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# Perclose ProGlide® 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](http://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 access sites using a procedural sheath greater than 8F it is recommended that a vascular surgeon or a surgeon with vascular training be available in case surgical conversion to control bleeding and to close the vessel is needed.

## **2.0 DEVICE DESCRIPTION**

The Perclose ProGlide Suture-Mediated Closure (SMC) System is designed to deliver a single monofilament polypropylene suture to close femoral vessel 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.

The accessories (Perclose® Snared Knot Pusher and Suture Trimmer) are included, and are designed to position the tied suture knot to the top of the access site. The Perclose Suture Trimmer is also designed to trim the trailing limbs of suture.

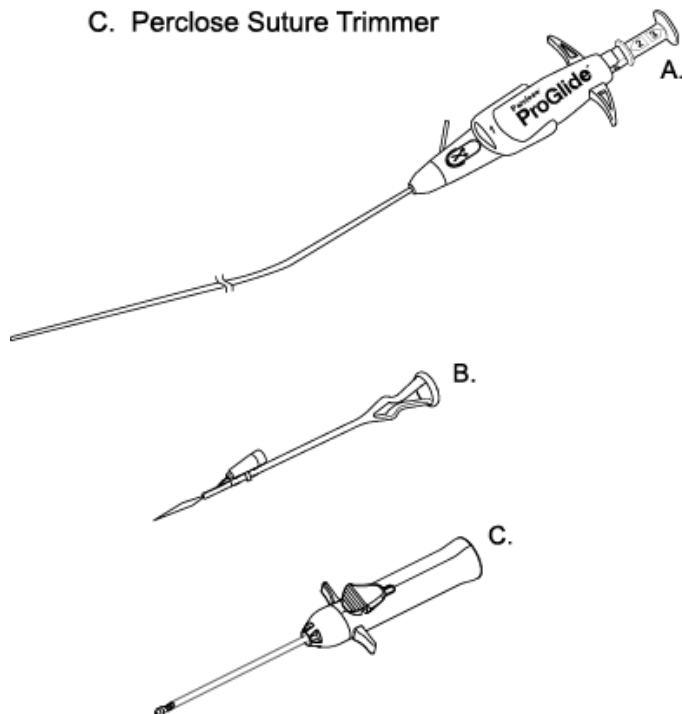
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The Perclose ProGlide SMC System is designed for use in closing common femoral artery and vein access sites. **The Perclose ProGlide SMC System is depicted in Figure 2.0-1.**

**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. Store in a cool, dry place.

**Perclose ProGlide SMC System includes:**

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

### **4.0 INDICATIONS**

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

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

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

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

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

## **5.0 CONTRAINDICATIONS**

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

## **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 or vein.

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

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

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## 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, as per hospital protocol, post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the vessel.
4. Do not deploy the Perclose ProGlide SMC device at an angle greater than 45 degrees, as this may cause a cuff miss.
5. There are no reaccess restrictions if previous access site repairs were achieved with Abbott Vascular SMC devices.
6. If significant blood flow is present around the Perclose ProGlide SMC device, do not deploy needles. Remove the Perclose ProGlide SMC device over a 0.038" (or smaller) guidewire and insert an appropriately sized introducer sheath.
7. When pushing the plunger assembly to advance the needles, stabilize the device to ensure the device does not twist or move forward during deployment. Twisting the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly push the plunger assembly. Excessive force on the plunger during deployment could potentially cause breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.
8. Do not apply excessive force to the lever when returning the foot to its original position **(marked #4)** down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever of the device or attempting to remove the device without closing the lever could cause breakage of the device and / or lead to vessel trauma, which may necessitate intervention and / or surgical removal of the device and vessel repair.
9. **Do not advance or withdraw the Perclose ProGlide SMC device against resistance until the cause of that resistance has been determined** (see Section 11.3 Single SMC DEVICE PLACEMENT section). **Excessive force used to advance or torque the Perclose ProGlide SMC device should be avoided, as this may lead to significant vessel damage and / or breakage of the device, which may necessitate intervention and / or surgical removal of the device and vessel repair.**
10. If excessive resistance in advancing the Perclose ProGlide SMC device is encountered, withdraw the device over a 0.038" (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.

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13. During closure of access sites using a 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide SMC device.
  14. During closure of access sites using a procedural sheath > 8F, in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide SMC devices, the physician should assess the situation. Based on the physician assessment of the amount of bleeding use manual compression, compression assisted devices and / or a surgical repair to obtain hemostasis.
  15. During closure of access sites using a procedural sheath > 8F, in those cases where the implanting physician is not a vascular surgeon, it is recommended that a vascular surgeon or a surgeon with vascular training be available during the procedure to perform any necessary surgical intervention.

## **8.0 SPECIAL PATIENT POPULATION**

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 in the artery during the catheterization procedure.
- Patients in whom introducer sheaths < 5F or > 24F were used in the vein during the catheterization procedure.
- Patients with small femoral arteries or veins (< 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 having arterial access other than the common femoral artery or vein.
- 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 at any time prior.
- 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 one ipsilateral arterial puncture 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.

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- Patients who are morbidly obese (Body Mass Index  $\geq 40$  kg/m<sup>2</sup>).
  - Patients with active systemic or cutaneous infection or inflammation.

