PERCLOSE® A•T
6F Suture-Mediated Closure (SMC) System
Instructions for Use

℞ ONLY

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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, so please refer to the Abbott Vascular website (www.abbottvascular.com/ifu) for the most current version at the time of the procedure.

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

1.0 CAUTION

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

2.0 DEVICE DESCRIPTION

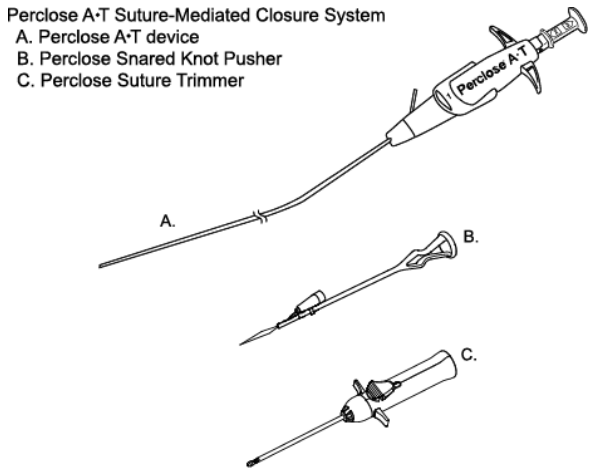
The Perclose A•T (auto tie) Suture-Mediated Closure (SMC) System is designed to deliver polyester suture to close femoral artery puncture sites following diagnostic or interventional procedures. The Perclose A•T device has one suture and two needles.

The Perclose A•T SMC device is composed of a sheath and a guide. The guide houses the needles and the foot, and precisely controls the placement of these needles around the puncture site. A marker lumen is contained within the guide, with the intraluminal port of the lumen positioned at the distal end of the needle guide. Proximally, the marker lumen exits from the handle of the device. The marker lumen allows a pathway for back-bleeding from the femoral artery to ensure proper device positioning. The Perclose A•T tracks over a standard 0.038” (or smaller) guide wire.

A knot pusher accessory (Perclose Snared Knot Pusher **and/or** Perclose Suture Trimmer) is included, and is designed to position the tied suture knot to the arteriotomy. The Perclose Suture Trimmer is also designed to trim the trailing limbs of suture.

The Perclose A•T 6F SMC System is designed for use in 5F to 8F access sites. The Perclose A•T SMC System is depicted in Figure 1.

Figure 1



3.0 INDICATIONS FOR USE

The Perclose A•T 6F SMC System is indicated for the percutaneous delivery of suture for closing the common femoral artery access site of patients who have undergone diagnostic or interventional catheterization procedures using 5F to 8F sheaths.

The Perclose A•T 6F SMC System reduces the time to hemostasis, ambulation (10 feet), and discharge in patients who have undergone diagnostic or interventional catheterization procedures without complicating clinical conditions (refer to **PRECAUTIONS** and **SPECIAL PATIENT POPULATIONS**).

4.0 CONTRAINDICATIONS

There are no known contraindications to the use of this device. Attention is drawn to the warnings, precautions, and special patient populations.

5.0 WARNINGS

Do not use the Perclose A•T 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 A•T SMC device and accessories are intended for single use only.

Do not use the Perclose A•T 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 A•T 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.

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

Do not use the Perclose A•T SMC System if the puncture site is located in the superficial femoral artery or the profunda femoris artery, since such puncture sites may result in a pseudoaneurysm, intimal dissection, or an acute vessel closure (thrombosis of small artery lumen). Perform a femoral angiogram to verify the location of the puncture site.

