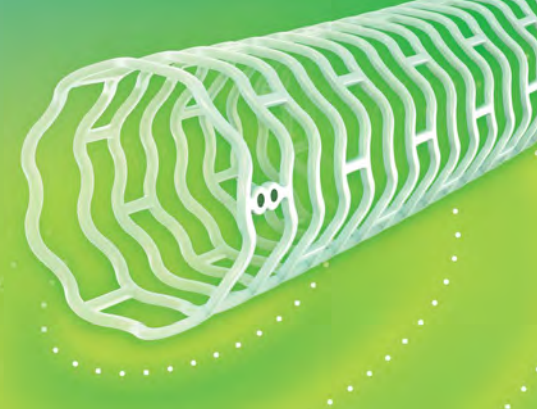

Esprit™ BTK
Everolimus Eluting Resorbable Scaffold System

CASE REPORT
Courtesy of Matthew C. Bunte, MD, MS

SUCCESSFUL TREATMENT OF RB6 ANKLE WOUNDS WITH ESPRIT™ BTK SCAFFOLDS

An 80-year-old female with a complex medical history presented with non-healing wounds on her right medial and lateral ankle, classified as Rutherford Becker Category 6. The treatment involved balloon angioplasty and Supera™ Stents placement above-the-knee, with calcium modification balloon and Esprit™ BTK scaffolds below-the-knee, resulting in successful revascularizataion and wound healing within 3 weeks.

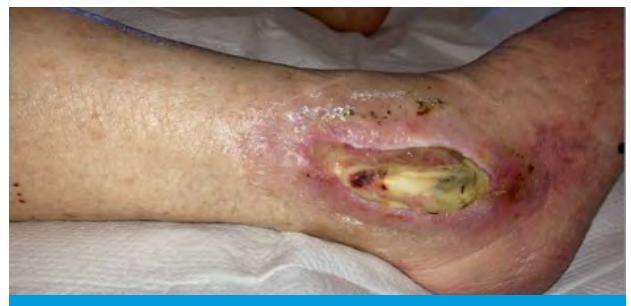

Figure 1
Lateral ankle ulcer

PATIENT PRESENTATION

An 80-year-old female with a medical history of Type 1 Diabetes, CAD, and 3v CABG presented with non-healing wounds on the right medial and lateral ankle. The patient was classified as Rutherford Becker Category 6 (**Figure 1**).

Diagnostic Findings

ABI was 0.80. No applicable CT findings or previous angiogram findings.

I/O Inflow/Outflow

Both the SFA and Popliteal artery had flow-limiting lesions above the target tibial lesion, which were treated with balloon angioplasty and overlapping 5.5x150 and 5.5x100 Supera™ Stents. Distal outflow was reasonable beyond the target tibial lesion.

P Prepare the Lesion

A 0.014″ Hi-Torque Command™ ES & 0.018″ support catheter was used to access the tibial arteries. Severe stenosis was noted both in the Tibioperoneal (TP) trunk and the proximal Posterior Tibial (PT) artery (**Figure 5a**). The target lesions in the TPT and PT artery were measured via IVUS, with reference vessel diameters of 4.0 mm and 2.75 mm, respectively (**Figure 2a/b**) each measuring 12 mm in length. The lesion in the PT was treated with preferred calcium modification system, and then a 2.5x20 mm NC balloon. The 2nd target lesion in the TPT was pre-dilated with 4.0x20mm NC balloon @ 16 ATM.