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

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

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## 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 two 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

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### 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 ( $69.9 \pm 6.6$  vs.  $73.2 \pm 8.8$ ) 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 Population<sup>1</sup> - ProGlide vs. SEVAR)**

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

<sup>1</sup> Defined as all patients who were randomized and treated

<sup>2</sup> By Clopper-Pearson exact confidence interval

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

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### 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:
  - o Access site pseudoaneurysm or AV fistula documented by ultrasound
  - o Access site hematoma  $\geq 6$  cm
  - o Post-discharge access site-related bleeding requiring  $> 30$  minutes to re-achieve hemostasis
  - o Lower extremity arterial emboli or stenosis that is attributed to arterial access or closure
  - o Deep vein thrombosis
  - o Access site-related vessel laceration
  - o Transient access site-related nerve injury
  - o Access site wound dehiscence
  - o Access site related lymphocele
  - o 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 ( $106.5 \pm 44.9$  vs.  $141.1 \pm 73.4$ ,  $p = .0076$ ). 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 ( $9.8 \pm 17$  vs.  $22.7 \pm 22.9$  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<br>N = 50                    | SEVAR<br>N = 50                        | Difference<br>(95% CI) <sup>1</sup>         | Superiority Test<br><i>p</i> -value |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------------------------------|---------------------------------------------|-------------------------------------|
| <b>Procedure Time (minutes)</b><br>[95% Confidence Interval] <sup>1</sup>                                             | 106.5 ± 44.9<br>(50)<br>[93.7, 119.2] | 141.1 ± 73.4<br>(50)<br>[120.3, 162.0] | -34.7<br>[-58.9, -10.4]                     | 0.0076 <sup>3</sup>                 |
| <b>Minor Ipsilateral Access Site Complications at 30 days<sup>5</sup></b><br>[95% Confidence Interval] <sup>2</sup>   | 22.0% (11/50)<br>[11.5%, 36.0%]       | 30.0% (15/50)<br>[17.9%, 44.6%]        | -8.0%<br>[-25.1%, 9.1%]                     | 0.4954 <sup>4</sup>                 |
| Minor Ipsilateral Access Site Vascular Complications at 30 days<br>[95% Confidence Interval] <sup>2</sup>             | 4.0% (2/50)<br>[0.5%, 13.7%]          | 8.0% (4/50)<br>[2.2%, 19.2%]           | -4.0%<br>[Assumptions not met] <sup>6</sup> | --                                  |
| Narcotic Analgesic Use for Ipsilateral Access Site Pain at 30 days<br>[95% Confidence Interval] <sup>2</sup>          | 18.0% (9/50)<br>[8.6%, 31.4%]         | 28.0% (14/50)<br>[16.2%, 42.5%]        | -10.0%<br>[-26.4%, 6.4%]                    | --                                  |
| <b>Time to Actual Hospital Discharge (hours)</b><br>[95% Confidence Interval] <sup>1</sup>                            | 31.4 ± 16.9<br>(50)<br>[26.6, 36.2]   | 45.7 ± 59.9<br>(48)<br>[28.3, 63.1]    | -14.3<br>[-32.3, 3.7]                       | --                                  |
| <b>Time to Ambulation (hours)</b><br>[95% Confidence Interval] <sup>1</sup>                                           | 17.8 ± 7.2 (50)<br>[15.7, 19.9]       | 20.5 ± 16.9<br>(48)<br>[15.6, 25.5]    | -2.7<br>[-8.0, 2.5]                         | --                                  |
| <b>Ipsilateral Pain Scale Score at Pre-Discharge</b><br>[95% Confidence Interval] <sup>1</sup>                        | 2.1 ± 2.2 (50)<br>[1.5, 2.7]          | 2.6 ± 2.4 (49)<br>[1.9, 3.3]           | -0.5<br>[-1.4, 0.4]                         | --                                  |
| <b>Time to Hemostasis for Ipsilateral Access Site (minutes)<sup>3</sup></b><br>[95% Confidence Interval] <sup>2</sup> | 9.8 ± 17.0 (50)<br>[5.0, 14.7]        | 22.7 ± 22.9<br>(47)<br>[16.0, 29.4]    | -12.9<br>[-21.1, -4.7]                      | --                                  |
| <b>Closure Device Success</b><br>[95% Confidence Interval] <sup>2</sup>                                               | 96.0% (48/50)<br>[86.3%, 99.5%]       | N/A                                    | N/A                                         | --                                  |
| <b>Access Site Closure Success</b><br>[95% Confidence Interval] <sup>2</sup>                                          | 94.0% (47/50)<br>[83.5%, 98.7%]       | N/A                                    | N/A                                         | --                                  |

<sup>1</sup>By normal approximation

<sup>2</sup>By Clopper-Pearson exact confidence interval

<sup>3</sup>By two-sample t-test, pre-specified hypothesis test based hierarchical test procedure.

