

EverFlex[™] Self-Expanding Peripheral Stent System

Instructions for Use

DEVICE DESCRIPTION

The EverFlex[™] Self-Expanding Peripheral Stent System is a self-expanding Nitinol stent system intended for permanent implantation. The self-expanding stent is made of a nickel titanium alloy (Nitinol) and comes pre-mounted on a 6F, 0.035" over-the-wire delivery system. The stent is cut from a Nitinol tube in an open lattice design, and has tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency.

The Delivery System, as shown in Figures 1, 1a, and 1b, includes an inner subassembly (1) and outer subassembly (2), which are locked together with a safety lock (3). The inner subassembly terminates distally in a flexible catheter tip (4) and originates proximally at the hub (5).

The distal portion of the Delivery System for the 20 – 150 mm stents, as shown in Figure 1a, is comprised of two radiopaque markers, one marker distal (6) and one marker/retainer proximal (7) to the stent, on the inner subassembly.

The distal portion of the Delivery System for the 200 mm stents, as shown in Figure 1b, includes the same components as those in Figure 1a except for the radiopaque markers: one marker/retainer distal (13) and one marker/holder proximal (14) to the stent, on the inner subassembly.

The outer sheath connects proximally to the manifold subassembly (8). The self-expanding stent is constrained within the space between the inner and outer subassemblies. This space is flushed prior to the procedure through the stopcock (9). The outer subassembly has a radiopaque marker at its distal end (10).

The stent is positioned at the target lesion using the two radiopaque markers on the inner subassembly and the radiopaque markers on the stent.

For stent deployment, turn the safety lock counterclockwise to unlock the outer subassembly. The outer subassembly retracts by pulling the distal grip (11) toward the proximal grip (12). Stent deployment is complete when the radiopaque marker on the outer subassembly passes the proximal radiopaque marker on the inner subassembly.

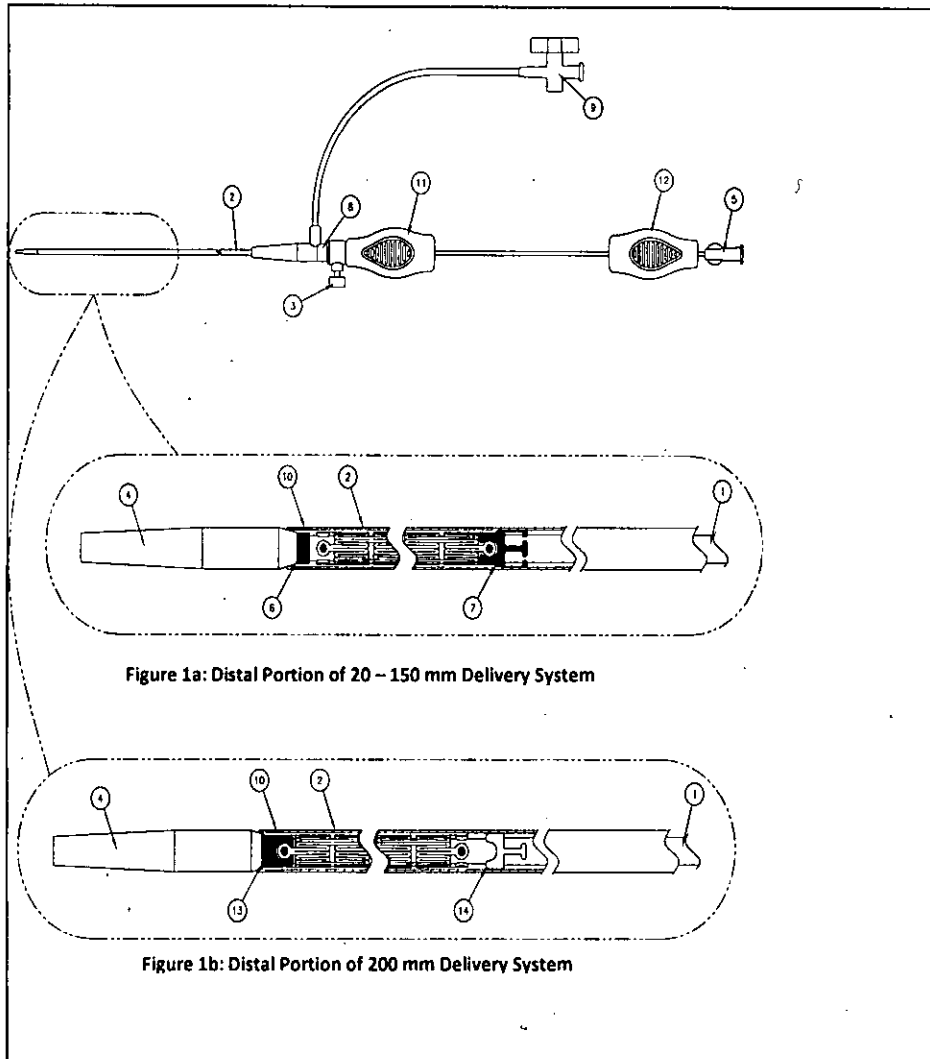


Figure 1a: Distal Portion of 20 – 150 mm Delivery System

Figure 1b: Distal Portion of 200 mm Delivery System

Figure 1 – Delivery System

- | | |
|--|---|
| 1. Inner Subassembly | 8. Manifold Subassembly |
| 2. Outer Subassembly | 9. Stopcock |
| 3. Safety Lock | 10. Outer Subassembly Distal Marker Band |
| 4. Distal Catheter Tip | 11. Distal Grip |
| 5. Proximal Hub | 12. Proximal Grip |
| 6. Inner Subassembly Distal Marker Band | 13. Inner Subassembly Distal Marker Band/Retainer |
| 7. Inner Subassembly Proximal Marker Band/Retainer | 14. Inner Subassembly Proximal Marker/Holder |

INDICATIONS FOR USE

The EverFlex Self-Expanding Peripheral Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 180mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 – 7.5mm.

CONTRAINDICATIONS

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated.
- Patients with known hypersensitivity to nickel titanium.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

WARNINGS

- The device is provided **STERILE** for single use only. Do not reprocess or resterilize. Reprocessing and resterilizing could increase the risk of patient infection and risk of compromised device performance.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to stent or vessel. Carefully withdraw the stent system without deploying the stent.
- If resistance is felt when initially pulling back on the distal grip, do not force deployment. Carefully withdraw the stent system without deploying the stent.
- If resistance is met during delivery system withdrawal, advance the outer sheath until the outer sheath marker contacts the catheter tip and withdraw the system as one unit.

PRECAUTIONS

- Carefully inspect the sterile package and device prior to use to verify that no damage occurred during shipment.
- Do not exceed 300 psi / 20 ATM while flushing the delivery system.
- Do not use if the stent is partially deployed upon removal from the package, or before starting the deployment procedure.
- Support from a sheath is necessary to minimize lengthening or shortening during stent deployment.
- Always use a sheath during the implant procedure to protect both the vessel and puncture site.
- Failure to pre-dilate the lesion may impair the ability to remove the stent system after stent deployment.
- The stent system is not designed for recapturing or repositioning after establishing vessel apposition.
- Failure to hold the proximal grip in a fixed position may result in partial deployment, foreshortening, lengthening or increased deployment force.
- The stent is not designed to be lengthened or shortened past its nominal length. Excessive stent lengthening or shortening may increase the risk of stent fracture.
- Use caution when crossing a deployed stent with any adjunct device.
- Stent should not be expanded past its nominal diameter.

ADVERSE EVENTS

The EverFlex Self-Expanding Stent System was evaluated in a study titled the US StuDY for EvalUating EndovasculaR TreAtments of Lesions in the Superficial Femoral Artery and Proximal Popliteal By using the EverFlex Nitinol STent SYstem II (DURABILITY II). A total of 287 subjects were enrolled. The primary objective was to evaluate the safety and effectiveness of primary stenting using the EverFlex Self-Expanding Stent System compared to percutaneous transluminal angioplasty (PTA) performance goals for the treatment of stenotic, restenotic or occluded lesions (non-stented) of the native superficial femoral artery or the superficial femoral and proximal popliteal arteries.

Table 1 provides a summary of the adverse events documented in the DURABILITY II study. The data are presented as a percentage of subjects experiencing an AE followed by the total number of events in brackets.