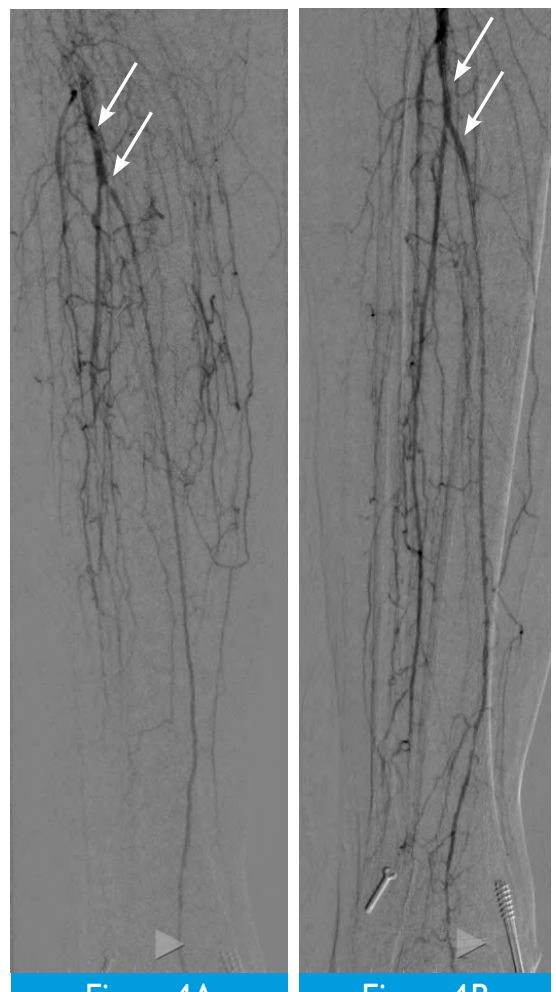

Figure 4A
Pre treatment tibials

Figure 4B
Post treatment tibials

INDICATIONS
The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm.

See Important Safety Information referenced within.
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Abbott

S Size the Scaffold

Sizing 1-1 to IVUS reference vessel diameters, a 2.5 x 18 mm Esprit™ BTK scaffold in the target proximal PT lesion (**Figure 3a**), and a second 3.75x18mm Esprit™ BTK scaffold was delivered in the TPT target lesion (**Figure 3b**).

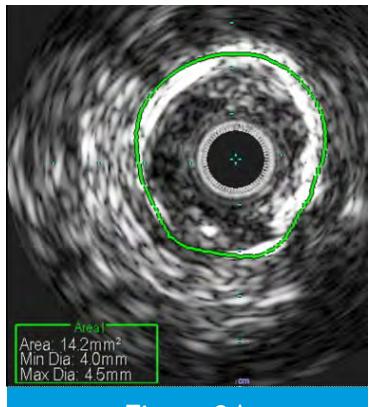

Figure 2A
TPT IVUS 4.0 mm

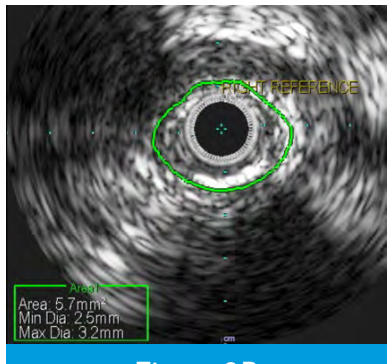

Figure 2B
PT IVUS 2.5 mm

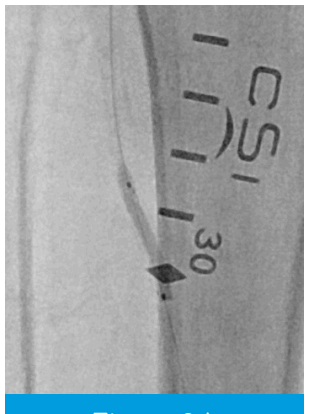

Figure 3A
3.75x18 mm scaffold
in the proximal PT

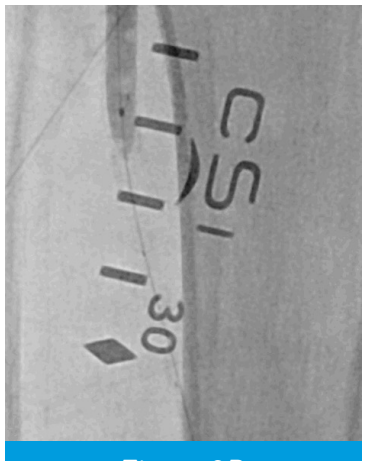

Figure 3B
2.5x18 mm scaffold
in TPT

P Post Dilatation

Post-dilatation was performed using non-compliant balloons with diameters of 4.0 mm and 2.75 mm, respectively, at 16 ATMs to ensure scaffold apposition against the vessel wall.

