Abbott

CREATING THE FUTURE OF HEALTH

WITH LIFE-CHANGING TECHNOLOGY

HOSPITAL EFFICIENCY REDEFINED

WITH ABBOTT'S HEMOSTASIS MANAGEMENT SOLUTIONS

Perclose ProGlide™
Suture-Mediated
Closure System

Prostar XL™
Percutaneous Vascular
Surgical System

StarClose SE™
Vascular Closure
System

FemoStop™ Gold
Compression
Assist Device

RadiStop™
Compression
Assist Device

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

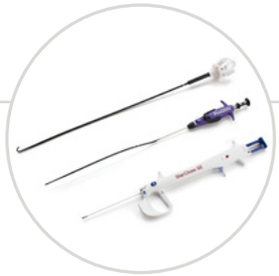
Information contained herein for DISTRIBUTION in the U.S. only.

WE'VE GOT YOU COVERED

Abbott is committed to providing hemostasis management solutions to help patients and hospitals thrive. Time management, patient and staff flow, hospital costs, and throughput can all impact overall hospital efficiency. Our hemostasis management portfolio aims to drive hospital efficiency through:

- ✓ Early ambulation
- ✓ Reducing patient length of stay
- ✓ Lowering complications
- ✓ Improving patient outcomes
- ✓ Optimizing nursing time
- ✓ Driving overall hospital efficiency
- ✓ Improving patient flow

Our portfolio offers complete solutions for arterial and venous access procedures such as Coronary, Peripheral, Electrophysiology and Structural Heart.



VASCULAR CLOSURE SYSTEMS

	ARTERIAL ACCESS	VENOUS ACCESS
Perclose ProGlide™ SMC System	5-21F [Max OD 26F[1]]	5-24F [Max OD 29F[1]]
StarClose SE™ VC System	5-6F	–
Prostar XL™ PVS System	8.5-10F	–

COMPRESSION ASSIST SYSTEMS

FOR FEMORAL ARTERY OR VEIN

FemoStop™ Gold Compression Assist Device

FOR RADIAL ARTERY

RadiStop™ Compression Assist Device

1. Tests performed by and data on file at Abbott. (Max. OD 26F = 0.340 inches = 8.62 mm; Max. OD 29F = 0.378 inches = 9.59 mm).

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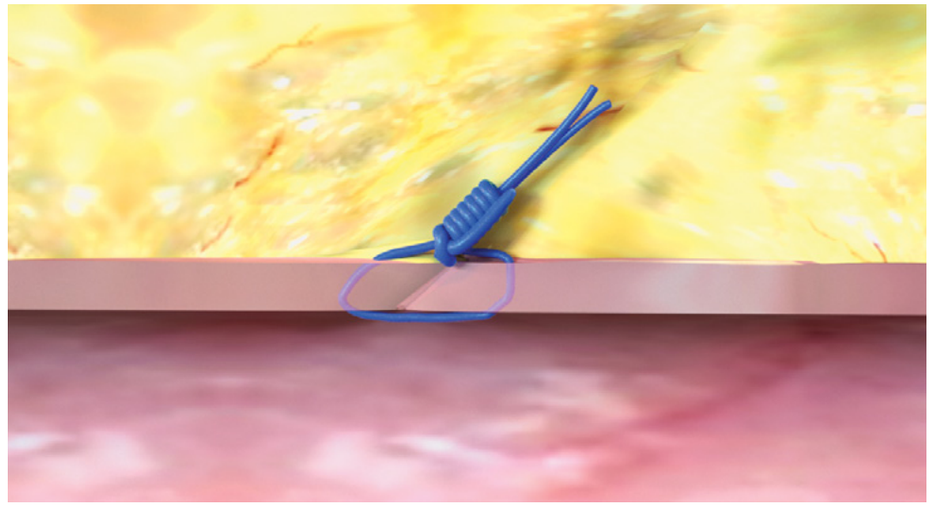
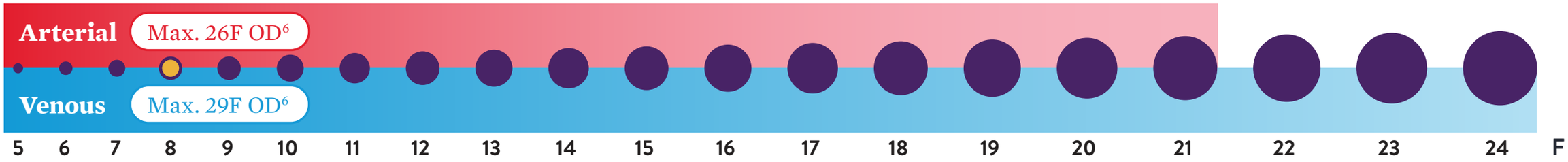
DON'T JUST CLOSE. REPAIR.

Perclose ProGlide™ SMC System delivers a secure, non-masking percutaneous suture to the access site that promotes primary healing[1] and has no re-access restrictions[2]. In addition, the device offers the following benefits:

- Reduced time to hemostasis, ambulation and discharge compared to manual compression[2,3]
- Ability to challenge and confirm closure on the table[2]
- Minimized inflammatory response[2]
- Significantly lower blood transfusions, infections, mortality, and shorter length of stay compared to surgical cutdown for large bore-arterial access[4]
- Low major access site-related complications for large-bore venous access[5]



PERCLOSE PROGLIDE™ SMC SYSTEM HAS THE BROADEST INDICATION* FOR BOTH FEMORAL ARTERIAL AND VENOUS ACCESS.



*As compared to MANTA‡, Angio-Seal‡, Celt ACD‡, ExoSeal‡, Mynx‡, Vascade‡. Data on file at Abbott.

1. Primary intention healing occurs where vessel wall edges are brought together, adjacent to each other. This can be achieved with sutures and other methods. Advances in Skin & Wound Care: Healing by Intention. Salcido, Richard. 2017. 2. U.S. Perclose ProGlide SMC System Instructions for Use. 3. Time to hemostasis, ambulation and discharge applies to the arterial access. U.S. Perclose ProGlide SMC System Instructions for Use. 4. Perclose ProGlide Versus Surgical Closure Outcomes - Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018. 5. The Use of the Perclose ProGlide Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. Kar, Saibal; Hermiller, James; et al. CRT 2018. 6. For sheath sizes greater than 8F, at least two devices and pre-close technique are required. U.S. Perclose ProGlide SMC System Instructions for Use. Tests performed by and data on file at Abbott. (Max. OD 26F = 0.340 inches = 8.62 mm; Max. OD 29F = 0.378 inches = 9.59 mm).

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MAXIMIZING EFFICIENCY AND OUTCOMES FOR EP LABS

The Perclose ProGlide™ Suture-Mediated Closure System is used in Electrophysiology procedures to help increase lab efficiency, minimize avoidable costs, and enhance the patient experience[1].

THE PERCLOSE PROGLIDE™ ADVANTAGE

IMMEDIATE AND DURABLE HEMOSTASIS
Can be confirmed and challenged on the table[2] while patient is on full-dose anticoagulants[3].

FDA APPROVED
for use in common femoral veins with small and large sheaths (5F-24F[2], Max OD 29F[4]).

2 AMBULATION IN 2 HOURS[2]

1.9% Low Major Complication Rate[5]

NO Late Recurrences of Bleeding[2]

THE USE OF PERCLOSE PROGLIDE™ SMC SYSTEM CAN HELP:

INCREASE EP Lab Efficiency	MINIMIZE Avoidable Costs	ENHANCE Patient Experience
Faster Hemostasis and Ambulation	X Monitoring	Shorter Bed Rest and Hospital Stay
Optimization of Clinical Resources	X Re-Bleeding	Less Pain Medication
Faster Patient Turnover	X In-Patient Stay	Less Need For Foley Catheter
	X Pain Medication	
	X Foley Catheter UTI's	
	X Access-Site Complications	

1. S. Verma. Adopting a Strategy of Early Ambulation and Same-Day Discharge for Atrial Fibrillation Ablation Cases - EP Lab Digest - May 2019 2. U.S. Perclose ProGlide SMC System Instructions for Use. 3. Mahavdaven VS et al. Pre-closure of femoral venous access sites used for large-sized sheath insertion with the Perclose device in adults undergoing cardiac intervention. 4. Max. OD 29F/0.378 inches/9.59 mm. Tests performed by and data on file at Abbott. 5. Kar S, et al. The Use of the Perclose ProGlide Suture-Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. CRT 2018.

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UNIQUE SYSTEMS TO MEET YOUR NEEDS

STARCLOSE SE™ VASCULAR CLOSURE SYSTEM

StarClose SE™ Vascular Closure System is indicated for 5-6F arterial access procedures and provides safe, easy and extravascular percutaneous closure for diagnostic or interventional procedures.

StarClose SE™ Vascular Closure System

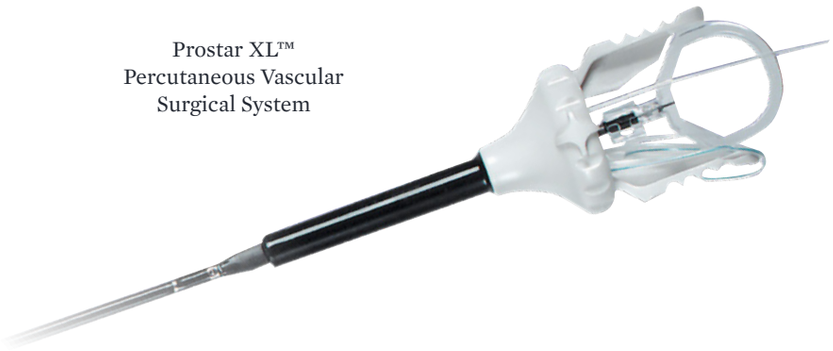
3.5 min[1*+] | 8.3 min[1+] | 60.8 min[1+]

HEMOSTASIS | AMBULATION | DISCHARGE

PROSTAR XL™ PERCUTANEOUS VASCULAR SURGICAL SYSTEM

Prostar XL™ Percutaneous Vascular Surgical System is indicated for 8.5-10F arterial access sites and uses two braided sutures to provide secure closure. When compared to manual compression, Prostar XL™ PVS System reduces time to hemostasis, ambulation, and discharge[2].

Prostar XL™ Percutaneous Vascular Surgical System



*RISE subjects received a protocol-required three-minute groin hold.

+Diagnostic patients in the RISE study.

1. Burke et al. StarClose Vascular Closure System (VCS) is Safe and Effective in Patients Who Ambulate Early Following Successful Femoral Artery Access Closure - Results from the RISE Clinical Trial. CCI 2012, 80:45-52. 2. Baim, Donald S., et al. "Suture-mediated closure of the femoral access site after cardiac catheterization: results of the suture to ambulate and discharge (STAND I and STAND ii) trials." American Journal of Cardiology 85.7 (2000): 864-869.

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HANDS-FREE RELIABLE COMPRESSION

FEMOSTOP™ GOLD COMPRESSION ASSIST DEVICE

The FemoStop™ Gold Compression Assist Device uses hands-free compression of the femoral artery or vein to offer precise hemostasis management and patient comfort.

- The adjustable belt fits securely so that small patient movements may not cause the device to slip and patients can rest comfortably
- Hands-free compression
  - Allows multiple patients to be monitored at one time, increasing staff efficiency
  - Minimizes staff exposure to blood and reduces neck, arm and wrist fatigue

FemoStop™ Gold Compression Assist Device

RadiStop™ Compression Assist Device

RADISTOP™ COMPRESSION ASSIST DEVICE

The RadiStop™ Compression Assist Device provides hands-free, reliable compression after cannulation of the radial artery and enhanced support of the patient's hand for improved comfort.

