markers on the trailing end of the stent. A uniquely designed isolation sheath (blue, attached to the deployment handle) improves control and accuracy of stent delivery.

Figure 1. Abre venous self-expanding stent system



2 Intended purpose

The intended purpose of the Abre system is to restore lumen patency and blood flow.

2.1 Indications for Use

The Abre venous self-expanding stent system is intended for use in the iliofemoral veins for the treatment of symptomatic venous outflow obstruction.

2.2 Intended users

The Abre stent system is intended for use by physicians who have experience with interventional techniques in the vascular system.

2.3 Contraindications

- Do not use the Abre system with patients with known hypersensitivity to nickel titanium (nitinol).
- Do not use the Abre system with patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter or proper placement of the stent or the stent delivery system.
- Do not use the Abre system with patients in whom anticoagulant or antiplatelet therapy is contraindicated.

3 Warnings

- This device was designed for single use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination, which could result in patient injury, illness, or death.
- If unusually high resistance is encountered when advancing the Abre delivery system over the guidewire, assess the cause of the resistance before proceeding.
- If high resistance is felt when initially rotating the thumbwheel, do not force deployment. Carefully withdraw the system and do not use it.
- Do not use in patients with a total venous occlusion that cannot be dilated to allow passage of the guidewire.
- Do not use the device with contralateral access.
- Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures.

4 Precautions

- Federal law restricts this device to sale by or on the order of a physician.
- Use of the Abre stent in vessel beds other than the iliofemoral vein region has not been studied.
- Abre stent system implant procedures should only be performed by physicians that have experience with interventional techniques in the vascular system.
- Appropriate stent size selection is crucial and ensures appropriate stent apposition to the vessel wall. Stent undersizing can lead to stent migration and suboptimal luminal diameter. Use *Table 11* for guidance in selecting the appropriate stent size.
- Carefully inspect the sterile package and device before use to verify that no damage occurred during shipment. Do not use the stent system if it is damaged or compromised.
- Carefully remove the system from the tray and tube without kinking the system. Do not use the system if it is kinked.
- Do not use the stent system if the Abre stent is partially deployed before starting the procedure.
- Gain access at a distance far enough from the intended treatment site to ensure that the introducer sheath does not intrude into the intended treatment site. Gaining access too close to the intended treatment site can lead to difficulty with stent deployment.
- Always use an introducer sheath during the implant procedure to protect both the vessel and

puncture site.

- Ensure that the locking pin remains in locked position until the target site is reached.
- If the retractable sheath (silver) is exposed beyond the hemostatic valve when the stent is positioned for deployment, pull the introducer sheath back so that the hemostatic valve covers the end of the isolation sheath (blue) and is not in direct contact with the retractable sheath. Friction from direct contact between the retractable sheath and the hemostatic valve can cause difficult stent deployment or inaccurate stent placement.
- Do not reposition the Abre stent after establishing apposition against the vessel wall. Repositioning the stent may cause stent elongation, stent fracture, or vessel damage.
- The Abre delivery system is not designed for recapturing the stent.
- The Abre stent is not designed to be lengthened or shortened from its nominal length. Excessive stent lengthening or shortening can increase the risk of stent fracture.
- If resistance is felt when withdrawing the system, do not force withdrawal. Forcing withdrawal can cause catheter separation and embolism.
- Use care when crossing a deployed Abre stent with any adjunct device to avoid stent dislodgement or damage to the adjunct device.
- Dispose of the delivery system and accessories in accordance with applicable laws, regulations, and hospital procedures, including those regarding biohazards, microbial hazards, and infectious substances.

5 Potential adverse events

The potential adverse events (or complications) that may occur or require intervention with the use of this device include, but are not limited to, the following:

- Access failure
- Access site infection
- Allergic reaction to contrast medium or procedure medications
- Allergic reaction to nitinol or other device materials
- Aneurysm
- AV fistula
- Bleeding
- Bruising
- Death
- Device breakage
- Device maldeployment
- Edema
- Embolization
- Fever
- Hematoma
- Hypertension
- Hypotension, nausea, or other vasovagal response
- Infection
- Myocardial infarction, arrhythmia, or other cardiovascular insufficiency
- Open surgical repair
- Pain
- Pseudoaneurysm
- Renal insufficiency or renal failure (new or worsening)
- Respiratory distress or pulmonary embolism
- Sepsis
- Stent fracture
- Stent malapposition
- Stent malposition
- Stent migration
- Stroke, paradoxical embolism, transient ischemic attack, or intracerebral hemorrhage
- Tissue necrosis
- Venous occlusion, restenosis, or thrombosis, within or outside of stented segment
- Vessel damage, including intimal injury, dissection, perforation, or rupture

6 Summary of clinical studies

The clinical evidence supporting the safety and effectiveness of the Abre venous self-expanding stent system for symptomatic iliofemoral venous outflow obstruction was derived from an Investigational Device Exemption (IDE) study, the ABRE Study. A summary of the ABRE Study is presented below.