Patient Follow-Up

Post-procedural images demonstrated brisk flow through TPT & PT (**Figure 4b**), with increased outflow through pedal arteries post-intervention (**Figure 5b**). Follow-up 3 weeks post procedure demonstrated significant healing improvement in Lateral and Medial Ankle Ulcers.

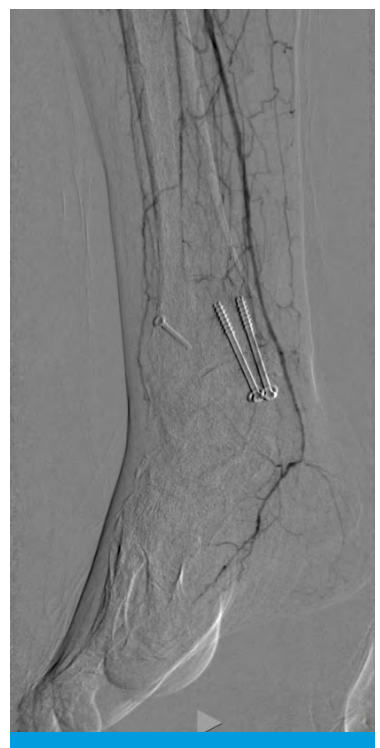

Figure 5A
Pre treatment
pedal flow

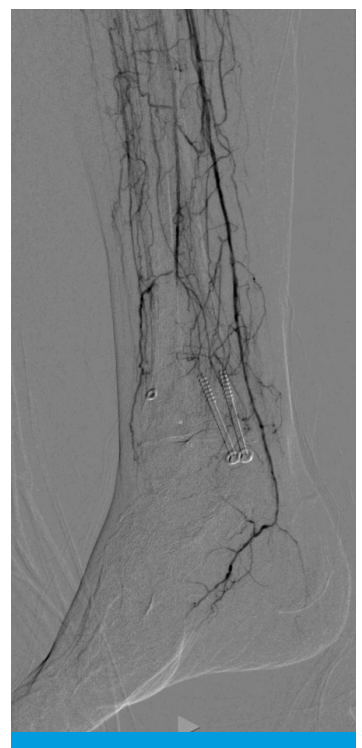

Figure 5B
Post treatment
pedal flow

See Important Safety Information referenced within.

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IMPORTANT SAFETY INFORMATION

℞ ONLY Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

INDICATIONS

The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm.

CONTRAINDICATIONS

The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is contraindicated for use in:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.
- Patients with hypersensitivity or contraindication to everolimus or structurally related compounds or known hypersensitivity to scaffold components poly(L-lactide), poly(D, L-lactide), and platinum.

WARNINGS

- **This device is intended for single use only.** Do not reuse, reprocess, or re-sterilize. Note the product "Use-by" date on the package. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and / or delivery system and / or lead to device failure, which may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and / or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device and / or delivery system may lead to injury, illness, or death of the patient.
- The Esprit™ BTK System is intended to perform as a system. The scaffold should not be removed for use with other dilatation catheters.
- The Esprit™ BTK System should not be used in conjunction with other non-everolimus drug eluting devices in the same vessel as the Esprit™ BTK Scaffold.
- It is not recommended to use this scaffold to treat lesions located at any joint or other hinge points, such as the knee or ankle. The recommended region for below-the-knee (BTK) treatment with the Esprit™ BTK Scaffold is the infrapopliteal arteries at a location ≥ 10 cm above the proximal margin of the ankle mortise. The Esprit™ BTK Scaffold has not been tested for use outside the recommended implant locations.
- This product should not be used in patients with aneurysms immediately adjacent to the scaffold implantation site.
- Insertion of the Esprit™ BTK System and implantation of the scaffold should be performed only under fluoroscopic observation with radiographic equipment providing high resolution images.
- **Quantitative imaging is strongly recommended to accurately measure and confirm appropriate vessel sizing (reference vessel diameter ≥ 2.5 mm).** If quantitative imaging determines a vessel size < 2.5 mm, do not implant the Esprit™ BTK Scaffold.
- Adequate lesion preparation prior to scaffold implantation is required to ensure safe delivery of the scaffold across the target lesion. It is not recommended to treat patients having a lesion that prevents complete inflation of an angioplasty balloon.
- **Successful pre-dilatation with residual diameter stenosis of < 30% by visual estimation is required for treatment of the target lesion; < 20% by visual estimation is preferred.**
- Ensure the scaffold is not post-dilated beyond the allowable expansion limits.
- Use of appropriate anticoagulant and / or antiplatelet therapy per standard of care is recommended for use of this scaffold system.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.
- Judicious selection of patients is necessary, since the use of this device carries the associated risk of scaffold thrombosis, vascular complications, and / or bleeding events.

