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PEVAR on the Rise

An interview and case report from Prof. Giovanni Pratesi, MD, on the utility of suture-mediated closure after percutaneous endovascular aneurysm repair.

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With the availability of low-profile devices on the rise, can you discuss some of the clinical benefits of percutaneous aortic aneurysm repair (PEVAR) compared to traditional surgical cutdown?

Percutaneous endovascular aneurysm repair has a great advantage to further minimize the invasiveness of endovascular aortic procedures. Compared to femoral exposure, a percutaneous approach allows for a broader use of local anesthesia, a shorter operation, and an earlier ambulation time. By avoiding skin incision in the groin, PEVAR contributes to reduced overall patient discomfort, length of stay, and wound complications.

The continuous improvement of PEVAR's clinical safety and effectiveness can be explained by two main factors: First, advances in stent graft technology have allowed for a progressive profile reduction, which culminated in the commercialization of ultra-low-profile stent grafts with a 14-F outer diameter delivery system. Secondly, the growing operator experience with suture-mediated closure devices has permitted more accurate patient selection and a fully standardized procedure.

Despite the fact that several patient-, operator-, and procedure-related factors (eg, common femoral artery [CFA] calcification, obesity, scarred groins, sheath size, and operator experience) have been identified as potentially able to affect PEVAR outcomes, device profile and operator learning curve have been shown to have the strongest association with an improved technical success rate, which is currently around 98%.[1]

Could you share some insight into the history of the preclose technique?

PEVAR was first described in 1999 by Haas et al, who demonstrated the feasibility of closing large access sites with the Prostar XL closure device (Abbott Vascular) using the preclose technique.[2] This technique necessitates that a suture-mediated closure device be deployed before the insertion of a large-bore sheath; otherwise, the needles of the device will not be engaged through the vessel wall, and vessel closure will not be possible. Prostar was CE Mark approved to close up to 24 F. More recently, a modification of this technique using two Perclose ProGlide closure devices (Abbott Vascular), has been proposed and received US Food and Drug Administration approval for the closure of femoral access sites up to 21 F.

Despite the previous lack of high-level clinical evidence based on randomized, controlled trials, PEVAR applicability continues to grow and is now suitable for use in approximately 90% of EVAR cases.[3] In our center's opinion, the introduction of ProGlide played a major role in the escalation of PEVAR use. We have performed 100% of our PEVAR cases using ProGlide for many years, and this trend has been observed in many European and international centers.

Several reasons can be cited to support this paradigm shift. First, ProGlide has a lower profile compared to Prostar (6 F vs 10 F, respectively) and could be safer to use in the presence of smaller femoral arteries and iliac tortuosity. Secondly, the ProGlide system is based on a single 3–0 monofilament polypropylene suture; it offers better performances compared to the 3–0 braided polyester sutures of the Prostar XL in terms of progression in the subcutaneous tissues, which often require a preventive, time-consuming channel preparation. Additionally, the pre-tied knot of the ProGlide device eliminates any potential problems related to the formation of the slip knot needed with the Prostar XL.

What are the benefits of using suture-mediated closure devices?

The use of suture-mediated closure devices has the great advantage of performing a real surgical suture in an endovascular fashion without the need of surgical cutdown. In this way, it is possible to reduce patient discomfort and prevent any wound-related complications.

Using a polypropylene suture exactly like in open surgery has the advantage of avoiding the need for

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any additional hemostatic materials. Effectiveness of hemostasis can be tested immediately at the end of the procedure without the risk of late failure due to dislodgment of anchors or plugs. Moreover, when sutures are placed in tension, it is possible to downsize the profile of the sheath from 24 F to 6 or 10 F, for example, in order to keep vascular access during complex procedures like branched thoracoabdominal aortic aneurysm repair without compromising blood flow to the limbs. This keeps arterial access available for a few days after the procedure in case additional procedures are expected, without risk of bleeding or need for additional punctures. Future access in the groin, which can be performed without temporal limits, will be in almost virgin territory because of the minimal reaction to prolene suture.

More recently, a wide spectrum of new closure devices has been proposed for percutaneous closure of large-bore femoral access. All these systems are based on different kinds of technologies and are still under investigation and not yet approved for clinical use.

How is the learning curve with this technique? Do you have any clinical tips for optimizing outcomes?