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

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

<sup>6</sup>Insufficient 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 Days<sup>1</sup>**

|                                                                                                                                                                                                  | <b>ProGlide<br/>N = 50</b> | <b>SEVAR<br/>N = 50</b> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|-------------------------|
| <b>Major Ipsilateral Access site Vascular Complications at 30 Days</b>                                                                                                                           | 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)             |
| <b>Minor Ipsilateral Access Site Vascular Complications at 30 days</b>                                                                                                                           | 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 ≥ 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)             |

<sup>1</sup> Include only each subject's first occurrence of each event

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### **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  $71.1 \pm 6.9$  years. The major ipsilateral access site vascular complication rate was 4.5 % (1/22). The mean procedure time was  $118.2 \pm 43.4$  minutes and the average time to ipsilateral hemostasis was  $7.7 \pm 6.8$  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 Trial<sup>1</sup> 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  $28.9 \pm 22.7$  hours and  $30.1 \pm 33.9$  hours for the post-close and pre-close patients respectively. The secondary endpoint of time to hemostasis was  $10.9 \pm 42.0$  minutes and  $8.2 \pm 51.0$  minutes for the post-close and pre-close patients respectively, versus  $7.9 \pm 6.4$  hours for the control group patients,  $p < 0.0001$ , and the secondary endpoint of time to ambulation was  $4.7 \pm 7.1$  hours and  $6.5 \pm 11.4$  hours for the post-close and pre-close patients respectively.

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<sup>1</sup>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.

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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 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%)  $\geq 6$  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%)  $\geq 6$  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 |
|-------------------------------------|------------------------------------------|-----------------------------------------|
| <b>Treated patients (per event)</b> | <b>N = 225</b>                           | <b>N = 160</b>                          |
| 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)           | N = 224                                  | N = 160                                 |
| mean±SD                             | 10.9±42.0                                | 8.2±51.0                                |
| (min. max.)                         | (1.0, 324.0)                             | (0.1, 639.0)                            |
| Median                              | 3.0                                      | 1.5                                     |
| [quartiles]                         | [2.0, 5.0]                               | [0.0, 5.0]                              |
| Time to Ambulation (hrs)            | N = 225                                  | N = 160                                 |
| mean±SD                             | 4.7±7.1                                  | 6.5±11.4                                |
| (min. max.)                         | (0.1, 71.4)                              | (0.05, 100.9)                           |
| Median                              | 2.4                                      | 2.2                                     |
| [quartiles]                         | [1.6, 4.5]                               | [1.2, 5.0]                              |
| Time to Discharge (hrs)             | N = 225                                  | N = 160                                 |
| mean±SD                             | 28.9±22.7                                | 30.1±33.9                               |
| (min. max.)                         | (2.2, 240.2)                             | (2.7, 292.6)                            |
| Median                              | 24.4                                     | 22.5                                    |
| [quartiles]                         | [22.0, 27.2]                             | [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 Trial<sup>2</sup> 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

<sup>2</sup> 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.

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<br>Post-Close Patients | The Closer IDE Trial<br>Pre-Close Patients |
|-------------------------------------------------|---------------------------------------------|--------------------------------------------|
| <b>Treated patients (per event)</b>             | <b>N = 225</b>                              | <b>N = 160</b>                             |
| 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%)                                   |
| <b>Incidence of Complications (per patient)</b> |                                             |                                            |
| Any complication <sup>†</sup>                   | 6 (2.7%)                                    | 3 (1.9%)                                   |
| Major complication <sup>†</sup>                 | 2 (0.9%)                                    | 2 (1.2%)                                   |
| No major complication                           | 223 (99.1%)                                 | 158 (98.8%)                                |

\* Major complication

<sup>†</sup> Per patient; some patients may have experienced more than one complication.

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*.

### 10.3 The REALISM Clinical Trial – ProGlide Cohort

A retrospective analysis was performed to evaluate the safety and effectiveness of the ProGlide SMC in closing large-sized venous access sites through a retrospective data collection from the EVEREST II/REALISM Continued Access Registry Study (REALISM). The retrospective

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analysis included subjects in whom ProGlide was used as the primary method for large bore venous access-site closure during the MitraClip index procedure with a 24F vascular sheath.

### 10.3.1 Methods

The analysis population was derived from a subset of REALISM subjects who were enrolled in the REALISM High Risk (HR) cohort, REALISM Non-High Risk (NHR) cohort, and REALISM Compassionate Use (CU) cohort. REALISM was a continued access study within the EVEREST II trial, which included subjects receiving the MitraClip index procedure with MitraClip sheath of 24F. REALISM enrolled 958 subjects, of whom 899 subjects were enrolled per the protocol and 59 as compassionate use. The **ProGlide cohort** was selected from subjects enrolled in the seven (7) REALISM sites with high frequency use of vessel closure devices (VCD  $\geq$  15 cases), and who received at least one ProGlide as their primary closure device during the MitraClip index procedure. Of the seven (7) sites, one (1) site did not use ProGlide and another site only used ProGlide for arterial access, and therefore the ProGlide cohort comprised of five (5) sites with a total of 159 subjects. Similarly, a **Manual Compression cohort (MC cohort)** of 230 subjects was identified from seven (7) sites that reported high frequency MC usage of  $\geq$  25 cases each without the use of any VCD. Subjects in both cohorts had MitraClip implanted into the mitral valve with access through the common femoral vein.

In the ProGlide Cohort, three (3) sub-groups were predefined: ProGlide Alone vs ProGlide Plus, Male vs Female, and One ProGlide vs Two ProGlides. The ProGlide Alone group included subjects in whom at least one ProGlide was used with brief adjunctive MC  $\leq$  10 minutes. The ProGlide Plus group included subjects in whom at least one ProGlide with prolonged MC  $>$  10 minutes or other secondary closure methods were used. None of the sub-groups are powered for statistical significance.