- The plate provides support and distributes the pressure over the back of the wrist to ensure that the venous flow is not obstructed
- The interventionalist can use RadiStop™ before, during, and after the procedure to fixate the wrist in a flexed position which allows easier access to the radial artery

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ORDERING INFORMATION

Perclose ProGlide™ Suture-Mediated Closure System (5-21F Arterial, 5-24F Venous)

PRODUCT CODE	DESCRIPTION	QUANTITY
12673-03	(1) Perclose ProGlide™ 6F Suture Mediated Closure Device, (1) Suture Trimmer, (1) Snared-Knot Pusher	10 per box

StarClose SE™ Vascular Closure System (5-6F Arterial)

PRODUCT CODE	DESCRIPTION	QUANTITY
14679-01	(1) Clip Applier, (1) 0.038″ 50 cm J-Tip Guide Wire, (1) 6F Dilator, (1) 6F Exchange Sheath	10 per box

Prostar XL™ Percutaneous Vascular Surgical System (8.5-10F Arterial)

PRODUCT CODE	DESCRIPTION	QUANTITY
12322-01	(1) Prostar XL™ Percutaneous Vascular Surgical System, (1) Knot Pusher	5 per box

FemoStop™ Gold Compression Assist Device (Arterial and Venous)

PRODUCT CODE	DESCRIPTION	QUANTITY
C11165	(1) Compression Arch with Pneumatic Dome, (1) Integrated Digital Manometer, (1) Adjustable Belt, (1) Pinch Clamp	10 per box

RadiStop™ Compression Assist Device (Arterial)

PRODUCT CODE	DESCRIPTION	QUANTITY
C11177	RadiStop™ Compression Assist Device	10 per box

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

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IMPORTANT SAFETY INFORMATION

Perclose ProGlide™ Suture-Mediated Closure (SMC) System

INDICATIONS

The Perclose ProGlide™ SMC System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide™ SMC System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths.

For access sites in the common femoral vein using 5F to 24F sheaths.

For arterial and venous sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and / or interventional catheterization procedures and who has been trained by an authorized representative of Abbott Vascular.

Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

During closure of access sites using a procedural sheath greater than 8F it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to close the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device. Attention is drawn to the WARNINGS and PRECAUTIONS sections.

WARNINGS

Do not use the Perclose ProGlide™ SMC device or accessories if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Perclose ProGlide™ SMC device and accessories are intended for single use only.

Do not use the Perclose ProGlide™ SMC System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral artery or vein.

Do not use the Perclose ProGlide™ SMC System if the puncture is through the posterior wall or if there are multiple punctures, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose ProGlide™ SMC System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, or the bifurcation of these vessels, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral artery or vein.

PRECAUTIONS

1. Prior to use, inspect the Perclose ProGlide™ SMC System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
2. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose ProGlide™ SMC System. Employ appropriate groin management, as per hospital protocol, post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the vessel.
4. Do not deploy the Perclose ProGlide™ SMC device at an angle greater than 45 degrees, as this may cause a cuff miss.
5. There are no reaccess restrictions if previous access site repairs were achieved with Abbott Vascular SMC devices.
6. If significant blood flow is present around the Perclose ProGlide™ SMC device, do not deploy needles. Remove the Perclose ProGlide™ SMC device over a 0.038" (0.97mm) (or smaller) guidewire and insert an appropriately sized introducer sheath.
7. When pushing the plunger assembly to advance the needles, stabilize the device to ensure the device does not twist or move forward during deployment. Twisting the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly push the plunger assembly. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
8. Do not apply excessive force to the lever when returning the foot to its original position **(marked #4)** down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever of the device or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.
9. **Do not advance or withdraw the Perclose ProGlide™ SMC device against resistance until the cause of that resistance has been determined** (see Section **11.3** Single SMC DEVICE PLACEMENT section). **Excessive force used to advance or torque the Perclose ProGlide™ SMC device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.**
10. If excessive resistance in advancing the Perclose ProGlide™ SMC device is encountered, withdraw the device over a 0.038" (0.97 mm) (or smaller) guidewire and reinsert the introducer sheath or use manual compression.
11. Remove the Perclose ProGlide™ sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. In using this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.
13. During closure of access sites using a 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC device.
14. During closure of access sites using a procedural sheath > 8F, in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC devices, the physician should assess the situation. Based on the physician assessment of the amount of bleeding use manual compression, compression assisted devices and / or a surgical repair to obtain hemostasis.
15. During closure of access sites using a procedural sheath > 8F, in those cases where the implanting physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary surgical intervention.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use of suture mediated closure devices may include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to device components
- Anemia
- Arterial stenosis / occlusion
- Arteriovenous fistula
- Bleeding / hemorrhage
- Bruising / hematoma
- Death
- Deep vein thrombosis
- Device entrapment
- Device failure / malfunction / misplacement
- Diminished pulses distal to closure site
- Embolism
- Hypotension / hypertension
- Infection / sepsis
- Inflammation
- Intimal tear / dissection
- Ischemia distal to closure site
- Nerve injury
- Numbness
- Pain
- Perforation
- Pseudoaneurysm
- Pulmonary embolism
- Retroperitoneal hematoma / bleeding
- Thrombus formation
- Vascular injury
- Vasoconstriction / vasospasm
- Vasovagal episode
- Wound dehiscence

PROSTAR XL™ Percutaneous Vascular Surgical System

INDICATIONS FOR USE

The Prostar XL™ PVS System is indicated for the percutaneous delivery of sutures for closing the common femoral artery access site and reducing the time to hemostasis and time to ambulation (patient walks ten feet) of patients who have undergone catheterization procedures using 8.5F to 10F sheaths. (Refer to PRECAUTIONS, SPECIAL PATIENT POPULATIONS sections).

CONTRAINDICATIONS

None known.

WARNINGS

The outer pouch of the Prostar XL™ PVS System and the individual accessories provides the sterile barrier. Do not use the Prostar PVS System or accessories if the packaging or sterile barrier have been previously opened or damaged, or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Prostar XL™ PVS System and accessories are intended for single use only.

Do not use the Prostar XL™ PVS System if the puncture site is proximal to the inguinal ligament as this may result in a retroperitoneal hematoma.

PRECAUTIONS

1. The Prostar XL™ PVS device and accessories should only be used by physicians (or other healthcare professionals authorized by or under the direction of such physicians) after they have been trained in the use of the Prostar XL™ PVS System and accessories, e.g., participation in a Prostar XL™ PVS System training program or equivalent.
2. Observe sterile technique at all times when using the Prostar XL™ PVS System. Employ appropriate groin management, as per hospital protocol, post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the artery.
4. Adequate knot security requires accepted surgical technique as warranted by surgical circumstances and the experience of the operator.
5. There are no reaccess restrictions if previous arteriotomy repairs were achieved with an Abbott Vascular Suture Mediated Device.
6. Do not insert the Prostar XL™ device into the femoral artery at an angle greater than 45 degrees to the longitudinal plane of the artery.
7. **Do not advance or withdraw the Prostar XL™ device against resistance until the cause of that resistance has been determined** (see CLINICAL PROCEDURE-Device Placement section). **Excessive force used to advance or torque the Prostar XL™ device should be avoided as it may lead to significant arterial damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and arterial repair.**
8. If excessive resistance in advancing the Prostar XL™ device is encountered, withdraw the Prostar XL™ device over a 0.038" (or smaller) guide wire and reinsert the introducer sheath or use conventional compression therapy.
9. In the event suture breakage occurs after an initial knot has been tied, care should be taken to avoid excessive force if the reintroduction of the Prostar XL™ device or introducer sheath is required. Any resistance to introduction should result in advancement of an introducer sheath small enough to be introduced without undue force.
10. If significant blood flow is evident through or around the barrel of the Prostar XL™ device, do not deploy needles. Remove the Prostar XL™ device over a 0.038" (or smaller) guide wire and insert an appropriately sized introducer sheath.
11. Remove the Prostar XL™ sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. Do not attempt to re-deploy Prostar XL™ needles after the needles have been "backed-down" into the sheath (refer to the **TECHNIQUE FOR NEEDLE BACK-DOWN** section).
13. In the event bleeding from the femoral access site persists after the use of the Prostar XL™ device and accessories, use conventional compression therapy.

ADVERSE EVENTS

The following adverse events have been reported and may occur include

• Device Malfunction • Device Complication • Vascular Repair • Ultrasound Guided Compression • Transfusion • Infection Requiring IV Antibiotics • Hematoma > 6 cm • AV Fistula • Nerve Injury • Pseudoaneurysm

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IMPORTANT SAFETY INFORMATION (CONT.)

StarClose SE™ Vascular Closure System

INDICATIONS FOR USE

The StarClose SE™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis, ambulation, and dischargeability in patients who have undergone diagnostic endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

The StarClose SE™ Vascular Closure System is indicated for use to allow patients who have undergone diagnostic endovascular catheterization procedures to ambulate and be eligible for discharge as soon as possible after device placement.

The StarClose SE™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis and ambulation in patients who have undergone interventional endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.

CAUTION

Federal law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and therapeutic catheterization procedures and who has been trained by an authorized representative of Abbott Vascular.

Prior to use, the operators must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

CONTRAINDICATIONS

The StarClose SE™ Vascular Closure System is contraindicated for use in patients with known hypersensitivity to nickel-titanium.

WARNINGS

Do not use the StarClose SE™ Vascular Closure System if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The StarClose SE™ Vascular Closure System and accessories are intended for single use only.

Do not use the StarClose SE™ Vascular Closure System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the StarClose SE™ Vascular Closure System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site.

Do not use the StarClose SE™ Vascular Closure System if the puncture is through the posterior wall or if there are multiple punctures, since such punctures may result in a retroperitoneal hematoma.

Do not use the StarClose SE™ Vascular Closure System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen).

Perform a femoral angiogram to verify the location of the puncture site.

PRECAUTIONS

1. The StarClose SE™ Vascular Closure System should be used only by operators trained in diagnostic and interventional catheterization procedures who have been certified by an authorized representative of Abbott Vascular Inc.

2. The StarClose SE™ Vascular Closure System is provided sterile and non-pyrogenic in unopened, undamaged packaging. Products are sterilized with ethylene oxide and intended for single use only. Do not resterilize. Store in a cool, dry place.

3. Prior to use, inspect the StarClose SE™ Vascular Closure System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.

4. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the StarClose SE™ Vascular Closure System. Employ appropriate groin management, as per hospital protocol, post-procedure and post-hospital discharge to prevent infection.

5. Use a single wall puncture technique. Do not puncture the posterior wall of the artery.

6. Do not use the StarClose SE™ Vascular Closure System to close vessels with diameters less than 5 mm.

7. Do not deploy the Clip in areas of calcified plaque.

8. The StarClose SE™ Vascular Closure System can ONLY be used with the StarClose Exchange System (included in the StarClose SE™ Vascular Closure System packaging).

9. **Do not advance or withdraw the StarClose SE™ Vascular Closure Device against resistance until the cause of that resistance has been determined.** Excessive force used to advance or torque the StarClose SE™ device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate interventional and / or surgical removal of the device and vessel repair.

ADVERSE EVENTS

Potential adverse events that could be associated with the use of this device include:

Major Vascular Complications • Vascular Injury Requiring Repair • Surgery • Angioplasty • Ultrasound Guided Compression • Thrombin Injection or Other Percutaneous Procedure • New Ipsilateral Lower Extremity Ischemia • Access

Site-related Bleeding Requiring Transfusion • Access Site-related Infection Requiring Intravenous Antibiotics or Prolonged Hospitalization • Access Site-related Nerve Injury Requiring Intervention • Death • Minor Vascular Complications • Pseudoaneurysm • Arteriovenous Fistula • Hematoma (≥ 6 cm) • Late Access Site-related Bleeding • Transient Lower Extremity Ischemia • Ipsilateral Deep Vein Thrombosis • Transient Access Site-related Nerve Injury • Access Site-related Vessel Injury • Access Site Wound-related Dehiscence • Access Site-related Bleeding Requiring ≥ 30 minutes to Re-achieve Hemostasis • Localized Access Site Infection Treated with IM or Oral Antibiotics • UADE

FemoStop™ Gold Femoral Compression System

INDICATIONS FOR USE

The FemoStop™ Femoral Compression System is indicated for use in the compression of the femoral artery or vein after vessel cannulation and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.