Although there is no consensus in the literature on the number of procedures needed to be identified as an expert operator, operator experience is one of the most important keys to successful PEVAR. Expertise in the use of ProGlide for peripheral procedures with small-bore sheaths, like carotid stenting or peripheral revascularization, can be useful but not mandatory.

From our center's point of view, the learning curve for this technique is multifactorial. First of all, as for any endovascular technique, patient selection is crucial for the success of the procedure. Scarred groins, obesity, small-diameter CFAs, anterior calcified spot plaques, and high femoral bifurcation do not represent absolute contraindications to PEVAR but indicate needs to be analyzed on preoperative CT scan. Furthermore, accurate selection of the puncture site is mandatory. When one or more of the previously mentioned factors are identified, ultrasound-guided puncture is strongly recommended in order to locate the healthier segment of the CFA. Finally, proper knowledge of the device and meticulous execution of the closure technique are important points as well.

It is crucial to always leave the guidewire in place until acceptable hemostasis is achieved. In case of suboptimal hemostasis, another ProGlide device can be advanced and deployed over the wire; in case of failure with major bleeding, a sheath or a balloon can be advanced into the external iliac artery and used to endovascularly clamp the vessel while preparing for a more relaxed femoral cutdown.

Another useful tip is to advance a small Teflon pledget over the two sutures touching the arterial wall to increase the hemostasis. This is particularly useful when approaching a CFA with anterior plaque, which can experience some minor persistent bleeding not solved solely with additional manual compression.

What are the economic advantages of ProGlide?

Despite representing an additional cost for the procedure, the use of suture-mediated closure devices has several economic advantages. Considering only economic factors, the shortening of operation time and length of stay is associated with EVAR cost reduction. In addition, progressive decrease in endograft profile allows the use of a single ProGlide for each femoral access, leading to further cost reduction.

However, in order to evaluate the overall cost effectiveness of EVAR, we cannot look at the femoral access modality alone; a global evaluation of pre-, intra-, and postoperative periods needs to be considered. In our unit, all the preoperative assessments, including duplex ultrasonography, CT scan, and laboratory tests, are performed in an outpatient setting, and patients are admitted the same day of surgery or the day before. Our standard-risk EVAR protocol includes local anesthesia with mild sedation, totally percutaneous EVAR in the angiosuite with a fixed C-arm, and transfer to the ward at the end of the operation. All patients undergo aortic and femoral access site duplex evaluation before ambulation, which normally occurs within 6 hours of the procedure, and are discharged on the first or second postoperative day based on the clinical risk of the individual patient.

When you consider all these aspects together, you can easily understand the economic advantages of percutaneous access, which have to be combined with the improvement of patients' quality of life that is derived from a less-invasive operation.

What were the most significant takeaways from your Italian PEVAR registry (IPER) data?

The IPER registry is a prospective multicenter registry carried out to provide real-world data on the contemporary management of PEVAR with the aims of reporting intraoperative and 30-day technical success and complication rates and to identify patient, operator, and procedural factors affecting outcomes. It is the first and largest prospective multicenter study carried out on a cohort of unselected patients who underwent PEVAR with differ-

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ent endografts in well-trained centers by highly experienced operators.

Between January 2010 and December 2014, 2,381 PEVAR procedures were performed at seven Italian high-volume centers (operators with an experience of at least 50 PEVAR procedures) in 1,322 consecutive patients. Results of the IPER registry confirm the high technical success rate of PEVAR when performed by experienced operators, even in the presence of demanding anatomies. Percutaneous access was technically successful in 96.8% (2,305 CFAs) of procedures. The causes of surgical conversion in 3.2% of procedures included acute bleeding (54 cases) and acute CFA occlusion (22 cases) as a result of suture break, not sliding knot or detachment of the atheromatous plaque in the posterior wall. The 1-month PEVAR failure rate was 0.25% (six cases) consisting of two pseudoaneurysms and four CFA occlusions that required surgical open femoral repair in all the cases. No infection, arteriovenous fistula, or neurological damage was observed. Femoral calcification represents the only independent predictor of percutaneous access failure at multivariate analysis. No significant association was observed with sex, obesity, CFA diameter, level of CFA bifurcation, and sheath size.