This retrospective analysis reports baseline subject characteristics and comorbidities, ProGlide usage information, effectiveness of achieving hemostasis (including time to hemostasis) during the index procedure, and adverse events up to 30 days. The primary endpoint was the rate of freedom from major femoral vein access-site related complications at 30-days post MitraClip index procedure. The pre-specified acceptance criterion for the rate of freedom from major femoral vein access-site related complications at 30-days post-procedure was  $\geq$  90%. Major complication is defined as any event leading to death, life-threatening or major bleeding, surgical intervention, hospitalization, visceral ischemia, or neurological impairment. This list includes development of the following:

- Femoral vein stenosis ( $>$  50%) development at the puncture site related to closure technique;
- Development of deep vein thrombosis in the target limb;
- Significant venous bleeding, retroperitoneal bleeding/hematoma, or hematoma at the access site requiring transfusion or surgical intervention;
- Hematoma that does not require transfusion or surgical intervention;
- Access site-related wound dehiscence or venous access site infection requiring intravenous, intramuscular or oral antibiotics, and/or leading to a prolonged hospitalization;

- Venous access site injury, including vessel laceration, requiring surgical repair, angioplasty, ultrasound-guided compression or thrombin injection;
- Re-bleeding at access site that requires treatment or re-hospitalization;
- AV fistula;
- Pseudoaneurysm;
- Access site-related nerve injury.

Minor complications are defined as those complications that did not require transfusion, surgery, or re-hospitalization. Adverse events from baseline to 30 days were reviewed to identify any potential femoral vein access-site related complications, which upon identification, were subsequently adjudicated by an independent Clinical Event Committee (CEC).

### 10.3.2 Results – ProGlide Cohort

**Subject Selection:** Of the 159 subjects in the ProGlide cohort, 98 subjects (61.6%) were from the REALISM High Risk cohort, 37 subjects (23.3%) from the REALISM Non-High Risk cohort, and 24 subjects (15.1%) from the REALISM Compassionate Use cohort. All subjects completed their discharge evaluations. Four (4) subjects died before their 30-day visits and two (2) missed their 30-day visits, and therefore 153 subjects reported 30-day assessments.

**Subject demographics:** The ProGlide cohort reflected subjects with varying degrees of heart failure. The cohort included elderly subjects with a mean age of 76 years. Male subjects accounted for 52.8%. Subjects presented with multiple comorbidities including high rates of congestive heart failure (CHF) (89.2%), atrial fibrillation (AF) (64.7%), coronary artery disease (CAD) (67.7%), hypertension (84.8%), diabetes (26.4%) moderate to severe renal disease (24.5%), chronic obstructive pulmonary disease (COPD) (23.3%), and NYHA class III (59.7%) and IV (24.5%). History of prior percutaneous interventions (37.7%) and cardiovascular surgery (42.1%) were common in this cohort.

**Primary Endpoint:** The freedom from major femoral vein access-site related complications was 98.1% at 30-days, which met the pre-specified safety acceptance criteria of 90% for the ProGlide cohort (**Table 10.3-1**). ProGlide group is defined as subjects who had received at least one ProGlide as the primary intended method to close femoral vein access site during the index procedure with or without adjunctive closure methods (manual compression or subcutaneous stitch). A total of 16 adjudicated complications, in 13 subjects, were reported through 30 days, of which only five (5) events in three (3) subjects were major complications. The remaining 11 adjudicated complications, in 10 subjects, were considered minor.

**Table 10.3-1: Freedom from Major Femoral Vein Access-Site Related Complication Through 30 Days (ProGlide Cohort<sup>4</sup>) (Per Subject Analysis)**

| Events <sup>1</sup>                                                            | ProGlide<br>(N=159 <sup>3</sup> ) | Clinical Acceptance<br>Criteria |
|--------------------------------------------------------------------------------|-----------------------------------|---------------------------------|
| <b>Freedom from Major Femoral Vein Access-Related Complication<sup>2</sup></b> | 98.1% (156/159)                   | 90%                             |

<sup>1</sup> Includes only each subject's first occurrence of each event.

<sup>2</sup> The major femoral vein access-related complication is defined as access site or access-related vascular injury (dissection, stenosis, perforation,

rupture, arterio-venous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life-threatening or major bleeding, visceral ischemia, or neurological impairment.

<sup>3</sup> The denominator excludes subjects who withdrew or lost to follow up before the 30-day visit early window (27 days post-procedure) without any femoral vein access-related complication.

<sup>4</sup> ProGlide group is defined as subjects who had received at least one ProGlide as the primary intended method to close femoral vein access site during the index procedure with or without adjunctive closure methods (manual compression or subcutaneous stitch).

**Summary of Safety:** The adjudicated major femoral vein access-site related complications through 30 days were reported as non-hierarchical subject counts (**Table 10.3-2**). The major complication rate was low at 1.9%. Five (5) major complications in three (3) subjects were reported within 30 days: one (1) hematoma requiring intervention and one (1) pseudo-aneurysm, one (1) hematoma and one (1) re-bleeding within 48 hours, and one (1) deep vein thrombosis in the target limb 6-days post-procedure. All cases achieved hemostasis within 2 minutes without MC or secondary closure devices.