7 Primary clinical study

7.1 Study design

The ABRE Study was a prospective, multi-center, single-arm study. Safety and effectiveness were designed to be evaluated against performance goals developed from the scientific literature. A total of 200 subjects were included at 24 investigational sites in the United States and Europe. Subjects were categorized as acute Deep Vein Thrombosis (DVT), Post-Thrombotic Syndrome (PTS), or Non-thrombotic Iliac Vein Lesion (NIVL).

Subjects in the ABRE Study were evaluated at a screening visit, during the index procedure, through hospital discharge, and then at 30 days, 6 months, and 12 months. Additional follow-up evaluations are ongoing at 24 months and 36 months post-procedure.

Subjects eligible for enrollment were males and non-pregnant females 18 to 80 years of age, with at least 1 clinical indicator of lower extremity venous disease: Clinical-Etiological-Anatomical-Pathophysiological score (CEAP) ≥3, Venous Clinical Severity Score pain score (VCSS) ≥2, and/or suspected DVT. All subjects had venographic and/or Intravascular Ultrasound (IVUS) diagnosis of non-malignant venous obstruction (occlusion or ≥50% in diameter reduction or ≥50% area reduction by IVUS) within the Common Iliac Vein (CIV), External Iliac Vein (EIV), and/or Common Femoral Vein (CFV) per the Clinical Investigational Plan (CIP). Subjects with acute DVT within 14 days of onset of associated symptoms were included in the study if the acute DVT was treated and venography confirmed 30% or less residual thrombus.

Subjects were not permitted to be enrolled in the study if they had peripheral arterial disease symptoms in the target-limb or active vasculitic inflammatory disorder. Subjects were also excluded from the study if they had 1 or more of the following: vena cava obstruction, lesions extending into the Inferior Vena Cava (IVC), bilateral iliofemoral venous lesions requiring planned treatment within 12 months, or a previously placed stent in the ipsilateral venous vasculature.

Endpoint-related safety events were adjudicated by an independent Clinical Events Committee (CEC). An independent Data Safety Monitoring Board (DSMB) monitored participant safety and the continued validity and scientific merit of the study.

7.2 Primary Endpoints

The primary effectiveness endpoint of the study was primary patency, evaluated at 12 months post-procedure. Primary patency at 12 months was defined as meeting all of the following criteria: freedom from occlusion of the stented segment of the target lesion, freedom from restenosis ≥50% of the stented segment of the target lesion, and freedom from clinically driven TLR. Clinically driven was defined as the recurrence of symptoms present at baseline or the onset of new symptoms including, but not limited to: venous pain, swelling, dermatitis, or ulceration related to the target limb, as adjudicated by the CEC.

The primary safety endpoint of the study was the incidence of composite MAEs at 30 days post-procedure. The components of the 30-day MAE composite included: all-cause death occurring post-procedure, clinically significant (i.e. symptomatic, confirmed by Computed Tomography (CT) pulmonary angiography) pulmonary embolism, major bleeding complication (procedural), stent thrombosis, and stent migration. Stent thrombosis was defined as occlusion of the stented venous segment occurring at any time following stent placement. Stent migration was defined as position change of a properly sized venous stent, with displacement of the stent outside of the intended treatment segment after the index procedure. Stent migration was determined with regard to a reference anatomic structure. All MAEs were adjudicated by a CEC, except for stent thrombosis and stent migration, which were confirmed by core laboratory.

The following secondary endpoints were evaluated through 12 months (24-month and 36-month evaluations will be performed according to each endpoint definition):

- Device success, defined as successful delivery and deployment of the Abre stent in the target lesion with successful removal of the delivery system.
- Lesion success, defined as venographic evidence of <50% final residual stenosis of the stented segment of the target lesion after post-dilation, when applicable, and as assessed by core laboratory. If the core laboratory was unable to assess the venographic evidence, site-reported “post-stenting” data were used.
- Procedure success, defined as lesion success without procedure-related MAEs prior to hospital discharge within 30 days.
- Primary assisted patency at 12 months, defined as uninterrupted patency of the stented segment of the target lesion with a secondary intervention, also known as an adjunctive treatment (e.g. balloon venoplasty, subsequent stenting, etc.).