CONTRAINDICATIONS

- Severe peripheral vascular disease due to the risk of arterial thrombosis.
- Critical limb ischemia.
- Overlying skin necrosis and/or infection.
- Arterial injuries above or near the inguinal ligament.
- The inability to adequately compress due to e.g. coexisting very large hematomas, excessive pain or discomfort (despite anesthetics/analgesics).
- Patients not suitable for compression of their femoral artery due to leg edema, femoral nerve compression, or arterial obstruction.
- Femoral artery graft or vein graft due to the risk of damage.
- Ultrasound-guided compression repair of infected femoral pseudoaneurysms.

WARNINGS

- For one time use only. Do not reuse or resterilize. Do not use if the original sterile package is not intact. Inspect the system carefully prior to use to verify that all parts are present and undamaged.
- Reuse after cleaning attempts, resterilization and repackaging may result in patient/user infections, product deterioration leading to, e.g. reduced concentration of dome pressure, causing bleeding. Do not disassemble or attempt to repair the system.
- Adequate compression may not be obtained in markedly obese patients.
- Avoid releasing pressure suddenly to reduce any risk of flushing thrombotic material into the artery. Release of thrombotic material may result in embolization which could lead to patient injury.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may occur. A brief interruption at least every three hours of pressure is recommended during long compression periods. Inappropriately long compression and/or immobilization may increase the risk for thrombosis or embolization which could lead to patient injury or death.
- If arterial/venous hemostasis is not achieved, significant bleeding may occur which could result in patient injury or death.
- While removing the sheath, ensure that the pressure applied is kept low, to avoid damage to the vessel or a "milking" effect. Allowance for slight bleeding at the site is preferred to preclude introduction of thrombus to the vessel.
- To prevent limb ischemia, do not leave artery completely blocked for more than 3 minutes. Check pedal pulse periodically to confirm whether or not flow remains in the vessels.
- To minimize the risk for arterial/venous fistula formation, venous hemostasis should be achieved prior to removal of the arterial sheath.
- Do not apply pressure to a femoral artery stent due to risk of damage.

PRECAUTIONS

- The FemoStop™ Femoral Compression System should only be used for compression of the femoral artery or vein after vessel cannulation by or on the order of physicians trained in femoral artery or vein compression procedures.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- When removing the sheath for an Intra-Aortic Balloon Pump (IABP), the Instruction for Use for the IABP should be followed as appropriate.
- For successful compression, the system must be snug and secure around the patient's hips before pressure is applied. Do not over-tighten the belt.
- For successful compression, the system must be correctly positioned throughout the procedure so that pressure is applied to the point intended.
- On very obese patients, it may be necessary to tighten the belt slightly more to enhance downward compression.
- When using the system on obese patients, fatty tissue may be displaced giving a false impression of a developing hematoma.
- Placement of the system may not be suitable on large patients, or patients with very wide hips as the belt may be too short. An abdominal strap/tape may be used to pull excessive adipose tissue away from dome.
- The target inflation pressure should be 10-20mmHg above the systolic pressure, or higher if necessary to control the bleeding. Exceeding pressures of 200mmHg may indicate the need to tighten the belt or reposition the dome.
- Careful monitoring of the dome pressure during the initial period of use is recommended, as the elastic material of the dome may stretch slightly during the first few minutes. You may notice a slight drop in pressure on the manometer. If this occurs, reinflate to initial pressure.
- Ensure that the control knob on the pump is closed when increasing the pressure and open when decreasing the pressure.
- Ensure that the pinch clamp is open when increasing or decreasing the pressure.
- Use of the FemoStop™ Femoral Compression System is not intended to replace careful monitoring of the patient's puncture site. The patient should not be left completely unattended during the time of compression.
- The compression system is for single use only.
- Avoid exposing the pump to any liquid.
- After use, this product may be a potential biohazard. Handle and dispose of all such devices in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- The temperature range on the label represents the temperature for long-term storage.

ADVERSE EVENTS

Possible adverse effects that may result from the use of this device include but are not limited to:

- tissue necrosis
- blistering of the skin/skin abrasion
- compression injuries to nerves with subsequent sensory and motor deficits
- femoral artery and/or vein thrombosis
- embolization
- bleeding or hematoma
- arterio-venous fistula or pseudoaneurysm
- acute distension or rupture of a pseudoaneurysm during compression repair

Additional warnings and precautions for ultrasound-guided compression repair of a pseudoaneurysm in the femoral artery

WARNINGS

- To prevent limb ischemia, do not leave artery completely blocked for more than 3 minutes.
- Use color Doppler to periodically confirm whether or not flow remains in the vessels.
- Do not leave the system on the patient for inappropriately long compressions, as tissue damage may occur.
- During long compression periods, pressure should be briefly interrupted at least every three hours. Use manual compression during this break to limit new flow into the pseudoaneurysm.
- Inappropriately long compression and/or immobilization may increase the risk for thrombosis or embolization which could lead to patient injury or death.

PRECAUTIONS

- The FemoStop™ Femoral Compression System should only be used for ultrasound-guided compression repair of a pseudoaneurysm in the femoral artery, by physicians trained in the treatment of pseudoaneurysm.
- Remove any residual ultrasound gel from the skin overlying the point to be compressed as it may cause the system to slip out of position during the application of pressure.
- Exceeding pressures of 200mmHg may indicate the need to tightly secure the belt or reposition the arch.

Information contained herein for DISTRIBUTION in the U.S. only.

IMPORTANT SAFETY INFORMATION (CONT.)

℞ ONLY RadiStop™
Compression Assist Device

INDICATIONS

RadiStop™ Compression Assist Device is indicated in the compression of the radial artery after catheterization.

CONTRAINDICATIONS

RadiStop™ Compression Assist Device is contraindicated in patients who do not have two functional arteries (ulnar and radial). RadiStop™ Compression Assist Device should not be used on patient having an abnormal Allen's test.

WARNINGS

- For one time use only. Do not resterilize or reuse. Inspect the sealed sterile packaging prior to use. Do not use if the original sterile package is not intact. Reuse after cleaning attempts, resterilization and repackaging may result in patient/user infections.
- Do not leave the system on for inappropriately long compressions, as tissue damage may be produced. A brief interruption every three (3) hours of pressure is recommended during long compression periods.
- Do not use RadiStop™ Compression Assist Device without the support plate. The support plate ensures that the venous flow is not obstructed.

PRECAUTIONS

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Use of RadiStop™ Compression Assist Device is not intended to replace careful monitoring of the patient's puncture site.
- The patient should not be left completely unattended during the time of compression.

ADVERSE EVENTS

Potential complications which may be encountered during catheterization via the radial route include but are not limited to puncture of the posterior wall of the artery, artery occlusion, hematoma, paresthesia and ischemia.

CAUTION: These products are intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at *www.vascular.eifu.abbott* 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.

Information contained herein for DISTRIBUTION in the U.S. only.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.cardiovascular.abbott
 MAT-2005840 v1.0

Abbott

Perclose ProGlide®

Suture-Mediated Closure System

DON'T JUST CLOSE.

REPAIR.

TO LEARN MORE, VISIT
WWW.ABBOTTVESSELCLOSURE.COM

INDICATIONS

The Perclose ProGlide SMC System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide SMC System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths.

For access sites in the common femoral vein using 5F to 24F sheaths.

For arterial and venous sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

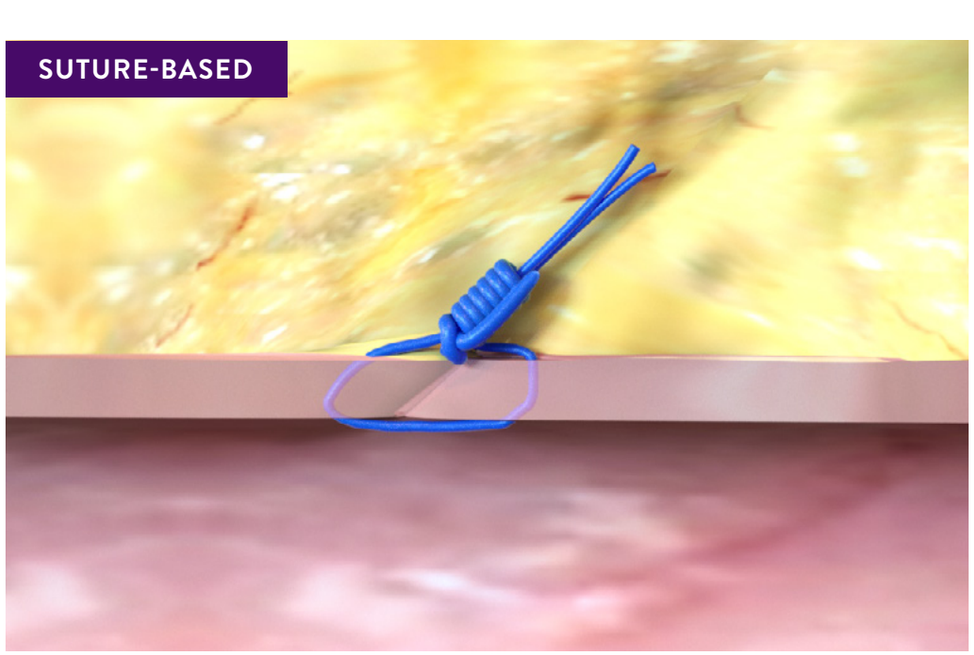
IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

Abbott

DON'T JUST CLOSE. REPAIR.

Perclose ProGlide® provides percutaneous surgical repair with a suture by delivering a secure, non-masking percutaneous repair. Perclose ProGlide® promotes primary intention healing[1] with less scarring[2] and reduces time to hemostasis, ambulation, and discharge[3,4].

SUTURE-BASED

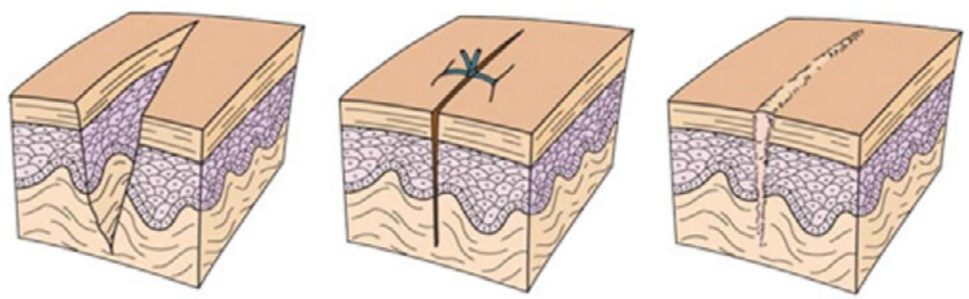


The use of Perclose ProGlide® for repair of large-bore arterial access is associated with significantly lower blood transfusions, infections, mortality, and length of stay compared to cutdown[5].

The use of Perclose ProGlide® for large-bore venous access is also associated with low major access site-related complications[6].

