
Perclose ProGlide®
6F Suture-Mediated Closure (SMC) System
Instructions for Use



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TO ENSURE PROPER DEPLOYMENT AND USE OF THIS DEVICE AND TO PREVENT INJURY TO PATIENTS, READ ALL INFORMATION CONTAINED IN THESE INSTRUCTIONS FOR USE.

Note: This IFU may be revised from time to time. Please refer to the Abbott Vascular website (www.abbottvascular.com/ifu) for the most current version at the time of the procedure.

If you have difficulties accessing this document or would like to request a paper copy at no extra cost, please contact: Abbott Vascular Customer Service at 1-800-227-9902.

1.0 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.

2.0 DEVICE DESCRIPTION

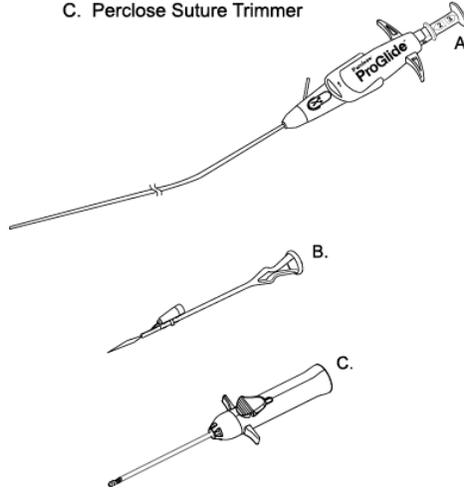
The Perclose ProGlide Suture-Mediated Closure (SMC) System is designed to deliver a single monofilament polypropylene suture to close femoral artery puncture sites following diagnostic or interventional catheterization procedures.

This Perclose ProGlide SMC device is composed of a plunger, handle, guide, and sheath. The Perclose ProGlide tracks over a standard 0.038" (or smaller) guidewire. A hemostasis valve restricts the blood flow through the sheath with or without the guidewire in place. The guide houses the needles, and the foot, and precisely controls the placement of these needles around the puncture site. The handle is used to stabilize the device during use. The plunger advances the needles and is used to retrieve the suture. A marker lumen is contained within the guide, with the intraluminal port of the lumen positioned at the distal end of the guide. Proximally, the marker lumen exits from the body of the device. The marker lumen allows a pathway for back-bleeding (obtaining mark) from the femoral artery to ensure proper device positioning.

Knot pusher accessories (Perclose[®] Snared Knot Pusher and/or Suture Trimmer) are included, and are designed to position the tied suture knot to the top of the arteriotomy. The Perclose Suture Trimmer is also designed to trim the trailing limbs of suture.

The Perclose ProGlide 6F SMC System is designed for use in 5F to 21F access sites. **The Perclose ProGlide SMC System is depicted in Figure 2.0-1.**

Figure 2.0-1
Perclose ProGlide Suture-Mediated Closure System
A. Perclose ProGlide device
B. Perclose Snared Knot Pusher
C. Perclose Suture Trimmer



3.0 HOW SUPPLIED

The Perclose ProGlide SMC device and accessories are provided sterile and non-pyrogenic in unopened, undamaged packages. Products are sterilized with ethylene oxide and intended for single use only. Do not resterilize. The device and primary packaging do not contain latex. Store in a cool, dry place.

Perclose ProGlide 6F SMC System

List/REF 12673

includes:

- One (1) Perclose ProGlide 6F SMC device
- One (1) Perclose Snared Knot Pusher **and**
Perclose Suture Trimmer

Accessories

Perclose Snared Knot Pusher

List/REF 12352

Perclose Suture Trimmer

List/REF 12427, 82122

QuickCut, Perclose, and Perclose ProGlide are registered trademarks of Abbott Laboratories.

4.0 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.

5.0 CONTRAINDICATIONS

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

6.0 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.

7.0 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 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.

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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 5-8 F 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 8.5-21 F 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.

8.0 SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the Perclose ProGlide SMC Devices have not been established in the following special patient populations:

- Patients in whom introducer sheaths < 5F or > 21F were used during the catheterization procedure.
- Patients with small femoral arteries (< 5 mm in diameter).
- Patients with access sites above the most inferior border of the inferior epigastric artery (IEA) and/or above the inguinal ligament based upon bony landmarks.
- Patients with access sites in the profunda femoris or superficial femoral arteries, or the bifurcation of these vessels.
- Patients having a hematoma, pseudoaneurysm or arteriovenous fistula present prior to sheath removal.
- Patients with femoral artery calcium which is fluoroscopically visible at access site.
- Patients with severe claudication, iliac or femoral artery diameter stenosis greater than 50% or previous bypass surgery or stent placement in the vicinity of access site.
- Patients with access sites in vascular grafts.
- Patients with prior intra-aortic balloon pump at access site.
- Patients with ipsilateral femoral venous sheath during the catheterization procedure.
- Patients with ipsilateral arterial access sites punctured and compressed within 48 hours of closure. Note: The previous/initial puncture site may have the potential to re-bleed due to an unstable clot and/or anticoagulants, even if the new puncture site is successfully closed with Perclose ProGlide SMC device.
- Patients where there is difficulty inserting the introducer sheath or greater than 2 ipsilateral arterial punctures at the start of the catheterization procedure.
- Patients with antegrade punctures.
- Patients with intra-procedural bleeding around access site.
- Patients receiving glycoprotein IIb/IIIa inhibitors before, during, or after the catheterization procedure.
- Patients who are pregnant or lactating.
- Patients with bleeding diathesis or coagulopathy.
- Patients younger than 18 years of age.
- Patients who are morbidly obese (Body Mass Index ≥ 40 kg/m²).
- Patients with active systemic or cutaneous infection or inflammation.

Before considering early discharge, assess the patient for the following clinical conditions:

- conscious sedation
- anticoagulation, thrombolytic, or antiplatelet therapy
- unstable cardiac status
- hematoma at the closure site
- hypotension
- pain while walking
- bleeding at the closure site
- any comorbid condition requiring observation

The presence of any of the above factors has generally led to the deferral of early discharge recommendations.

9.0 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

10.0 CLINICAL STUDIES

10.1 THE PEVAR CLINICAL TRIAL

The PEVAR trial was a prospective, multicenter, randomized concurrently-controlled clinical trial. Patients with AAA who were suitable candidates for endovascular repair using the Endologix's Powerlink Stent Graft with the 21F IntuiTrak Delivery System and for percutaneous femoral artery closure who met the prospectively defined inclusion/exclusion criteria were randomized to treatment with the IntuiTrak System via a totally percutaneous access approach (PEVAR=Test) or via a standard vascular exposure cutdown approach (SEVAR=Control). Randomization was carried out in a 2:1 PEVAR: SEVAR manner. PEVAR patients had their femoral artery access sites closed using either the ProGlide or another closure system. Prior to the randomization of the first patient at each investigational site, a minimum of 2 patients were treated in a roll-in phase at the investigational site. Roll-in patients underwent the same treatment and follow-up as the randomized patients.

The PEVAR trial included the Independent Access Site Closure Study which was a set of analyses designed to evaluate the safety and effectiveness of the ProGlide using the pre-close technique to percutaneously close ipsilateral femoral artery access sites up to 21F sheath size. The primary analysis was based on a non-inferiority hypothesis test to demonstrate the ProGlide arm is non-inferior to the SEVAR arm. Data from the ProGlide (n=50) and SEVAR (n=50) arms, are briefly presented below.