Table 1: Summary of Adverse Events

Adverse Event	Events at ≤ 30 days	Events at ≤ 1 Year	Total Events
Total Subjects with AEs*	45.3% (129/285) [210]	86.1% (242/281) [756]	87.8% (252/287) [1111]
Allergic reaction	1.4% (4/285) [4]	1.8% (5/281) [5]	1.7% (5/287) [5]
Amputation	0.4% (1/285) [1]	0.7% (2/281) [2]	1.4% (4/287) [4]
Angina	0.4% (1/285) [1]	4.3% (12/281) [13]	7.0% (20/287) [22]
Arrhythmia	0.7% (2/285) [2]	2.8% (8/281) [9]	3.8% (11/287) [12]
Arterial dissection/perforation	14.0% (40/285) [42]	15.3% (43/281) [49]	15.0% (43/287) [51]
Bleeding disorders (including GI, lymphatic)	1.8% (5/285) [5]	5.0% (14/281) [15]	6.6% (19/287) [22]
Cerebrovascular accident		1.8% (5/281) [5]	2.8% (8/287) [8]
Death**		0.7% (2/281) [2]	1.4% (4/287) [4]
Edema	1.8% (5/285) [5]	5.0% (14/281) [14]	6.6% (19/287) [22]
GI bleeding	0.4% (1/285) [1]	1.4% (4/281) [4]	2.1% (6/287) [6]
Hematoma at vascular access site	3.9% (11/285) [11]	3.9% (11/281) [11]	3.8% (11/287) [11]
Hypertension/hypotension	2.1% (6/285) [6]	4.3% (12/281) [12]	4.9% (14/287) [16]
Infection, local or systemic including bacteremia or septicemia	0.4% (1/285) [1]	3.6% (10/281) [11]	5.6% (16/287) [22]
Myocardial infarction		1.1% (3/281) [3]	2.1% (6/287) [6]

Adverse Event	Events at ≤ 30 days	Events at ≤ 1 Year	Total Events
Other Cardiac Disorders	0.7% (2/285) [2]	8.5% (24/281) [26]	9.8% (28/287) [34]
Other GU Disorders	0.7% (2/285) [2]	3.2% (9/281) [10]	4.9% (14/287) [17]
Other Gastrointestinal Disorders	3.2% (9/285) [11]	12.8% (36/281) [52]	13.9% (40/287) [69]
Other Musculoskeletal disorders	4.6% (13/285) [15]	14.9% (42/281) [52]	20.2% (58/287) [81]
Other Respiratory Issues	0.4% (1/285) [1]	10.7% (30/281) [34]	14.6% (42/287) [54]
Other Vascular Disorders	5.3% (15/285) [16]	21.7% (61/281) [81]	32.1% (92/287) [133]
Percutaneous revascularization	0.4% (1/285) [1]	4.3% (12/281) [14]	4.5% (13/287) [17]
Pseudoaneurysm	1.4% (4/285) [4]	1.4% (4/281) [4]	1.4% (4/287) [4]
Renal Insufficiency/Failure		1.1% (3/281) [3]	1.4% (4/287) [4]
Restenosis	1.4% (4/285) [4]	21.7% (61/281) [66]	32.8% (94/287) [113]
Slow/no flow during procedure	0.7% (2/285) [2]	0.7% (2/281) [2]	0.7% (2/287) [2]
Stent/Vessel thrombosis	0.4% (1/285) [1]	3.6% (10/281) [11]	4.2% (12/287) [13]
Vessel spasm	0.4% (1/285) [1]	0.4% (1/281) [1]	0.3% (1/287) [1]
Other	18.9% (54/285) [71]	46.3% (130/281) [245]	51.6% (148/287) [358]

* Note: The denominators in each column represent the number of subjects with adverse events for the reported time period (285 subjects at ≤30 days; 281 subjects at ≤1 year; 287 total subjects).
**Note: Count of AEs labeled "death" is less than total number of study deaths since death may be attributable to other AEs.

POTENTIAL ADVERSE EVENTS

The potential adverse effects (e.g., complications) that may occur and/or require intervention with the use of this device include, but are not limited to:

- Abrupt or sub-acute closure
- Allergic reaction to device materials or procedure medications
- Allergic reaction to Nitinol
- Amputation
- Aneurysm
- Angina
- Arrhythmia
- Arterio-venous fistula
- Artery perforation or rupture
- Bleeding requiring transfusion
- Bruising
- Contrast medium reaction/renal failure
- Death
- Device breakage
- Dissection or intimal flap
- Edema
- Embolism
- Failure to deploy stent
- Fever
- Gastrointestinal bleeding due to anticoagulation
- Hematoma
- Hypertension/hypotension
- Infection
- Inflammation
- Intraluminal thrombus
- Myocardial infarction
- Pain
- Partial stent deployment
- Pseudoaneurysm
- Renal failure requiring dialysis
- Renal insufficiency (new or worsening)
- Restenosis
- Sepsis
- Shock
- Stent collapse or fracture
- Stent migration
- Stent misplacement
- Stroke
- Surgical or endovascular intervention
- Thrombosis/occlusion of the stent
- Transient ischemic attack
- Venous thromboembolism
- Vessel spasm

CLINICAL STUDIES

The US Study for Evaluating Endovascular Treatments of Lesions in the Superficial Femoral Artery and Proximal Popliteal By using the EverFlex Nitinol Stent System II (DURABILITY II) study was a prospective, multi-center, non-randomized, single arm study. DURABILITY II compared percutaneous transluminal angioplasty (PTA) and primary stenting with the EverFlex™ stent to performance goals of PTA alone in the treatment of atherosclerotic lesions of the native superficial femoral artery (SFA) or the superficial femoral and proximal popliteal arteries. The safety and effectiveness performance goals were based on an aggregate of published trial data as described by VIVA physicians Inc. (VPI). DURABILITY II was conducted at 40 US and four European investigational sites. A total of 287 subjects were enrolled. Eligible subjects either had stenotic, restenotic (non-stented) or occluded lesions. The reference vessel diameter of the treated subjects was to be 4.5-7.5 mm and the lesion length from 4-18 cm long. Subjects had to have Rutherford Clinical Categories of 2-4. Subject follow-up occurred at 30 days, 6 months, 1, 2 and 3 years post-procedure. The primary safety endpoint for the study was major adverse event (MAE) rate at 30 days and the primary effectiveness endpoint was primary stent patency rate at 1 year.

Subject Eligibility Criteria

Subjects with stenosis of the native superficial femoral artery or the superficial femoral and proximal popliteal arteries, who consented to participate, were eligible for inclusion in the DURABILITY II study. To be included, they had to be at least 18 years old.

Subject Follow-up

Table 2 summarizes subject follow-up compliance in the DURABILITY II study. Percentages are based on subjects expected for each follow-up visit. Subjects expected for each follow-up visit included those who had completed the visit and those who had not completed the visit but for whom the visit window had closed.

Table 2: Summary of Subject Compliance

Time	Compliance
Pre-discharge	100% (287/287)
30 Days	98% (280/287)
6 Months	96% (275/287)
1 Year	92% (263/287)
2 Year	81% (72/89)
3 Year	79% (11/14)

Baseline demographics and clinical characteristics are presented in Table 3.