PRIMARY INTENTION

Primary Wound Healing With Suture Repair



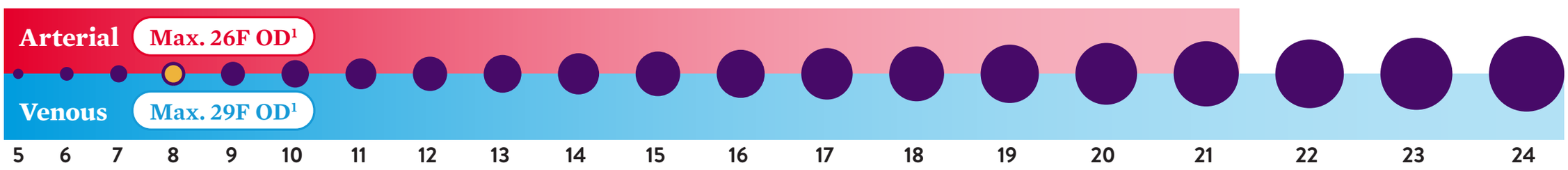
Clean Incision | Early Suture | "Hairline" Scar

1. Primary intention healing occurs where vessel wall edges are brought together, adjacent to each other. This can be achieved with suture, stitches, staples, and clips.
2. Mercandetti, Michael. Wound Healing and Repair. Medscape. WebMD, 19 May 2017. Web. March 21, 2018.
3. Time to hemostasis, ambulation, and discharge applies to the arterial access.
4. U.S. Perclose ProGlide® Instructions for Use.
5. Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.
6. The Use of the Perclose ProGlide Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. Kar, Saibal; Hermiller, James; et al. CRT 2018.

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

BROADEST INDICATION*

The Perclose ProGlide® vascular closure system has the **broadest indication for both femoral arterial and venous access**



For Common Femoral Access Sites

		Max. OD[1]
Artery	5-21F[2]	26F
Vein	5-24F[2]	29F

*As compared to Angio-Seal®, Celt ACD®, ExoSeal®, Mynx®, Vascade®. Data on file at Abbott.

1. Max. OD 26F/0.340 inches/8.62 mm; Max. OD 29F/0.378 inches/9.59 mm. Tests performed by and data on file at Abbott.
2. For sheath sizes greater than 8F, at least two devices and pre-close technique are required.

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

BROADEST INDICATION* FOR BOTH FEMORAL ARTERIAL AND VENOUS ACCESS

PARALLELS THE SURGICAL GOLD STANDARD

- Associated with significantly lower blood transfusions, infections, mortality, and shorter length of stay compared to surgical cutdown[1]
- Secure repair with pre-tied polypropylene monofilament suture
- Minimal intravascular footprint

PROMOTES VESSEL HEALING

- Minimized inflammatory response[2]
- No re-access restrictions after using Abbott vascular closure devices

GIVES IN-LAB CONFIDENCE

- Low access site-related complication[1,3], reduces time to hemostasis, ambulation, and discharge[4,5]
- Suture repair can be challenged and confirmed on the table
- Ability to maintain wire access

*As compared to Angio-Seal®, Celt ACD®, ExoSeal®, Mynx®, Vascade®. Data on file at Abbott.

1. Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.
2. Mercandetti, Michael. Wound Healing and Repair. Medscape. WebMD, 19 May 2017. Web. March 21, 2018.
3. The Use of the Perclose ProGlide Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. Kar, Saibal; Hermiller, James; et al. CRT 2018.
4. Applies to arterial access.
5. U.S. Perclose ProGlide® Instructions for Use.

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

DEVICE OVERVIEW

PERCLOSE PROGLIDE®

Guide Wire Exit Port – Allows for guide wire insertion and removal

Foot – Provides tactile confirmation of correct device position when open

Suture Knot – Biocompatible USP 3-0 Class I monofilament polypropylene suture

Marker Lumen – Provides visual confirmation of correct device positioning

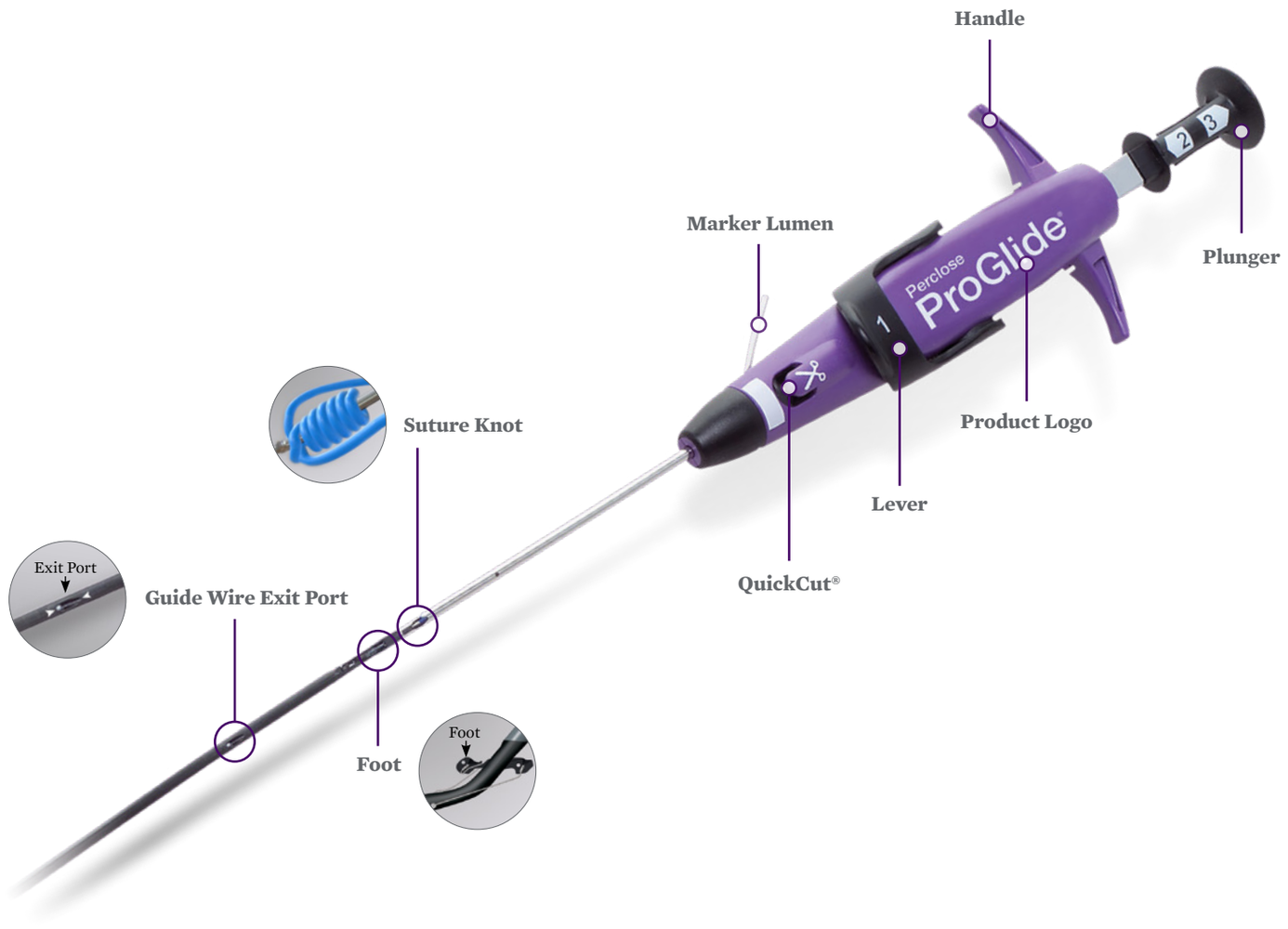
QuickCut® – Allows for suture cutting

Lever – Opens and closes the Foot

Product Logo – Indicates suture deployment position

Handle – For device stabilization

Plunger – Deploys the needles and suture



IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

DEVICE OVERVIEW (CONTINUED)

SNARED KNOT PUSHER

Snared Knot Pusher – Advances Suture Knot

Snare Tab – Pull to load suture through Snare

SUTURE TRIMMER

Suture Trimmer – Advances Suture Knot and allows subcutaneous suture trimming

Suture Gate – Open and close to capture suture

Trimming Lever (Red) – Pull to cut suture

Thumb Knob – Slide to open and close Suture Gate

SNARED KNOT PUSHER

SUTURE TRIMMER

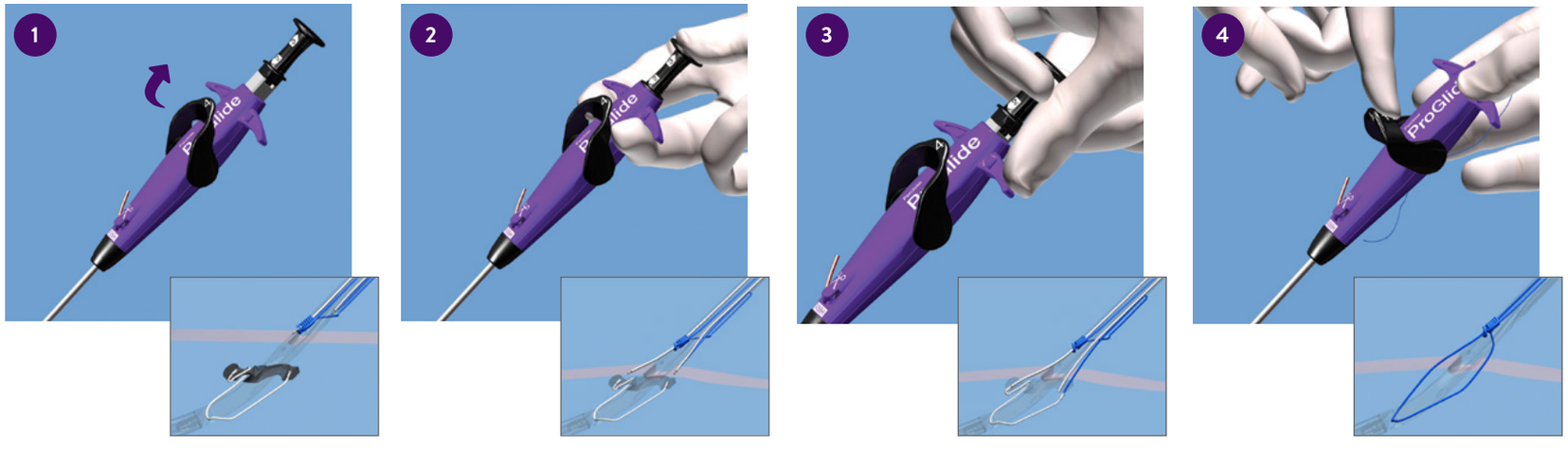
IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

Perclose ProGlide®
Suture-Mediated Closure System

DON'T JUST CLOSE. **REPAIR.**

FOUR KEY STEPS TO SUTURE DEPLOYMENT

1. Advance device and lift Lever (open Foot)
2. Maintain retraction and depress Plunger (deploy Needles)
3. Pull back Plunger (deploy Suture)
4. Lower Lever (close Foot)



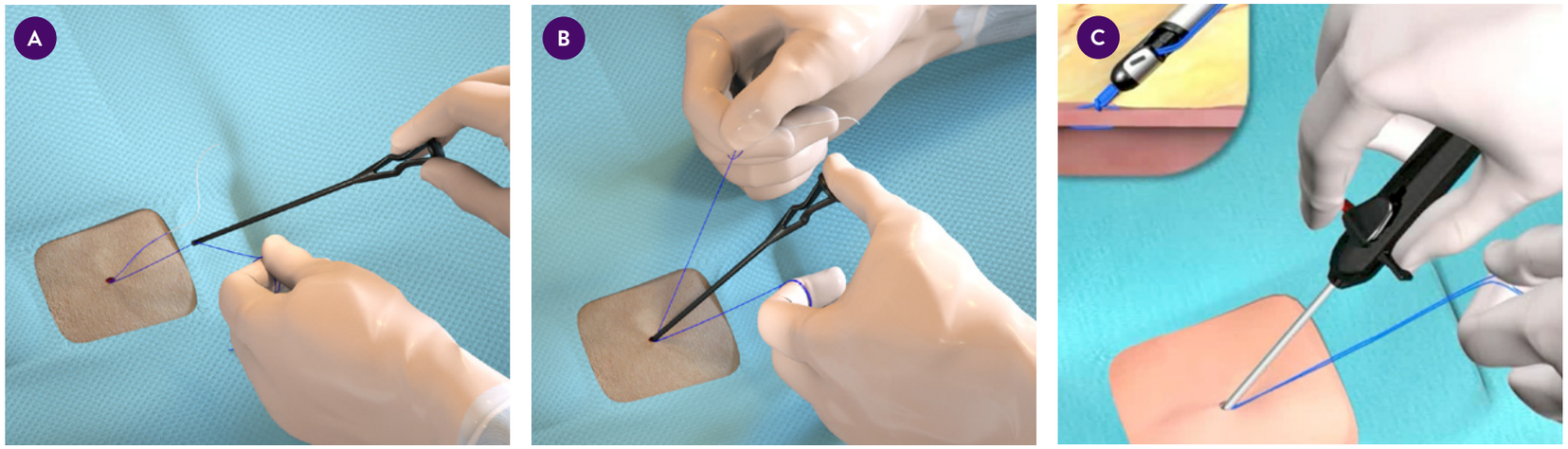
SUTURE MANAGEMENT

Snared Knot Pusher – Advances Suture Knot
Suture Trimmer – Trims suture

A. Snare blue (rail) suture limb through Snared Knot Pusher

B. Advance Suture Knot then lock Suture Knot by pulling white (non-rail) suture limb

C. Trim suture limbs by pulling Trimming Lever on Suture Trimmer



Refer to the **Instructions for Use** for additional information.