- Secondary patency at 12 months, defined as patency of the stented segment of the target lesion after subsequent intervention for an occlusion.
- TLR through 30 days, 6, 12, 24, and 36 months, defined as any re-intervention of the stented segment of the target lesion.
- MAEs through 6, 12, 24, and 36 months, including all-cause death occurring post-procedure, clinically significant (i.e. symptomatic, confirmed by CT pulmonary angiography) pulmonary embolism, major bleeding complication (post-procedural), stent thrombosis, and stent migration. All MAEs were adjudicated by a CEC, except for stent thrombosis and stent migration, which were confirmed by the core laboratory.
- Delayed stent migration at 12, 24, and 36 months, defined as position change of a venous stent observed with an imaging modality >1 cm from its original location at the conclusion of the index procedure, as determined with regard to a reference anatomic structure.
- Stent fracture at 30 days, 12, 24, and 36 months, defined as fracture or breakage of any portion of the stent determined by X-ray for the first 30 subjects at 30 days and for all subjects (including the first 30 subjects) at 12, 24, and 36 months.
- Change in Venous Insufficiency Epidemiological and Economic Study – Quality of Life/Symptoms (VEINES-QOL/Sym) Scores at 6, 12, 24, and 36 months, compared to baseline.
- Change in Villalta Score at 6, 12, 24, and 36 months, compared to baseline.
- Change in Euro-Qol 5 Dimension (EQ-5D) Quality of life Score at 6, 12, 24, and 36 months, compared to baseline.
- Change in VCSS Score at 6, 12, 24, and 36 months, compared to baseline.
- Major bleeding complications at 30 days, 6, 12, 24, and 36 months.
- Medical resource utilization through 36 months, including length of stay and re-hospitalizations.

7.3 Subject demographics and baseline characteristics

A total of 260 subjects signed the ABRE Study informed consent form and were evaluated against inclusion and exclusion criteria for the study. Of these 260 subjects, 200 were implanted with at least one Abre stent. Out of 200 implanted subjects, 191 subjects returned for a 12-month visit, for a follow-up completion rate of 95.5% (191/200). A total of four subjects exited the study prior to completing the 12-month visit. These study exits included two subject deaths (unrelated to the study device or procedure), one subject who was lost to follow-up, and one subject who exited the study due to incarceration. Five subjects missed the 12-month visit.

Site-reported subject demographic data are presented in *Table 1* below.

Table 1. Demographics

Parameter[a]	**ABRE (N=200 Subjects)**
Age at Time of Enrollment (years)	
N	200
Mean ± SD	51.5 ± 15.9
Median	53.0
Min, Max	18, 80
Gender at Birth	
Female	66.5% (133/200)
Male	33.5% (67/200)
BMI (kg/m^2)	
N	200
Mean ± SD	29.5 ± 7.1
Median	28.8
Min, Max	14.9, 53.5
Ethnicity[b]	
Hispanic or Latino	7.0% (14/200)
Not Hispanic or Latino	80.0% (160/200)
Not Available	13.0% (26/200)
Race[b]	
White	78.5% (157/200)
Black or African American	8.5% (17/200)
Asian	2.0% (4/200)

Parameter[a]	ABRE (N=200 Subjects)
Native Hawaiian/Other Pacific Islander	0.0% (0/200)
American Indian or Alaska Native	0.0% (0/200)
Not Available	11.0% (22/200)
Other	0.0% (0/200)

[a] Site-reported data

[b]France does not permit the collection of Race and Ethnicity data from study subjects.

Site-reported baseline medical history is summarized in *Table 2*.