6.0 PRECAUTIONS

1. The Perclose A•T SMC System is 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.
2. Prior to use, inspect the Perclose A•T 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.
3. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose A•T SMC System. Employ appropriate groin management post procedure and post hospital discharge to prevent infection.
4. Use a single wall puncture technique. Do not puncture the posterior wall of the artery. Avoid posterior wall suture placement.
5. Do not insert the SMC device into the femoral artery at an angle greater than 45 degrees to the longitudinal plane of the artery.
6. There are no reaccess restrictions if previous arteriotomy repairs were achieved with Abbott Vascular SMC devices.
7. **Do not advance or withdraw the Perclose A•T SMC device against resistance until the cause of that resistance has been determined** (see SMC DEVICE PLACEMENT section)**. Excessive force used to advance or torque the Perclose A•T 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.**
8. If excessive resistance in advancing the Perclose A•T SMC device is encountered, withdraw the device over a 0.038” (or smaller) guide wire and reinsert the introducer sheath or use conventional compression therapy.
9. If significant blood flow is present around the Perclose A•T SMC device, do not deploy needles. Remove the Perclose A•T SMC device over a 0.038” (or smaller) guide wire and insert an appropriately sized introducer sheath.
10. Remove the Perclose A•T 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.
11. 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 forceps or needle holders.
12. Use conventional compression methods in the event bleeding from the femoral access site persists after the use of the Perclose A•T SMC device.

7.0 SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the Perclose A•T SMC System have not been established in the following patient populations:

- Patients with introducer sheaths < 5F or > 8F during the catheterization procedure.
- Patients with ipsilateral arterial access sites punctured and compressed within 48 hours of closure.
- Patients with access sites in the profunda femoris or superficial femoral arteries.
- Patients with access sites distal to the bifurcation of the superficial femoral and profunda femoris arteries.
- 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 small femoral arteries (< 5 mm in diameter).
- Patients with severe claudication, iliac or femoral artery diameter stenosis greater than 50%, or previous bypass surgery or stent placement in the vicinity of access site.
- Patients with access sites in vascular grafts.
- Patients with prior intra-aortic balloon pump at access site.
- Patients with ipsilateral femoral venous sheath during the catheterization procedure.
- Patients with which there is difficulty inserting the introducer sheath or greater than 2 ipsilateral arterial punctures at the start of the catheterization procedure.
- Patients with intra-procedural bleeding around access site.
- Patients receiving glycoprotein IIb/IIIa inhibitors before, during, or after the catheterization procedure.
- Patients younger than 18 years of age.
- Patients who are pregnant or lactating.
- Patients with bleeding diathesis or coagulopathy.
- Patients who are morbidly obese (Body Mass Index > 35 kg/m^2).
- Patients with active systemic or cutaneous infection or inflammation.
- Patients with access sites above the most inferior border of the inferior epigastric artery (IEA) and/or above the inguinal ligament based upon bony landmarks.
- Patients with antegrade punctures.

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.

8.0 ADVERSE EVENTS IN THE CLOSER IDE TRIAL

The Closer IDE Trial[1] was designed as a multi-center, multi-operator, prospective registry enrolling 225 patients in the post-close arm and 160 patients in the pre-close arm. The post-close arm studied the use of The Closer 6F system following interventional procedures using 5F to 6F sheaths. The pre-close arm studied the use of The Closer 6F system following interventional procedures using 7F to 8F sheaths utilizing the pre-close technique. The pre-specified analysis of the primary safety endpoint of the IDE Trial was the incidence of the combined rate of major complications at 30 days of patients undergoing interventional catheterization procedures. Post treatment, ultrasound evaluations were performed 0 to 15 days post discharge to verify detection of clinical complications. Two major complications were reported in each of the post-close and pre-close arms of The Closer IDE Trial. Neither of the two major complications reported in the post-close or pre-close arms were considered unanticipated events. No delayed major hemorrhagic events were reported despite early ambulation and early discharge of the patients with The Closer SMC device. The adverse events that were observed during the trial are reported in Table 1.

Table 1. Percentage of Patients Experiencing Adverse Events

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

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

* Major complication

¶ Per patient; some patients may have experienced more than one complication.