PRECAUTIONS

- Scaffold placement should not be performed in patients with known allergies to contrast agent that cannot be medically managed.
- It is not recommended to treat patients having a lesion with excessive tortuosity proximal to or within the lesion.
- When multiple scaffolds are required, only combinations of Esprit™ BTK Scaffolds must be used. Any potential interaction with other drug-eluting or coated devices has not been evaluated.
- The delivery system is intended for deployment of the scaffold only and should not be used to dilate other locations.
- Implantation of the scaffold should be performed **only** by physicians who have received appropriate training.
- As with all catheter-based procedures, scaffold placement should be performed at facilities where patient can be prepared for necessary intervention and / or surgical removal of the device and vessel repair as per facility protocol.
- Pre-dilatation should be performed with an angioplasty balloon. Cutting or scoring balloons can be used per physician discretion, if the lesion appears to be mildly calcified.
- Failure to pre-dilate the vessel may impair nominal / optimal scaffold delivery.
- Implanting a scaffold may lead to dissection of the vessel distal and / or proximal to the scaffold, requiring additional intervention. **Note:** In cases of bailouts, bailout treatment of the target lesion can be done using the Esprit™ BTK Scaffold of the appropriate length. If an appropriate length Esprit™ BTK Scaffold is not available, physicians should use standard of care.
- An unexpanded scaffold may be retracted into the introducer sheath **one time only.** An unexpanded scaffold should not be reintroduced into the artery once it has been pulled back into the introducer sheath.
- Post-dilatation is strongly recommended for optimal scaffold apposition. When performed, post-dilatation should be performed at high pressure (> 16 atm) with a non-compliant balloon up to 0.5 mm larger than the nominal scaffold diameter.
- Use an appropriately sized non-drug coated balloon to pre-dilate the lesion. When treating a long lesion, scaffold the distal portion of the lesion prior to scaffolding the proximal portion of the lesion.
- Ensure that the scaffolded area covers the entire lesion / dissection site and that no gaps exist between scaffolds.
- The extent of the patient's exposure to drug and polymer is directly related to the number of scaffolds implanted. The safety of everolimus, polymer, and polymer breakdown products was evaluated in pre-clinical studies and the biocompatibility assessment of the Esprit™ BTK Scaffold.
- The safety and effectiveness of the Esprit™ BTK Scaffold in patients with prior brachytherapy of the target lesion or the use of brachytherapy for treated-site restenosis in the Esprit™ BTK Scaffold have not been established. Both vascular brachytherapy and the Esprit™ BTK Scaffold alter arterial modeling. The potential combined effect on arterial remodeling by these two treatments is not known.
- The safety and effectiveness of the Esprit™ BTK System have not been established in clinical trials with the use of either mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser atherectomy catheters.
- Formal drug interaction studies have not been performed with the Esprit™ BTK Scaffold because of limited exposure to everolimus eluted from the scaffold.
- Everolimus, the Esprit™ BTK Scaffold's active pharmaceutical ingredient, is an immunosuppressive agent. Therefore, consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglyceride levels, which in some cases required treatment.
- Non-clinical testing has demonstrated the Esprit™ BTK Scaffold is MR Conditional. A person with the Esprit™ BTK Scaffold may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.
  - Static magnetic field strength of 7 Tesla or less
- The Esprit™ BTK Scaffold should not migrate in this MRI environment. MRI at 7 Tesla or less may be performed immediately following the implantation of the Esprit™ BTK Scaffold.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to:

Allergic reaction or hypersensitivity to contrast agent, anesthesia, scaffold materials (poly[L-lactide] [PLLA], poly[D, L-lactide] [PDLLA], platinum, or everolimus), and drug reactions to anticoagulation or antiplatelet drugs

- Vascular access complications which may require transfusion or vessel repair, including:
  - Catheter site reactions
  - Bleeding (ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage)
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, and laceration
  - Embolism (air, tissue, plaque, thrombotic material, or device)
  - Peripheral ischemia
- Target artery complications which may require additional intervention, including:
  - Total occlusion or abrupt closure
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture
  - Embolism (air, tissue, plaque, thrombotic material, or device)
  - Artery or scaffold thrombosis
  - Stenosis or restenosis
  - Vasospasm
  - Tissue prolapse / plaque shift
- Bleeding (non-access site)
- Additional surgery such as peripheral artery bypass graft surgery or amputation
- Peripheral nerve injury, neuropathy
- Compartment syndrome
- Tissue necrosis, gangrene, ulcer and acute limb ischemia
- Reperfusion injury
- New or worsening pain
- Intervention due to
  - Damaged scaffolds
  - Partial scaffold deployment
  - Scaffold migration / unintentional placement of scaffold
- Other general surgical risks, including:
  - Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias, and blocks)
  - Stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA)
  - Venous thromboembolism (including pulmonary embolism)
  - Nausea and vomiting
  - Hypotension / hypertension
  - Infection – local and systemic (including post-procedural)
  - Fever
  - Blood cell disorders including heparin-induced thrombocytopenia (HIT) and other coagulopathy
  - Death
- System organ failures:
  - Cardiac Failure
  - Cardio-respiratory arrest (including pulmonary edema)
  - Respiratory failure
  - Renal failure
  - Shock

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IMPORTANT SAFETY INFORMATION (CON'T)

The risks described below include the anticipated adverse events referenced in the contraindications, warnings, and precautions sections of the everolimus labels / SmPCs and / or observed at incidences ≥ 10% in clinical trials with oral everolimus for different indications. Refer to the drug SmPCs and labels for more detailed information and less frequent adverse events.

- Abdominal pain
- Anemia
- Angioedema (increased risk with concomitant angiotensin-converting enzyme [ACE] inhibitor use)
- Arterial thrombotic events
- Bleeding and coagulopathy (including hemolytic uremic syndrome [HUS], thrombotic thrombocytopenic purpura [TTP], and thrombotic microangiopathy; increased risk with concomitant cyclosporine use)
- Constipation
- Cough
- Diabetes mellitus
- Diarrhea
- Dyspnea
- Embryo-fetal toxicity
- Erythema
- Erythroderma
- Headache
- Hepatic artery thrombosis (HAT)
- Hepatic disorders (including hepatitis and jaundice)
- Hypersensitivity to everolimus active substance, or to other rapamycin derivates
- Hypertension
- Infections (bacterial, viral, fungal, or protozoan infections, including infections with opportunistic pathogens). Polyoma virus-associated nephropathy (PVAN), JC virus-associated progressive multiple leukoencephalopathy (PML), fatal infections and sepsis have been reported in patients treated with oral everolimus.
- Kidney arterial and venous thrombosis
- Laboratory test alterations (elevations of serum creatinine, proteinuria, hypokalemia, hyperkalemia; hyperglycemia, dyslipidemia including hypercholesterolemia and hypertriglyceridemia; abnormal liver function tests; decreases in hemoglobin, lymphocytes, neutrophils, and platelets)
- Lymphoma and skin cancer
- Male infertility
- Menstrual irregularities
- Nausea
- Nephrotoxicity (in combination with cyclosporine)
- Non-infectious pneumonitis (including interstitial lung disease)
- Oral ulcerations
- Pain
- Pancreatitis
- Pericardial effusion
- Peripheral edema
- Pleural effusion
- Pneumonia
- Pyrexia
- Rash
- Renal failure
- Upper respiratory tract infection
- Urinary tract infection
- Venous thromboembolism
- Vomiting
- Wound healing complications (including wound infections and lymphocele)