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

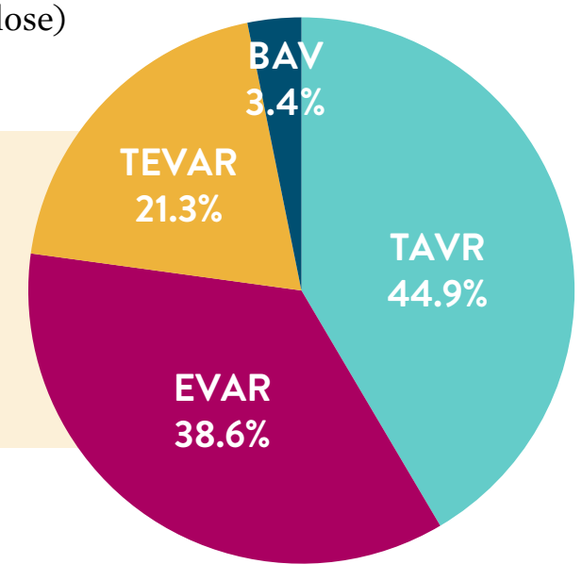
REAL-WORLD EVIDENCE ON REPAIR OF LARGE-BORE ARTERIAL ACCESS

Perclose ProGlide® vs. Surgical Cutdown

The Perclose ProGlide® vs. Surgical Cutdown retrospective study was designed to compare clinical outcomes and complication rates among patients undergoing closure of large-bore arterial access using Perclose ProGlide® (Perclose) vs. Surgical Cutdown (Cutdown) in a real-world setting.

KEY FINDINGS

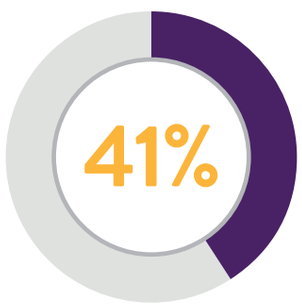
The use of Perclose ProGlide® for repair of large-bore arterial access is associated with significantly **lower blood transfusions, infections, mortality, and length of stay compared to Surgical Cutdown**.



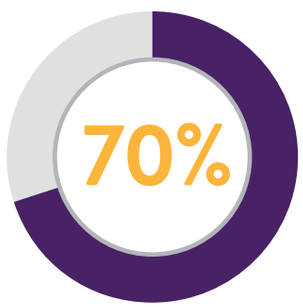
Patients may have had multiple procedures during index admission

PERCLOSE PROGLIDE® PATIENTS

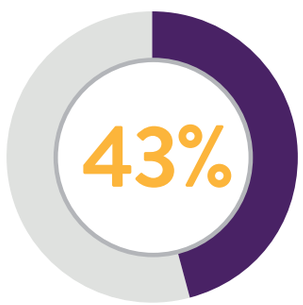
Less likely to require a blood transfusion



Less likely to have an infection



Less likely to die within 30 days post-procedure



Shorter hospital stay

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

Source: Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.

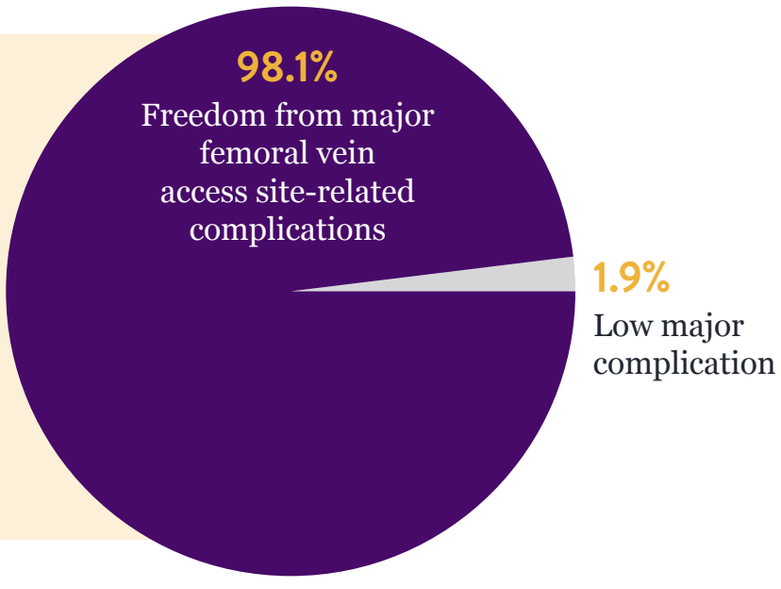
CLINICAL EVIDENCE ON CLOSURE OF LARGE-BORE VENOUS ACCESS

Perclose ProGlide® Cohort in the REALISM* Clinical Trial

A prospective analysis was performed to evaluate the safety and effectiveness of Perclose ProGlide® in closing large-sized venous access sites through a retrospective data collection. The prospective analysis included subjects in whom Perclose ProGlide® was used as the primary method for large-bore venous access site closure during the MitraClip® index procedure with a 24F vascular sheath.

KEY FINDINGS

- Major complication was low at 1.9%
- Freedom from major femoral vein access site-related complications was 98.1% at 30 days
- Perclose ProGlide® is safe and effective in the closure of venous access site with up to 24F sheath



Low major complications at 30 days

INDICATION FOR USE

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

*EVEREST II/REALISM Continued Access Registry Study.

Source: U.S. Perclose ProGlide® Instructions for Use.

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

CPT® CODE FOR VESSEL ACCESS AND CLOSURE FOR ENDOGRAFT PROCEDURES

CPT® CODE	DESCRIPTION	WORK RVU	TOTAL RVU	NATIONAL AVERAGE MEDICARE PHYSICIAN PAYMENT
+34713	Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12F or larger), including ultrasound guidance, when performed, unilateral	2.50	3.74	$135

- This code is applicable only for aortic and iliac artery repair procedures using an endograft.
- This code can be listed twice for bilateral procedures. This will result in a total payment of 150% of the base payment rate (National Average Payment = $135 x 1.5 = $203).
- Effective January 1, 2018.

Source: CY2018 Physician Fee Schedule, Final Rule, Centers for Medicare & Medicaid Services [CMS-1676-F]

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

ORDERING INFORMATION

DESCRIPTION	STOCK NUMBER	UNITS PER PACKAGE	INCLUDES
Perclose ProGlide® Suture-Mediated Closure System	12673-03	10	(1) Perclose ProGlide® Suture-Mediated Closure Device (1) Suture Trimmer (1) Snared Knot Pusher

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

IMPORTAN SAFETY INFORMATION

Rx ONLY Perclose ProGlide® Suture-Mediated Closure (SMC) System

INDICATIONS

The Perclose ProGlide SMC System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide SMC System is used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths.

For access sites in the common femoral vein using 5F to 24F sheaths.

For arterial and venous sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in diagnostic and / or interventional catheterization procedures and who has been trained by an authorized representative of Abbott Vascular.

Prior to use, the operator must review the Instructions for Use and be familiar with the deployment techniques associated with the use of this device.

During closure of access sites using a procedural sheath greater than 8F it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to close the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device. Attention is drawn to the WARNINGS and PRECAUTIONS sections.

WARNINGS

Do not use the Perclose ProGlide SMC device or accessories if the packaging or sterile barrier has been previously opened or damaged or if the components appear to be damaged or defective.

DO NOT RESTERILIZE OR REUSE. The Perclose ProGlide SMC device and accessories are intended for single use only.

Do not use the Perclose ProGlide SMC System if the sterile field has been broken where bacterial contamination of the sheath or surrounding tissues may have occurred, since such a broken sterile field may result in infection.

Do not use the Perclose ProGlide SMC System if the puncture site is located above the most inferior border of the inferior epigastric artery (IEA) and / or above the inguinal ligament based upon bony landmarks, since such a puncture site may result in a retroperitoneal hematoma. Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral artery or vein.

Do not use the Perclose ProGlide SMC System if the puncture is through the posterior wall or if there are multiple punctures, since such punctures may result in a hematoma or retroperitoneal bleed.

Do not use the Perclose ProGlide SMC System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, or the bifurcation of these vessels, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site. NOTE: This may require both a Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO) angiogram to adequately visualize where the sheath enters the femoral artery or vein.

PRECAUTIONS

1. Prior to use, inspect the Perclose ProGlide SMC System to ensure that the sterile packaging has not been damaged during shipment. Examine all components prior to use to verify proper function. Exercise care during device handling to reduce the possibility of accidental device breakage.
2. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose ProGlide SMC System. Employ appropriate groin management, as per hospital protocol, post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the vessel.
4. Do not deploy the Perclose ProGlide SMC device at an angle greater than 45 degrees, as this may cause a cuff miss.
5. There are no reaccess restrictions if previous access site repairs were achieved with Abbott Vascular SMC devices.
6. If significant blood flow is present around the Perclose ProGlide SMC device, do not deploy needles. Remove the Perclose ProGlide SMC device over a 0.038″ (0.97mm) (or smaller) guidewire and insert an appropriately sized introducer sheath.
7. When pushing the plunger assembly to advance the needles, stabilize the device to ensure the device does not twist or move forward during deployment. Twisting the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly push the plunger assembly. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
8. Do not apply excessive force to the lever when returning the foot to its original position **(marked #4)** down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever of the device or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.
9. **Do not advance or withdraw the Perclose ProGlide SMC device against resistance until the cause of that resistance has been determined** (see Section **11.3** Single SMC DEVICE PLACEMENT section). **Excessive force used to advance or torque the Perclose ProGlide SMC device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.**
10. If excessive resistance in advancing the Perclose ProGlide SMC device is encountered, withdraw the device over a 0.038″ (0.97 mm) (or smaller) guidewire and reinsert the introducer sheath or use manual compression.
11. Remove the Perclose ProGlide sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. In using this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.
13. During closure of access sites using a 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide SMC device.
14. During closure of access sites using a procedural sheath > 8F, in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide SMC devices, the physician should assess the situation. Based on the physician assessment of the amount of bleeding use manual compression, compression assisted devices and / or a surgical repair to obtain hemostasis.
15. During closure of access sites using a procedural sheath > 8F, in those cases where the implanting physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary surgical intervention.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use of suture mediated closure devices may include, but are not limited to, the following:

- Allergic reaction or hypersensitivity to device components
- Anemia
- Arterial stenosis / occlusion
- Arteriovenous fistula
- Bleeding / hemorrhage
- Bruising / hematoma
- Death
- Deep vein thrombosis
- Device entrapment
- Device failure / malfunction / misplacement
- Diminished pulses distal to closure site
- Embolism
- Hypotension / hypertension
- Infection / sepsis
- Inflammation
- Intimal tear / dissection
- Ischemia distal to closure site
- Nerve injury
- Numbness
- Pain
- Perforation
- Pseudoaneurysm
- Pulmonary embolism
- Retroperitoneal hematoma / bleeding
- Thrombus formation
- Vascular injury
- Vasoconstriction / vasospasm
- Vasovagal episode
- Wound dehiscence

CONTINUED >>>

IMPORTANT SAFETY INFORMATION

℞ ONLY MITRACLIP CLIP DELIVERY SYSTEM

INDICATION FOR USE

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

CONTRAINDICATIONS

The MitraClip Clip Delivery System is contraindicated in DMR patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- **DO NOT use MitraClip outside of the labeled indication. Treatment of non-prohibitive risk DMR patients should be conducted in accordance with standard hospital practices for surgical repair and replacement.**
- MitraClip is intended to reduce mitral regurgitation. The MitraClip procedure is recommended to be performed when an experienced heart team has determined that reduction of MR to ≤2+ is reasonably expected following the MitraClip. If MR reduction to ≤2+ is not achieved, the benefits of reduced symptoms and hospitalizations, improved quality of life, and reverse LV remodeling expected from MitraClip may not occur.
- The MitraClip Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip System to avoid user injury.
- Use of the MitraClip should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death.
- Inspect all product prior to use. DO NOT use if the package is opened or damaged.

PRECAUTIONS

- Patient Selection:
  - Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:
    - 30-day STS predicted operative mortality risk score of
      - ≥8% for patients deemed likely to undergo mitral valve replacement or
      - ≥6% for patients deemed likely to undergo mitral valve repair
    - Porcelain aorta or extensively calcified ascending aorta.
    - Frailty (assessed by in-person cardiac surgeon consultation)
    - Hostile chest
    - Severe liver disease / cirrhosis (MELD Score >12)
    - Severe pulmonary hypertension (systolic pulmonary artery pressure >2/3 systemic pressure)
    - Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery (IMA) at high risk of injury, etc.
  - Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60mm. MitraClip should be used only when criteria for clip suitability for DMR have been met.
- The major clinical benefits of MitraClip are reduction of MR to ≤2+ resulting in reduced hospitalizations, improved quality of life, reverse LV remodeling and symptomatic relief in patients who have no other therapeutic option. No mortality benefit following MitraClip therapy has been demonstrated.
- The heart team should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and may also include appropriate physicians to assess the adequacy of heart failure treatment and valvular anatomy.
- The heart team may determine an in-person surgical consult is needed to complete the assessment of prohibitive risk. The experienced mitral valve surgeon and heart team should take into account the outcome of this surgical consult when making the final determination of patient risk status.
- For reasonable assurance of device effectiveness, pre-procedural evaluation of the mitral valve and underlying pathologic anatomy and procedural echocardiographic assessment are essential.
- The inside of the outer pouch is not a sterile barrier. The inner pouch within the outer pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.
- Note the “Use by” date specified on the package.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip procedure.

Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Aneurysm or pseudo-aneurysm; Arrhythmias; Atrial fibrillation; Atrial septal defect requiring intervention; Arterio-venous fistula; Bleeding; Cardiac arrest; Cardiac perforation; Cardiac tamponade/ Pericardial Effusion; MitraClip erosion, migration or malposition; MitraClip Device thrombosis; MitraClip System component(s) embolization; Coagulopathy; Conversion to standard valve surgery; Death; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Drug reaction to anti-platelet/anticoagulation agents/contrast media; Dyspnea; Edema; Emboli (air, thrombus, MitraClip Device); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip to the intended site; Failure to retrieve MitraClip System components; Fever or hyperthermia; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Hemorrhage requiring transfusion; Hypotension/hypertension; Infection and pain at insertion site; Infection and pain at incision site; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea/vomiting; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure/atelectasis/pneumonia; Septicemia; Single leaflet device attachment (SLDA); Skin injury or tissue changes due to exposure to ionizing radiation; Stroke or transient ischemic attack (TIA); Urinary tract infection; Vascular trauma, dissection or occlusion; Vessel spasm; Vessel perforation or laceration; Worsening heart failure; Worsening mitral regurgitation; Wound dehiscence

CAUTION: These products are 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 *manuals.sjm.com* 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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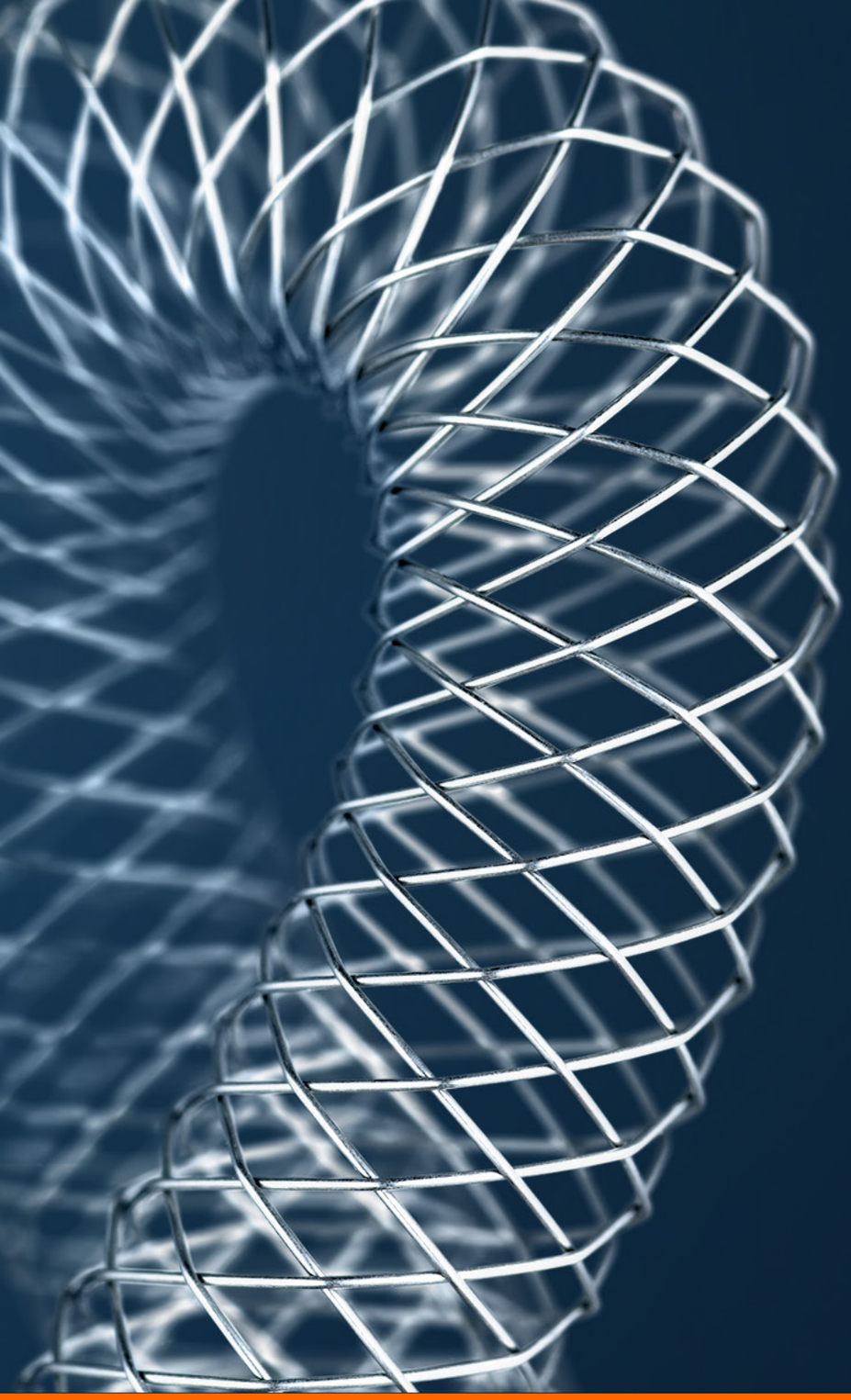


Supera™
Peripheral Stent System

RESULTS MATTER.

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

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.

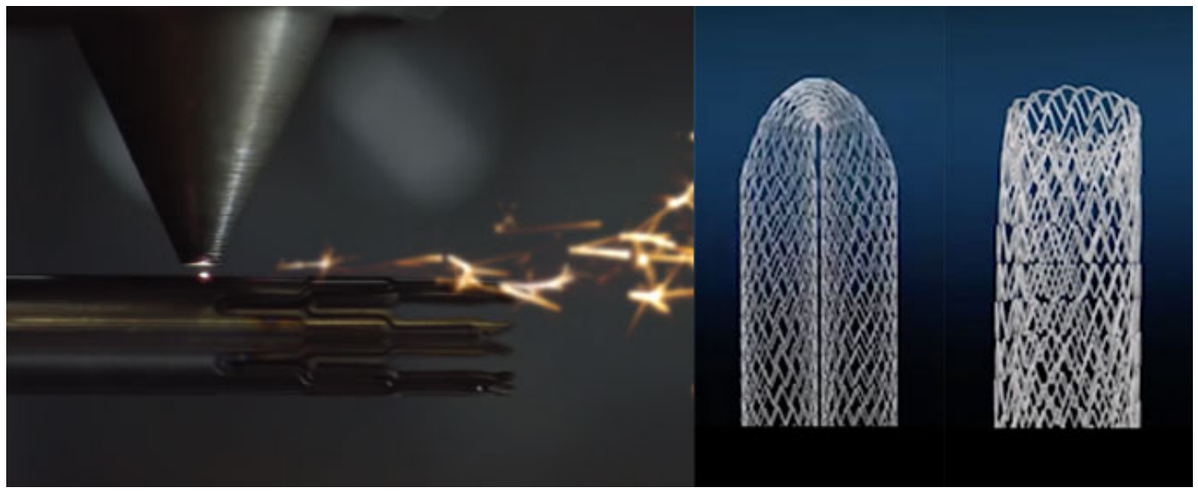
Abbott

ENGINEERED FOR DURABILITY

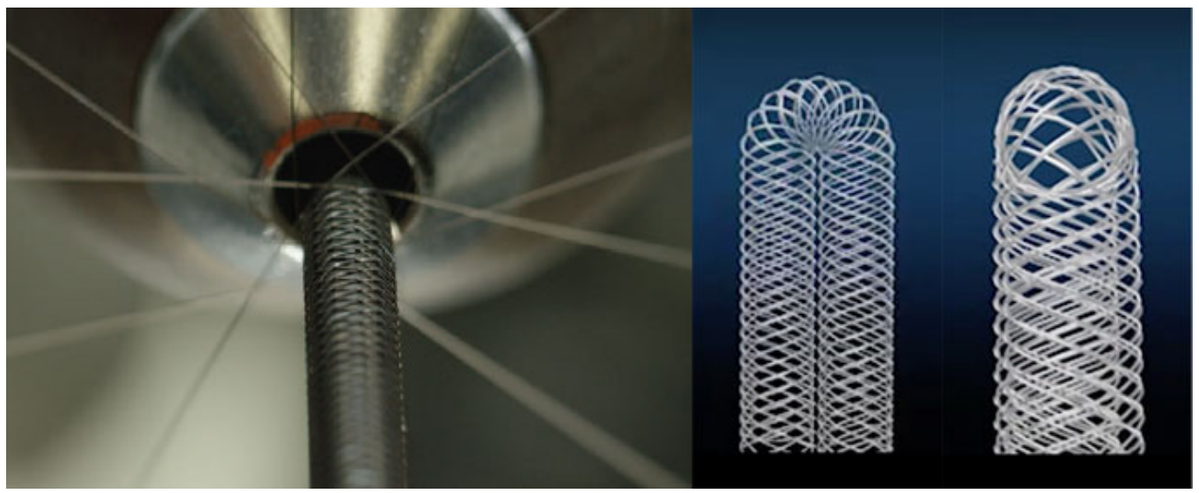
A unique stent design with unparalleled performance[1,2]

Supera™ Stent offers **outstanding flexibility**[1] **and kink resistance**[2] to withstand the challenging environment of the SFA and proximal popliteal.

