Protégé™

GPS Self-expanding Peripheral Stent System

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Protégé™ GPS self-expanding peripheral stent system is a self-expanding Nitinol stent system intended for permanent implantation. The Protégé GPS self-expanding stent (Protégé GPS stent) is made of a nickel titanium alloy (Nitinol) and comes pre-mounted on a 6 F 0.035" over-the-wire (OTW) 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 Protégé™ GPS delivery system, as shown in **Figure 1** and **1a**, is comprised of an inner subassembly (1) and outer (2) subassembly, 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, as shown in **Figure 1a** is comprised of two radiopaque markers, one marker distal (6) and one marker/retainer proximal (7) to the constrained stent, are 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.

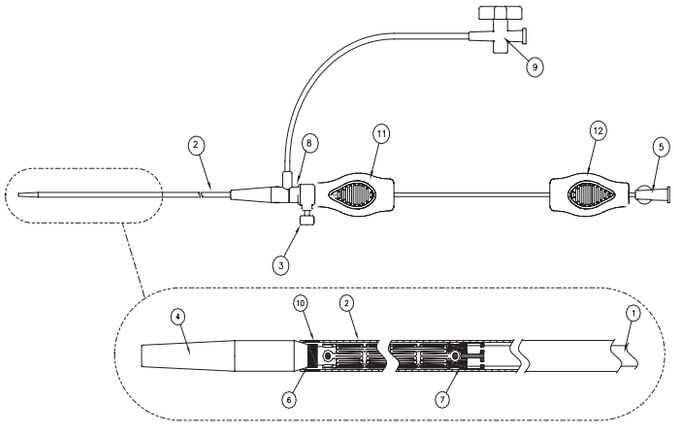

Figure 1a: Distal Portion of 20 – 80 mm Delivery

Figure 1: Stent on Delivery System

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

INDICATIONS FOR USE

The Protégé™ GPS self-expanding peripheral stent system is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameter of 7.5 – 11 mm.

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 peripheral stent system and the Protégé™ GPS self-expanding stent system (the stents) were evaluated in a study titled DURABILITY Iliac. A total of 75 subjects were enrolled; 45 of these subjects were implanted with the Protégé GPS stent(s). The primary objective was to confirm the safety and effectiveness of primary stenting using the stents for the treatment of stenotic, restenotic or occluded lesions in the common and external iliac arteries.

Table 1 provides a summary of the Clinical Events Committee (CEC) adjudicated Serious Adverse Events (SAEs) for all subjects implanted with the Protégé GPS stent in the DURABILITY Iliac study. They are summarized by MedDRA System/Organ Class and include all reported serious adverse events, regardless of study device, study procedure or study requirement relatedness. The data are presented as a percentage of subjects experiencing SAEs followed by the total number of events in brackets.

Table 1: Summary of Serious Adverse Events

MedDRA System Organ Class (MedDRA Preferred Term)	**≤ 30 Days % (n/N) [Events]**	**≤ 9 Months % (n/N) [Events]**	**≤ 3 Years % (n/N) [Events]**
Total*	**15.6% (7/45) [9]**	**35.6% (16/45) [24]**	**40% (18/45) [49]**
Cardiac disorders (Acute myocardial infarction, Angina pectoris, Angina unstable, Atrial fibrillation, Cardiac failure, Coronary artery disease)	2.2% (1/45) [1]	6.7% (3/45) [4]	13.3% (6/45) [12]
Congenital, familial and genetic disorders (Gastrointestinal angiodysplasia haemorrhagic)	0.0% (0/45) [0]	2.2% (1/45) [1]	2.2% (1/45) [1]
Gastrointestinal disorders (Colitis ischaemic, Gastrointestinal haemorrhage, Retroperitoneal haemorrhage)	2.2% (1/45) [1]	4.4% (2/45) [2]	6.7% (3/45) [3]
General disorders and administration site conditions (Chest pain, Device occlusion, Thrombosis in device)	0.0% (0/45) [0]	2.2% (1/45) [1]	8.9% (4/45) [5]
Infections and infestations (Diverticulitis, Pneumonia, Upper respiratory tract infection)	0.0% (0/45) [0]	4.4% (2/45) [2]	4.4% (2/45) [3]
Injury, poisoning and procedural complications (Arterial restenosis, In-stent arterial restenosis, Incisional hernia, Vascular pseudoaneurysm)	4.4% (2/45) [2]	11.1% (5/45) [5]	17.8% (8/45) [9]
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Lung neoplasm malignant, Prostate cancer)	0.0% (0/45) [0]	2.2% (1/45) [1]	4.4% (2/45) [2]
Nervous system disorders (Presyncope)	2.2% (1/45) [1]	2.2% (1/45) [1]	2.2% (1/45) [1]
Renal and urinary disorders (Nephrolithiasis)	0.0% (0/45) [0]	0.0% (0/45) [0]	2.2% (1/45) [1]
Respiratory, thoracic and mediastinal disorders (Chronic obstructive pulmonary disease)	0.0% (0/45) [0]	0.0% (0/45) [0]	2.2% (1/45) [1]
Vascular disorders (Arterial stenosis, Artery occlusion, Hypertensive crisis, Iliac artery occlusion, Iliac artery stenosis, Peripheral artery dissection)	8.9% (4/45) [4]	15.6% (7/45) [7]	20% (9/45) [11]