There may be other potential adverse events that are unforeseen at this time.

Rx ONLY HI-TORQUE Guide Wires for PTA

INDICATIONS

This HI-TORQUE guide wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA), in arteries such as the femoral, popliteal and infra-popliteal arteries. This guide wire may also be used with compatible stent devices during therapeutic procedures.

The guide wire may also be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature.

CONTRAINDICATIONS

Not intended for use in the coronary or cerebral vasculature.

WARNINGS

This device is not designed for use with atherectomy devices. This device is designed and intended for ONE-TIME USE ONLY. Do not resterilize and / or reuse.

Carefully observe the instructions under "Do Not" and "Do" below. Failure to do so may result in vessel trauma, guide wire damage, guide wire tip separation, or stent damage. If resistance is observed at any time, determine the cause under fluoroscopy and take remedial action as needed. Use the most suitable guide wire for the lesion being treated.

Do Not:

- Push, auger, withdraw, or torque a guide wire that meets excessive resistance.
- Torque a guide wire if the tip becomes entrapped within the vasculature.
- Allow the guide wire tip to remain in a prolapsed condition.
- Deploy a stent such that it will entrap the wire between the vessel wall and the stent.

Do:

- Advance or withdraw the guide wire slowly.
- Use the radiopaque marker of the interventional device to confirm position.
- Examine the tip movement under fluoroscopy before manipulating, moving, or torquing the guide wire.
- Observe the wire under fluoroscopy for tip buckling, which is a sign of resistance.
- Maintain continuous flush while removing and reinserting the guide wire to prevent air from entering the catheter system. Perform exchanges slowly to prevent air entry and / or trauma.
- When reintroducing the guide wire, confirm that the interventional device tip is free within the vessel lumen and that the tip is parallel to the vessel wall.
- Use extreme caution when moving a guide wire through a non-endothelialized stent, or through stent struts, into a bifurcated vessel. Use of this technique involves additional patient risks, including the risk that the wire may become caught on the stent strut.

PRECAUTIONS

Guide wires are delicate instruments and should be handled carefully. Prior to use and when possible during the procedure, inspect the guide wire carefully for bends, kinks, or other damage. Do not use damaged guide wires. Using a damaged guide wire may result in vessel damage and / or inaccurate torque response.

Confirm the compatibility of the guide wire diameter with the interventional device before actual use.

Free movement of the guide wire within the interventional device is an important feature of a steerable guide wire system, because it gives the user valuable tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guide wire movement.

Never attach the torque device to the modified portion of the proximal end of the extendible guide wire; otherwise, guide wire damage may occur, preventing the ability to attach the DOC™ Guide Wire Extension.

HI-TORQUE Guide Wires with Hydrophilic Coating: Avoid abrasion of the hydrophilic coating. Do not withdraw or manipulate the hydrophilic-coated wire through a metal cannula or sharp-edged object.

ADVERSE EVENTS

Potential Adverse Events associated with use of this device may include the following but not limited to perforation, dissection, occlusion, myocardial infarction, embolism and infection.

Rx ONLY Supera™ Peripheral Stent System

INDICATIONS

The Supera™ Peripheral Stent System is indicated to improve luminal diameter in the treatment of patients with symptomatic *de novo* or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and / or proximal popliteal artery with reference vessel diameters of 4.0 to 7.5 mm, and lesion lengths up to 140 mm.