10.1.1 Methods

All patients underwent pre-procedure assessments prior to enrollment in the trial. The protocol required clinical assessments prior to discharge, at 1 month and 6 months. An independent clinical events committee adjudicated potential endpoint events of both major and minor ipsilateral access site vascular complications. The enrollment has been completed and all 6-month visits have been completed. The following assessments were required at pre-discharge, 1 month, and 6 months:

- Medication review (1 and 6 months only)
- Physical exam, including overall health and physical assessment, lower extremity sensorimotor exam and access site assessment
- Serum creatinine, blood urea nitrogen, hematocrit and hemoglobin
- ABI
- Contrast-enhanced CT scan of the abdomen and pelvis (1 month only)
- Bilateral femoral duplex ultrasound (pre-discharge and 6 month only)
- SF-36 QOL (1 and 6 months only)
- Pain scale
- Adverse events

10.1.2 Results of the Independent Access Site Closure Study for the Randomized ProGlide vs. SEVAR Arms

Patient Demographics

In general, baseline demographics were comparable between the ProGlide and the SEVAR patients. There was a difference in age between the ProGlide and SEVAR arms (69.9 ± 6.6 vs.

73.2 ± 8.8) which did not appear to affect the overall study outcome, based on additional adjusted analysis.

Primary Endpoint

The primary endpoint for the Independent Access Site Closure Study of the PEVAR trial was the major ipsilateral access site vascular complication rate at 30 days for patients treated percutaneously (PEVAR ProGlide arm [Test]) compared to that of patients treated using standard surgical vascular access (SEVAR group [Control]).

Major ipsilateral access site vascular complications are a composite of the following events:

- access site vascular injury requiring surgical repair, angioplasty, or ultrasound-guided compression, or thrombin injection
- new onset lower extremity ischemia that is attributed to arterial access or closure causing a threat to the viability of the limb and requiring surgical or additional percutaneous intervention
- access site-related bleeding requiring transfusion
- access site-related infection requiring intravenous antibiotics or a prolonged hospitalization
- access site-related nerve injury that is permanent or requires surgery

The study results show that at 30 days, ProGlide patients had a 6.0% (3/50) major ipsilateral access site vascular complication rate vs. the SEVAR patients who had a 10% (5/50) major ipsilateral access site vascular complication rate. The non-inferiority test for the primary endpoint revealed a p value = 0.0048 and resulted in the rejection of the null hypothesis, demonstrating that ProGlide is non-inferior to SEVAR in the closure of femoral artery access sites up to 21F sheath size (Table 10.1.2-1).

Table 10.1.2-1: Non-inferiority Test for Primary Endpoint – Per Subject Analysis (Modified Intent-to-Treat Population¹ - ProGlide vs. SEVAR)

	ProGlide N = 50	SEVAR N = 50	p-value³
Major Ipsilateral Access Site Vascular Complication at 30 days [95% Confidence Interval] ²	6.0% (3/50) [1.3%, 16.5%]	10.0% (5/50) [3.3%, 21.8%]	0.0048

¹Defined as all patients who were randomized and treated

²By Clopper-Pearson exact confidence interval

³One-sided p-value and 95% confidence interval for non-inferiority test by using asymptotic test statistics with non-inferiority margin of 10%

Select Secondary Endpoints

In the Independent Access Site Closure Study of the PEVAR trial, the following select secondary endpoints were also evaluated.

- Procedure time was defined as elapsed time from the first skin break to final closure (skin to skin time)

-
- Minor ipsilateral access site complications included minor ipsilateral access site vascular complications and narcotic analgesic use for ipsilateral access site pain at 30 days. Minor ipsilateral access site vascular complications included:
 - Access site pseudoaneurysm or AV fistula documented by ultrasound,
 - Access site hematoma ≥ 6 cm
 - Post-discharge access site-related bleeding requiring > 30 minutes to re-achieve hemostasis
 - Lower extremity arterial emboli or stenosis that is attributed to arterial access or closure
 - Deep vein thrombosis
 - Access site-related vessel laceration
 - Transient access site-related nerve injury
 - Access site wound dehiscence
 - Access site related lymphocele
 - Localized access site infection treated with intramuscular or oral antibiotics
 - Time to actual hospital discharge was defined as elapsed time from sheath removal to actual physical discharge from the hospital.
 - Time to ambulation was defined as elapsed time between sheath removal and time when the patient stands and walks at least 20 feet without re-bleeding.
 - Ipsilateral pain score at pre-discharge
 - Time to hemostasis for the ipsilateral access site was defined as elapsed time from sheath removal to first observed cessation of CFA bleeding (excluding cutaneous or subcutaneous oozing).
 - Closure device success was defined as successful achievement of index procedure ipsilateral access site hemostasis with percutaneous closure without surgical intervention.
 - Ipsilateral access site closure success was defined as successful achievement of hemostasis with percutaneous closure devices and without surgical intervention and freedom from major ipsilateral access site vascular complications within 48 hours of the index procedure or hospital discharge, whichever occurs first.

As shown in **Table 10.1.2-2**, the ProGlide arm had a 25% shorter procedure time than the SEVAR arm (106.5 ± 44.9 vs. 141.1 ± 73.4 , $p=.0076$). There were no differences in the minor ipsilateral access site complications, time to actual hospital discharge, time to ambulation and ipsilateral pain score at pre-discharge between the ProGlide and SEVAR arms. In the ProGlide arm, the time to hemostasis for the ipsilateral access site was 57% shorter than in the SEVAR arm (9.8 ± 17 vs. 22.7 ± 22.9 minutes, 95% CI of the difference $[-21.1, -4.7]$). In addition, the ProGlide arm achieved a closure device success rate and access site closure success rate at 96% and 94%, respectively.

Table 10.1.2-2: Select Secondary Endpoints

Secondary Endpoints	ProGlide N = 50	SEVAR N = 50	Difference (95% CI)¹	Superiority Test p-value
Procedure Time (minutes) [95% Confidence Interval] ¹	106.5 ± 44.9 (50) [93.7, 119.2]	141.1 ± 73.4 (50) [120.3, 162.0]	-34.7 [-58.9, -10.4]	0.0076 ³
Minor Ipsilateral Access Site Complications at 30 days⁵ [95% Confidence Interval] ²	22.0% (11/50) [11.5%, 36.0%]	30.0% (15/50) [17.9%, 44.6%]	-8.0% [-25.1%, 9.1%]	0.4954 ⁴
Minor Ipsilateral Access Site Vascular Complications at 30 days [95% Confidence Interval] ²	4.0% (2/50) [0.5%, 13.7%]	8.0% (4/50) [2.2%, 19.2%]	-4.0% [Assumptions not met] ⁶	--
Narcotic Analgesic Use for Ipsilateral Access Site Pain at 30 days [95% Confidence Interval] ²	18.0% (9/50) [8.6%, 31.4%]	28.0% (14/50) [16.2%, 42.5%]	-10.0% [-26.4%, 6.4%]	--
Time to Actual Hospital Discharge (hours) [95% Confidence Interval] ¹	31.4 ± 16.9 (50) [26.6, 36.2]	45.7 ± 59.9 (48) [28.3, 63.1]	-14.3 [-32.3, 3.7]	--
Time to Ambulation (hours) [95% Confidence Interval] ¹	17.8 ± 7.2 (50) [15.7, 19.9]	20.5 ± 16.9 (48) [15.6, 25.5]	-2.7 [-8.0, 2.5]	--
Ipsilateral Pain Scale Score at Pre- Discharge [95% Confidence Interval] ¹	2.1 ± 2.2 (50) [1.5, 2.7]	2.6 ± 2.4 (49) [1.9, 3.3]	-0.5 [-1.4, 0.4]	--
Time to Hemostasis for Ipsilateral Access Site (minutes)³ [95% Confidence Interval] ²	9.8 ± 17.0 (50) [5.0, 14.7]	22.7 ± 22.9 (47) [16.0, 29.4]	-12.9 [-21.1, -4.7]	--
Closure Device Success [95% Confidence Interval] ²	96.0% (48/50) [86.3%, 99.5%]	N/A	N/A	--
Access Site Closure Success [95% Confidence Interval] ²	94.0% (47/50) [83.5%, 98.7%]	N/A	N/A	--