CASE REPORT

Percutaneous EVAR in an Obese Patient

A 69-year-old man was admitted to our unit with a diagnosis of an asymptomatic abdominal aortic aneurysm (AAA) with a maximum diameter of 7 cm. He had multiple atherosclerotic risk factors including hypertension, type 2 diabetes mellitus, chronic atrial fibrillation treated with oral anticoagulant therapy, severe obesity (weight, 145 kg; height, 1.9 m; body mass index, 40.2 kg/m^2), and a previous smoking habit. Preoperative CT angiogram evaluation showed the presence of an appropriate proximal aortic neck (diameter, 28.3 mm; length, 23 mm) and distal iliac landing zones (right side: diameter, 16.2 mm and length, 58.8 mm; left side: diameter, 16.5 mm and length, 60.6 mm) without significant angulations and tortuosity, confirming the feasibility of standard EVAR. A detailed evaluation of the femoral access vessels with 3D reconstruction and vessel analysis revealed the presence of regular CFA diameters (right CFA, 10.8 mm; left CFA, 10.9 mm) with a normal position of the femoral bifurcation in relation to the inguinal ligament and minus calcified plaques on the posteromedial wall bilaterally (Figures 1 and 2). Based on the aneurysm and access vessel anatomy, PEVAR was planned despite the fact that the subcutaneous tissue at the level of the CFAs was more than 10 cm bilaterally (Figure 3).

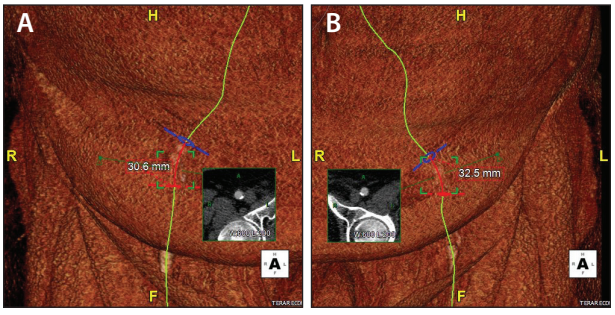

Figure 1. Preoperative CT angiogram with axial image and 3D reconstruction of the right and left CFA with soft tissue visualization (A, B); red line with measurements refers to the distance between the inguinal ligament and CFA bifurcation; green transverse line in the target indicates the ideal puncture level.

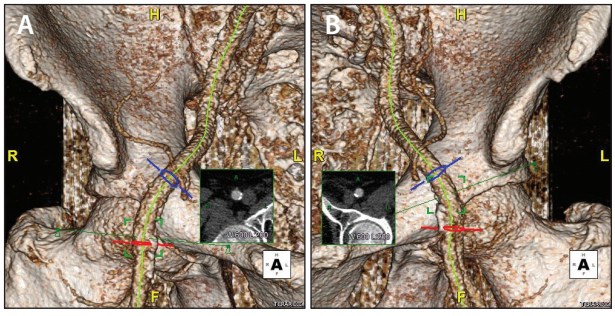

Figure 2. Preoperative CT angiogram with axial image and 3D reconstruction of the right and left CFA with bone landmark (A, B); red line with measurements refers to the distance between the inguinal ligament and CFA bifurcation; green transverse line in the target indicates the ideal puncture level.

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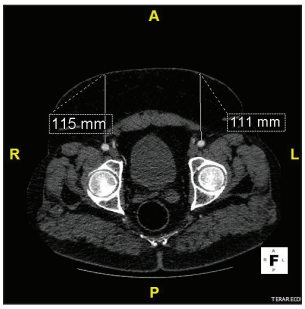

Figure 3. CT angiogram axial evaluation of the subcutaneous tissue.

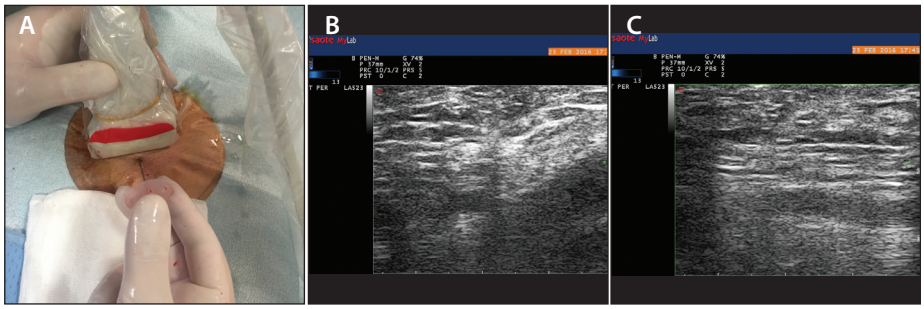

Figure 4. Ultrasound-guided CFA puncture (A) with needle identification on transverse (B) and longitudinal (C) axis.

