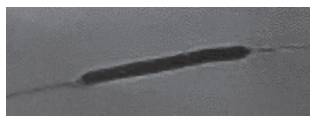
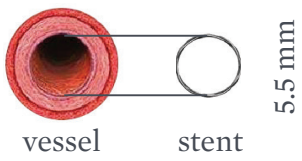
Supera™
Peripheral Stent System

THREE KEYS FOR OPTIMAL STENT DEPLOYMENT

1 PRE-DILATE
- Pre-dilate the lesion to ≥ the outer diameter of the stent
- Longer inflation times recommended

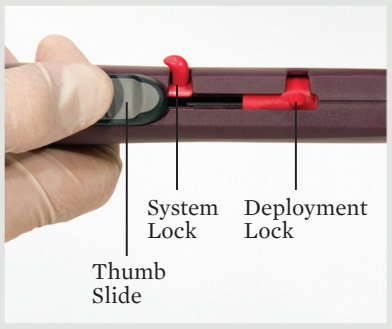


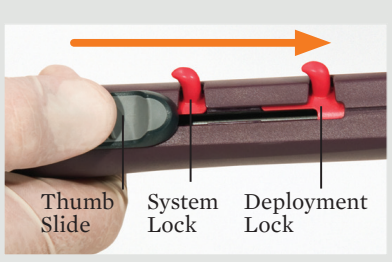
2 SIZE 1:1
- Match stent size 1:1 to vessel diameter
- Do not oversize the stent

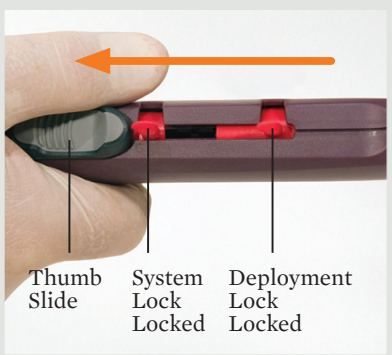


3 DEPLOY SLOWLY
- Magnify imaging to observe cell geometry
- Use short, even throws of the Thumb Slide
- Open the Deployment Lock and fully advance Thumb Slide to completely release the stent
- Visually confirm stent release
- Retract the tip and lock the Thumb Slide before withdrawal
- Post-dilate as needed

Deployment Steps and Technique

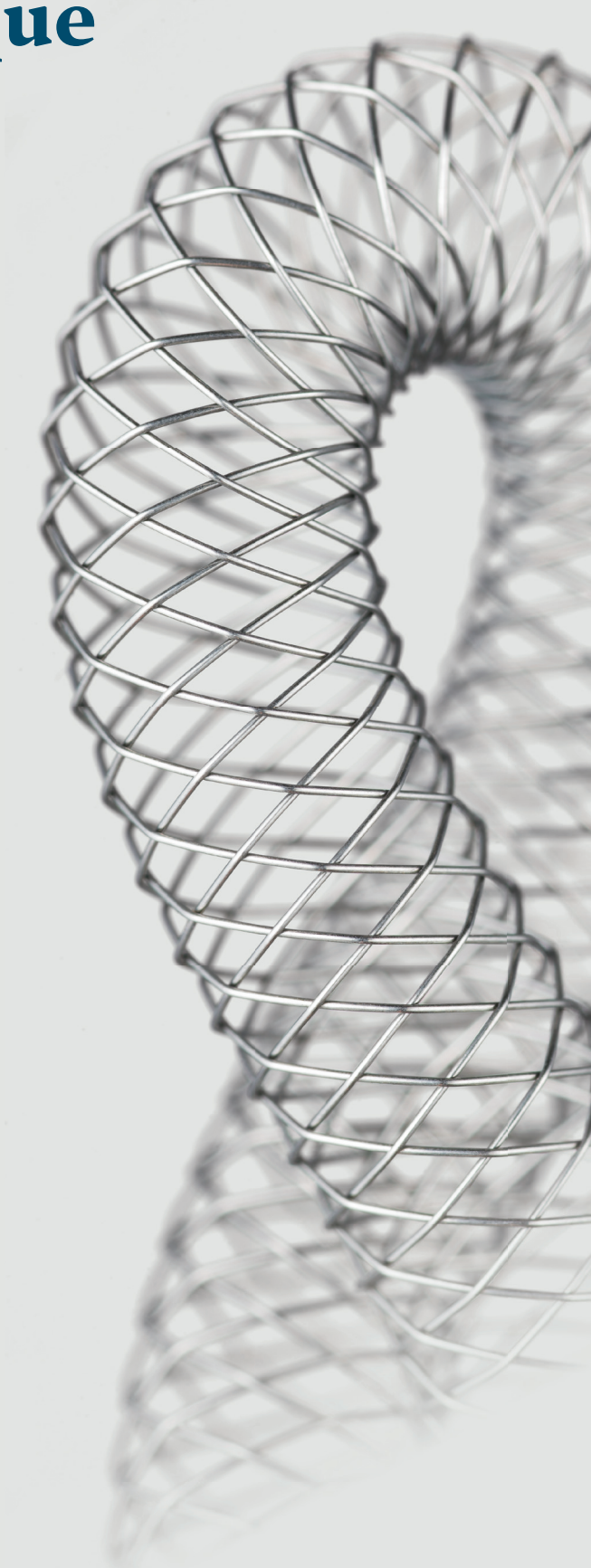






1. Flush the delivery system with saline, wipe the outer sheath to activate the hydrophilic coating, and load the distal end of the tip onto a 0.014″ or 0.018″ guide wire.
2. Advance the catheter until the Distal Sheath Marker and Stent Length Marker encompass the target lesion.
3. Rotate only the System Lock to the unlocked position.
4. Increase and maintain magnification for entire procedure to better visualize stent deployment.
5. Under fluoroscopy, initiate stent deployment by advancing the Thumb Slide while allowing the outer sheath to retract proximally.
6. Under fluoroscopy, continuously and slowly retract and advance the Thumb Slide multiple times. Shorter Thumb Slide advancements may provide greater control. Repeat until Thumb Slide advancement no longer deploys the stent.
7. Rotate the Deployment Lock to the unlocked position and fully advance the Thumb Slide to completely release the stent.
8. Confirm under fluoroscopy that the entire stent is released.
9. Fully retract the Thumb Slide to the starting position, then rotate the System Lock and Deployment Lock into the locked position.
10. Remove the device under fluoroscopy.
11. Post-dilate as needed.

Prior to use, see Supera™ IFU.



SUPERA™ IS LIKE NO OTHER STENT

See Important Safety Information on reverse.

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 6.5 mm, and lesion lengths up to 140 mm.

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IMPORTANT SAFETY INFORMATION

℞ ONLY

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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 hypercoaguability and / or other coagulopathy
- 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)

A patient with this device can be scanned safely only under specific conditions. Failure to follow the conditions may result in severe injury.

Non-clinical testing has demonstrated the Supera™ Stents are MR conditional for lengths up to 250 mm. A patient with this stent can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Highest spatial gradient magnetic field of 2,500 Gauss/cm or less
- 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 for 15 minutes of scanning (per pulse sequence), operating in the Normal Operating Mode (i.e., MR system mode of operation where there is no physiological stress to the patient). The legs of the patient should not be touching during the procedure.

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 *eifu.abbottvascular.com* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

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