¹By normal approximation

²By Clopper-Pearson exact confidence interval

³By two-sample t-test, pre-specified hypothesis test based hierarchical test procedure.

⁴By Fisher's Exact Test, pre-specified hypothesis test based hierarchical test procedure.

⁵A composite endpoint including minor Ipsilateral Access site vascular complications and narcotic analgesic use for Ipsilateral access site pain at 30 days

⁶Insufficient sample size or small frequency in the numerator for the validity of normal approximation assumption

ADVERSE EVENTS

Adverse events related to major and minor ipsilateral access site vascular complications that occurred within the first 30 days are listed in **Table 10.1.2-3**.

Table 10.1.2-3: Major and Minor Ipsilateral Access Site Vascular Complications through 30 Days¹

	ProGlide N = 50	SEVAR N = 50
Major Ipsilateral Access site Vascular Complications at 30 Days	6.0% (3/50)	10.0% (5/50)
Access site vascular injury requiring surgical repair, angioplasty, or ultrasound-guided compression, or thrombin injection	2.0% (1/50)	2.0% (1/50)
New onset lower extremity ischemia that is attributed to arterial access or closure causing a threat to the viability of the limb and requiring surgical or additional percutaneous intervention	4.0% (2/50)	4.0% (2/50)
Access site-related bleeding requiring transfusion	2.0% (1/50)	4.0% (2/50)
Access site-related infection requiring intravenous antibiotics or a prolonged hospitalization	0.0% (0/50)	0.0% (0/50)
Access site-related nerve injury that is permanent or requires surgery	0.0% (0/50)	2.0% (1/50)
Minor Ipsilateral Access Site Vascular Complications at 30 days	4.0% (2/50)	8.0% (4/50)
Access site pseudoaneurysm or AV fistula documented by ultrasound	0.0% (0/50)	0.0% (0/50)
Access site hematoma \geq 6cm	0.0% (0/50)	2.0% (1/50)
Post-discharge access site-related bleeding requiring > 30 minutes to re-achieve hemostasis	0.0% (0/50)	0.0% (0/50)
Lower extremity arterial emboli or stenosis that is attributed to arterial access or closure	4.0% (2/50)	4.0% (2/50)
Deep vein thrombosis	0.0% (0/50)	0.0% (0/50)
Access site-related vessel laceration	0.0% (0/50)	0.0% (0/50)
Transient access site-related nerve injury	0.0% (0/50)	2.0% (1/50)
Access site wound dehiscence	0.0% (0/50)	0.0% (0/50)
Access site related lymphocele	0.0% (0/50)	0.0% (0/50)
Localized access site infection treated with intramuscular or oral antibiotics	0.0% (0/50)	0.0% (0/50)

¹ Include only each subject's first occurrence of each event

10.1.3 Clinical Data from the Roll-in Phase

There were 22 patients treated in the ProGlide roll-in phase of the PEVAR trial. The mean age of this treatment group was 71.1 ± 6.9 years. The major ipsilateral access site vascular complication rate was 4.5 % (1/22). The mean procedure time was 118.2 ± 43.4 minutes and the average time to ipsilateral hemostasis was 7.7 ± 6.8 minutes for the roll-in phase. Additionally, the closure device success rate and the access site closure success rate were both

95.5% respectively. These results were comparable to the ProGlide arm in the randomized phase and substantiated the safety and effectiveness of the ProGlide device.

CONCLUSION

The Perclose ProGlide SMC device, using a pre-close technique, is non-inferior to the standard vascular surgical cutdown in the closure of femoral artery access sites up to 21F sheath size. The Perclose ProGlide SMC device can be safely and effectively used to close femoral artery access sites up to 21F sheath size. Additionally, use of the ProGlide pre-close technique can result in shorter procedure time and shorter time to achieve hemostasis.

10.2 THE CLOSER IDE CLINICAL TRIAL THE CLOSER IDE CLINICAL TRIAL

The previous generation suture mediated closure device was known as the Closure and Closure S SMC Systems. The CLOSER IDE trial provided safety and effectiveness data which supported an indication for closing femoral arteries up to 8F and the addition of interventional catheterization procedures.

The Closer IDE Trial¹ was designed as an equivalency trial for the 30-day primary combined safety endpoint of freedom from major complications and a primary efficacy endpoint of time to discharge when compared to the control group (STAND II Trial). The study prospectively examined the safety and effectiveness of femoral artery closure using The Closer 6F SMC Device following interventional catheterization procedures using 5F to 8F sheaths. Two hundred twenty five (225) patients were enrolled in post-close arm and one hundred sixty (160) patients were enrolled in the pre-close arm of The Closer IDE Trial. In the post-close arm, the deployment of The Closer device occurred at the end of the catheterization procedure. In the pre-close arm, The Closer device was deployed in two steps with suture delivery at the beginning of the catheterization procedure with knot tying and knot delivery occurring at the end of the procedure.

Procedural success was achieved in 223 patients (99.1%) in the post-close arm and 158 patients (98.8%) in the pre-close arm. Time to discharge was 28.9 ± 22.7 hours and 30.1 ± 33.9 hours for the post-close and pre-close patients respectively. The secondary endpoint of time to hemostasis was 10.9 ± 42.0 minutes and 8.2 ± 51.0 minutes for the post-close and pre-close patients respectively, versus 7.9 ± 6.4 hours for the control group patients, $p < 0.0001$, and the secondary endpoint of time to ambulation was 4.7 ± 7.1 hours and 6.5 ± 11.4 hours for the post-close and pre-close patients respectively.

Device success was 92.0% (207/225 patients) in the post-close arm and 89.4% (143/160 patients) in the pre-close arm. Failure to deploy The Closer occurred in 17 (7.6%) patients in the post-close arm and 15 (9.4%) patients in the pre-close arm.

A major complication was defined as surgical repair of vascular injury, ultrasound-guided compression, groin related transfusion, or groin related infection requiring IV antibiotics and extended hospitalization. The primary safety endpoint was the combined rate of major complications at 30 days. For the post-close arm, one patient received a blood transfusion

¹ Perclose ProGlide is a design evolution of The Closer 6F SMC system. The results of The Closer IDE Trial are applicable to the Perclose ProGlide 6F SMC System because of system similarities.

subsequent to a retroperitoneal bleed. Another patient underwent surgical repair of a vascular injury and received a blood transfusion subsequent to the intervention. Both patients were free of symptoms at time of follow up. For the pre-close arm, one patient developed a hematoma > 6 cm as a result of insufficient hemostasis. Subsequently, the patient required vascular surgery to repair the femoral artery and received blood transfusions intraoperatively. The second patient received IV antibiotic therapy for a local infection that presented post discharge. Both patients reported no further sequelae at time of follow-up.