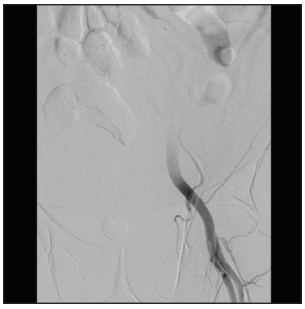

Figure 5. Angiographic visualization through a 6-F sheath to confirm the appropriate puncture site.

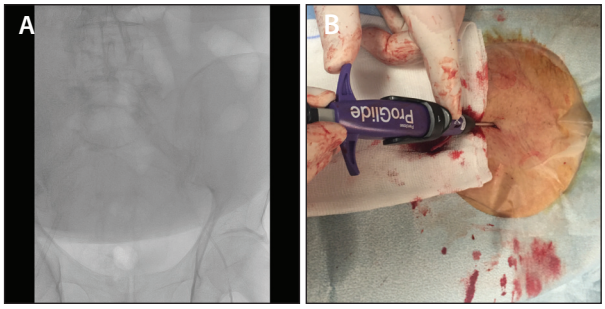

Figure 6. ProGlide in place before suture deployment. Note the needles inside the delivery system at the level of the CFA (A) and the 12:00 position of the device indicating an anteroposterior position of the suture (B).

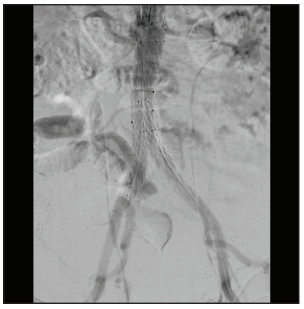

Figure 7. Completion angiogram showing aneurysm exclusion with normal patency of the visceral arteries and access vessels.

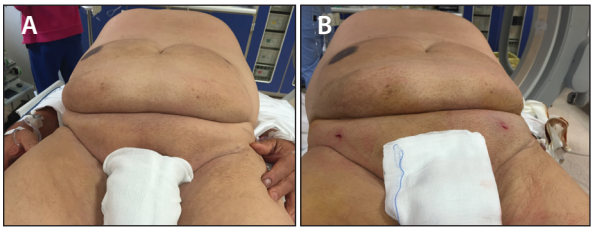

Figure 8. Pre- and postoperative comparison of the patient's inguinal regions. The advantages of PEVAR are well evident: only two small incisions indicate that the operation was performed.

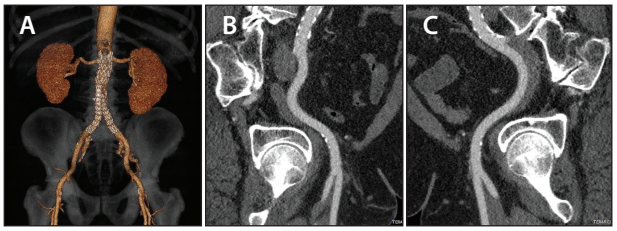

Figure 9. Thirty-day CT angiogram confirming AAA exclusion (A) with normal patency of both CFAs as shown by the curved planar reformation curved vessel lumen reconstruction (B, C).

The operation was performed in the angiosuite, which was fully equipped with a flat-detector x-ray system (Allura Xper, Philips Healthcare), and the patient was placed under local anesthesia with mild sedation. Ultrasound guidance (MyLab ClassC, Esaote) was used to get access to both CFAs (Figure 4), and a short 6-F sheath was advanced over a standard 0.035-inch guidewire bilaterally. After angiographic control of the correct puncture site (Figure 5), a single 6-F ProGlide was deployed (Figure 6) using the preclose technique and subsequently exchanged with a short 10-F sheath on both sides. EVAR was successfully carried out with standard technique using a new-generation, ultra-low-profile endograft, characterized by suprarenal active fixation, trimodular design, and 14-F outer-diameter delivery system (Incraft, Cordis Corporation). According to preoperative sizing, a 34-mm proximal aortic body (AB3498) and two 20-mm iliac limbs were used (IL2010, bilaterally).