Table 3: Demographics and Baseline Clinical Characteristics

Subject Characteristics	N=287
Age (yrs.)	
Mean ± SD (N)	67.7 ± 10.7 (287)
Range (min, max)	(39.4, 93.3)
Male	66.2% (190/287)
Race	
White/Caucasian	88.9% (255/287)
African	7.7% (22/287)
Asian	0.7% (2/287)
Hispanic	2.4% (7/287)
Other	0.3% (1/287)
Risk Factors	
Diabetes	42.5% (122/287)
Type I	3.1% (9/287)
Type II	39.4% (113/287)
Hyperlipidemia	86.1% (247/287)
Hypertension	88.2% (253/287)
Renal Insufficiency	9.8% (28/287)
Current smoker	39.0% (112/287)
Medical History	
Angina	17.4% (50/287)
Arrhythmia	13.9% (40/287)
Congestive heart failure (CHF)	9.4% (27/287)
Stroke	6.3% (18/287)
Transient ischemic attack (TIA)	4.9% (14/287)
Myocardial infarction	20.9% (60/287)
Non-healing ischemic ulcer in the lower extremities	1.4% (4/287)
Amputation of the lower extremities	1.0% (3/287)
Previous interventions in the superficial femoral or popliteal arteries	41.1% (118/287)

Clinical Characteristics	
Rutherford Clinical Category	
2=Moderate claudication	39.4% (113/287)
3=Severe claudication	55.7% (160/287)
4=Ischemic rest pain	4.5% (13/287)
5=Minor tissue loss	0.3% (1/287)
Ankle Brachial Index	
Mean \pm SD (N)	0.69 \pm 0.19 (281*)
Range (min, max)	(0.06, 1.38)
*ABI not available for 6 subjects due to non-compressible arteries	

Table 4 presents baseline characteristics (assessed by the angiographic core laboratory except as otherwise noted), including lesion location, length and pre-procedure vessel diameter. Per site assessment, normal-to-normal lesion was determined by measuring the length of the target lesion from healthy tissue to healthy tissue. In contrast, 20-to-20 lesion length was determined by measuring between the proximal and distal points at which the lesion was 20% stenosed by the angiographic core laboratory. The mean lesion length was 109.6 mm by the normal-to-normal method and 89.1 mm by the 20-to-20 method.

Table 4: Baseline Target Lesion Characteristics

Lesion Characteristics	N=287
SFA Location	
Superior SFA	27.5% (79/287)
Inferior SFA	70.4% (202/287)
Popliteal	2.1% (6/287)
Lesion length (mm) (Normal-to-normal)*	
Mean \pm SD (N)	109.6 \pm 45.0 (287)
Range (min, max)	(10.0, 180.0)
Lesion Length (mm) (20-to-20)	
Mean \pm SD (N)	89.1 \pm 44.8 (287)
Range (min, max)	(7.3, 200.9)
Pre-procedure Reference Vessel Diameter (mm)	
Mean \pm SD (N)	4.8 \pm 0.9 (287)
Range (min, max)	(2.7, 8.0)
Pre-procedure Minimum Lumen Diameter (mm)	
Mean \pm SD (N)	0.7 \pm 0.8 (287)
Range (min, max)	(0.0, 2.7)
Pre-procedure Diameter Stenosis (%)	
Mean \pm SD (N)	85.8 \pm 16.2 (287)
Range (min, max)	(50.7, 100.0)
Occlusion	48.1% (138/287)
Bend	100.0% (287/287)
Calcification	
None/Mild	30.0% (86/287)
Moderate	26.8% (77/287)
Severe	43.2% (124/287)
Ulcerated	10.5% (30/287)
Aneurysm	1.0% (3/287)
* Normal-to-normal lesion length assessed per site investigator	

Clinical Results

The primary effectiveness analysis was specified to occur using the first 232 single-stent subjects. Because the primary safety analysis was pre-specified to occur using all 287 enrolled subjects, safety and effectiveness data from the 287-patient Intent-to-Treat cohort using the same endpoints and definitions were also available. Because this larger analysis yielded similar results as the analysis of the first 232 single-stent subjects, the results of the analysis of the full cohort are presented.

Primary Safety Endpoint

The primary safety endpoint was the major adverse event rate at 30 days. MAE was defined as clinically-driven target lesion revascularization (TLR), amputation of treated limb, or all-cause mortality, as adjudicated by the Clinical Event Committee (CEC). The 30 day MAE rate was 0% (Table 5). The 97.5% upper confidence bound was 1.1% (as calculated by the Exact method), which is less than the performance goal (PG) of 12%.

Table 5: Summary of Primary Safety Endpoint

MAE within 30 Days	N = 284*	97.5% Upper Confidence Bound	Performance Goal	Objective Met
Subjects with MAE within 30 Days	0.0% (0/284) [0]	1.1%	12%	Yes
Death	0.0% (0/284) [0]	---	---	---
Amputation of treated limb	0.0% (0/284) [0]	---	---	---
Clinically-driven TLR	0.0% (0/284) [0]	---	---	---

*The denominator included subjects who had completed the 30-day follow-up visit (N=280) and those who did not complete the 30-day visit but came back for late follow-up visits (N=4). Three (3) subjects with no reported MAEs prior to 30 days, who did not complete the 30-day visit, and were without any further follow-up information, were not included in the analysis.

Primary Effectiveness Endpoint

The primary effectiveness endpoint was primary stent patency, defined as Peak Systolic Velocity (PSV) ratio < 2.0 at the stented target lesion with no clinically-driven reintervention within the stented segment as measured at the 1-year follow-up day. Primary stent patency was evaluated in all enrolled subjects with evaluable 1-year data (N=226, excluding out-of-window duplexes) and was achieved in 67.7% (153/226) of the subjects (Table 6). The 97.5% lower confidence bound of 61.2% is greater than the PG of 57%. Therefore, the primary effectiveness endpoint was met and the null hypothesis is rejected.

In twenty-seven (27) subjects, the 1-year duplex data were evaluable but obtained out of the 1-year follow-up visit window. If the 27 subject with out-of-window duplexes were included in the analysis, the primary stent patency would be achieved in 68.4% (173/253) of the subjects.

Table 6: Summary of Primary Effectiveness Endpoint

Primary Effectiveness Endpoint	Primary Stent Patency Rate	99.26% Lower Confidence Bound	Performance Goal	Objective Met
Single-stent & multi-stent subjects (Exclude Out-of-Window Duplex)	67.7% (153/226)	61.2%	57.0%	Yes
Single-stent & multi-stent subjects (Include Out-of-Window Duplex)	68.4% (173/253)	62.3%	57.0%	Yes

The primary stent patency rate was also analyzed using the Kaplan-Meier method. The analysis cohort consisted of all enrolled subjects.

As presented in Figure 2 and Table 7, the freedom from loss of primary patency (PSVR < 2.0 and no clinically-driven reintervention within the stented segment) at 1 year was 77.2%.

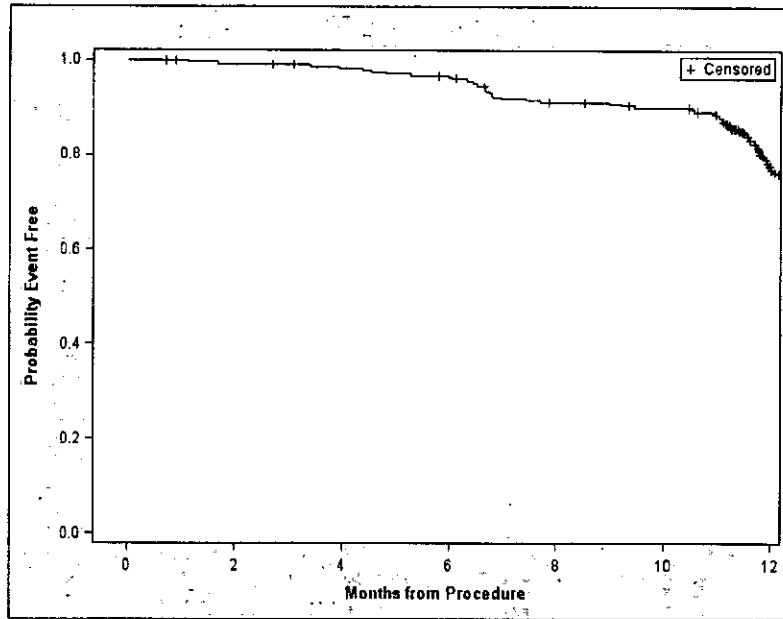


Figure 2: Freedom from Loss of Primary Patency

Table 7: Probability of Freedom from Loss of Primary Patency

Month	# At Risk	Cumulative # Events	Cumulative Censored	Probability Event Free	95% CI
0	287	0	0	100%	-
1	285	0	2	100%	-
6	273	9	5	96.8%	94.0%-98.3%
12	181	61	45	77.2%	71.7%-81.8%

Table 8 provides stent patency at 1-year broken out by lesion length, as assessed by the Corelab.