The incidence of vascular complication other than major was a secondary safety endpoint of the study and in the post-close arm consisted of one (0.4%) false aneurysm, one (0.4%) infection requiring IM and PO antibiotics, two (0.9%) ≥ 6 cm hematomas, and two (0.9%) retroperitoneal bleeds not requiring intervention. For the pre-close arm, the incidence of vascular complication other than major consisted of one (0.6%) ≥ 6 cm hematoma and one (0.6%) groin infection requiring PO antibiotics. All patients were free of symptoms at time of follow up. The results of the effectiveness measures are summarized in **Table 10.2-1**.

Table 10.2-1: Principle Effectiveness Results

(All patients enrolled in The Closer IDE Trial;
n=225 for the post-close arm; n=160 for the pre-close arm)

Effectiveness Measures*	The Closer IDE Trial Post-Close Patients	The Closer IDE Trial Pre-Close Patients
Treated patients (per event)	n=225	n=160
Procedural success	223 (99.1%)	158 (98.8%)
Device success	207 (92.0%)	143 (89.4%)
Device failure	17 (7.6%)	15 (9.4%)
Device malfunction	16 (7.1%)	14 (8.8%)
Device complication	1 (0.4%)	1 (0.6%)
Time to Hemostasis (mins) mean±SD (min. max.) Median [quartiles]	n=224 10.9±42.0 (1.0, 324.0) 3.0 [2.0, 5.0]	n=160 8.2±51.0 (0.1, 639.0) 1.5 [0.0, 5.0]
Time to Ambulation (hrs) mean±SD (min. max.) Median [quartiles]	n=225 4.7±7.1 (0.1, 71.4) 2.4 [1.6, 4.5]	n=160 6.5±11.4 (0.05, 100.9) 2.2 [1.2, 5.0]
Time to Discharge (hrs) mean±SD (min. max.) Median [quartiles]	n=225 28.9±22.7 (2.2, 240.2) 24.4 [22.0, 27.2]	n=160 30.1±33.9 (2.7, 292.6) 22.5 [20.2, 26.1]

*The number of patients listed under effectiveness measures is less than the total patients studied due to missing data for some patients. Device success = acute success using the device only or the device + adjunctive (non-arterial) compression.

Thus, the Perclose ProGlide SMC System reduced the time to hemostasis, ambulation (10 feet) and discharge in patients who had undergone diagnostic or interventional catheterization procedures without complicating clinical conditions (refer to **PRECAUTIONS** and **SPECIAL PATIENT POPULATIONS**).

ADVERSE EVENTS IN THE CLOSER IDE TRIAL

The Closer IDE Trial² was designed as a multi-center, multi-operator, prospective registry enrolling 225 patients in the post-close arm and 160 patients in the pre-close arm. The post-close arm studied the use of The Closer 6F system following interventional procedures using 5F to 6F sheaths. The pre-close arm studied the use of The Closer 6F system following interventional procedures using 7F to 8F sheaths utilizing the pre-close technique. The pre-specified analysis of the primary safety endpoint of the IDE Trial was the incidence of the combined rate of major complications at 30 days of patients undergoing interventional catheterization procedures. Post treatment, ultrasound evaluations were performed 0 to 15 days post discharge to verify detection of clinical complications. Two major complications were reported in each of the post-close and pre-close arms of The Closer IDE Trial. Neither of the two major complications reported in the post-close or pre-close arms were considered unanticipated events. No delayed major hemorrhagic events were reported despite early ambulation and early discharge of the patients with The Closer SMC device. The adverse events that were observed during the trial are reported in **Table 10.2-2**.

Table 10.2-2: Percentage of Patients who experienced Adverse Events

(All patients enrolled in The Closer IDE Trial;
n=225 for post-close arm; n=160 for pre-close arm)

Safety Measures, n (percent)	The Closer IDE Trial Post-Close Patients	The Closer IDE Trial Pre-Close Patients
Treated patients (per event)	n=225	n=160
Device Failure	17 (7.6%)	15 (9.4%)
Surgical repair*	1 (0.4%)	1 (0.6%)
U/S guided compression*	0 (0.0%)	0 (0.0%)
Transfusion*	2 (0.9%)	1 (0.6%)
Infection requiring IV Abx*	0 (0.0%)	1 (0.6%)
Hematoma \geq 6 cm	2 (0.9%)	1 (0.6%)
AV-fistula	0 (0.0%)	0 (0.0%)
Pseudoaneurysm	1 (0.4%)	0 (0.0%)
Vascular narrowing	0 (0.0%)	0 (0.0%)
Infection requiring IM\PO Abx	1 (0.4%)	1 (0.6%)
Retroperitoneal bleed	2 (0.9%)	0 (0.0%)
Incidence of Complications (per patient)		
Any complication [†]	6 (2.7%)	3 (1.9%)
Major complication [†]	2 (0.9%)	2 (1.2%)
No major complication	223 (99.1%)	158 (98.8%)

* Major complication

[†] Per patient; some patients may have experienced more than one complication.

² Perclose ProGlide is a design evolution of The Closer 6F SMC System. The results of The Closer IDE Trial are applicable to the Perclose ProGlide 6F SMC System because of system similarities.

No groin or device related deaths were reported in The Closer IDE Trial among the post-close or pre-close study patients. Other adverse events potentially associated with the use of The Closer SMC System were reported as an underlying event or did not occur during the clinical study. These include: deep vein thrombosis, infection extending hospitalization, late bleeding, wound dehiscence, vessel laceration, local pulse deficits or ischemia, embolization, transitory local irritation, nerve injury and vascular spasm. In addition, polyester surgical sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester surgical sutures are not absorbed, nor are any significant change in tensile strength known to occur *in vivo*.

11.0 THE PERCLOSE PROGLIDE SMC SYSTEM CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the Perclose ProGlide SMC System. The techniques and procedures described below are not intended as a substitute for the operator's experience and judgment in treating any specific patients.