*A total of 45/75 subjects were implanted with the Protégé GPS stent in the DURABILITY Iliac study.

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 injury (e.g., dissection, perforation, or rupture)
- Bleeding requiring transfusion
- Bruising
- Contrast medium reaction/renal failure
- Death
- Device breakage
- 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
- Renal insufficiency
- 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
- Worsening claudication or rest pain

CLINICAL STUDIES

The DURABILITY Iliac study was a prospective, multi-center, non-randomized, single arm study to evaluate the EverFlex™ self-expanding stent system and the Protégé™ GPS self-expanding stent system (the stents) for the treatment of stenotic, restenotic (from PTA or adjunct therapy, not including stents or stent grafts) or occluded lesions of the common and/or external iliac arteries. The objective of the study was to confirm the safety and effectiveness of primary stenting.

A total of 75 subjects were enrolled at 13 US and two European investigational sites; 45 of the 75 subjects had Protégé GPS stent(s) implanted. Subject follow-up occurred at pre-discharge, 30 days, 9 months, 1, 2 and 3 years post-procedure. The primary outcome for the study was Major Adverse Event (MAE) rate at 9 months. Secondary outcomes were MAE Rate at 30 days, primary patency rate at 9 months, change of ankle-brachial index at 30 days and 9 months, device success, change in walking impairment questionnaire score at 30 days and 9 months, and clinically driven target vessel revascularization at 30 days and 9 months.

SUBJECT ELIGIBILITY CRITERIA

Eligible subjects had claudication defined as Rutherford Clinical Category Score of 2 - 4. Target lesions were stenotic, restenotic (from PTA or adjunct therapy, not including stents or stent grafts) or occluded lesions. The reference vessel diameter of the target lesion was to be ≥ 4.5 and ≤11 mm and the lesion length ≤ 10 cm. To be included, they had to be at least 18 years old and consent to participate.

SUBJECT FOLLOW-UP

Table 2 summarizes subject follow-up compliance in the DURABILITY Iliac study. Percentages are based on the number of subjects implanted with Protégé GPS stent(s) that completed a visit.

Table 2: Summary of Subject Compliance

Time	Compliance*
Pre-discharge	100% (45/45)
30-Day	97.8% (44/45)
9 Month	88.9% (40/45)

*A total of 45/75 subjects were implanted with the Protégé GPS stent(s) in the DURABILITY Iliac study.

Baseline demographics and clinical characteristics for subjects implanted with the Protégé GPS stent(s) are presented in **Table 3**.