Table 8: Primary Stent Patency at 1-Year by Lesion Length as Assessed by Corelab

Primary Stent Patency at 1-Year	Lesion Length 0-150 mm	Lesion Length >150-180 mm	Lesion Length >180 mm
Protocol-defined primary analysis	71.8% (145/202)	50.0% (8/16)	0.0% (0/8)
Kaplan-Meier analysis of freedom from loss of primary patency	80.8%	65.0%	14.8%

X-rays on 260 stents (248 subjects) were available for analysis by the angiographic core laboratory for stent fractures at 1 year. Stent fractures identified by the core laboratory were evaluated and classified by the Stent Fracture Committee. One subject had a class V fracture in the single stent implanted. The stent fracture rate was 0.4% (1/260) at 1 year (Table 9).

Table 9: Stent Fracture at 1 Year¹

	N=260 *
Stent Fracture	0.4% (1/260)
Class I - One strut fracture	0.0% (0/260)
Class II - Multiple strut fracture	0.0% (0/260)
Class III - Complete linear horizontal fracture without displacement	0.0% (0/260)
Class IV - Complete linear horizontal fracture with displacement	0.0% (0/260)
Class V- Trans-axial spiral fracture with displacement	0.4% (1/260)
* Denominator was number of stents in 248 subjects who had completed the 1-year follow-up visit and for whom evaluable X-rays were available.	

Supplemental Clinical Information

DURABILITY I² (Study Measuring the Durability of the PROTÉGÉ® EverFlex™ Stent in Lesions of the Superficial Femoral Artery), was a multi-center, non-randomized, prospective study. It was designed to evaluate the safety and efficacy of the EverFlex stent in the treatment of de novo, restenotic or reoccluded SFA lesions in symptomatic PAD patients. The study enrolled 151 subjects (151 target lesions) between August, 2006 and June, 2007 at 13 centers in Europe. Technical Success was achieved in all patients. The primary patency (defined as PSVR < 2.5) rate at 12 months was 72.2%. The target lesion revascularization rate was 20.9% at 12 months. The secondary patency rate at 12 months was 89.1% (115/129). Stent fractures were found in 10 of 123 subjects with available x-ray data, resulting in a 12-month stent fracture rate of 8.1%. Elongation of the EverFlex stent during implantation was identified in 90% (9/10) of the fractured stents at 12 months. An improvement of Rutherford classification was achieved in 91.8% (123/134) of patients at 12 months.

PROCEDURE

Preparation Procedures

- **WARNING:**
- The device is provided STERILE for single use only. Do not reprocess or resterilize. Reprocessing and resterilizing could increase the risk of patient infection and risk of compromised device performance.

1. Required Items for Implantation Procedure

- 5-10 cc syringe filled with heparinized saline
- 0.035" Exchange guidewire
- Hemostatic sheath
- PTA Balloon

2. Select Stent Size

Measure the diameter of the reference vessel (proximal and distal to lesion). Refer to Table 10 below for stent diameter sizing. Measure the length of the target lesion. Choose a stent length that will extend proximal and distal to the target lesion.

Table 10: Stent Diameter and Length Sizing

Stent Diameter (mm)	Reference Vessel Diameter (mm)	Stent Length (mm)
6	4.5 – 5.5	20, 30, 40, 60, 80,100, 120, 150, 200
7	5.5 – 6.5	20, 30, 40, 60, 80,100, 120, 150, 200
8	6.5 – 7.5	20, 30, 40, 60, 80,100, 120, 150, 200

¹ Jaff M, Dake M, Pompa J, Ansel G, Yoder T. Standardized evaluation and reporting of stent fractures in clinical trials of noncoronary devices. *Catheter Cardiovasc Interv.* Sep 2007;70(3):460-462.

² Bosiers M, Torsello et al. Nitinol Stent Implantation in Long Superficial Femoral Artery Lesions: 12-Month Results of the DURABILITY I Study. *J Endovasc Ther* 2009;16:261-269.

3. Preparation of Stent Delivery System

- a. Open the shelf box to reveal the pouch containing the stent and delivery catheter.
- b. After careful inspection of the pouch, looking for damage to the sterile barrier, carefully peel open the outer pouch and extract the tray with contents.
- c. Set the tray on a flat surface. Carefully pull the lid off the tray and remove the stent/delivery system.

CAUTION: Carefully inspect the sterile package and device prior to use to verify that no damage occurred during shipment.

- d. Verify the device is locked by tightening the safety lock clockwise.

CAUTION: Do not exceed 300 psi / 20 ATM while flushing the delivery system.

- e. Attach a 5-10 cc syringe filled with heparinized saline to the stopcock on the manifold. Open the stopcock and vigorously inject saline into the annular space between the shafts until it comes out the outer sheath.
- f. Attach a 5-10 cc syringe filled with heparinized saline to the proximal luer lock injection hub. Inject the saline solution through the guidewire lumen until it comes out the catheter tip.
- g. Examine the distal end of the catheter to ensure the stent is flush with the outer subassembly. If a gap exists between the catheter tip and outer subassembly, open the safety lock and gently pull the inner shaft in a proximal direction until the gap is closed. Lock the safety lock after the adjustment by turning the knob clockwise.

CAUTION: Do not use if the stent is partially deployed upon removal from the package, or before starting the deployment procedure.

Stent Deployment Procedure

1. Insertion of Sheath and Guidewire

- a. Gain femoral access using a sheath with a hemostatic valve that is compatible with a 6F delivery system. The sheath should be of adequate length to provide support of stent delivery system beyond the aortoiliac arch.

CAUTION: Support from a sheath is necessary to minimize lengthening or shortening during stent deployment.

- b. Insert a guidewire of appropriate length across the target lesion via the sheath.

CAUTION: Always use a sheath during the implant procedure to protect both the vessel and puncture site.

2. Dilation of Lesion

Pre-dilate the lesion using standard PTA techniques. Remove the PTA balloon from the patient while maintaining lesion access with the guidewire.

CAUTION: Failure to pre-dilate the lesion may impair the ability to remove the stent system after stent deployment

3. Introduction of Stent Delivery System

Advance the device over the guidewire through the hemostatic valve and sheath.

WARNING: If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to stent or vessel. Carefully withdraw the stent system without deploying the stent.

4. Stent Deployment

- a. Advance the delivery system until the distal (leading) radiopaque inner subassembly marker is distal to the target lesion.

NOTE: For the 200 mm stent delivery system, the stent will move back approximately 5 mm from the distal retainer upon initial release.

- b. Pull back on the delivery system until there is no slack in the delivery system and the radiopaque inner subassembly markers extend distal and proximal to the target lesion.
- c. Open the safety lock by turning the knob counterclockwise.
- d. Initiate stent deployment by pinning down (holding) the inner subassembly (proximal grip) in a fixed position and pulling the outer subassembly (distal grip) toward the proximal grip as shown in Figure 3.

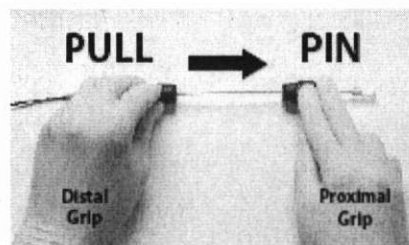


Figure 3: Stent Deployment

e. Once initial deployment is visible on fluoroscopy and prior to achieving vessel apposition, reposition stent as needed using radiopaque markers.

NOTE: It is recommended to lock the safety lock in order to ensure that there is no relative movement between the grips during repositioning.

CAUTION: The stent system is not designed for recapturing or repositioning after establishing vessel apposition.

f. During deployment of the stent, the whole length of the flexible deployment system should be kept as straight as possible. In order to ensure that no slack is introduced into the delivery system, hold the proximal grip stationary and fixed. Deployment is complete when the outer subassembly marker passes the proximal inner shaft stent marker and the stent is released.

WARNING: If resistance is felt when initially pulling back on the distal grip, do not force deployment. Carefully withdraw the stent system without deploying the stent.

CAUTION: Failure to hold the proximal grip in a fixed position may result in partial deployment, foreshortening, lengthening or increased deployment force.

CAUTION: The stent is not designed to be lengthened or shortened past its nominal length. Excessive stent lengthening or shortening may increase the risk of stent fracture.

NOTE: If a second stent is needed, place the more distal stent first. If overlap of sequential stents is necessary, the amount of overlap should be kept to a minimum.

5. Post Stent Deployment

a. While using fluoroscopy following stent deployment, withdraw the entire delivery system as one unit, over the guidewire, into the catheter sheath and out of the body. Remove the delivery system from the guidewire.