CONTRAINDICATIONS

The Supera™ Peripheral Stent System is contraindicated in:

- 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.
- Patients who cannot receive antiplatelet or anticoagulation therapy. Based on *in vivo* thrombogenicity testing, the device should not be used in patients who cannot be anticoagulated as there may be some thrombus formation in the absence of anticoagulation.

WARNINGS

- This device is intended for single-use only. Do not reuse. Do not resterilize. Do not use if the package is opened or damaged.
- Use this device prior to the "Use by" date as specified on the device package label. Store in a dry, dark, cool place.
- DO NOT use if it is suspected that the sterility of the device has been compromised.
- Persons with known hypersensitivities to Nitinol and / or its components
- (e.g., nickel-titanium) may suffer an allergic reaction to this implant.
- Administer appropriate antiplatelet therapy pre- and post-procedure.
- Careful attention should be paid when sizing and deploying the stent to prevent stent elongation. In the SUPERB clinical study, stent elongation was associated with a decrease in patency at 12 months.

PRECAUTIONS

The Supera™ Peripheral Stent System should only be used by physicians and medical personnel trained in vascular interventional techniques and trained on the use of this device.

- The long-term safety and effectiveness of the Supera™ Peripheral Stent System has not been established beyond three years.
- The safety and effectiveness of the Supera™ Peripheral Stent System has not been established in patients who:
  - are less than 18 years old
  - are pregnant or lactating
  - have in-stent restenosis of the target lesion
  - have known hypersensitivity to any component of the stent system (e.g., nickel)
  - cannot tolerate contrast media and cannot be pre-treated
  - have uncontrolled hypercoagulability and / or another coagulopathy

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IMPORTANT SAFETY INFORMATION (CON'T)

- This device is not designed for use with contrast media injection systems or power injection systems.
- The flexible design of the Supera™ stent may result in variation in the deployed stent length.

Magnetic Resonance Imaging (MRI) Safety Information

Nonclinical testing has demonstrated that the Supera™ stent, in single and in overlapped configurations up to 250 mm in length, is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial gradient magnetic field of 2,500 Gauss/cm (25 T/m)
- Maximum MR whole-body-averaged specific absorption rate (SAR) of
  - 2 W/kg for landmarks (i.e., center of RF coil) above the umbilicus
  - 1 W/kg for landmarks below the umbilicus and above the mid-thigh
  - 0.5 W/kg for landmarks below the mid-thigh

Under the scan conditions defined above, the Supera™ stent is expected to produce a maximum temperature rise of 7.6 °C after 15 minutes of continuous scanning.

In nonclinical testing, the image artifact caused by the device extends approximately 2 cm from the Supera™ stent when imaged with a gradient echo or spin echo sequence and a 3T MRI system

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to:

- Abrupt closure
- Allergic reaction (contrast medium; drug; stent material)
- Amputation or limb loss
- Aneurysm or pseudoaneurysm in vessel or at vascular access site
- Angina or coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial or ventricular tachycardia, atrial or ventricular fibrillation)
- Arteriovenous fistula
- Bleeding complications requiring transfusion or surgical intervention
- Death
- Detachment of a system component or implantation in an unintended site
- Embolization, arterial or other (e.g., air, tissue, plaque, thrombotic material, or stent)
- Emergent surgery
- Fever
- Hematoma or hemorrhagic event, with or without surgical repair
- Hyperperfusion syndrome
- Hypertension / hypotension
- Infection
- Myocardial infarction
- Pain (leg, foot, and / or insertion site)
- Partial stent deployment
- Peripheral nerve injury
- Pulmonary embolism
- Renal failure or insufficiency
- Restenosis of vessel in stented segment
- Shock
- Stent malapposition or migration, which may require emergency surgery to remove stent
- Stent strut fracture
- Thrombosis or occlusion
- Stroke
- Transient ischemic attack
- Venous thromboembolism
- Vessel dissection, perforation, or rupture
- Vessel spasm or recoil
- Worsening claudication or rest pain

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *manuals.eifu.abbott* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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