Table 2. Baseline medical history

Parameter[a]	ABRE (N=200 Subjects)
Hypertension	31.0% (62/200)
Hyperlipidemia	28.5% (57/200)
Diabetes Mellitus	10.5% (21/200)
Smoking	
Active	12.0% (24/200)
Previous	30.5% (61/200)
Never	57.5% (115/200)
Cancer (Ongoing or Remission)	11.0% (22/200)
Pulmonary	29.5% (59/200)
Chronic Obstructive Pulmonary Disease	4.5% (9/200)
Pulmonary Embolism	17.0% (34/200)
Pulmonary Hypertension	1.0% (2/200)
Asthma	12.5% (25/200)
Vascular	83.0% (166/200)
Stroke	0.0% (0/200)
Transient Ischemic Attack	1.0% (2/200)
Peripheral Artery Disease	3.5% (7/200)
Known Family History of DVT	22.0% (44/200)
Previous History of Venous Thromboembolism	52.0% (104/200)
Venous Claudication	30.0% (60/200)
Lymphedema	15.0% (30/200)
Hypercoagulability Syndrome/Thrombophilia	11.5% (23/200)
Cardiac	7.0% (14/200)
Congestive Heart Failure	3.0% (6/200)
Ischemic Heart Disease	3.5% (7/200)
Previous Myocardial Infarction	3.0% (6/200)

[a]Site-reported data

Table 3 presents site-reported baseline clinical characteristics.

Table 3. Target limb clinical characteristics

Parameter[a]	ABRE (N=200 Subjects)
Target Limb	
Left	92.0% (184/200)
Right	8.0% (16/200)
Presence of Lymphedema	14.6% (29/198)
CEAP Classification[b]	
C0 - No visible or palpable signs of venous disease	0.6% (1/166)
C1 - Telangiectasias or reticular veins	0.6% (1/166)
C2 - Varicose veins	2.4% (4/166)
C3 - Edema	62.0% (103/166)
C4a - Pigmentation or eczema	13.3% (22/166)
C4b - Lipodermatosclerosis or atrophie blanche	6.6% (11/166)
C5 - Healed venous ulcer	6.6% (11/166)
C6 - Active venous ulcer	7.8% (13/166)
Villalta Score	
N	199
Mean ± SD	11.2 ± 5.7
Median	11.0
Min, Max	0.0, 32.0
VCSS Score	
N	199
Mean ± SD	8.8 ± 4.7
Median	8.0
Min, Max	1.0, 27.0

[a] Site-reported data

[b]PTS and NIVL subjects only; CEAP assessment is not applicable for acute DVT subjects

7.4 Procedural data

Site-reported index procedure characteristics are summarized in *Table 4*. The largest category of subjects, 47.5%, were included in the PTS primary indication category, 36% were included in the NIVL category, and the remaining 16.5% were categorized as having had an acute DVT.

Table 4. Procedural characteristics

Parameter[a]	ABRE (N=200 Subjects)
Primary Indication	
Acute DVT	16.5% (33/200)
Post Thrombotic Syndrome	47.5% (95/200)
Non-Thrombotic Iliac Vein Lesion	36.0% (72/200)
Access Site	
Common Femoral	23.5% (47/200)
Femoral	49.0% (98/200)
Internal Jugular	3.5% (7/200)
Popliteal	20.0% (40/200)
Superficial Vein	2.5% (5/200)
Other	1.5% (3/200)

[a]Site-reported data

As shown in *Table 5*, an average of 1.5 stents per subject were implanted during the index procedure. One or more stents were implanted in the CIV in 96% of subjects, in the EIV in 80.5% of subjects, and in the CFV in 44% of subjects. The mean total stented length was 134.3 mm.

Table 5. Venography core laboratory stent implant data

Parameter	ABRE (N=200 Subjects)
Subjects with[a]	
1 Abre Stent Implanted	55.5% (111/200)
2 Abre Stents Implanted	38.5% (77/200)
3 Abre Stents Implanted	5.5% (11/200)
> 3 Abre Stents Implanted	0.5% (1/200)
Number of Abre Stents Implanted per Subject[a]	
N	200
Mean ± SD	1.5 ± 0.6
Median	1.0
Min, Max	1, 4
Stented Vein Location[a]	
Common Iliac Vein	96.0% (192/200)
External Iliac Vein	80.5% (161/200)
Common Femoral Vein	44.0% (88/200)
% Diameter Stenosis	
N	193
Mean ± SD	14.2 ± 8.2
Median	11.7
Min, Max	2, 48
Total Stented Length (mm)	
N	192
Mean ± SD	134.3 ± 58.0
Median	121.5
Min, Max	49, 283

[a]Site-reported data were used when venography core laboratory-reported data were not available

7.5 Safety and effectiveness results

7.5.1 Primary effectiveness results

The primary patency rate at 12 months was 88.0% (162/184). For the primary effectiveness endpoint, 184 evaluable subjects were included in the primary analysis and 16 subjects were excluded per the SAP due to the following: four subjects did not have sufficient clinical follow-up of at least 330 days (two deaths and two study exits), four subjects missed the 12-month visit. The remaining eight subjects were censored from the analysis due to having a CEC-adjudicated non-clinically driven TLR. The lower limit of the 97.5% one-sided confidence interval (CI) was 82.5%, which was significantly higher than the performance goal of 75%, demonstrating that the primary effectiveness endpoint was met (p-value <0.0001). *Table 6* displays the 12-month primary patency rate as well as the individual components of primary patency. Among the subjects evaluable for primary patency, the freedom from occlusion rate at 12 months was 99.5%, the freedom from restenosis rate at 12 months was 92.9%, and the freedom from clinically driven TLR rate through 12 months was 92.4%.