WARNING: If resistance is met during delivery system withdrawal, advance the outer subassembly until the outer subassembly marker contacts the catheter tip and withdraw the system as one unit.

b. Using fluoroscopy, visualize the stent to verify full deployment.

c. If incomplete expansion exists within the stent at any point along the lesion, post deployment balloon dilation may be performed.

CAUTION: Use caution when crossing a deployed stent with any adjunct device.

CAUTION: Stent should not be expanded past its nominal diameter.

d. To dilate the stent, select an appropriate size PTA balloon catheter and dilate with conventional technique. The inflation diameter of the PTA balloon should approximate the diameter of the reference vessel.

e. Confirm full stent expansion is complete, then remove the PTA balloon from the patient.

f. Remove the guidewire and sheath from the body.

g. Close entry wound as appropriate.

h. Discard the delivery system, guidewire and sheath.

MRI INFORMATION

MR Conditional

Non-clinical testing demonstrated that the EverFlex Self-Expanding Peripheral Stent System stent is MR Conditional. A patient may be scanned safely, immediately after stent placement under the following conditions:

- Static magnetic field of 3-Tesla or 1.5T.
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less.
- Normal operating mode (maximum WBA-SAR of 2.0 W/kg) for 15 minutes of scanning.

MRI-Related Temperature Rise

In non-clinical testing, the EverFlex Self-Expanding Peripheral Stent System stent produced the following temperature rises during MRI performed for 15-minutes of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3-Tesla/128-MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems:

	1.5-T	3.0-T
Single, 8mm x 80mm		
MR system reported, whole body averaged SAR (W/kg)	2.9	2.9
Calorimetry measured values, whole body averaged SAR (W/kg)	2.1	2.7
Highest temperature rise (°C)	2.0	2.4
Single, 8mm x 120mm		
	1.5-T	3.0-T













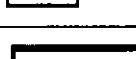
MR system reported, whole body averaged SAR (W/kg)	2.9	2.9
Calorimetry measured values, whole body averaged SAR (W/kg)	2.1	2.7
Highest temperature rise (°C)	2.9	3.7
Single, 8mm x 200mm	1.5-T	3.0-T
MR system reported, whole body averaged SAR (W/kg)	2.9	2.9
Calorimetry measured values, whole body averaged SAR (W/kg)	2.1	2.7
Highest temperature rise (°C)	3.9	4.5

These temperature changes will not pose a hazard to a patient under the conditions indicated above. It is recommended that patients register conditions under which the implant may be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

Artifact Information

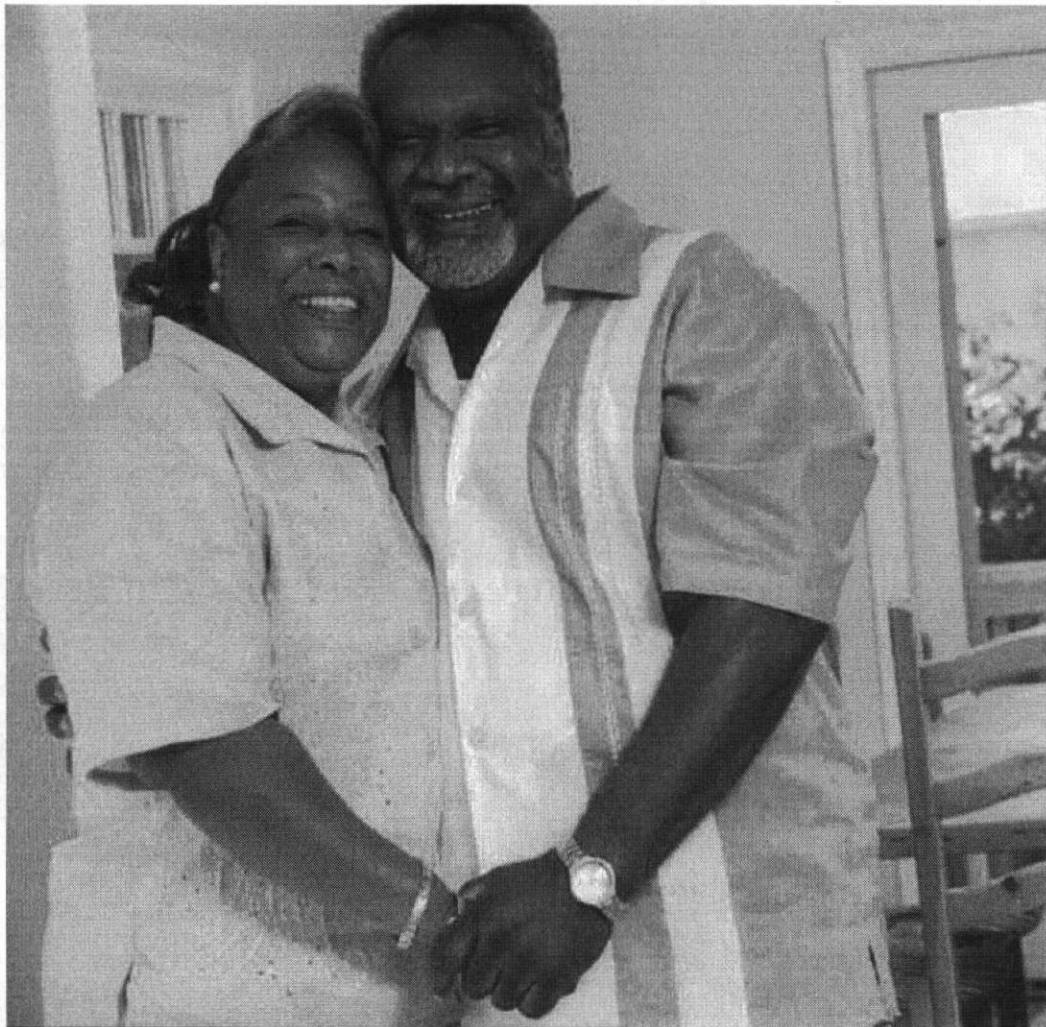
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

SYMBOL LEGEND

	Manufacturer
	Consult instructions for use
	Sterilized using ethylene oxide
	Catalogue number
	Batch code
	Keep dry
	Keep away from sunlight
	Use by
	Do not reuse
	Do not use if package is damaged
	Telephone
	Facsimile
	For prescription use only

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Patient Brochure

A Guide to Peripheral Artery Stenting



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EverFlex™

Self-Expanding Peripheral Stent System

GLOSSARY OF MEDICAL TERMS

Angiogram - An X-ray image of blood vessels produced with a liquid called contrast. The angiogram indicates the area of blockage in your arteries.

Ankle-Brachial Index (ABI) - A non-invasive test used to determine the degree of peripheral arterial occlusive disease within the legs.

Artery/arteries - A blood vessel that carries oxygen-rich blood away from the heart to the entire body.

Blood Thinner - Medicines that slow the clotting of blood before, during, and/or after the endovascular procedure.

Blood Vessel - Any of the arteries or veins that carry blood to and from the heart to the rest of the body.

Blood Clots - A formation of blood into small beads that restricts blood flow.

Catheterization Lab (Cath Lab) - A room where endovascular procedures are performed.

Catheter - A small, flexible, plastic tube that carries fluids to a vessel or allows tracking of endovascular devices like PTA balloons or stents to be used to treat disease.

Cholesterol - A substance that circulates in the blood and plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat.

Contrast - The liquid dye used to view your blood vessel under X-ray.

Heart Attack - Tissue damage to the heart caused by a lack of oxygen from reduced blood flow to coronary arteries.

Ischemic - Pain from restricted blood flow into the arteries.

IV (Intravenous) - Fluid injecting within a vein during an endovascular procedure.

Magnetic Resonance Angiogram (MRA) - An MRI that is performed with contrast dye to image blood vessels.

Magnetic Resonance Imaging (MRI) - A non-invasive test that uses a magnet to produce three dimensional images of blood vessels.

Plaque - A build-up of fatty substances like calcium or cholesterol that create a narrowing of the artery.

Popliteal Arteries - The arteries that pass through your knee.

Stent - A small, wire-mesh tube delivered through a catheter and placed at the site of the narrowing to open a vessel and restore blood flow. The metal used in most stents is nickel titanium. A stent is permanently implanted into the vessel.