Table 3: Demographics and Baseline Clinical Characteristics

Subject Characteristics	N=45*
Age (yrs.), Mean± SD (N), [Median] (Min, Max)	62.4 ± 9.2 (45) [62.0] (41.0, 78.0)
Male	73.3% (33/45)
Race	
Caucasian	91.1% (41/45)
African American	6.7% (3/45)
Asian	0.0% (0/45)
American Indian or Alaska Native	0.0% (0/45)
Native Hawaiian or other Pacific Islander	2.2% (1/45)
Other	0.0% (0/45)
Ethnicity	
Hispanic	2.2% (1/45)
Not Hispanic	97.8% (44/45)
Risk Factors and Medical History	
Diabetes	17.8% (8/45)
Type I	12.5% (1/8)
Type II	87.5% (7/8)
Hyperlipidemia	64.4% (29/45)
Hypertension	68.9% (31/45)
Renal insufficiency	0.0% (0/45)
Current smoker	64.4% (29/45)
Angina	13.3% (6/45)
Arrhythmia	6.7% (3/45)
Congestive Heart Failure (CHF)	6.7% (3/45)
Stroke	4.4% (2/45)
Transient Ischemic Attack (TIA)	4.4% (2/45)
Myocardial Infarction (MI)	24.4% (11/45)
Non-healing ischemic ulcers in the lower extremities	0.0% (0/45)
Amputation of the lower extremities	0.0% (0/45)
Peripheral Intervention**	17.8% (8/45)
Clinical Characteristics	
Rutherford Clinical Category	
2=Moderate claudication	22.2% (10/45)
3=Severe claudication	77.8% (35/45)
4=Ischemic rest pain	0.0% (0/45)
Ankle-Brachial Index (ABI)	0.67 ± 0.19 (45) [0.67] (0.12, 1.05)

*A total of 45/75 subjects were implanted with the Protégé GPS stent(s) in the DURABILITY Iliac study.

**Types of historical peripheral interventions included: PTA, Stenting, Atherectomy or other types of interventions. There was no history of Cryoplasty, Laser interventions, or Bypass.

Table 4 presents baseline characteristics assessed by the angiographic core laboratory for the subjects treated with the Protégé GPS stent(s).

Table 4: Baseline Target Lesion Characteristics

Lesion Characteristics	N=47 (# of lesions)*
Right Iliac Artery	51.1% (24/47)
Common	75.0% (18/24)
External	25.0% (6/24)
Left Iliac Artery	48.9% (23/47)
Common	73.9% (17/23)
External	26.1% (6/23)
Lesion Morphology	
Distance from Ostium (mm)	25.4 ± 36.8 (47) [0.0] (0.0, 168.0)
Lesion Length (mm)	47.1 ± 28.3 (47) [32.4] (15.0, 122.2)
Eccentric Lesion	59.6% (28/47)
Bend	13.4 ± 14.1 (47) [10.0] (0.0, 80.0)
Thrombus	0.0% (0/47)
Any Calcification	74.5% (35/47)
None/Mild	25.5% (12/47)
Moderate	48.9% (23/47)
Severe	25.5% (12/47)
Ulceration present	27.7% (13/47)
Aneurysm present	8.5% (4/47)
TASC II	
Type A	55.3% (26/47)
Type B	34.0% (16/47)
Type C	6.4% (3/47)
Type D	4.3% (2/47)
Quantitative Angiographic Results	
Pre-procedure Reference Diameter (mm)	8.4 ± 1.4 (47) [8.2] (5.9, 11.7)
Pre-procedure Minimal Lumen Diameter (mm)	2.0 ± 1.4 (47) [2.3] (0.0, 5.5)
Pre-procedure % Diameter Stenosis	76.2 ± 15.5 (47) [72.9] (51.6, 100.0)
Percent Total Occlusions (100% stenosis)	23.4% (11/47)

*A total of 45 subjects with 47 target lesions were implanted with the Protégé GPS stent(s). One subject had two target lesions, one treated with the Protégé GPS stent and one treated with the EverFlex stent.

CLINICAL RESULTS

Primary Outcome

The primary outcome of the study is MAE rate at 9 months (270 days) post-procedure. An MAE was defined as a composite of periprocedural death, in hospital MI, clinically-driven target lesion revascularization, and amputation of treated limb, as adjudicated by the Clinical Event Committee (CEC). The 9-month MAE rate for subjects implanted with the Protégé GPS stent(s) was 2.2% (1/45) (**Table 5**).