**Table 10.3-2: Summary of Adjudicated Major Femoral Vein Access-Site Related Complications Through 30 Days (ProGlide Cohort<sup>3</sup>): Non-Hierarchical by Subject**

| Non-Hierarchical Major Events <sup>1</sup>                                                                                                                                   | 0-48 hours<br>(Subject<br>count) | >48 hours-<br>30 days<br>(Subject<br>count) | 0-30 days<br>(Subject<br>count) | Total<br>number of<br>events from<br>0 to 30 days |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------|---------------------------------|---------------------------------------------------|
| <b>Major Femoral Vein Access-Related Complications<sup>2</sup></b>                                                                                                           | 1.3% (2/159)                     | 0.6% (1/159)                                | 1.9% (3/159)                    | 5                                                 |
| Femoral vein stenosis (>50% development at the puncture site related to closure technique)                                                                                   | 0.0% (0/159)                     | 0.0% (0/159)                                | 0.0% (0/159)                    | 0                                                 |
| Development of deep vein thrombosis in the target limb                                                                                                                       | 0.0% (0/159)                     | 0.6% (1/159)                                | 0.6% (1/159)                    | 1                                                 |
| Significant venous bleeding, retroperitoneal bleeding/hematoma, or hematoma at the access site requiring transfusion or surgical intervention                                | 0.6% (1/159)                     | 0.0% (0/159)                                | 0.6% (1/159)                    | 1                                                 |
| Hematoma that does not require transfusion or surgical intervention                                                                                                          | 0.6% (1/159)                     | 0.0% (0/159)                                | 0.6% (1/159)                    | 1                                                 |
| Access site-related wound dehiscence or venous access site infection requiring intravenous, intramuscular or oral antibiotics, and/or leading to a prolonged hospitalization | 0.0% (0/159)                     | 0.0% (0/159)                                | 0.0% (0/159)                    | 0                                                 |
| Venous access site injury, including vessel laceration, requiring surgical repair, angioplasty, ultrasound-guided compression or thrombin injection                          | 0.0% (0/159)                     | 0.0% (0/159)                                | 0.0% (0/159)                    | 0                                                 |
| Re-bleeding at access site that requires treatment or re-hospitalization                                                                                                     | 0.6% (1/159)                     | 0.0% (0/159)                                | 0.6% (1/159)                    | 1                                                 |
| AV Fistula                                                                                                                                                                   | 0.0% (0/159)                     | 0.0% (0/159)                                | 0.0% (0/159)                    | 0                                                 |
| Pseudoaneurysm                                                                                                                                                               | 0.6% (1/159)                     | 0.0% (0/159)                                | 0.6% (1/159)                    | 1                                                 |
| Access site-related nerve injury                                                                                                                                             | 0.0% (0/159)                     | 0.0% (0/159)                                | 0.0% (0/159)                    | 0                                                 |

<sup>1</sup> Includes only each subject's first occurrence of each event.

<sup>2</sup> The major femoral vein access-related complication is defined as access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arterio-venous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life-threatening or major bleeding, visceral ischemia, or neurological impairment.

<sup>3</sup> ProGlide group is defined as subjects who had received at least one ProGlide as the primary intended method to close femoral vein access site during the index procedure with or without adjunctive closure methods (manual compression or subcutaneous stitch).

The adjudicated minor femoral vein access-site related complications through 30 days were also reported as non-hierarchical subject counts. There were 10 subjects with minor complication (6.3%). The total number of minor complications through 30 days was 11, including

four (4) hematoma events not requiring treatment (2.5%; 4/159) and seven (7) re-bleeds requiring treatment (4.4%; 7/159). All minor complications occurred within 48-hours post-procedure and were resolved by 30 days.

**Summary of Effectiveness:** ProGlide was an effective device for primary intended hemostasis of venous closure sites. Majority of subjects (69.2%) achieved hemostasis with ProGlide alone without additional secondary closure methods. Adjunctive closure methods included MC (17.6%, 28/159) and subcutaneous stitch (12.6%, 20/159), and one (1) subject received an AngioSeal along with ProGlide and MC. Within the ProGlide cohort, two (2) ProGlide devices were used predominantly to achieve hemostasis (90.6%, 144/159), a practice attributed to the arterial closure IFU which requires at least two (2) ProGlides if the transcatheter device sheath is greater than 8F as is the case with the 24F MitraClip. The remaining 9.4% cases used single ProGlide for access-site closure.

On average, hemostasis was achieved in  $5.92 \pm 6.19$  minutes in the ProGlide cohort. The mean time to achieve hemostasis with ProGlide alone was 5.15 minutes. This time increased to 9.3 minutes when adjunctive MC was used. When a secondary vessel closure method (namely subcutaneous stitch) was used, the mean time to achieve hemostasis was 5.8 minutes (**Table 10.3-3**). Overall, secondary closures were mostly initiated when there was a failure to achieve hemostasis using ProGlide and MC, which occurred in 12.6% of patients.