7.5.2 Primary safety results

The primary safety rate at 30 days was 2.0% (4/200). The upper bound of the one-sided 97.5% CI was 5.0%, which was significantly lower than the 12.5% performance goal, demonstrating that the primary safety endpoint was met (p-value <0.0001). *Table 6* also displays the data for each component of the composite MAE rate at 30 days. A total of four subjects were reported as having a total of four MAEs within 30 days of the index procedure: three stent thrombosis and one clinically significant pulmonary embolism. No subject deaths, major bleeding complications, or stent migrations occurred during the 30 days following the index procedure.

Table 6. Principal effectiveness and safety results

Parameter	ABRE (N=200 Subjects)	95% Confidence Interval
Primary Effectiveness Endpoint – Primary Patency at 12 Months	88.0% (162/184)	[82.5%, 92.4%]

Parameter	ABRE (N=200 Subjects)	95% Confidence Interval
Freedom from Occlusion of the Stented Segment	99.5% (183/184)	[97.0%,100.0%]
Freedom from Restenosis (≥50%) of the Stented Segment	92.9% (171/184)	[88.2%, 96.2%]
Freedom from Clinically Driven Target Lesion Revascularization	92.4% (170/184)	[87.6%, 95.8%]
Primary Safety Composite Endpoint – MAE within 30 Days	2.0% (4/200)	[0.5%,5.0%]
All-cause Death Occurring Post-procedure	0.0% (0/200)	[0.0%,1.8%]
Clinically Significant Pulmonary Embolism	0.5% (1/200)	[0.0%, 2.8%]
Major Bleeding Complication (Procedural)	0.0% (0/200)	[0.0%,1.8%]
Stent Thrombosis	1.5% (3/200)	[0.3%, 4.3%]
Stent Migration	0.0% (0/200)	[0.0%,1.8%]

7.5.3 Summary of Secondary Endpoint Results

Table 7 shows the results for the acute and late success secondary endpoints.

Table 7. Acute and late success secondary endpoints

Parameter	ABRE (N=200 Subjects) (N=302 Devices)
Acute Success	
Device Success	100.0% (302/302)
Lesion Success	100.0% (200/200)
Procedure Success	99.0% (198/200)
Late Success	
Primary Assisted Patency at 12 Months	91.8% (169/184)
Secondary Patency at 12 Months	92.9% (171/184)

Cumulative outcomes for the safety-related secondary endpoints through 12 months are shown below in *Table 8*. TLR was defined as any reintervention of the stented segment of the target lesion. The TLR rate, which includes both clinically driven and non-clinically driven TLRs, was 11.2% at 12 months. The MAE rate was 6.1% within 360 days. The individual components of this composite MAE rate are also shown. There were two deaths reported in the study, the first occurred 66 days from the index procedure and the second occurred 252 days from the index procedure. Both deaths were adjudicated by the CEC as not related to the procedure and not related to the study device.

No stent fractures or delayed stent migrations were reported through 12 months. No procedure-related bleeding complications were reported.

Table 8. Cumulative complications within 12 months

Parameter	ABRE (N=200 Subjects)
TLR within 360 Days[a]	11.2% (22/196)
MAE within 360 Days[a]	6.1% (12/197)
All-cause Death Occurring Post-procedure	1.0% (2/197)
Clinically Significant Pulmonary Embolism	0.5% (1/195)
Major Bleeding Complication (Post-procedural)	0.5% (1/195)
Stent Thrombosis	4.1% (8/195)
Stent Migration	0.0% (0/195)
Stent Fracture through 12 Months[b]	0.0% (0/180)
Delayed Stent Migration through 12 Months[b]	0.0% (0/181)

Parameter	ABRE (N=200 Subjects)
Major Bleeding Related to Index Procedure within 360 Days[a]	0.0% (0/195)

[a]Safety endpoints (MAE, TLR, and Major Bleeding) included subjects with an event or a minimum number of follow-up days per timepoint.