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

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

9.0 THE CLOSER IDE CLINICAL TRIAL

The Closer IDE Trial[2] 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 twentyfive (225) patients were enrolled in post-close arm and one hundred sixty (160) patients were enrolled in the pre-close arm of The Closer IDE Trial. In the post-close arm, the deployment of The Closer device occurred at the end of the catheterization procedure. In the pre-close arm, The Closer device was deployed in two steps with suture delivery at the beginning of the catheterization procedure with knot tying and knot delivery occurring at the end of the procedure.

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

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

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

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

The incidence of vascular complication other than major was a secondary safety endpoint of the study and in the post-close arm consisted of one (0.4%) false aneurysm, one (0.4%) infection requiring IM and PO antibiotics, two (0.9%) ≥ 6 cm hematomas, and two (0.9%) retroperitoneal bleeds not requiring intervention. For the pre-close arm, incidence of vascular complication other than major consisted of one (0.6%) ≥ 6 cm hematoma and one (0.6%) groin infection requiring PO antibiotics. All patients were free of symptoms at time of follow up. The results of the effectiveness measures are summarized in Table 2.

Table 2. Principal Effectiveness Results

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

Effectiveness Measures*	**The Closer IDE Trial Post-Close Patients**	**The Closer IDE Trial Pre-Close Patients**
Treated patients (per event)	**n=225**	**n=160**
Procedural success	223 (99.1%)	158 (98.8%)
Device success	207 (92.0%)	143 (89.4%)
Device failure	17 (7.6%)	15 (9.4%)
Device malfunction	16 (7.1%)	14 (8.8%)
Device complication	1 (0.4%)	1 (0.6%)
Time to Hemostasis (mins)	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.

10.0 THE PERCLOSE A•T 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 A•T 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.

10.1 Examination and Selection of Products

1. Select the Perclose A•T 6F SMC device for closure of 5F to 8F introducer sheath access sites.
2. After carefully inspecting the packaging of the Perclose A•T SMC device and accessories for damage to the sterile barrier, remove the device from the package.
3. Exercise care when using additional surgical instruments, such as forceps or needle holders, during device handling to reduce the possibility of accidental device breakage.

4. Verify marker lumen patency by flushing the lumen with saline until the saline exits from the marker port. **Do not use the Perclose A•T SMC device if the marker lumen is not patent.**

10.2 Arterial Site and Puncture Considerations

1. Puncture the anterior wall of the common femoral artery at an angle of approximately 45 degrees.
2. Avoid side wall or posterior wall femoral artery punctures.
3. Prior to deployment of the Perclose A•T SMC device, evaluate the femoral artery site for size, calcium deposits, tortuosity, and for disease or dissections of the arterial wall by performing femoral angiography, to avoid posterior wall suture placement and possible ligation of the anterior and posterior walls of the femoral artery.
4. Puncture locations are located in the common femoral artery below the level of the inguinal ligament and above the common femoral artery bifurcation.
5. There are no reaccess restrictions if previous arteriotomy repairs were achieved with Abbott Vascular SMC devices.

10.3 SMC Device Placement

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

1. Perform a femoral angiogram through the introducer sheath to verify that the access site is in the common femoral artery. To avoid posterior wall suture placement and possible ligation of the anterior and posterior walls of the femoral artery, **fluoroscopically evaluate the femoral artery for size, calcium, tortuosity, and for disease or dissections of the arterial wall.**
2. Place a 0.038" (or smaller) guide wire through the introducer sheath. Remove the introducer sheath while applying pressure on the groin to maintain hemostasis.
3. Backload the SMC device over the guide wire until the guide wire exit port of the sheath is just above the skin line. Remove the guide wire before the exit port crosses the skin line.
4. Continue to advance the device just until a continuous drip of blood is evident from the marker lumen. Position the device at a 45-degree angle. Deploy the foot by lifting the lever **(marked #1)** on top of the handle. **Do not deploy the foot unless a continuous drip of blood is evident from the marker lumen.**
5. Gently pull the device back to position the foot against the arterial wall. If proper position of the foot has been achieved, blood marking will cease or be significantly reduced. If marking does not stop or significantly change, gently adjust the angle of the device to stop blood marking.
6. While maintaining device position, deploy needles by pushing on the plunger assembly **(in the direction marked #2)** until the collar of the plunger makes contact with the proximal end of the device body. Visually confirm that the collar of the plunger is in contact with the body of the device.
7. 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 one end of a link. The other end of the link will be attached to the anterior needle. The posterior needle will be free of suture. Pull back on the plunger until the suture is pulled taut.
8. Do not attempt to redeploy the SMC needles in the event of failure to capture suture.