**Table 10.3-3: Summary of ProGlide Effectiveness on Hemostasis (ProGlide Cohort<sup>5</sup>)**

| Characteristics                                                                            | ProGlide<br>(N=159)   |
|--------------------------------------------------------------------------------------------|-----------------------|
| <b>Time to Achieve Hemostasis (min)</b>                                                    |                       |
| Mean $\pm$ SD (n)                                                                          | 5.92 $\pm$ 6.19 (134) |
| Median (Q1, Q3)                                                                            | 4.50 (1.00, 8.00)     |
| Range (min, max)                                                                           | (0.00, 30.00)         |
| <b>ProGlide Without Any Adjunctive Closure Method</b>                                      | 69.2% (110/159)       |
| <b>Time to Achieve Hemostasis (min)</b>                                                    |                       |
| Mean $\pm$ SD (n)                                                                          | 5.15 $\pm$ 6.05 (95)  |
| Median (Q1, Q3)                                                                            | 3.00 (1.00, 7.00)     |
| Range (min, max)                                                                           | (0.00, 29.00)         |
| <b>ProGlide and Adjunctive Manual Compression (MC) Only</b>                                | 17.6% (28/159)        |
| <b>Time to Achieve Hemostasis (min)</b>                                                    |                       |
| Mean $\pm$ SD (n)                                                                          | 9.3 $\pm$ 7.3 (23)    |
| Median (Q1, Q3)                                                                            | 6.0 (5.0, 14.0)       |
| Range (min, max)                                                                           | (1, 30)               |
| <b>ProGlide and Adjunctive Manual Compression <math>\leq</math> 5 Minutes<sup>1</sup></b>  | 6.3% (10/159)         |
| <b>Time to Achieve Hemostasis (min)</b>                                                    |                       |
| Mean $\pm$ SD (n)                                                                          | 4.0 $\pm$ 1.7 (10)    |
| Median (Q1, Q3)                                                                            | 5.0 (3.0, 5.0)        |
| Range (min, max)                                                                           | (1, 5)                |
| <b>ProGlide and Adjunctive Manual Compression <math>\leq</math> 10 Minutes<sup>1</sup></b> | 10.1% (16/159)        |
| <b>Time to Achieve Hemostasis (min)</b>                                                    |                       |
| Mean $\pm$ SD (n)                                                                          | 5.1 $\pm$ 2.1 (16)    |
| Median (Q1, Q3)                                                                            | 5.0 (5.0, 6.0)        |
| Range (min, max)                                                                           | (1, 9)                |

| Characteristics                                                                                                                       | ProGlide<br>(N=159) |
|---------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <b>ProGlide and Adjunctive Manual Compression &gt;10 Minutes or Unknown <sup>1,2</sup></b><br><b>Time to Achieve Hemostasis (min)</b> | 7.5% (12/159)       |
| Mean ± SD (n)                                                                                                                         | 18.7 ± 5.9 (7)      |
| Median (Q1, Q3)                                                                                                                       | 18.0 (14.0, 22.0)   |
| Range (min, max)                                                                                                                      | (13, 30)            |
| <b>ProGlide and Secondary Vessel Closure Method Only</b><br><b>Time to Achieve Hemostasis (min)</b>                                   | 12.6% (20/159)      |
| Mean ± SD (n)                                                                                                                         | 5.8 ± 3.3 (16)      |
| Median (Q1, Q3)                                                                                                                       | 6.0 (3.0, 7.0)      |
| Range (min, max)                                                                                                                      | (1, 12)             |
| <b>Type of Secondary Closure Method</b>                                                                                               |                     |
| Subcutaneous Stitch                                                                                                                   | 100.0% (20/20)      |
| Other Closure Device                                                                                                                  | 0.0% (0/20)         |
| Surgical Repair                                                                                                                       | 0.0% (0/20)         |
| Data Not Available                                                                                                                    | 0.0% (0/20)         |
| <b>Reason to use Secondary Vessel Closure Method</b>                                                                                  |                     |
| ProGlide Device Deficiency                                                                                                            | 0.0% (0/20)         |
| Access Complication (s)                                                                                                               | 0.0% (0/20)         |
| Failure to Achieve Hemostasis                                                                                                         | 95.0% (19/20)       |
| Data Not Available <sup>4</sup>                                                                                                       | 5.0% (1/20)         |
| <b>Hemostasis Achieved by Using ProGlide, Manual Compression and Secondary Vessel Closure Method <sup>3</sup></b>                     | 0.6% (1/159)        |

<sup>1</sup> For subjects with missing manual compression time, the non-missing time to achieve hemostasis is used to determine the sub-category.

<sup>2</sup> Subjects with both manual compression time and time to achieve hemostasis missing are also included in this category.

<sup>3</sup> One (1) subject used Angio-seal as the secondary vessel closure method in addition to ProGlide and Manual Compression due to unknown reason. The subject had both manual compression time and time to achieve hemostasis unknown.

<sup>4</sup> Subject who used Secondary closure method with unknown reason was categorized in the Data not available category.

<sup>5</sup> ProGlide group is defined as subjects who had received at least one ProGlide as the primary intended method to close femoral vein access site during the index procedure with or without adjunctive closure methods (manual compression or subcutaneous stitch).

### 10.3.4 Sub-Group Analyses

Three (3) sub-group analyses were pre-specified: ProGlide Alone vs ProGlide Plus, Male vs Female, and One ProGlide vs Two ProGlides. These sub-group analyses were not powered.

#### 10.3.4.1 ProGlide Alone vs ProGlide Plus

The ProGlide Alone group involved 126 subjects in whom at least one ProGlide was used along with adjunctive MC ≤ 10 minutes. These subjects generally had numerically higher baseline comorbidities, such as atrial fibrillation, coronary artery disease, diabetics, hypocholesteremia, angina, MI and angina, prior percutaneous interventions and cardiovascular surgery, liver disease, and NYHA II compared to the ProGlide Plus group. The ProGlide Plus group included fewer subjects (n = 33) all of whom required at least one ProGlide with either prolonged MC > 10 minutes or a secondary closure device to achieve hemostasis.