[b]Stent Fracture and Delayed Stent Migration within 12 months included subjects who had scheduled visit-based evaluable imaging and unscheduled imaging up to day 420.

Clinical endpoints at 12 months evaluated changes in functional assessments (VCSS and Villalta) and quality of life (EQ-5D Index and VEINES-QoL) compared to baseline. Trends toward improvement were noted from baseline to 12 months for all four clinical measures, as shown in Table 9.

Table 9. Quality of life and venous functional assessment data

Assessment	Baseline Mean ± SE (n)	6 Months Mean ± SE (n)	12 Months Mean ± SE (n)
VEINES-QoL	49.9 ± 1.8 (200)	72.1 ± 1.8 (192)	72.8 ± 1.8 (192)
EQ-5D Index	0.66 ± 0.02 (200)	0.81 ± 0.01 (192)	0.80 ± 0.02 (192)
Villalta Score	11.2 ± 0.4 (199)	4.7 ± 0.3 (191)	4.2 ± 0.4 (192)
VCSS Score	8.8 ± 0.3 (199)	4.7 ± 0.3 (191)	4.3 ± 0.3 (192)

7.5.4 Summary of Adverse Events

A summary of the reported Adverse Events (AEs) and Serious Adverse Events (SAEs) through 360 days is presented in *Table 10* by relatedness to the device and to the procedure. Of the 276 events reported in 121 subjects, the majority were determined by the site to be unrelated to the device (236 events) and unrelated to the procedure (225 events). Of the 104 SAEs reported in 59 subjects, the majority were determined by the site to be unrelated to the device (70 events) and unrelated to the procedure (83 events). Nine subjects had device-reported SAEs (4.5%), and seven subjects had procedure-related SAEs (3.5%).

Table 10. Summary of AEs (non-SAEs) and SAEs through 360 days

Parameter[a]	Events	ABRE (N=200 Subjects)
Adverse Events (Non-SAEs)	276	121 (60.5%)
Device-Relatedness		
Related	4	4 (2.0%)
Possibly Related	36	32 (16.0%)
Not Related	236	108 (54.0%)
Procedure-Relatedness		
Related	16	12 (6.0%)
Possibly Related	35	25 (12.5%)
Not Related	225	106 (53.0%)
Serious Adverse Events (SAEs)	104	59 (29.5%)
Device-Relatedness		
Related	13	9 (4.5%)
Possibly Related	21	16 (8.0%)
Not Related	70	38 (19.0%)
Procedure-Relatedness		
Related	7	7 (3.5%)
Possibly Related	14	11 (5.5%)
Not Related	83	46 (23.0%)

[a]Table includes “Causal relationship” and “Probable” for Related; “Possible” and “Unlikely” for Possibly Related; “Not related” for Not Related.

7.6 Conclusion

The ABRE Study met its primary effectiveness and safety success criteria by exceeding the 12-month primary patency performance goal and by having a MAE rate at 30 days lower than the primary safety performance goal, respectively. In addition, patients demonstrated clinically meaningful improvement in

quality of life and functional assessments, including VEINES-QoL, EQ-5D index, Villalta, and VCSS. These results constitute valid scientific evidence demonstrating the Abre venous self-expanding stent system is proven to be safe and effective in the treatment of symptomatic iliofemoral venous obstruction.

8 Stent size selection

Considering the estimated anatomic vessel diameter, use *Table 11* to select the Abre stent diameter size. Choose a stent length that extends beyond both ends of the target lesion, with at least 1 cm on each side of the lesion to reduce the risk of restenosis.

Table 11. Sizing guide

Stent diameter (mm)	Estimated anatomic vessel diameter (mm)	Stent length (mm)
10	7.5–9.5	40, 60, 80, 100, 120, 150
12	9.5–11.5	60, 80, 100, 120, 150
14	11.5–13.5	60, 80, 100, 120, 150
16	13.5–15.5	60, 80, 100, 120, 150
18	15.5–17.5	60, 80, 100, 120, 150
20	17.5–19.0	60, 80, 100, 120, 150

Caution: Appropriate stent size selection is crucial and ensures appropriate stent apposition to the vessel wall. Stent undersizing can lead to stent migration and suboptimal luminal diameter. Use *Table 11* for guidance in selecting the appropriate stent size.

Table 12 provides foreshortening information for the Abre venous self-expanding stent.