Final angiography showed AAA exclusion with normal patency of the endograft, visceral arteries, and

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access vessels without signs of endoleak or limb kinking (Figure 7). Successful percutaneous hemostasis was obtained on both sides (Figure 8) by tightening the predeployed polypropylene sutures of the ProGlide closure system, and the patient was transferred directly to the ward. After 6 hours, a duplex ultrasound evaluation of the aorta and access vessels revealed the regular AAA exclusion with normal patency of both CFAs in absence of active bleeding, hematoma, or stenosis. The patient was therefore allowed to ambulate and was discharged in good health on the second postoperative day. A routine 30-day CT angiogram confirmed persistent clinical success of the PEVAR procedure concerning aneurysm exclusion and access vessel management (Figure 9).

DISCUSSION

This case clearly underlines the utility of PEVAR even in more challenging CFA anatomies, such as an obese patient. From a surgical point of view, it is well recognized that these patients, in cases of femoral cutdown, are at increased risk of wound complications, including lymphocele, infection, and dehiscence. On the other hand, obesity has long been considered a risk factor for technical failure of percutaneous access as well. However, conflicting data are reported in the literature on this issue, and more recent experiences do not confirm this observation anymore.

In our unit, decision making for access vessel modality in obese patients is part of a multifactorial approach to the disease. First of all, we perform an accurate evaluation of the inguinal region and CFA's preoperative anatomy. We look at CFA diameter, level of the CFA bifurcation, and presence of calcification; when more than one of the previous factors is observed, we contraindicate the use of PEVAR. Endograft selection is finalized to confirm EVAR feasibility using a low-profile endograft. In fact, in obese patients, we routinely use ultra-low-profile endografts with 14- to 15-F outer-diameter delivery systems that allow for preimplantation of just one single ProGlide. By avoiding the need for multiple femoral accesses and sheath exchanges, it is possible to additionally reduce the risk of PEVAR technical failure. Finally, ultrasound-guided access is mandatory in all obese patients in order to perform a correct femoral puncture, which is well recognized as the strongest predictor for a successfully percutaneous procedure.

In conclusion, PEVAR is a safe and effective procedure and can be used with high technical success rates even in the presence of more demanding anatomy only if an accurate multifactorial evaluation of pre-, intra-, and postoperative factors is performed. ■

1. Pratesi G, Barbante M, Pulli R, et al; IPER Registry Collaborators. Italian percutaneous EVAR (IPER) registry: outcomes of 2381 percutaneous femoral access sites' closure for aortic stent-graft. J Cardiovasc Surg. 2015;56:889-898.
2. Haas PC, Krajcer Z, Diethrich EB. Closure of large percutaneous access sites using the Prostar XL percutaneous vascular surgery device. J Endovasc Surg. 1999;6:168-170.
3. Nelson PR, Kracjer Z, Kansal N, et al. A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). J Vasc Surg. 2014;59:1181-1193.

The author would like to thank the members of the IPER Registry Collaborative Group for their hard work and contributions to the registry:

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Rx ONLY

Perclose ProGlide® 6F 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 access site of patients who have undergone diagnostic or interventional catheterization procedures using 5F to 21F sheaths. For sheath sizes greater than 8 Fr, 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 arteriotomy sites using an 8.5 – 21F procedural sheath, which requires the use of at least two devices, 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 arteriotomy 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.

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.

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 artery.
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 arteriotomy 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" (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 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" (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 arteriotomy 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 arteriotomy sites using an 8.5 – 21F procedural sheath, 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 arteriotomy sites using an 8.5 – 21F procedural sheath, 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 complications associated with use 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 • Extended hospitalization / delayed time to ambulation • Infection / sepsis • Inflammation • Intimal tear / dissection
• Ischemia distal to closure site • Nerve injury • Numbness • Pain
• Perforation • Pseudoaneurysm • Retroperitoneal hematoma / bleeding
• Surgical exposure / closure of common femoral artery • Thrombus formation
• Vascular injury • Vasovagal episode • Vasoconstriction / vasospasm
• Wound dehiscence

Rx ONLY

PROSTAR XL®
Percutaneous Vascula
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

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) or at eifu.abbottvascular.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

AP2943908-US Rev. A.