11.1 Examination and Selection of Products

1. Select the Perclose ProGlide SMC device(s) for closure of 5F to 21F introducer sheath access sites.
2. After carefully inspecting the packaging of the Perclose ProGlide SMC device and accessories for damage to the sterile barrier, remove the device from the package.
3. Exercise care when using additional instruments, such as clamps, forceps or needle holders during device handling, to reduce the possibility of accidental device breakage or damage to the suture.
4. Verify marker lumen patency by flushing the marker lumen with saline until the saline exits the marker port. **Do not use the Perclose ProGlide SMC device if the marker lumen is not patent.**

11.2 Arterial Site and Puncture Considerations

1. An extremely deep tissue tract can influence needle trajectory, which prevents the Perclose ProGlide SMC device needles from engaging the cuffs, or secure knot tying, as the Suture Trimmer may not be able to advance the knot to the arterial wall for complete apposition before locking the knot. An extremely deep tissue tract may require a long access needle and/or upon inserting the Perclose ProGlide device, requires compression of the subcutaneous tissue (with the body of the device) to be able to obtain pulsatile flow.
2. Before inserting the access needle, use of ultrasound guidance to visualize the common femoral artery or fluoroscopy to visualize the femoral head is recommended. When using the femoral head as a reference point, target the middle of the femoral head as the puncture site. Performing a femoral angiogram through the introducer sheath (or procedural sheath) to verify that the access site is in the common femoral artery is recommended before anticoagulants are given.
3. Puncture the anterior wall of the common femoral artery at an angle of approximately 45 degrees. Avoid side wall or posterior wall femoral artery punctures.
4. Prior to deployment of the Perclose ProGlide SMC device, perform a femoral angiogram to evaluate the femoral artery site for vessel size, calcium deposits, tortuosity, and for disease or dissections of the arterial wall to avoid device cuff misses (device needles not engaging with the cuffs) and/or posterior wall suture placement and possible ligation of the anterior

and posterior walls of the femoral artery. Angiographically verify that the puncture is on the anterior wall of the common femoral artery. The puncture should be proximal to the bifurcation of the superficial femoral artery and the profunda femoris branch and distal to the inferior margin of the inferior epigastric artery.

5. There are **no** femoral artery reaccess restrictions after using Abbott Vascular closure devices.

11.3 SMC Device Placement 5F-8F Sheath, including Optional Pre-Close (11.3.1) and Maintaining Wire Access Techniques (11.3.2)

The following instructions detail the deployment sequence to close the access site of a catheterization procedure performed through a 5F to 8F sheath size.

1. Place a 0.038" (or smaller) guidewire through the procedural (or introducer) sheath. Remove the procedural sheath while applying pressure on the groin to maintain hemostasis.
2. Backload the device over the guidewire until the guide wire exit port of the device sheath is just above the skin line. Remove the guidewire before the exit port crosses the skin line.
3. Continue to advance the device just until brisk pulsatile flow of blood is evident from the marker lumen. The device lever (**marked #1**) and logo should be facing the ceiling (12 o'clock). Position the device at a 45-degree angle. Deploy the foot by lifting the lever (**marked #1**) on the body of the device. **Do not deploy the foot unless brisk pulsatile flow of blood ("mark") is evident from the marker lumen.**
4. Gently pull the device back to position the foot against the arterial wall. If proper position of the foot has been achieved, tactile sensation will be felt **AND** blood marking will cease or be significantly reduced to a slight drip. If marking does not stop or significantly change, evaluate the angiogram for femoral artery size, calcium deposits, tortuosity, disease and for location of the puncture (ensure footplate is not in bifurcation or side branch). Reposition the device to stop blood marking or reinsert the wire, remove the device to hold manual compression or insert a new sheath.
5. While maintaining device position, stabilize the device with your free hand (the one not used to deploy the device) to maintain the gentle retraction and to ensure the device does not twist or move forward during deployment. Use your other hand to deploy needles by pushing on the plunger assembly (**in the direction marked #2**) until you visually confirm that the collar of the plunger makes contact with the proximal end of the body. Do not use excessive force or repeatedly push the plunger assembly. After visually confirming contact with the body of the device only **one time**, this step is complete.
6. Using your thumb as a fulcrum on the handle, gently disengage the needles by pulling the plunger assembly back (**in the direction marked #3**) and completely remove the plunger and needles from the body of the device. One suture limb will be attached to the anterior needle. The posterior needle will be free of suture. Pull back on the plunger until the suture is taut, which confirms that all the suture has been fully retracted from the body of the device.
7. Do not attempt to redeploy the needles if the suture limb is not attached to the anterior needle. Reinsert the guidewire, and remove the device over the wire. Insert a new Perclose ProGlide SMC device to complete the procedure.
8. Use the QuickCut[®] suture-trimming mechanism located on the body of the device to cut the suture from the anterior needle distal of the link. Use of a new, sterile scalpel or scissors is optional.

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9. Relax the device and then return the foot to its original closed position by pushing the lever **(marked #4)** down to the body of the device. Do not attempt to remove the device without closing the lever.
 10. Deliberately retract the Perclose ProGlide SMC device to release the suture knot. Continue to gently withdraw the device until the guide wire exit port is visible above the skin line.
 11. Slightly rotate the device until you can see the two suture limbs in the bend of the distal guide. Grasp the suture adjacent to the device sheath and pull the suture ends through the distal end of the proximal guide. The rail suture limb is blue and is the longer of the two suture limbs. This rail suture limb will be used to advance the knot. The shorter, non-rail suture limb is white tipped and will be used to lock the knot.
 12. Continue with Knot Advancement (Section 11.5). If closing over the wire continue with Section 11.3.2.

11.3.1 OPTIONAL, PRE-CLOSE TECHNIQUE

The Perclose ProGlide suture can be placed around the arteriotomy at the beginning of the procedure and knot advancement can be placed on hold until the procedure is complete. Steps 1-4 are necessary when using the pre-close technique.

1. After completing steps 1-10 of Device Placement as described in Section 11.3, slightly rotate the device until you can see the two suture limbs in the bend of the distal guide. Grasp the sutures adjacent to the sheath. While holding the two suture limbs tightly together, gently pull both suture ends through the distal end of the proximal guide.
2. Immediately place a shodded hemostat or clamp to hold the two suture limbs together at the distal end of the non-rail suture limb (shortest blue limb with white tip). To prevent knot advancement or locking of the knot, care must be taken not to pull on the individual suture limbs until the clamp is securely holding the two limbs together.
3. After securing the suture limbs and before inserting the procedural sheath, gently pull on the clamp until the suture is taut to **remove any suture slack from the tissue tract**.
4. Place the clamped suture under a sterile towel during the procedure. NOTE: The monofilament suture can be damaged by opening and closing the clamp. If you want to attach the suture to the drape, it is recommended that you use a second clamp with the tip placed through the handle of the first clamp and attach the second clamp to the drape.
5. At the end of the catheterization, reinsert the guidewire into the procedural sheath.
6. Knot advancement to close the arteriotomy will resume starting with step 11.3.2 (In step # 3, the procedural sheath will be removed instead of a ProGlide Device.)

11.3.2 OPTIONAL, MAINTAINING WIRE ACCESS DURING KNOT ADVANCEMENT (CLOSING OVER THE WIRE)

If the operator chooses to maintain wire access, reinsert the guidewire after exposing the guide wire exit port at skin level AND after the sutures have been harvested from the distal guide but before removing the device for knot advancement. Steps 1-8 are necessary when closing over the wire.

1. There should be sufficient guidewire exposed out of the guide wire exit port before removing the device.
2. Wrap the rail limb (long blue limb) of suture around your left index finger, low close to skin level.