Table 5: Summary of Primary Outcome

9-Month MAE	N=45* % (n/N) [Events]
9-Month MAE	2.2% (1/45) [1]
Periprocedural Death	0.0% (0/45) [0]
In-hospital MI	0.0% (0/45) [0]
Clinically-driven TLR	2.2% (1/45) [1]
Amputation of the Treated limb	0.0% (0/45) [0]

*A total of 45/75 subjects were implanted with the Protégé GPS stent(s) in the DURABILITY Iliac study. Forty (40) out of 45 completed the 9-month follow-up visit - Four subjects exited the study prior to the 9-month visit: One subject was Lost to Follow-up 53 days post-procedure, the second subject withdrew 175 days post-procedure, investigators withdrew the third and fourth subject 296 and 358 days post procedure respectively. One subject missed their 9-month visit; however completed their 1, 2 and 3-Year follow-up visits; therefore all events that would have been reported through the 9-month visit for this subject were reported.

Figure 2 displays the freedom from Major Adverse Event at 9 months.

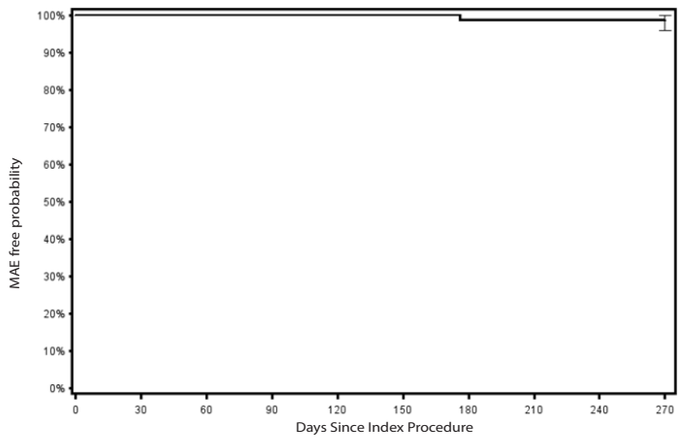

Figure 2: Freedom from MAE at 9 Months (270 days), All subjects (N=45)

Outcome Summary
Table 6 provides a summary of the primary and secondary outcome measures for the 45 subjects implanted with the Protégé GPS stent in the DURABILITY Iliac study.

Table 6: Summary of Primary and Secondary Outcomes

Primary Outcome Measures	**N=45***
9-Month MAE[1]	2.2% (1/45) [1]
Periprocedural Death	0.0% (0/45) [0]
In-hospital MI	0.0% (0/45) [0]
Clinically-driven TLR	2.2% (1/45) [1]
Amputation of the Treated limb	0.0% (0/45) [0]
Freedom from 9-Month MAE -KM Estimate	97.7%
Secondary Outcome Measures	**N=45***
30-Day MAE[1]	0.0% (0/45) [0]
Periprocedural Death	0.0% (0/45) [0]
In-hospital MI	0.0% (0/45) [0]
Clinically driven TLR	0.0% (0/45) [0]
Amputation of the Treated limb	0.0% (0/45) [0]
Primary Patency Rate at 9 Months - KM Estimate[2]	97.7%
Device Success[3]	100.0% (52/52)**
Freedom from clinically-driven TVR at 30 days -KM Estimate	100.0%
Freedom from clinically-driven TVR at 9 months KM Estimate	97.7%

* A total of 45/75 subjects were implanted with the Protégé GPS stent(s) in the DURABILITY Iliac study. Forty (40) out of 45 completed the 9-month follow-up visit - Four subjects exited the study prior to the 9-month visit: One subject was Lost to Follow-up 53 days post-procedure, the second subject withdrew 175 days post-procedure, investigators withdrew the third and fourth subject 296 and 358 days post procedure respectively. One subject missed their 9-month visit; however completed their 1, 2 and 3-Year follow-up visits; therefore all events that would have been reported through the 9-month visit for this subject were reported.

**A total of 45 subjects with 47 target lesions were implanted with the Protégé GPS stent using 51 Protégé GPS stents and one EverFlex stent.

Thirty-eight subjects had a single Protégé GPS stent implanted in one target lesion. Five subjects had two Protégé GPS stents implanted in one target lesion. One subject had two target lesions, each treated with one Protégé GPS stent; and one subject had two target lesions, one treated with the Protégé GPS stent and one treated with the EverFlex stent.