Table 12. Stent foreshortening

Stent diameter (mm)	Foreshortening data[a]		
	Min.	Max.	Std. dev.
10	-7.6%	3.3%	2.69%
12	-6.7%	0.7%	1.67%
14	-3.4%	1.0%	1.25%
16	-2.7%	3.3%	1.56%
18	-3.1%	1.5%	1.27%
20	-2.6%	2.5%	1.42%

[a] Foreshortening is a calculated value based on the difference between the stent length in the catheter and the stent length as deployed in the vessel. Foreshortening has a negative value when the stent shortens and a positive value when the stent lengthens.

9 Patient counseling information

In accordance with local regulations, healthcare providers should review the instructions for use for applicable information to be shared with the patient. A patient implant card, which contains identifying information about the implanted device, is included in the device package. After device implant, complete the patient implant card and provide it to the patient before they are discharged.

Healthcare providers should communicate the following instructions to their patients:

- Always carry their implant card with them.
- Access additional information about their device on the website that is listed on their patient implant card.
  Note: If the patient is unable to access the website, the healthcare provider must provide the information from the website to the patient.
- Always inform any healthcare personnel that they have an implanted device before any procedure has begun.
- Contact their healthcare provider if they notice any new or changing symptoms.

10 How supplied

Warning: This device was designed for single use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination, which could result in patient injury, illness, or death.

11 Directions for use

11.1 Required items for implant procedure

- 5-10 mL syringe filled with saline
- 0.89 mm (0.035 in) guidewire
- 9 Fr minimum hemostatic introducer sheath

- Balloon catheter

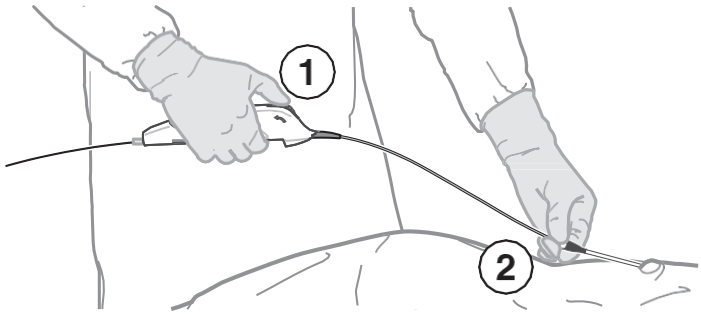
11.2 Preparation

1. Open the shelf box and remove the contents. Carefully inspect the pouch, looking for damage to the sterile barrier; then carefully peel open the pouch and extract the device by the handle.
   Caution: Carefully inspect the sterile package and device before use to verify that no damage occurred during shipment. Do not use the stent system if it is damaged or compromised.
   Caution: Carefully remove the system from the tray and tube without kinking the system. Do not use the system if it is kinked.
2. Attach a syringe filled with saline to the luer lock injection hub. Inject the saline through the guidewire lumen until it comes out of the catheter tip.
3. Examine the catheter to ensure that the Abre stent is fully contained within the retractable sheath (silver).
   Caution: Do not use the stent system if the Abre stent is partially deployed before starting the procedure.

11.3 Stent deployment

1. Insert the introducer sheath and the guidewire.
   a. Gain access at the appropriate site, using a compatible introducer sheath with a hemostatic valve.
      Caution: Gain access at a distance far enough from the intended treatment site to ensure that the introducer sheath does not intrude into the intended treatment site. Gaining access too close to the intended treatment site can lead to difficulty with stent deployment.
   b. Insert a guidewire of appropriate length across the target lesion via the introducer sheath.
      Caution: Always use an introducer sheath during the implant procedure to protect both the vessel and puncture site.
2. Predilate the lesion with a balloon catheter using standard techniques. Remove the balloon from the patient while maintaining access with the guidewire.
3. Introduce the Abre stent delivery system over the guidewire through the hemostatic valve and introducer sheath.
   Warning: If unusually high resistance is encountered when advancing the Abre delivery system over the guidewire, assess the cause of the resistance before proceeding.
   Caution: Ensure that the locking pin remains in locked position until the target site is reached.
4. Advance the Abre delivery system until the leading edge of the stent is beyond the target lesion.
5. Ensure that the isolation sheath (blue) remains inside the introducer sheath valve.
   Caution: If the retractable sheath (silver) is exposed beyond the hemostatic valve when the stent is positioned for deployment, pull the introducer sheath back so that the hemostatic valve covers the end of the isolation sheath (blue) and is not in direct contact with the retractable sheath. Friction from direct contact between the retractable sheath and the hemostatic valve can cause difficult stent deployment or inaccurate stent placement.
6. Remove the locking pin by holding the device handle with one hand and gently pulling the locking pin with the other hand.
7. While holding the device with one hand, use the other hand to gently support and position the isolation sheath at the hemostatic valve (see *Figure 3*). Do not constrict the retractable sheath during deployment.