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3. Remove the Perclose ProGlide SMC device with the right hand, while maintaining an adequate length of guidewire inside the artery. This allows placement of another Perclose ProGlide SMC device or a sheath in the event that hemostasis is not obtained.
 4. While removing the device with the right hand, simultaneously advance the knot to the arteriotomy by applying slow, consistent increasing tension to the rail suture limb, keeping the suture coaxial to the tissue tract. (During 5-8F procedures, do not advance the knot with the Snared Knot Pusher or the Suture Trimmer until the wire has been completely removed from the tissue track).
 5. Assess the site for adequate hemostasis. If bleeding is controlled, the operator should then remove the guidewire. Next, use the Snared Knot Pusher or Suture Trimmer, as described in Section 11.5.1 and 11.5.2, to advance and tighten the knot until complete closure is achieved. Confirm the security of the knot by having the patient cough and/or bend his/her leg (Active testing for hemostasis is only for 5F-8F sheaths. For 8.5F-21F sheath closures, active confirmation should not be performed; only visual confirmation of hemostasis should be employed.). Patients may be able to move freely in bed without head of bed or leg restrictions if the close is successful.
 6. If the wire is still in place and suture breakage occurs during knot advancement, or if hemostasis is not achieved, another Perclose ProGlide SMC device can be used to complete the procedure or a sheath can be inserted. Either remove the broken suture limbs or cut the suture limbs close to the knot (using the Suture Trimmer in Section 11.5.2 or a new, sterile scalpel or scissor).
 7. Care should be taken to avoid excessive force if the insertion of another Perclose ProGlide SMC device or introducer sheath is required. To avoid resistance, use an introducer sheath small enough to avoid undue force.
 8. If hemostasis cannot be achieved after the wire is removed, apply manual compression.

11.4 SMC Device Placement 8.5F - 21F Sheath

The following instructions detail the deployment sequence for closing the access site of an interventional catheterization procedure performed through 8.5F to 21F sheath size. The pre-close technique (incorporated in steps below) must be used when closing sheath sizes from 8.5F to 21F.

1. Place a 0.038" (or smaller) guidewire through the introducer sheath. Remove the introducer sheath while applying pressure on the groin to maintain hemostasis.
2. Backload the first of two ProGlide SMC devices over the guidewire until the guide wire exit port of the device sheath is just above the skin line. Remove the guidewire before the exit port crosses the skin line.
3. Continue to advance the device just until brisk pulsatile flow of blood is evident from the marker lumen. The device lever (**marked #1**) and logo should be facing the ceiling (12 o'clock).
4. Rotate the device approximately 30 degrees towards the patient's right side (approximately 10 o'clock (**Figure 1**)). Position the device at a 45-degree angle. Deploy the foot by lifting the lever (**marked #1**) on the body of the device. **Do not deploy the foot unless brisk pulsatile flow of blood ("mark") is evident from the marker lumen.**
5. Gently pull the device back to position the foot against the arterial wall. If proper position of the foot has been achieved, tactile sensation will be felt **AND** blood marking will cease or be significantly reduced to a slight drip. If marking does not stop or significantly change, evaluate the angiogram for femoral artery size, calcium deposits, tortuosity, disease and for

location of the puncture (ensure footplate is not in bifurcation or side branch). Reposition the device to stop blood marking (maintain the 30 degree rotation) or reinsert the wire and evaluate the situation before continuing the procedure.

6. While maintaining the device position, stabilize the device with your free hand (the one not used to deploy the device) to maintain the gentle retraction and to ensure the device doesn't twist or move forward during deployment. Use your other hand to deploy needles by pushing on the plunger assembly **(in the direction marked #2)** until you visually confirm that the collar of the plunger makes contact with the proximal end of the body. Do not use excessive force or repeatedly push the plunger assembly. After visually confirming contact with the body of the device only **one time**, this step is complete.
7. Using your thumb as a fulcrum on the handle, gently disengage the needles by pulling the plunger assembly back **(in the direction marked #3)** and completely remove the plunger and needles from the body of the device. One suture limb will be attached to the anterior needle. The posterior needle will be free of suture. Pull back on the plunger until the suture is taut, which confirms that the suture has been fully retracted from the body of the device.
8. Do not attempt to redeploy the needles if the suture limb is not attached to the anterior needle. Reinsert the guidewire, and remove the device over the wire. Insert a new Perclose ProGlide SMC device to complete the procedure.
9. Use the QuickCut[®] suture-trimming mechanism located on the body of the device to cut the suture from the anterior needle distal of the link. Use of a new, sterile scalpel or scissors is optional.
10. Relax the device and then return the foot to its original closed position by pushing the lever **(marked #4)** down to the body of the device. Do not attempt to remove the device without closing the lever.
11. Deliberately retract the Perclose ProGlide SMC device to release the suture knot. Continue to gently withdraw the device until the guide wire exit port is visible above skin line.
12. Slightly rotate the device until you can see the two suture limbs in the bend of the distal guide. Grasp the sutures adjacent to the sheath. While holding the two suture limbs **tightly together**, gently pull both suture ends through the distal end of the proximal guide.
13. **Immediately** place a shodded hemostat or clamp to hold the two suture limbs together at the distal end of the non-rail suture limb (shortest limb with white tip). To prevent knot advancement or locking of the knot, care must be taken not to pull on the individual sutures until the clamp is securely holding the two suture limbs together.
14. Gently pull on the clamp until the suture is taut to **remove any suture slack from the tissue tract**. Place the clamped suture on the **right side** of the patient under a sterile towel. It is important to identify which suture is deployed first, as this is the knot that needs to be advanced first at the end of the procedure. NOTE: The monofilament suture can be damaged by opening and closing the clamp. If you want to attach the suture to the drape, it is recommended that you use a second clamp with the tip placed through the handle of the first clamp and attach the second clamp to the drape.
15. Reinsert the guidewire. There should be sufficient guidewire inside the vessel and exposed out of the guide wire exit port for device exchange.
16. Remove the Perclose ProGlide SMC device, while holding compression above the puncture site and maintaining an adequate length of guidewire inside the artery. This allows placement of another Perclose ProGlide SMC device.

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17. Repeat steps 2-13 with the second ProGlide device. NOTE: In step 4, the second device should be rotated approximately 30 degrees towards the patient's left side (approximately 2 o'clock).
 18. Gently pull on the clamp until the suture is taut to **remove any suture slack from the tissue tract**. Place the clamped suture for the second device on the left side of the patient under a sterile towel. It is important to identify which suture was placed first and which suture was placed second. At the completion of the procedure, the suture knots will be advanced in the order they were placed. The knot from the first device (placed on the right side of the patient) would be advanced, followed by the knot from the second device (placed on the left side of the patient).
 19. **Knot advancement will be placed on hold at this point and the sutures set aside under sterile towels while the operator proceeds with the procedure.**
 20. When utilizing a pre-close technique, the Perclose ProGlide SMC device is exchanged for an appropriately sized introducer sheath.
 21. After completing the procedure, a hydrophilic or general purpose guidewire should be advanced into the artery. Maintain adequate length of guidewire in both the vessel and outside sheath to maintain access until hemostasis is achieved.
 22. Heavily irrigate the secured ProGlide sutures with heparinized saline to remove any dry blood.
 23. Remove the clamp from the first suture (patient's right side / 10 o'clock). The rail suture limb is blue and is the longer of the two suture limbs. This rail suture limb will be used to advance the knot. The shorter, non-rail suture limb is white tipped and will be used to lock the knot.
 24. Wrap the rail suture limb securely around your left forefinger, low close to skin level, and hold the suture coaxial to the tissue tract. **While maintaining guidewire access**, carefully remove the entire sheath system and simultaneously pull the rail limb with slow, consistent increasing tension. Avoid quick or jerky type movements with the suture limbs. Manual pressure should be applied proximal to the puncture site for hemostasis, while the sheath is removed and during initial suture advancement.
 25. **Do NOT lock the knot at this point.** Due to the size of the arteriotomy, use of the Snared Knot Pusher or Suture Trimmer (sections 11.5.1 and 11.5.2) may be needed to approximate the tissue edges. However, **DO NOT lock or excessively tighten the knot while the guidewire is still in the vessel.** Again place the suture limbs on the right side of the patient for easy identification as the first suture deployed.
 26. Remove the clamp from the second suture (patient's left side / 2 o'clock (**Figure 1**)) and **advance the knot using the same technique and maintaining guidewire access. Again, do NOT lock the knot.** Place the suture limbs on the left side of the patient for easy identification as the second suture placed.
 27. Assess for hemostasis. If brisk bleeding is observed, advance the first (patient's right side / 10 o'clock (**Figure 1**)) suture again and then advance the second (patient's left side / 2 o'clock (**Figure 1**)) suture again. Multiple knot advancements are common when closing larger arteriotomies. However, **DO NOT lock or excessively tighten the knot while the guidewire is still in the vessel. Until the wire is removed, some bleeding will be visible, but it should not be pulsatile blood flow.**
 28. If acceptable hemostasis is not observed, additional Perclose ProGlide SMC devices may be deployed at this point. Repeat steps 2-12 with the next ProGlide device. NOTE: In step 4, the third device should not be rotated. The device will be deployed in a straight cranial/caudal position (logo facing the ceiling / 12 o'clock (**Figure 1**)). After deployment of