1 Numbers are % (n/N) [Events]

2 Primary patency rate defined as a binary duplex ultrasound ratio ≤ 2.4 at the stented target lesion with no clinically-driven re-intervention within the stented segment

3 Device success was defined as the ability to deploy the stent as intended at the treatment site. The denominator includes number of stents implanted

Conclusion
Overall, the data supports the conclusion that the clinical benefits of primary stenting with the Protégé™ GPS stent, outweigh the risks in the intended population. The results of the study provide reasonable assurance that the Protégé GPS stent is safe and effective for the treatment of stenotic, restenotic or occluded lesions in the common and external iliac arteries.

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**

   Refer to **Table 7** for stent diameter sizing.

   Measure the diameter of the reference vessel (proximal and distal to lesion). Measure the length of the target lesion. Choose a stent length that will extend proximal and distal to the target lesion.

Table 7: Stent Diameter and Length Sizing

Device Diameter (mm)	Recommended Vessel Diameter (mm)	Introducer Sheath Size (F)	Guidewire Compatibility	Device Lengths (mm)	Catheter Lengths (cm)
9	7.5 - 8.5	6	0.035"	20, 30, 40, 60, 80	80, 120
10	8.5 – 9.5	6	0.035"	20, 30, 40, 60, 80	80, 120
12	9.5 – 11.0	6	0.035"	20, 30, 40, 60, 80	80, 120

Table 8 provides foreshortening data for the Protégé GPS stent.

Table 8: Stent Foreshortening

Diameter (mm)	Recommended Vessel Diameter (mm)	Foreshortening (%)*			Foreshortening Average*
		Min	Max	St. Dev.	
9x20	7.5 – 8.5	-3.4	1.0	1.3	-1.1
9x80	7.5 – 8.5	-2.9	-0.5	0.6	-1.8
10x20	8.5 – 9.5	-6.8	2.0	2.0	-1.1
10x80	8.5 – 9.5	-5.9	-2.0	0.9	-4.4
12x20	9.5 – 11.0	-3.7	4.5	1.8	1.5
12x80	9.5 – 11.0	-1.3	0.7	0.6	-0.2

* Foreshortening has a negative value when the stent shortens and a positive value when the stent lengthens.

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 knob 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 6 F delivery system. The sheath should be of adequate length to provide support of stent delivery system.

      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 shaft marker is distal to the target lesion.
   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**.

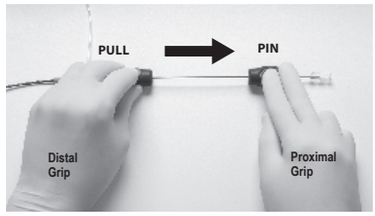

Figure 3: Stent Deployment

   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 Protégé GPS stent in single and overlapped conditions is MR Conditional for stents up to 155 mm. A patient may be scanned safely, immediately after stent placement under the following conditions:

- Static magnetic field of 3-Tesla or 1.5-Tesla
- Maximum spatial gradient magnetic field of 4,000-Gauss/cm (extrapolated) or less (40 T/m)
- The maximum whole-body averaged specific absorption rate (SAR) shall be limited to 2.0 W/kg (normal operating mode) for 15 minutes of scanning (per pulse sequence)

MRI-RELATED HEATING

Under the scan conditions defined above, the Protégé GPS stent is expected to produce a maximum temperature rise less than or equal to 4.2° C after 15 minutes of continuous scanning (per pulse sequence).

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

The maximum artifact size as seen on the gradient echo pulse sequence at 3-Tesla extends approximately 5 mm relative to the size and shape of the Protégé GPS stent. The lumen of the stent cannot be visualized using the T1-weighted, spin echo and gradient echo pulse sequences at 3-Tesla.

WARRANTY DISCLAIMER

Although this product has been manufactured under carefully controlled conditions, Covidien Inc. has no control over the conditions under which this product is used. Covidien Inc. 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. Covidien Inc. 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 Covidien Inc. 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.

SYMBOL LEGEND

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

CONTACT INFORMATION

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510319-001 (A) JAN/2015