Figure 2. Hand placement for stent deployment



1 Deploy
2 Position control

8. Initiate Abre stent deployment by slowly rotating the thumbwheel in the direction indicated by the arrow on the handle.
9. After the leading end of the stent has emerged from the retractable sheath, but before achieving vessel apposition, reposition the Abre stent as needed.
   Warning: If high resistance is felt when initially rotating the thumbwheel, do not force deployment. Carefully withdraw the system and do not use it.
   Caution: Do not reposition the Abre stent after establishing apposition against the vessel wall.

Repositioning the stent may cause stent elongation, stent fracture, or vessel damage.
Caution: The Abre delivery system is not designed for recapturing the stent.

10. Continue to rotate the thumbwheel until the stent is fully deployed.
Caution: The Abre stent is not designed to be lengthened or shortened from its nominal length. Excessive stent lengthening or shortening can increase the risk of stent fracture.
Note: If placement of sequential stents is necessary, ensure that there is sufficient overlap.

11.4 Post stent deployment

1. Withdraw the entire delivery system from the patient.
Caution: If resistance is felt when withdrawing the system, do not force withdrawal. Forcing withdrawal can cause catheter separation and embolism.
2. Perform post-deployment balloon dilation as needed, using an appropriately sized balloon catheter with conventional dilation techniques.
Caution: Use care when crossing a deployed Abre stent with any adjunct device to avoid stent dislodgement or damage to the adjunct device.
3. Confirm that the Abre stent is fully expanded; then remove the balloon catheter from the patient.
Note: Always visualize the stent by using imaging techniques to verify full vessel wall apposition.
4. Remove the guidewire and introducer sheath from the patient and discard the delivery system, guidewire, and introducer sheath.

12 Disposal

Caution: Dispose of the delivery system and accessories in accordance with applicable laws, regulations, and hospital procedures, including those regarding biohazards, microbial hazards, and infectious substances.

13 MRI safety information

13.1 MR Conditional

Nonclinical testing demonstrated that the Abre stent in single and overlapped conditions is MR Conditional for stents up to 150 mm.
A patient with this device can be scanned safely, immediately after stent placement, under the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient magnetic field of 4000 Gauss/cm or less (40 T/m)
- Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

MR image quality may be compromised if the area of interest is in the exact location or close to the position of the Abre stent.

13.2 MRI-related temperature rise

Under the scan conditions as defined in the previous section, “MR Conditional”, the Abre stent is expected to produce a maximum temperature rise less than or equal to 5.2°C after 15 minutes of continuous scanning (per pulse sequence). The effect of temperature rise in the MRI environment for stents with fractured struts is not known.

It is recommended that patients register conditions under which the implant can be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

13.3 Artifact information

In nonclinical testing, the maximum artifact size as seen on the gradient echo pulse sequence at 3.0 Tesla extends approximately 5 mm, relative to the size and shape of the Abre stent. The lumen of the stent can be visualized using the T1-weighted spin echo pulse sequence and the T1-weighted gradient echo pulse sequence at 3.0 Tesla.

14 Storage

Avoid exposing the Abre system to water, sunlight, extreme temperatures, and high humidity during storage. Store the Abre system under controlled room temperature. See the product label for the device use-by date. Do not use the device beyond the labeled use-by date.

15 Materials

The Abre stent is made of nitinol. Some patients are allergic to or can become sensitive to nickel. The Abre system is not made of any latex or PVC materials.

16 Disclaimer of warranty

The warnings contained in the product labeling provide more detailed information and are considered an integral part of this disclaimer of warranty. Although the product has been

manufactured under carefully controlled conditions, Medtronic has no control over the conditions under which this product is used.

Medtronic, therefore, disclaims all warranties, both express and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Medtronic shall not be liable to any person or entity for any medical expenses or any direct, incidental, or consequential damages caused by any use, defect, failure, or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind Medtronic to any representation or warranty with respect to the product.

The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this disclaimer of warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this disclaimer of warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this disclaimer of warranty did not contain the particular part or term held to be invalid.

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