this device, advance the knot in the same fashion. **DO NOT lock the knot or excessively tighten the knot while the guidewire remains in the vessel.**

29. Assess the site for adequate hemostasis. **If bleeding is controlled, the operator should then remove the guidewire.** With the rail suture limb (longer, blue limb) securely wrapped around the left forefinger, again advance the first suture (patient's right side / 10 o'clock (**Figure 1**)) and then place the Suture Trimmer or Snared Knot Pusher under the left thumb to assume a single-handed position and complete knot advancement with slow, consistent increasing tension until the suture is taut (guitar string tightness). With the Suture Trimmer or Snared Knot Pusher in place and the suture taut, tighten the knot by gently pulling the non-rail (shorter, white tipped) suture limb keeping it coaxial to the tissue tract.
30. **Do NOT cut the suture.** Follow the same steps to advance the second suture (patient's left side/ 2 o'clock (**Figure 1**)), coaxial to the tissue tract and lock the knot but **DO NOT cut the suture.** If applicable, advance the additional sutures and lock the knots in the order that they were placed (patient's right side/10 o'clock, patient's left side/2 o'clock, patient's midline /12 o'clock (**Figure 1**)), Assess bleeding. If hemostasis is deemed adequate cut the suture tails below the surface of the skin using the Suture Trimmer (Section 11.5.2) or a new, sterile scalpel or scissors.

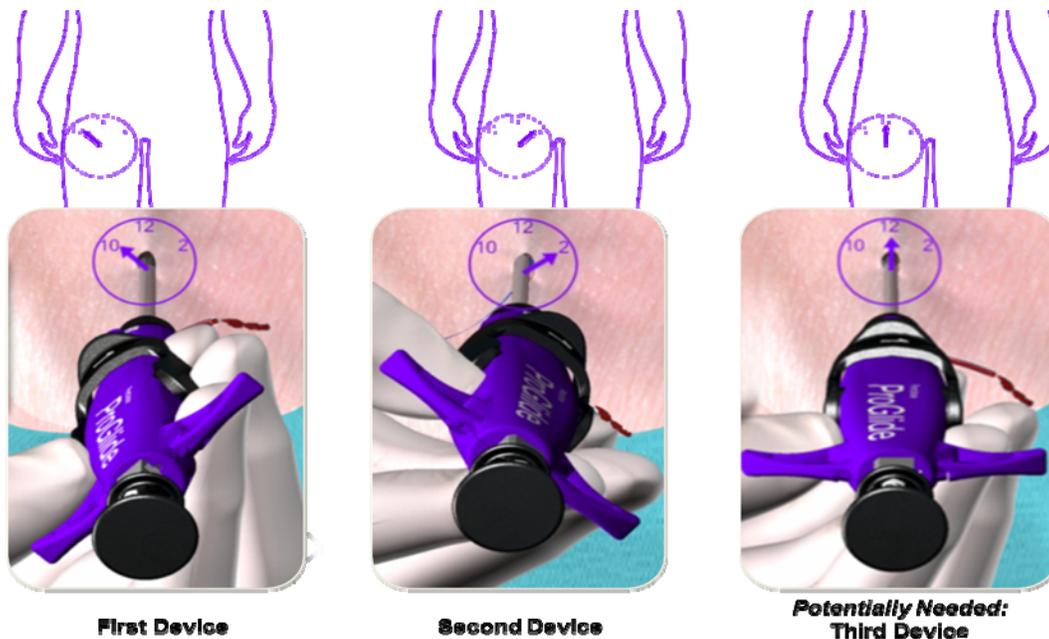


Figure 1: Device Orientation

11.5 Knot Advancement

11.5.1 IF THE SNARED KNOT PUSHER IS USED:

1. Place approximately 2 cm of the rail (longer, blue) limb of the suture into the snare at the distal end of the Snared Knot Pusher.
2. Load the suture into the Snared Knot Pusher by pulling the snare through the tip of the Snared Knot Pusher.
3. Once loaded, the Snared Knot Pusher should slide easily on the suture.

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4. Securely wrap the rail suture limb (longer blue limb) around your left forefinger, low close to skin level.
 5. Do not tighten the suture around the sheath. Completely remove the device or the arterial sheath (if the device was deployed at the beginning of the catheterization procedure) from the artery, while simultaneously pulling gently on the rail limb. Always keep the suture coaxial to the tissue tract.
 6. With the rail suture limb securely wrapped around your left forefinger, and held coaxial to the tissue tract, gently pull on the suture limb with slow, consistent increasing tension while advancing the Snared Knot Pusher into the tissue tract with your right hand until the knot reaches the arterial surface. **Avoid quick or jerky type movements with the suture limbs.**
 7. Place the Snared Knot Pusher under your left thumb to assume a single-handed position and complete knot advancement by slow, consist increasing tension on the left forefinger until the rail suture is taut (guitar string tightness).
 8. With the Snared Knot Pusher held in position and keeping the rail suture limb taut, tighten the knot by gently pulling on the non-rail (shorter, white tipped) suture limb keeping it coaxial to the tissue tract.
 9. Hemostasis of the access site is achieved when the knot is fully advanced to the arterial surface, the slack is gently pulled from the knot with the non-rail limb while the Snared Knot Pusher holds tension on the rail limb of the suture, and the tissue is in complete apposition.
 10. Remove the Snared Knot Pusher from the tissue tract, relax tension on the suture, and test for hemostasis by having the patient cough or bend his/her leg (Active testing for hemostasis is only for 5F-8F sheaths. For 8.5F-21F sheath closures, active confirmation should not be performed; only visual confirmation of hemostasis should be employed.). If hemostasis has not been achieved, assume the single-handed position for 20 seconds or until hemostasis is achieved. Secure the knot again by gently pulling coaxial on the white tipped non-rail suture limb. Do not apply excessive pressure to the suture.
 11. Confirm the security of the knot by having the patient cough and/or bend his/her leg. (Active testing for hemostasis is only for 5F-8F sheaths. Only visually confirm hemostasis for 8.5F-21F.) Use the Suture Trimmer (11.5.2) or new, sterile scalpel or scissor to cut the trailing suture limbs below the skin. Patients may be able to move freely in bed without head of bed or leg restrictions if the close is successful.
 12. If hemostasis cannot be achieved, apply manual compression until hemostasis is achieved.