9. Cut the suture from the anterior needle distal of the link.
10. Relax the device and then return the foot to its original position by pushing the lever **(marked #4)** on top of the device, down to its original position.
11. Withdraw the SMC device until the guide wire port exits the skin line. Grasp the suture adjacent to the sheath and pull the suture ends through the distal end of the proximal guide.

    If the SMC device deployment takes place at the beginning of the intervention, the closure procedure will be placed on hold at this point and the suture set aside under a sterile drape while the operator proceeds with the catheterization procedure. At the end of the catheterization, the closure procedure will resume starting at step #12 below.
12. The rail suture limb is green and is the suture limb that will be used to advance the knot. The non-rail suture limb is white.
13. If the operator chooses to maintain wire access, reinsert the guide wire after exposing the guide wire port at skin level and before knot advancement.
    - 13.1. The guide wire should be advanced well into the artery so that approximately 10 cm of the guide wire is exposed out of the guide wire exit port.
    - 13.2. Wrap the rail limb of the suture around your left index finger.
    - 13.3. Remove the Perclose A•T SMC device, while maintaining an adequate length of the guide wire inside the artery, to insert another Perclose A•T device if desired or an introducer sheath in the event that either of these actions becomes necessary.
    - 13.4. Advance the knot to the arteriotomy by applying tension to the rail suture limb. (Do not advance the knot with the Snared Knot Pusher or the Suture Trimmer until the wire has been completely removed from the patient).
    - 13.5. Assess the site for hemostasis. If site is hemostatic, the operator should then remove the wire and use the Snared Knot Pusher or Suture Trimmer, following the technique described below, to advance and tighten the knot further until complete closure is achieved. Confirm the security of the knot by having the patient cough and/or bend his/her leg.
    - 13.6. If hemostasis cannot be achieved, reinsert an introducer sheath, or apply manual compression.
14. *Knot advancement*
    - 14.1. ***If the Snared Knot Pusher is used:***
      - 14.1.1. Place approximately 2 cm of the rail (green) limb of the suture into the snare at the distal end of the Snared Knot Pusher.
      - 14.1.2. Load the suture into the Snared Knot Pusher by pulling the snare through the tip of the Snared Knot Pusher.
      - 14.1.3. Once loaded, the Snared Knot Pusher should slide easily on the suture.
      - 14.1.4. Securely wrap the rail suture limb around your left forefinger.
      - 14.1.5. Gently pull on the rail suture limb, keeping the suture coaxial to the tissue tract.
      - 14.1.6. **Completely remove the device or the arterial sheath** (if the device was deployed at the beginning of the catheterization procedure) **from the artery. Do not tighten the suture around the sheath.**
      - 14.1.7. With the rail suture limb securely wrapped around your left forefinger, place the Snared Knot Pusher under your left thumb to assume a single-handed position and complete knot advancement.

14.1.8. With the Snared Knot Pusher in place, tighten the knot by gently pulling on the non-rail (white) suture limb.

14.1.9. 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.