**Safety:** The major complications were low and occurred in the ProGlide Alone group (2.4% (3/126)) with 1.6% (2/126) complications occurring within the first 48 hours. There were no major complications in the ProGlide Plus group, through 30 days. Minor complications were similar in both groups with approximately 94% freedom from events (ProGlide Alone 6.3% (8/126) and

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ProGlide Plus 6.1% (2/33)). Within the limits of sample sizes, these results support the safe and effective use of ProGlide with or without adjunctive MC.

**Effectiveness:** The ProGlide Plus group had a numerically greater time to achieve hemostasis compared to the ProGlide Alone group ( $9.70 \pm 7.34$  (23) vs.  $5.14 \pm 5.65$  (111)). In the ProGlide alone group, 87.3% of subjects achieved hemostasis by using ProGlide without any adjunctive closure method, and 12.7% achieved hemostasis by using ProGlide and adjunctive manual compression. Additionally, the ProGlide Plus group compared to the ProGlide Alone group had a numerically higher percentage of subjects achieving hemostasis using ProGlide and adjunctive manual compression (36.4% (12/33) vs. 12.7% (16/126)).

#### 10.3.4.2 Male vs Female

A total of 84 male subjects and 75 female subjects were included in this sub-group analysis. Both groups had a similar mean age (males: 77 years; females: 74 years). Males reported numerically higher baseline incidences of key comorbidities including congestive heart failure, hypercholesterolemia, coronary and peripheral vascular disease (PVD), diabetes, COPD, and NYHA III/IV.

**Safety:** All 30 day major complications were reported in males 3.6% (3/84). There were no major complications in female through 30 days. However, because the event rates are low, larger dataset would be needed to confirm a gender difference. Among minor events, men 8.3% (7/84) had a numerically higher rate compared with women 4.0% (3/75).

**Effectiveness:** On average, both groups took comparable time to achieve hemostasis (men:  $5.69 \pm 6.37$  (70) vs women:  $6.18 \pm 6.02$  (64)). Males achieved numerically faster hemostasis than females when adjunctive MC or other secondary closure devices was used ( $6.9 \pm 4.7$  (11) vs.  $11.4 \pm 8.7$  (12)).

#### 10.3.4.3 One ProGlide vs Two ProGlide

Most of the subjects in this study received two (2) ProGlide (n = 144) and only fifteen (15) subjects received one (1) ProGlide. The most common reason for using more than one ProGlide was per IFU recommendation (93.8% (135/144) of the cases). Within the Two ProGlide group, 70.8% (102/144) did not require any adjunctive closure methods compared with 53.3% (8/15) in the One ProGlide group.

Both groups were similar in age (one ProGlide 75 (15) vs two ProGlide 76 years (144)). Both groups had approximately same rates of key risk factors of CHF, atrial fibrillation, angina, and COPD. The One ProGlide subjects had numerically higher rates of CAD, PVD, renal disease, and NYHA III, while the Two ProGlide subjects had numerically higher rates of cardiomyopathy, diabetes, history of CABG, and NYHA IV.

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**Safety:** Major complication rates at 30 days were numerically higher in the One ProGlide group at 6.7% (1/15) compared with 1.4% (2/144) in Two ProGlides. The very small sample size of the One ProGlide group must be considered when assessing the 30 day rate. Each group reported only one (1) major access-site complications within 48 hours post-procedure. The 30 day minor complication rate remained unchanged from the 30 day major complication rate for the one ProGlide group (6.7%) and was 6.3% (9/144) for the two ProGlide group. Given the disproportionate sample sizes of the two groups, the outcomes must be interpreted with caution.

**Effectiveness:** The subjects in the One ProGlide group took numerically longer to achieve hemostasis than those who received two (2) ProGlides ( $7.93 \pm 6.58$  (14) vs.  $5.69 \pm 6.13$  (120)). Additionally, the One ProGlide group reported a smaller percentage of subjects achieving hemostasis without any adjunctive methods compared to Two ProGlide (53.3% (8/15) vs. 70.8% (102/144)), a numerically higher percentage of use of adjunctive MC (33.3% (5/15) vs. 16.0% (23/144)) and required a numerically higher percentage of MC of  $\geq 10$  mins compared with the Two ProGlides group (20.0% (3/15) vs. 6.3% (9/144)).

### 10.3.5 RESULTS: Manual Compression Cohort

The MC Cohort consisted of 230 subjects: 156 (67.8%) from the REALISM High Risk cohort, 58 (25.2%) from the REALISM Non-High Risk cohort, and 16 (7.0%) from the REALISM Compassionate Use cohort. Their mean age of 77 years (230) and subjects in the MC cohort had high rates of CHF (94.8% (218/230), AF (62.9% (134/213), CAD (76.4% (175/229)), diabetes (33.0% (76/230)), moderate to severe renal (27.8% (64/230)), and COPD (28.4% (65/229)), and prior percutaneous intervention (35.4% (81/229)). In the MC cohort, 50% of the subjects achieved hemostasis with MC only; 49.6% and 0.4% of the subjects received MC plus a subcutaneous stitch or MC plus other closure device as a secondary method to facilitate hemostasis, respectively.

**Safety:** Thirty-two adjudicated access site complications were reported through 30 days: 10 major (4.4% (10/227)) and 22 (9.7% (22/227)) minor. The 30 day major complications were mostly venous bleeding (3.1% (7/227)) with the remaining being development of deep vein thrombosis (0.4% (1/227)), hematoma (0.4% (1/227)), re-bleeding (0.9% (2/227)), venous access site injury (0.9% (2/227)) and pseudo-aneurysm 0.9% (2/227). Minor complications mostly developed within 48-hours post-index procedure and were largely due to hematoma, and re-bleeding at the access site that requires treatment.