Stenting - The placement of a stent.

Superficial Femoral Arteries (SFA) - The arteries that extend from your pelvic region down to your knees.

Stroke - Tissue damage to the brain caused by lack of oxygen from reduced blood flow through the vessels supplying blood to the brain.

Transient Ischemic Attack (TIA) - Temporary symptoms of a stroke. This can put you at higher risk for a stroke.

Ultrasound - A visual image produced by sound waves (ultrasound) used to assess function of the heart.

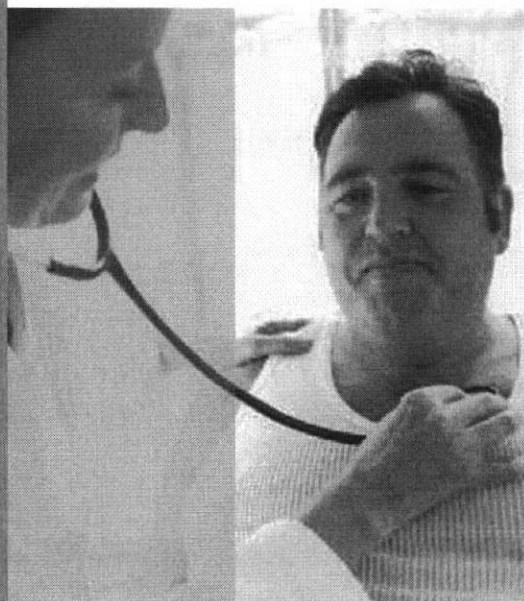
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What is PAD?

Peripheral arterial disease (PAD) is used to classify all non-coronary arterial diseases.

It is a buildup of plaque in the walls of arteries, which reduces or blocks the flow of blood to your limbs. PAD is most commonly seen in the legs.



How is PAD treated?

Your doctor may recommend one or more options for treating your PAD. Treatment options for PAD include lifestyle modifications, medications, surgery, and less-invasive procedures, such as placing a stent in the narrowed artery.

LIFESTYLE MODIFICATIONS

Lifestyle changes your doctor may recommend are:

- Quitting smoking and refraining from use of tobacco products
- Controlling high blood pressure and diabetes
- Having regular check-ups with your doctor
- Maintaining a diet of foods low in saturated fats and cholesterol
- Monitoring and controlling your lipids (good versus bad cholesterol levels)
- Achieving and maintaining a desirable weight, including regular exercise
- Properly controlling other physical ailments, such as atrial fibrillation and heart disease

MEDICATION

Your doctor may also prescribe blood thinner medications. Common drugs used include aspirin, Plavix™, Coumadin™ (also known as warfarin), or Ticlid™. These drugs lower your risk for blood clots. In addition, your doctor may prescribe medications to lower your blood pressure or cholesterol.

SUPERFICIAL FEMORAL ARTERY BALLOON ANGIOPLASTY AND STENTING

An angioplasty procedure uses a small tube (catheter) with a small balloon on the end to open the narrowed superficial femoral artery or popliteal artery by compressing the plaque against the vessel wall. This process is designed to expand the narrowed area so that it no longer restricts the flow of blood through the limb. The balloon is deflated and removed from the artery.

A stent is a metallic tube made of wire mesh that is placed in the opened artery. When expanded, the stent acts as a support that keeps the artery open and therefore restores normal blood flow. Over time, the artery wall heals around the stent, which continues to support the vessel.

SUPERFICIAL FEMORAL ARTERY BYPASS SURGERY

A man-made graft or one of your veins can be used as a detour (bypass) that actually creates a new pathway to carry blood to and through the legs.

ATHERECTOMY

In this minimally invasive procedure, a small catheter is inserted into the artery to remove plaque. This helps to restore blood flow through the artery without damaging the arterial wall or leaving anything behind.

WHAT PUTS ME AT RISK FOR PAD?

AGING – The risk of PAD increases dramatically with age

SMOKING – Those who smoke or have a history of smoking have a greater risk of developing PAD

DIABETES – One in three people over the age of 50 with diabetes is likely to have PAD

HIGH CHOLESTEROL – Excess cholesterol and fat in your blood contribute to the formation of plaque in arteries, reducing or blocking blood flow to your heart, brain, or limbs

HISTORY OF VASCULAR DISEASE, HEART ATTACK OR STROKE – If you have heart disease, you have a one in three chance of also having PAD

HIGH BLOOD PRESSURE – If you have high blood pressure, you may be at risk in developing plaque in the arteries

AFRICAN-AMERICAN OR HISPANIC ETHNICITY – Some minority groups are more than twice as likely to have PAD

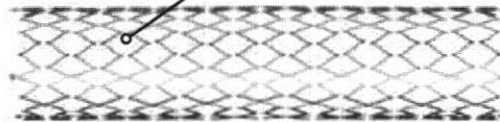
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EverFlex Self-Expanding Peripheral Stent System

DEVICE DESCRIPTION

The EverFlex Self-Expanding Peripheral Stent System contains a self-expanding stent system intended for permanent implantation. The stent is cut from a Nitinol tube in an open lattice design and has tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to open the vessel.

EverFlex Self-Expanding Peripheral Stent



WHEN SHOULD THE DEVICE NOT BE USED (CONTRAINDICATIONS)

You and your doctor should discuss whether this procedure is right for you. You should not use this device when:

- If you have an allergy to Nitinol (nickel, titanium), and/or tantalum. If you have had a skin reaction to metal jewelry or belt buckles you may be allergic to the metal used to make this stent. You should discuss with your doctor whether the potential benefits of implanting a stent outweigh the risks.
- If you cannot take aspirin or blood-thinning medications (also called antiplatelets or anticoagulants).
- If the physician decides that the blockage will not allow complete inflation of the angioplasty balloon or proper placement of the stent.

Stent Implant Procedure Risks and Benefits

WHAT ARE THE RISKS?

Be sure to ask any questions so that you thoroughly understand the procedure. Risks that could occur from the stent implant procedure are listed below and includes how often they were observed in a clinical study.

3-5%

- Blockage of a blood vessel by air, blood vessel debris, or blood clot
- Bruising
- Pain
- Bulging outside the vessel wall by blood (aneurysm)
- Chest pain
- Death
- Failure of the device to deploy
- Fever

1-3%

- Allergic reaction to device materials or procedure medication
- Bleeding
- Bulging inside the vessel wall by blood (pseudoaneurysm)
- General or localized swelling
- Low blood pressure
- Puncture or tearing of the arteries
- Heart attack
- High blood pressure
- Infection (skin, leg, groin or blood)
- Internal bleeding from procedure medications
- Irregular heart beat
- Kidney failure (new or worsening) that may require dialysis
- Kidneys not working properly (e.g. difficulty urinating)

≤ 1%

- Additional surgery on your leg
- Allergic reaction to contrast dye or renal failure
- Allergic reaction to Nitinol
- Amputation
- Blockage of a blood vessel by the procedural devices
- Breakage of the stent
- Leg artery spasm
- Mini-stroke or TIA
- Opening between your blood vessels (arterio-venous fistula)
- Re-narrowing of vessel
- Shock
- Stent movement
- Stent not placed at right location
- Stroke

Note: The above percentages are from Covidien clinical study data.

HOW WILL YOU BENEFIT?

The potential benefit of the stent procedure is improved blood flow to your leg and foot. Procedures that are done through the blood vessel have less risk of infection and complications compared to surgical procedures. This may provide a benefit to you.

WHAT ARE THE SYMPTOMS OF PAD?