14.1.10. Remove the Snared Knot Pusher from the tissue tract and test for hemostasis by having the patient cough or bend his/her leg. If hemostasis has not been achieved, assume the single-handed position for 20 seconds, or until hemostasis is achieved securing the knot again by gently pulling on the non-rail suture limb. **Do not apply excessive pressure to the suture.**

14.2. ***If the Suture Trimmer is used:***

14.2.1. Securely wrap the rail (green) limb of the suture around your left forefinger. Gently pull on the rail suture, keeping the suture coaxial to the tissue tract.

14.2.2. **Completely remove the Perclose A•T or the arterial sheath** (if the device was deployed at the beginning of the catheterization procedure) **from the artery. Do not tighten the suture around the sheath.**

14.2.3. Place the suture into the Suture Trimmer by retracting the thumb knob on the handle and using "Bow-string" technique, and load the suture into the window located at the distal end of the Suture Trimmer. Release the thumb knob to load the suture. The Suture Trimmer should slide easily on the suture.

14.2.4. With the rail (green) suture limb securely wrapped around your left forefinger, place the Suture Trimmer under your left thumb to assume a single-handed position and complete knot advancement.

14.2.5. With the Suture Trimmer in place, tighten the knot by gently pulling the non-rail (white) suture limb.

14.2.6. 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.

14.2.7. Remove the Suture Trimmer from the tissue tract and test for hemostasis by having the patient cough or bend his/her leg. If hemostasis has not been achieved, assume the single-handed position for 20 seconds, or until hemostasis is achieved, securing the knot again by gently pulling on the white non-rail suture limb. **Do not apply excessive pressure to the suture.**

15. If hemostasis cannot be achieved, apply manual compression.

16. Once hemostasis is achieved, use the Suture Trimmer to trim the sutures below the skin. While holding constant back tension on the suture limbs, load both limbs into the Suture Trimmer and advance to the arteriotomy. Trim the sutures by pulling back on the red Trimming Lever. Keep the Trimming Lever pulled back during retrieval of the Suture Trimmer and trimmed suture from the tissue tract. If only one suture limb has been loaded and trimmed, repeat the same technique on the other suture limb.

10.4 Suture Breakage

1. If suture breakage occurs prior to completing the initial knot, discard the suture material, reload the wire and remove the device over the guide wire. Use another Perclose A•T SMC device to complete the procedure.
2. If the suture is inadvertently tangled or removed prior to knot advancement, cut the suture distal to the knot, discard the suture material and remove the Perclose A•T SMC device over the guide wire. Use another Perclose A•T SMC device to complete the procedure.
3. If suture breakage occurs after an initial knot has been tied, care should be taken to avoid excessive force if the reintroduction of another Perclose A•T device or introducer sheath is required. To avoid resistance, use an introducer sheath small enough to be introduced without undue force.
4. In all cases, if an introducer sheath cannot be inserted, use manual compression to obtain hemostasis.

10.5 Post Procedure Patient Management

1. Apply an appropriate dressing to the access site.
2. Assess the insertion site as per hospital protocol.

10.6 Recommendation for Patient Ambulation and Discharge

Patients may be ambulated two hours after the Perclose A•T SMC device procedures. 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.

11.0 PRODUCT INFORMATION DISCLOSURE

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

12.0 HOW SUPPLIED

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

The Perclose A•T 6F SMC SystemList/REF 12337
includes:
One (1) Perclose A•T 6F SMC device
One (1) Perclose Snared Knot Pusher **and/or**
Perclose Suture Trimmer

Accessories

Perclose Snared Knot Pusher	**List/REF 12352**
Perclose Suture Trimmer	**List/REF 12427, 82122**

Perclose is a registered trademark of Abbott Laboratories.

Graphical Symbols for Medical Device Labeling

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

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This product and its use are protected
under one or more of the following patents:
5,304,184 5,476,469 5,720,757 5,746,755
5,797,929 5,810,850 6,117,145 6,132,440
6,136,010 6,348,059 6,746,457 6,964,668
7,001,400 7,060,078 EP 721313
Other patents pending.