STANDARD LASER-CUT NITINOL



INTERWOVEN NITINOL WIRE STENTS



SUPERA™ STENT

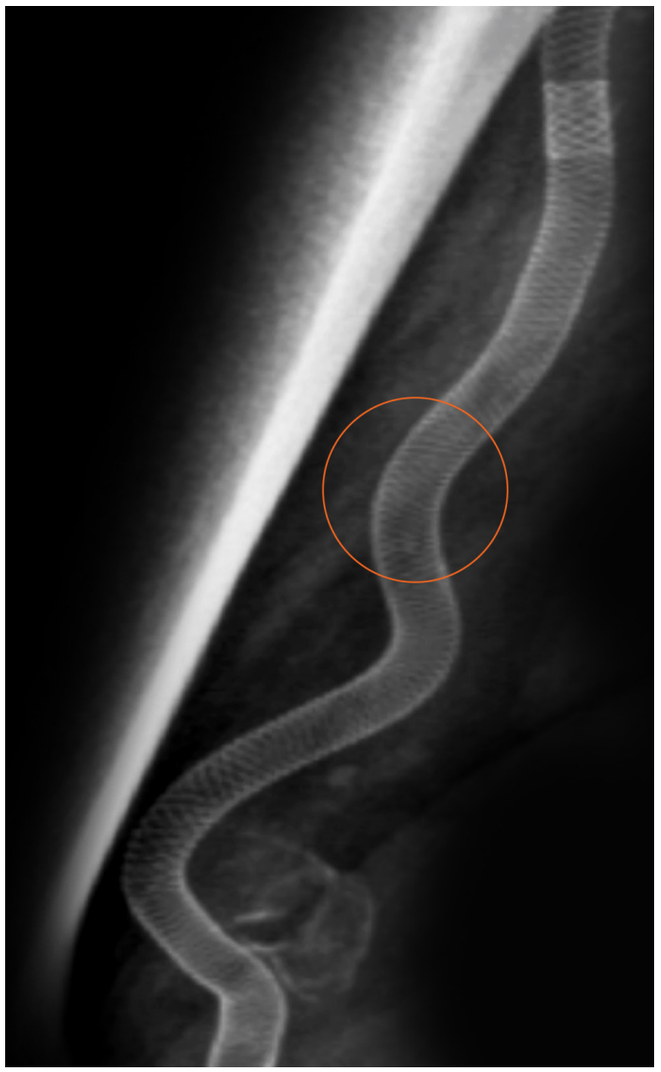


Image courtesy of Dr. Hans Biemans, Rivas Hospital Gorinchem, the Netherlands

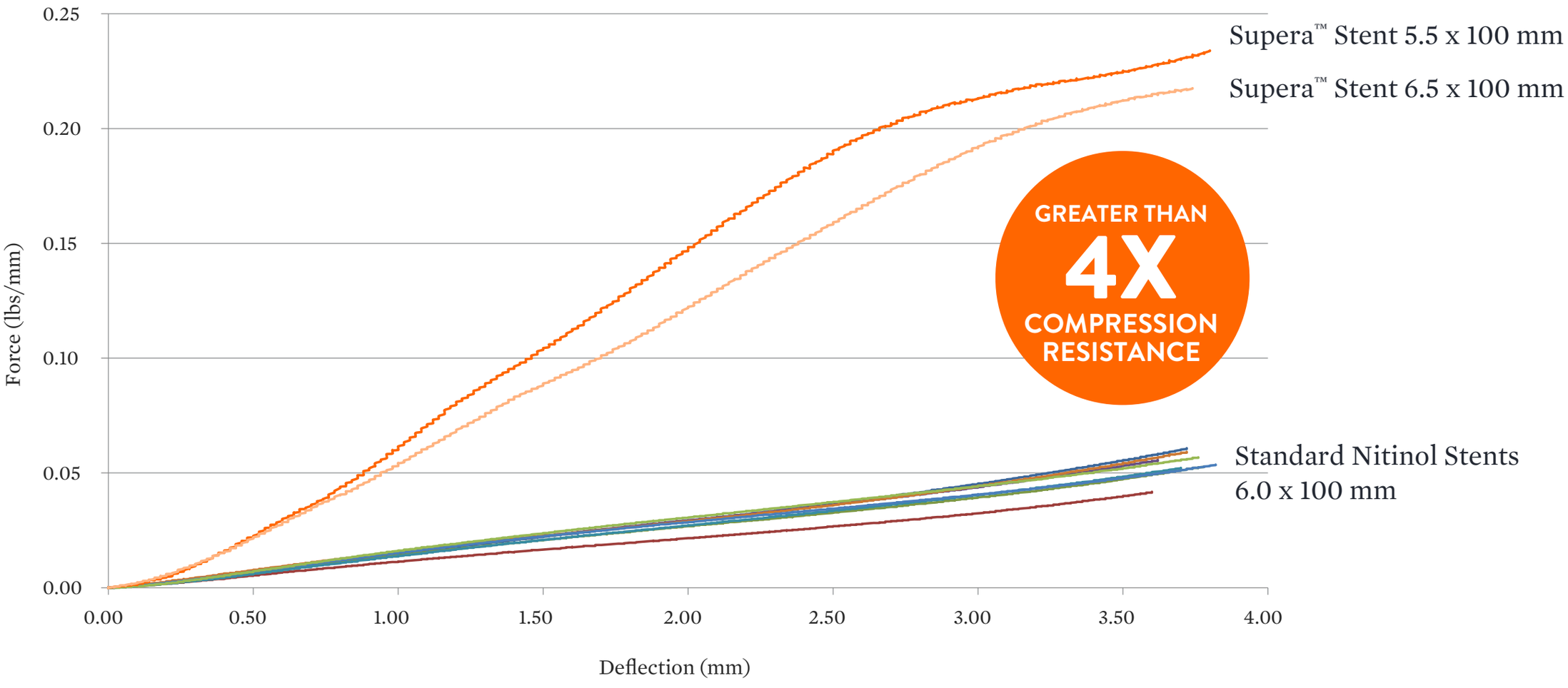
IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

1. Flexibility is defined as kink resistance. The Supera™ Stent sizes with the lowest kink resistance, as compared to 6.0 x 100 mm standard nitinol stents, are the 5.0 x 100 and 6.0 x 100 mm implants. Data on file at Abbott.
2. The compression resistance for a 5.5 x 100 mm Supera™ Stent is 20 lbf at 53% compression. This is four times the compression resistance of all other competitors. All other products compressed 53% with less than 5 lbf applied. Data on file at Abbott.

ENGINEERED FOR DURABILITY

Supera™ Stent offers greater than 4X the compression resistance[1]

of standard nitinol stents to ensure **a round lumen**[2] in complex anatomy and exerts **minimal chronic outward force.**[3,4]



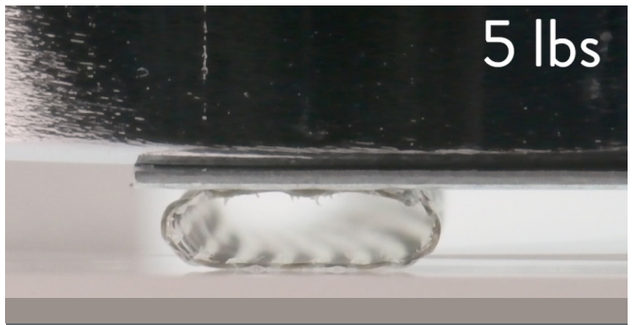
IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

1. 20 lbs compression resistance for 5.5 x 100 mm Supera™ Stent to achieve 53% compression. Four times the compression resistance of all other competitors. All other products compressed 53% with less than 5 lbs applied. Data on file at Abbott.
2. Characteristically round lumens supported by Arena, F.J., Arena, F.A. Intravascular Ultrasound Evaluation of Interwoven Nitinol Stents at Implant. *J Vasc Med Surg.* 2013:1;116.
3. Tests performed by and data on file at Abbott.
4. Measurements taken at upper limit of labeled vessel diameter mm. Data on file at Abbott.

ENGINEERED FOR DURABILITY

Supera™ Stent **maintains a round lumen** when 5 pounds of force is applied, standard nitinol laser-cut stents experience lumen compression.[1]

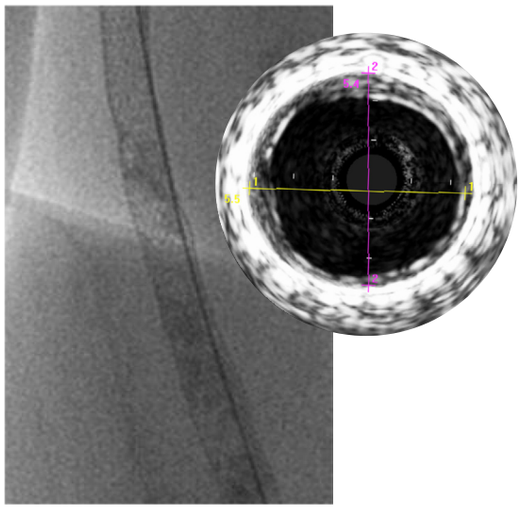
Supera™ Stent
6 mm



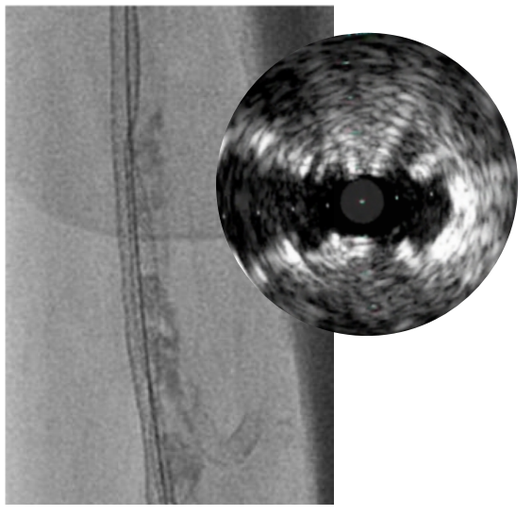
LASER-CUT STENT
6 mm

MORE THAN 4X
COMPRESSION RESISTANCE

SUPERA™ STENT



STANDARD NITINOL STENT



IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

1. 20 lbs compression resistance for 5.5 x 100 mm Supera™ Stent to achieve 53% compression. Four times the compression resistance of all other competitors. All other products compressed 53% with less than 5 lbs applied. Data on file at Abbott.