11.5.2 IF THE SUTURE TRIMMER IS USED:

1. Securely wrap the rail (longer, blue) limb of the suture around your left forefinger, low close to the skin.
2. Do not tighten the suture around the sheath. Completely remove the device or the arterial sheath (if the device was deployed at the beginning of the catheterization procedure) from the artery, while simultaneously pulling gently on the rail limb. Always keep the suture coaxial to the tissue tract.
3. With the rail (longer, blue) suture limb securely wrapped around your left forefinger, place the rail limb into the Suture Trimmer utilizing the following steps:
 1. Retract the Thumb Knob on the Suture Trimmer with right hand.
 2. Place the Suture Trimmer **under** the suture limb making an "x" or a "cross" between the suture limb and the mid-point of the Suture Trimmer.

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3. Slide the Suture Trimmer back to load the suture into the Suture Gate located at the distal end of the Suture Trimmer.
 4. Keeping the Thumb Knob retracted, turn the Suture Trimmer coaxial to the suture and then release the Thumb Knob to capture the suture in the Suture Gate. **Releasing the Thumb Knob before the suture is coaxial to the Suture Trimmer can cause the suture to be caught within the sliding mechanism at the distal tip and damage the suture.**
 5. Once the suture is loaded correctly, the Suture Trimmer should slide easily.
4. With the suture limb and Suture Trimmer coaxial to the tissue tract, move the knot to the arterial surface by advancing the Suture Trimmer with the right hand while placing slow, consistent increasing tension on the rail suture with the left forefinger. Avoid quick or jerkytype movements with the suture limbs. The Suture Trimmer and suture limbs should always remain coaxial to the tissue tract. The Thumb Knob should be at 12 o'clock (facing the ceiling) and the **Suture Trimmer should not be rotated.**
 5. With the rail (longer, blue) suture limb securely wrapped around the left forefinger, place the Suture Trimmer under the left thumb to assume a single-handed position and complete knot advancement with slow, consistent increasing tension until the suture is taut (guitar string tightness).
 6. With the Suture Trimmer held in position and keeping the rail suture limb taut, tighten the knot by gently pulling the non-rail (shorter, white tipped) suture limb, keeping it coaxial to the tissue tract.
 7. Hemostasis of the access site is achieved when the knot is fully advanced to the arterial surface, the slack is gently pulled from the knot with the non-rail limb while the Suture Trimmer holds tension on the rail limb of the suture, and the tissue is in complete apposition.
 8. Remove the Suture Trimmer from the tissue tract, relax tension on the suture, and test for hemostasis by having the patient cough or bend his/her leg (Active testing for hemostasis is only for 5F-8F sheaths. For 8.5F-21F sheath closures, active confirmation should not be performed; only visual confirmation of hemostasis should be employed.). If hemostasis has not been achieved, assume the single-handed position for 20 seconds or until hemostasis is achieved. Secure the knot again by gently pulling on the white tipped non-rail suture limb. Do not apply excessive pressure to the suture.
 9. Confirm the security of the knot by having the patient cough and/or bend his/her leg. (Active testing for hemostasis is only for 5F-8F sheaths. Only visually confirm hemostasis for 8.5F-21F.) Patients may be able to move freely in bed without head of bed or leg restrictions if the close is successful.
 10. Once hemostasis is achieved, use the Suture Trimmer to trim the sutures below the skin. While holding both suture limbs together and pulled taut, load both suture limbs into the Suture Trimmer (as described above) and advance the Suture Trimmer to the arterial surface. Trim the sutures by pulling back on the red Trimming Lever. Keep the Trimming Lever pulled back while removing the Suture Trimmer and trimmed suture limbs from the tissue tract. If only one suture limb has been loaded and trimmed, repeat the same technique on the other suture limb.
 11. If hemostasis cannot be achieved, apply manual compression until hemostasis is achieved.

11.6 Suture Breakage

1. If suture breakage occurs **before the knot** is tightened, and a wire is still in place, discard the suture material, and use another Perclose ProGlide SMC device to complete the procedure.
2. If suture breakage occurs **after a knot** has been advanced and/or tightened, and a wire is still in place, another Perclose ProGlide SMC device can be used to complete the procedure or a sheath can be inserted. Care should be taken to avoid excessive force if the reintroduction of another device or introducer sheath is required. To avoid resistance, use an introducer sheath small enough to be introduced without undue force.
3. In all cases, if another Perclose ProGlide SMC device or introducer sheath cannot be inserted, use manual compression to obtain hemostasis.
4. To prevent suture breakage, always pull on the suture limbs with slow, consistent increasing tension. Avoid quick or jerky type movements with the suture limbs.
5. To prevent damage to the suture and subsequent suture breaks, the Suture Trimmer and suture limbs should always remain coaxial to the tissue tract. The Thumb Knob should be at 12 o'clock (facing the ceiling) and the Suture Trimmer should not be rotated. When loading suture into the Suture Trimmer, keep the Thumb Knob retracted until the suture and Suture Trimmer are coaxial, then release the Thumb Knob to capture the suture in the Suture Gate.

11.7 Post Procedure Patient Management

1. Apply an appropriate dressing to the access site.
2. Assess the access site as per hospital standard of care.

11.8 Recommendation for Patient Ambulation and Discharge

Patients who have undergone a diagnostic or interventional procedure using 5-8F sheaths may be ambulated two hours after the Perclose ProGlide SMC device procedures.

For patients who have undergone an interventional catheterization procedure using 8.5 – 21F sheaths, post-procedure ambulation is at the discretion of the physician.

In determining whether to ambulate or discharge an individual patient, it is important to consider all clinical factors including, but not limited to, anticoagulation regimen, antiplatelet and thrombolytic agents administered, oozing or bleeding from the access site, venous access site hemostasis, the general cardiovascular condition of the patient, anesthetic levels, and the overall clinical condition of the patient.

12.0 PRODUCT INFORMATION DISCLOSURE

Abbott Vascular Inc. has exercised reasonable care in the manufacture of this device. Abbott Vascular Inc. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness, since handling and storage of this device, as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the control of Abbott Vascular Inc. directly affect this device and the results obtained from its use. Abbott Vascular Inc. shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this device. Abbott Vascular Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Graphical Symbols for Medical Device Labeling

	Batch code		Do not resterilize
	Date of Manufacture		Do not reuse
	Use by		Non-Pyrogenic
	Catalogue number		Latex Free
	Contents		Do not use product if packaging or sterile barrier has been previously opened or damaged.
	Contents (numeral represents quantity of units inside)		Store in a cool location (room temperature).
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.		Keep dry
	Consult instructions for use		Manufactured by
	Sterilized using ethylene oxide.		



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5,304,184	5,476,469	5,720,757	5,746,755
5,797,929	5,810,850	6,117,145	6,132,440
6,136,010	6,190,396	6,348,059	6,358,258
6,558,399	6,730,102	6,746,457	6,964,668
7,001,400	7,029,487	7,048,747	7,060,078
7,094,246	7,147,646	7,201,762	7,235,087
EP 721313	EP 1093346		

Other patents pending.

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