FATIGUE in the leg muscles (buttocks, thigh, or calf) that occurs during activities such as walking or climbing stairs

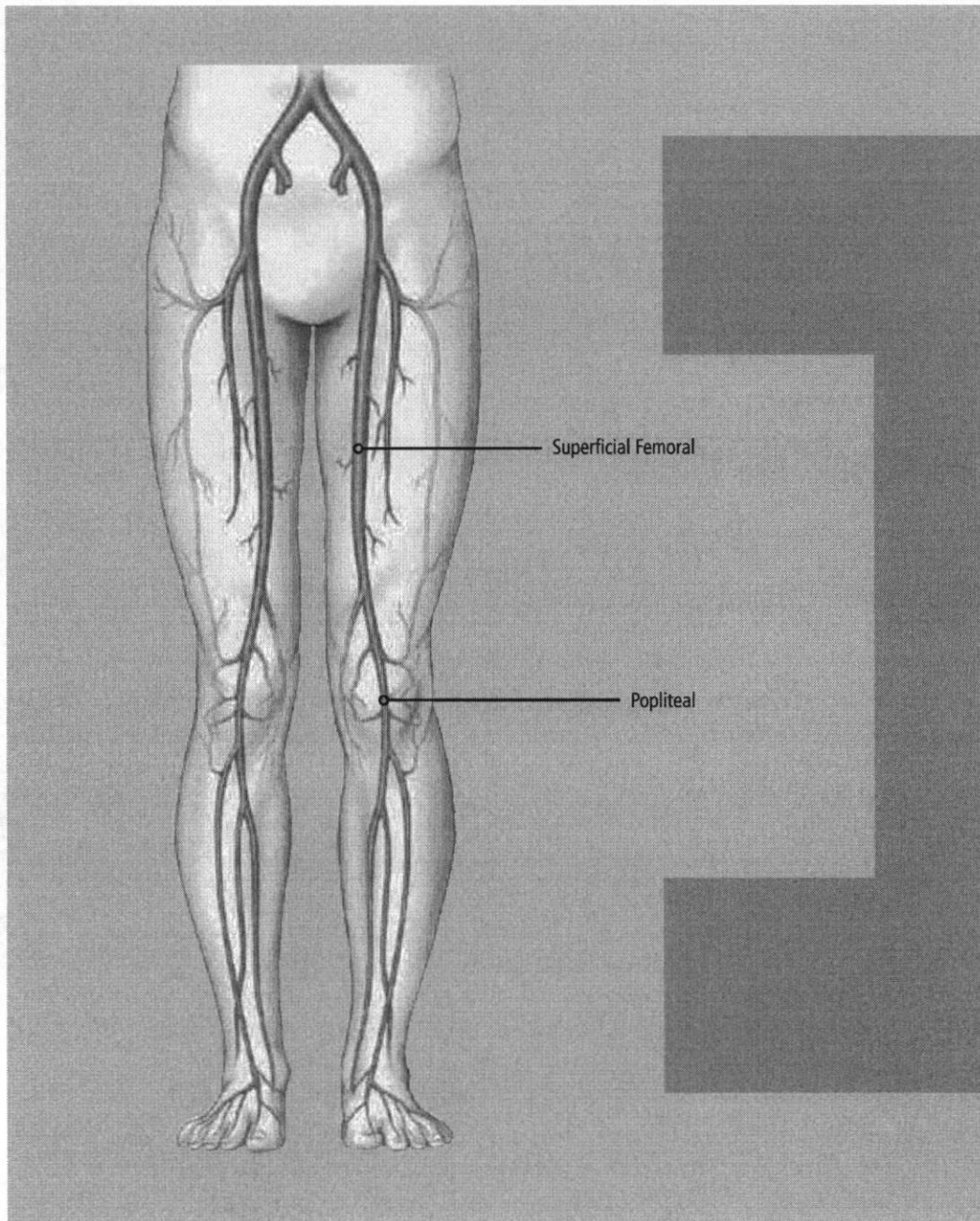
PAIN in the legs and/or feet that disturbs sleep

SORES OR WOUNDS on toes, feet, or legs that heal slowly, poorly or not at all

COLOR CHANGES in the skin of the feet, including paleness or blueness

LOWER TEMPERATURE in one leg compared with the other leg

POOR NAIL GROWTH and decreased hair growth on toes and legs



How is PAD diagnosed?

Whether you see a family physician, internist, physician's assistant, or nurse practitioner, the first step is to ask about your risk for PAD. Your provider will take a medical and family history, perform a physical, and conduct diagnostic tests.

PHYSICAL EXAM

During the physical exam, your health care provider may check:

- Pulse in your legs and feet to determine if there is sufficient blood flow
- Color, temperature, and appearance of your legs and feet
- Signs of poor wound healing on the legs and feet

DIAGNOSTIC TESTS

When checking for PAD, your health care provider may perform a simple non-invasive test called an ankle-brachial index (ABI). Painless and quick, the ABI compares the blood pressure readings in your ankles with the blood pressure readings in your arms.

Talk to your Doctor

Your doctor is in the best position to advise you of your diagnosis and treatment options. Early diagnosis and treatment can prevent complications associated with the progression of PAD. If your doctor suspects that you have PAD, your doctor may use one or more of the following tests to help diagnose your condition:

- **Ankle-Brachial Index:** The Ankle-Brachial Index (ABI) is a test done by measuring blood pressure at the ankle and the arm while a person is at rest. Measurements are usually repeated at the ankle and the arm after 5 minutes of walking on a treadmill. The result of the ABI test is used to predict the severity of PAD. A slight drop in your ABI with exercise means that you probably have PAD. This drop may be important because PAD can be linked to a higher risk of heart attack or stroke.
- **Superficial femoral artery ultrasound:** A sound-wave test that projects an image of the superficial femoral artery onto a screen. This test allows the size of the vessel to be measured and the flow of blood to the legs to be tracked. This can be helpful in identifying narrowing in the superficial femoral artery. This test is painless and does not require the use of needles, dye, or X-rays.
- **Fluoroscopy/Angiogram:** An X-ray based image obtained by injecting contrast dye through a small tube (catheter) inserted into an artery in the groin or arm. This procedure shows exactly where the narrowing is located and will help to guide further treatments.

If you will undergo a stenting procedure in your leg, this next section applies to you.



Peripheral Stent Procedure

BEFORE YOUR PROCEDURE

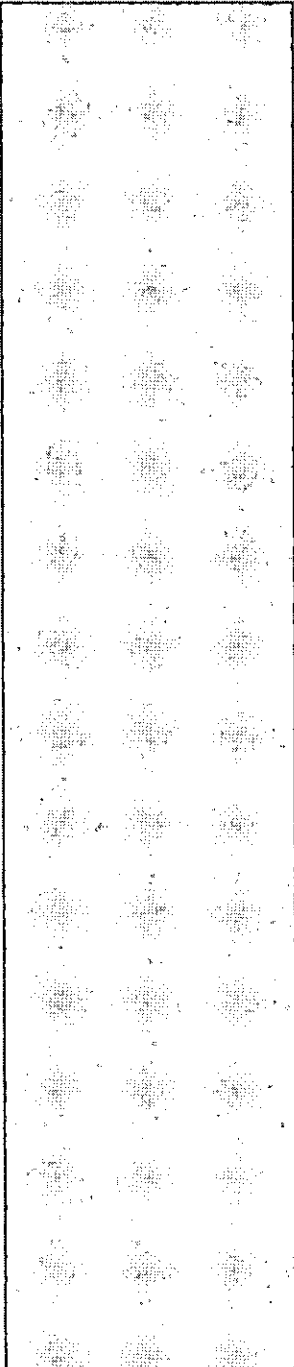
Before you go to the hospital, your doctor will give you instructions on any changes to your medication or diet necessary prior to your stent procedure. You will be asked to not eat or drink anything after midnight the night before your procedure. You should follow these instructions carefully and ask questions if you are uncertain or concerned.

At the hospital, be sure to tell your doctor about all prescriptions and other medications you are taking and any allergies you might have. Your doctor will explain the procedure to you and answer any questions or concerns you may have. You will change from your street clothes into a hospital gown, have an IV started and complete any remaining testing. Any necessary medications, such as sedatives and blood thinners, may be given to you by IV or mouth.