PROVEN CLINICAL PERFORMANCE

The Supera™ Stent is Clinically Proven and Widely Studied With Excellent Outcomes

91%

Patency (K-M) at 1-Year[4]
(When Nominally Deployed*)

94%

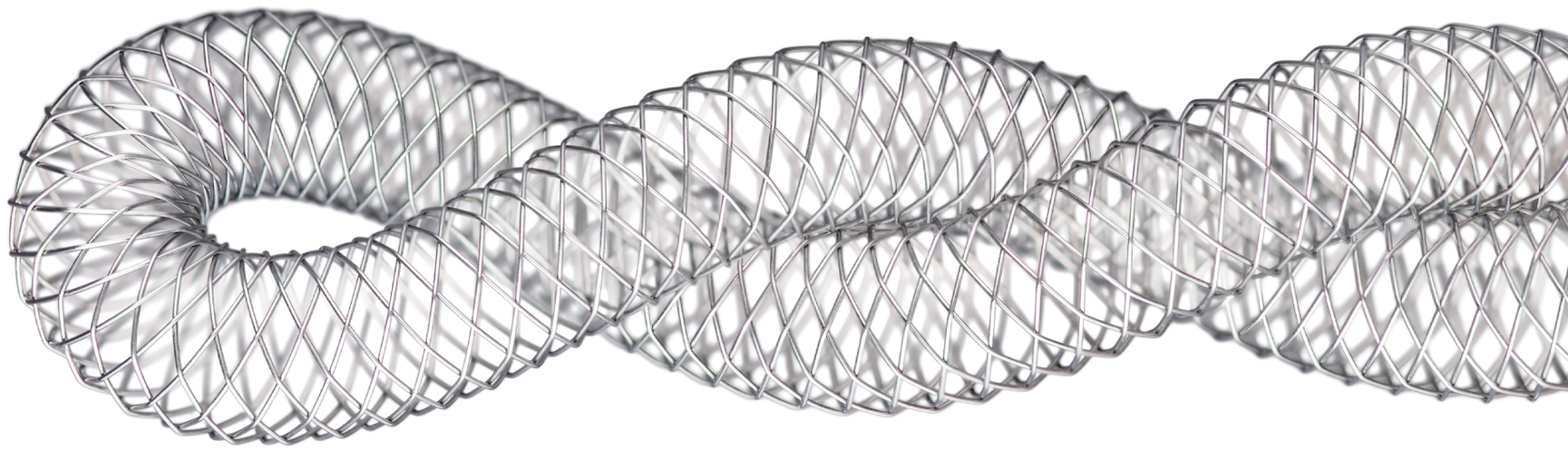
Freedom from TLR at 3-Years[4]
(When Nominally Deployed*)

>2,000

PATIENTS PUBLISHED IN 17 STUDIES WORLDWIDE AS EARLY AS 2011[1-17]

264

PATIENTS STUDIED IN THE SUPERB TRIAL[4]



* Nominal deployment is defined as the stent length upon deployment being within +/- 10% of the labeled stent length. This data is from a non-powered post-hoc analysis. Overall patency at 1 year was 86.3% and overall freedom from TLR at 3 years was 83%.

1. Brescia AA. et al., *J Vasc Surg.* 2015 Jun;61(6):1472-8. 2. Chan YC. et al., *J Vasc Surg.* 2015 Nov;62(5):1201-9. 3. Dumantepe M. *Vasc Endovascular Surg.* 2017 Jul;51(5):240-246. 4. Garcia L. et al., *Catheterization and Cardiovascular Interventions* 2017 Jun 1;89(7):1259-1267. 5. George JC. et al., *J Vasc Interv Radiol.* 2014 Jun;25(6):954-61. 6. Goltz JP. et al., *J Endovasc Ther.* 2012 Jun;19(3):450-6. 7. León LR Jr. et al., *J Vasc Surg.* 2013 Apr;57(4):1014-22. 8. Montero-Baker M. et al., *J Vasc Surg.* 2016 Oct;64(4):1002-8. 9. Myint M. et al., *J Endovasc Ther.* 2016 Jun;23(3):433-41. 10. Palena LM. et al., *J Endovasc Ther.* 2018 Oct;25(5):588-591. 11. Scheinert D. et al., *JACC Cardiovasc Interv.* 2013 Jan;6(1):65-71. 12. Scheinert D. et al., *J Endovasc Ther.* 2011 Dec;18(6):745-52. 13. Steiner S. et al., *J Endovasc Ther.* 2016 Apr;23(2):347-55. 14. Werner M. et al., *EuroIntervention.* 2014 Nov;10(7):861-8. 15. San Norberto EM. et al., *Ann Vasc Surg.* 2017 May;41:186-195. 16. Teymen B. et al., *Vascular.* 2018 Feb;26(1):54-61. 17. Bhatt H. et al., *Cardiovasc Revasc Med.* 2018 Jul;19(5 Pt A):512-515.

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

PROVEN CLINICAL PERFORMANCE

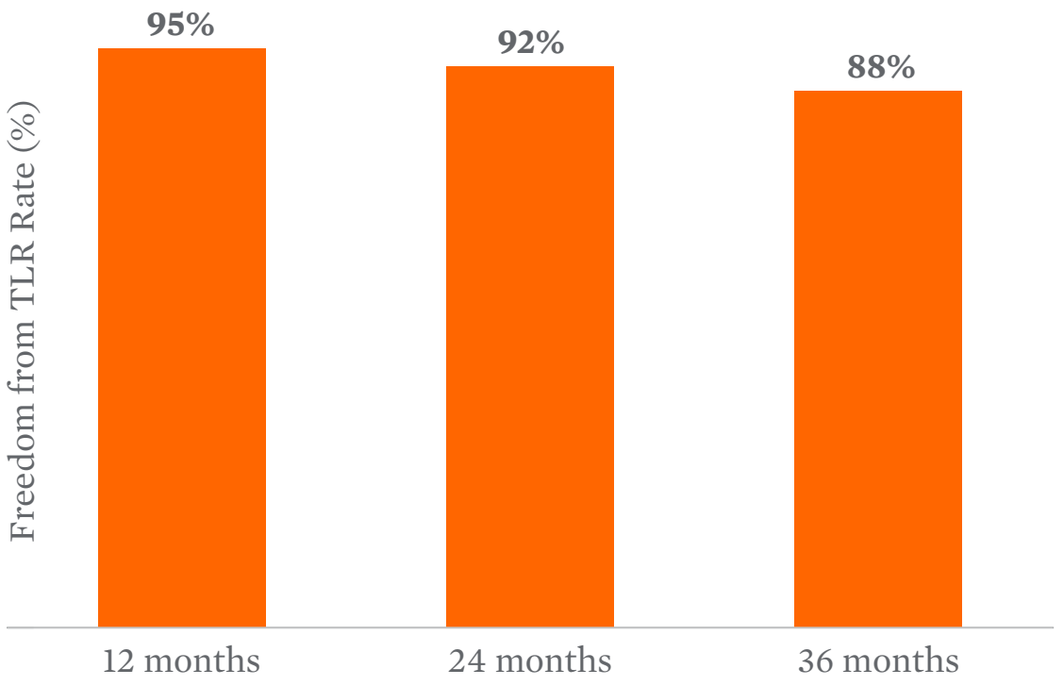
Supera™ Stent offers excellent outcomes in calcified lesions

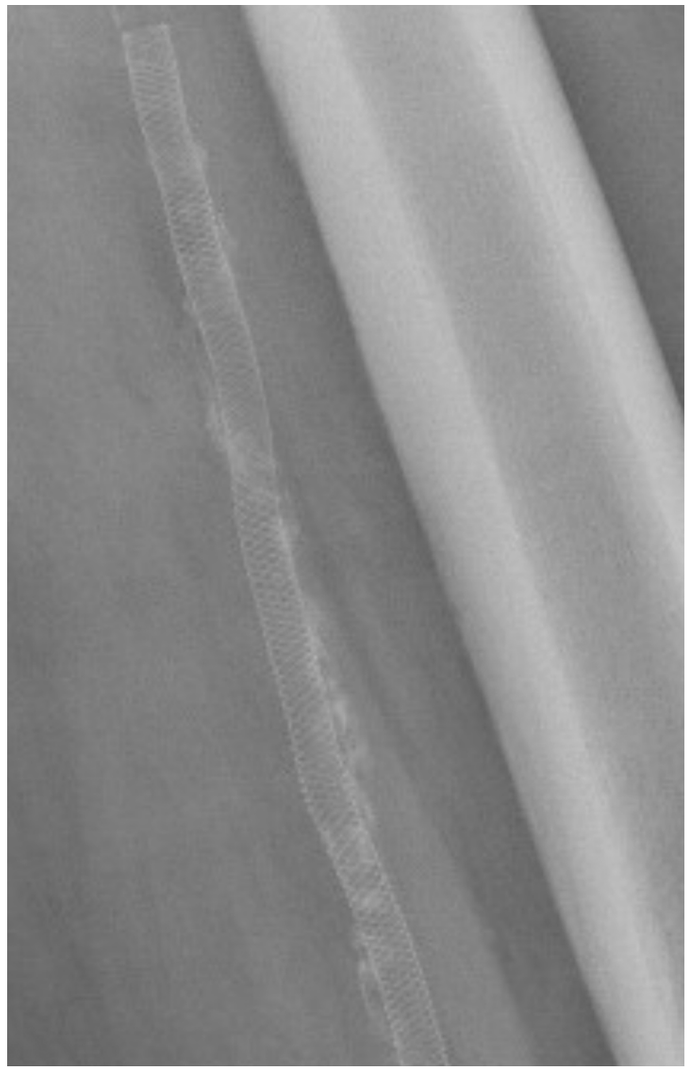
In lesions with severe calcium, Supera™ Stent provides **89% primary patency** (VIVA criteria) at 1 year and **88% freedom from TLR** out to 3 years in the SUPERB Trial.

PATENCY AT 1 YEAR IN SEVERE CALCIUM

% of Lesions with Severe Calcification (SUPERB Trial)	45% (n=118)
Patency (VIVA 12 months)	89%

FREEDOM FROM TLR OVER TIME IN SEVERE CALCIUM





IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

Sources: Garcia, Lawrence. The SUPERB Trial 3-Year Results VIVA 2014. Garcia, Lawrence A. et al., SUPERB Final 3-Year Outcomes Using Interwoven Nitinol Biomimetic Supera Stent. *Catheterization and Cardiovascular Interventions* 2017; 89(7):1259-1267.

PROVEN CLINICAL PERFORMANCE

Supera™ Stent Delivery System

- Unique thumb slide design
- 0.014″ and 0.018″ guide wire compatible
- Over-the-wire delivery system

SIZE MATRIX AND PART NUMBERS

	STENT DIAMETER (mm)	LENGTH (mm)							
		20	30	40	60	80	100	120	150
6F 120 cm	4.5	S-45-020-120-P6	S-45-030-120-P6	S-45-040-120-P6	S-45-060-120-P6	S-45-080-120-P6	S-45-100-120-P6	S-45-120-120-P6	—
	5.0	S-50-020-120-P6	S-50-030-120-P6	S-50-040-120-P6	S-50-060-120-P6	S-50-080-120-P6	S-50-100-120-P6	S-50-120-120-P6	—
	5.5	S-55-020-120-P6	S-55-030-120-P6	S-55-040-120-P6	S-55-060-120-P6	S-55-080-120-P6	S-55-100-120-P6	S-55-120-120-P6	S-55-150-120-P6
	6.0	S-60-020-120-P6	S-60-030-120-P6	S-60-040-120-P6	S-60-060-120-P6	S-60-080-120-P6	S-60-100-120-P6	S-60-120-120-P6	S-60-150-120-P6
	6.5	S-65-020-120-P6	S-65-030-120-P6	S-65-040-120-P6	S-65-060-120-P6	S-65-080-120-P6	S-65-100-120-P6	S-65-120-120-P6	S-65-150-120-P6

IMPORTANT SAFETY INFORMATION REFERENCED WITHIN

IMPORTANT SAFETY INFORMATION

℞ 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 6.5 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 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.

<u>Magnetic Resonance Imaging (MRI)</u>

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

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