**Effectiveness:** In the MC cohort, 50% (115/230) of the subjects received MC alone as the intended hemostasis method; 49.6% (114/230) and 0.4% (1/230) of the subjects received MC plus a subcutaneous stitch or MC plus other closure device as a secondary method to facilitate hemostasis, respectively.

### Conclusion

In summary, the primary objective of the study was to evaluate the safety and performance of ProGlide in closure of venous access site in subjects with a large-caliber femoral vein sheath (24F). The study results have demonstrated that the safety assessment of the ProGlide met the

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predefined acceptance safety criterion. Taken together, the study results show that ProGlide is safe and effective in the closure of the venous access site with up to 24F sheath.

### Study Limitations

The study had limitations since it was a retrospective analysis of a selected dataset within a trial in which the main objective was the evaluation of the MitraClip device. The design of the trial was not specific to the evaluation of ProGlide for large bore venous closure.

## 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 in the common femoral artery and 5F to 24F introducer sheath access sites in the common femoral vein.
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 Access 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 access site 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 or vein 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 access site for vessel size, calcium deposits, tortuosity, and for disease or

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dissections of the 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 vessel. 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** reaccess restrictions after using Abbott Vascular closure devices.

### **11.3 Single SMC Device Placement, 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 with a single device. For venous sheath size greater than 8F, at least one device and the pre-close technique is required. Follow Section 11.31 to close with one device using the pre-close technique.**

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 in the vessel 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 in the artery unless brisk pulsatile flow of blood ("mark") is evident from the marker lumen. In the vein, the flow of blood may not be pulsatile or blood may only fill the lumen.**
4. Gently pull the device back to position the foot against the vessel wall. If proper position of the foot has been achieved, tactile sensation will be felt. In the artery blood marking will cease or be significantly reduced to a slight drip. In the vein, there may be no change in blood marking. If marking does not stop or significantly change, evaluate the angiogram for device position in the vessel, vessel 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 sutures have been fully retracted from the body of the device.

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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.
  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 Pre-Close Technique**

**The Perclose ProGlide suture can be placed around the access site 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 access site 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)**

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**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.
3. Remove the Perclose ProGlide SMC device with the right hand, while maintaining an adequate length of guidewire inside the vessel. 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 access site 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 sheath closures greater than 8F, 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 Multiple SMC Device Placement**

**The following instructions detail the deployment sequence for closing the access site of a catheterization procedure with multiple devices using the pre-close technique.**

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 ProGlide SMC 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.

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3. Continue to advance the device until brisk pulsatile flow of blood is evident from the marker lumen. In the vein, the flow of blood may not be pulsatile or blood may only fill the marker lumen. The device lever (**marked #1**) and logo should be facing the ceiling.
  4. Rotate the device approximately 30 degrees towards the patient's right side. 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. For the vein, flow may be reduced or the marker lumen may only fill with blood.**
  5. Gently pull the device back to position the foot against the vessel wall. If proper position of the foot has been achieved, tactile sensation will be felt. In the artery, blood marking will cease or be significantly reduced to a slight drip. In the vein, there may be no change in blood marking. If marking does not stop or significantly change, evaluate the angiogram for device position in the vessel, vessel size, calcium deposits, tortuosity, disease and for location of the puncture to 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

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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 or vein. This allows placement of the second Perclose ProGlide SMC device.
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.
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). 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 access site, 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**

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- 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) 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) suture again and then advance the second (patient's left side) suture again. Multiple knot advancements are common when closing larger sheath sizes. 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 third ProGlide device. NOTE: In step 4, the third device should not be rotated. The device will be deployed with the logo facing the ceiling. 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) 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) 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 (first, second, third), 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.

## 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.
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 sheath (if the device was deployed at the beginning of the catheterization procedure) from the vessel, while simultaneously pulling gently on the rail limb. Always keep the suture coaxial to the tissue tract.

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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 vessel 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, consistent 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 sheath closures greater than 8F, 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 sheath closures greater than 8F.) 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 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.
  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**

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**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 sheath closures greater than 8F, 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 sheath closure greater than 8F). 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.

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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 sheaths greater than 8F, 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**

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### **13.0 PATENTS AND TRADEMARKS**

This product and / or its use may be covered by one or more of the following United States Patents: 6,136,010; 6,190,396; 6,358,258; 6,558,399; 6,730,102; 6,746,457; 6,964,668; 7,001,400; 7,029,487; 7,048,747; 7,094,246; 7,147,646; 7,201,762; 7,235,087; EP 721313; EP 1093346. Other U.S. patents pending. Foreign patents issued and pending.

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### Graphical Symbols for Medical Device Labeling

|                                                                                     |                                                                                             |                                                                                     |                                   |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------|
|    | Batch code                                                                                  |    | Do not resterilize                |
|    | Date of manufacture                                                                         |    | Do not reuse                      |
|    | Use by                                                                                      |    | Non-pyrogenic                     |
|    | Catalogue number                                                                            |   | Sterilized using ethylene oxide.  |
|    | Contents                                                                                    |    | Do not use if package is damaged. |
|    | Contents (numeral represents quantity of units inside)                                      |    | Keep away from sunlight           |
|    | CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. |   | Keep dry                          |
|  | Consult instructions for use                                                                |  | Manufacturer                      |

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