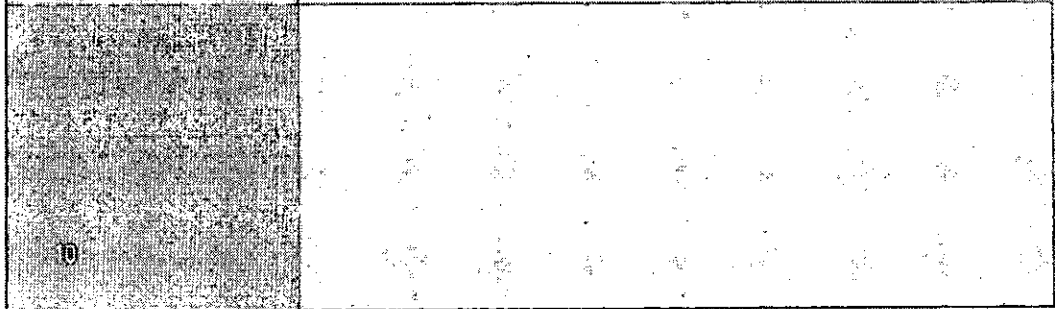
DURING YOUR PROCEDURE

1. Your procedure will occur in a catheterization laboratory. Physicians, nurses, and technologists will place you onto the procedure table and attach monitoring equipment to you for the stenting procedure.
2. You may be given additional medication to help you relax.
3. During the procedure, the room will be darkened and a large camera placed over you. The camera will rotate and move throughout the procedure.
4. Just prior to placing any catheters into an artery most likely in your groin, you will feel a small stinging sensation as your doctor numbs the area.
5. The doctor will use various wires and catheters to gain access to your superficial femoral or popliteal artery. These catheters will enter your body through the small incision in your groin. The catheters will travel through your body via your arteries until they reach the area to be treated. Because there are no nerve endings in your arteries, you will not be able to feel these wires and catheters moving inside you.
6. As your doctor treats you, he or she will take many X-ray pictures of you using the X-ray camera and contrast dye. This contrast dye may briefly make you feel warm as it is injected.
7. If the diseased area in your artery has caused the vessel to become very narrow, your doctor may use a small balloon to open it slightly. This will help your doctor reach the area where your stent will be placed. You may feel some pressure in your leg when the balloon is inflated.
8. Your doctor will use a special catheter to place the stent in the diseased area of your superficial femoral artery or popliteal artery. This catheter contains the stent in a compressed state. Your doctor will carefully align the catheter and deploy the stent.
9. After the EverFlex Self-Expanding Peripheral Stent is deployed, your doctor may use another balloon to ensure that your artery is fully opened and any plaque is pushed against the vessel wall. You may feel a small amount of pressure in your leg as the balloon is inflated. The stent will stay in place permanently.
10. When your doctor is satisfied that your artery has been treated properly, he or she will remove the catheter device from your body. The stent stays in your body.



After Your Procedure

Once your procedure is complete, you will be placed on bed rest in the hospital. The amount of time before you are allowed to stand or move freely will depend on how the incision from the catheter insertion is closed and what medication you have been given. During this time, the doctors and nurses will monitor you carefully. As always, you should let your doctor know immediately if you experience any unusual sensations such as pain, numbness, tingling, dizziness, or difficulty seeing, hearing, speaking, or swallowing.



YOUR RECOVERY

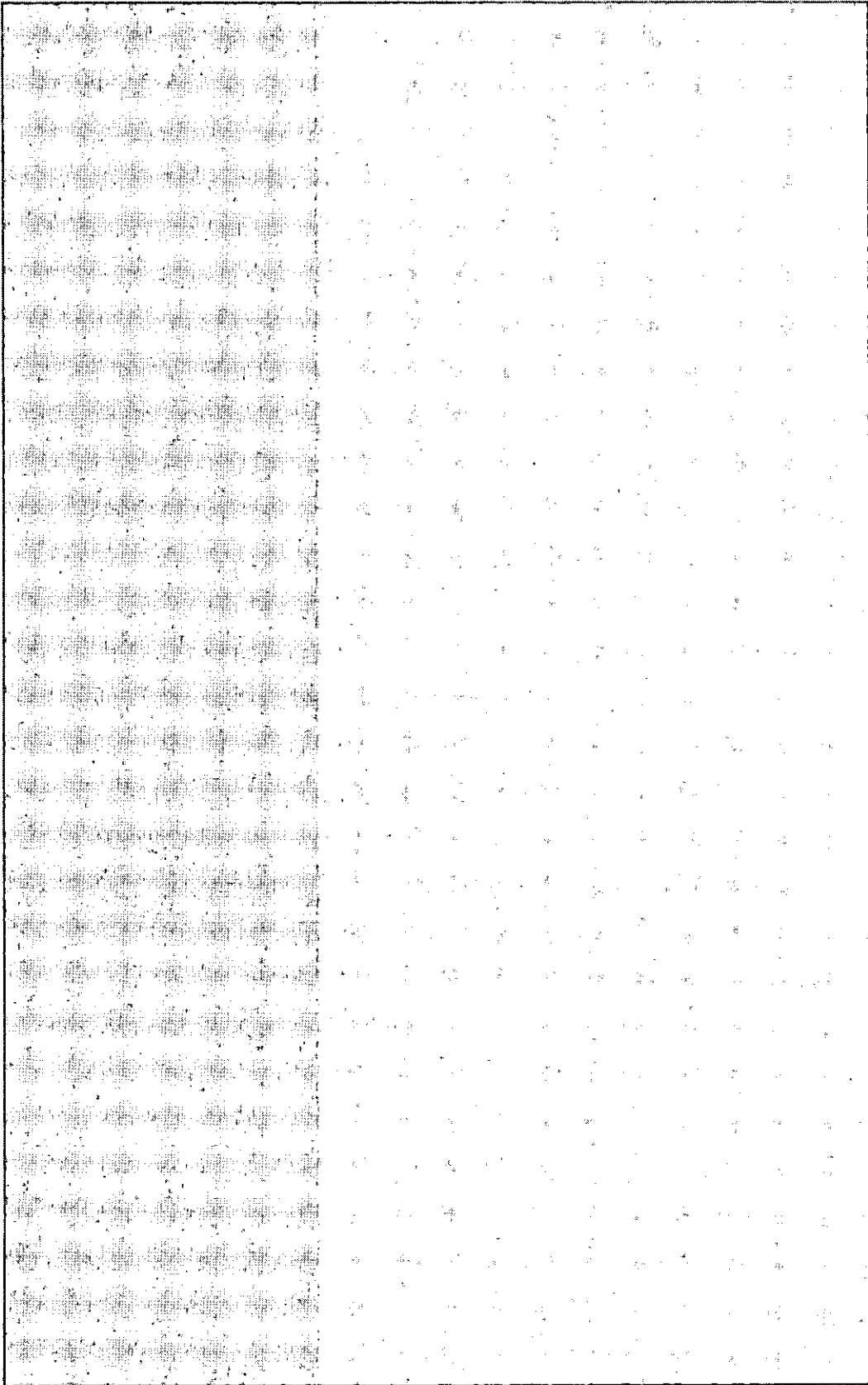
Before you leave the hospital, your doctor will give you guidelines for activities, diet, and medications. Because medications will be an important part of your treatment, your doctor will prescribe drugs that you should take at home to help prevent clots from forming. Always follow your doctor's instructions very carefully and ask questions if there is anything you do not understand. It is also important to keep all follow-up appointments that are scheduled so your doctor can follow your progress closely. He or she may give you tests such as an ECG, ultrasound, and/or blood work as part of the follow-up process. These tests are designed to detect any problems that may arise and will help your doctor to ensure your complete recovery.

You may need to have an MRI or MRA to look at your arteries some time after your stent implant. You can have an MRI or MRA at any time after your stent is implanted; the EverFlex™ Self-Expanding Peripheral Stent is MRI compatible. Before having an MRI, make sure you let the people operating the MRI equipment know that you have a stent. Please keep your Stent Implant Card with you and present it to the people running the MRI equipment so they know what type of equipment to use. The majority of patients who go home after a successful stent implantation have no further problems. If you do experience any discomfort or bleeding from your puncture site contact your doctor immediately. If your doctor is unavailable, contact your local emergency service and have them take you to the nearest hospital.

YOUR STENT IMPLANT CARD

Tell any dentist or doctor who treats you for any condition that you have a stent implant in your leg, and keep your Stent Implant Card with you at all times. Your Stent Implant Card identifies the doctor who implanted your stent and how to reach him or her, the hospital where the procedure took place, and the location in which the stent was placed. It also identifies important information about your stent, such as the size of the stent and the date the stent was manufactured. The card gives your doctor valuable information that is necessary if you need an MRI or MRA. There are also phone numbers on the card that your dentist or doctor can call if he or she has any questions. It is recommended that patients register conditions under which the implant may be scanned safely with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

NOTES





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