



Prostar[®] XL

10 FRENCH PERCUTANEOUS VASCULAR SURGICAL SYSTEM

INSTRUCTIONS FOR USE

Rx ONLY

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

DEVICE DESCRIPTION

The Prostar XL Percutaneous Vascular Surgical (Prostar XL PVS) device is designed to deliver polyester suture(s) to close femoral artery puncture sites following catheterization procedures. The Prostar XL device has two sutures and four needles.

The Prostar XL 10F device consists of a sheath, which contains two pairs of sutured needles, a needle guide, which precisely control the needles around the puncture site and a rotating barrel, which receives deployed needles. The Prostar XL sheaths have J-shaped tips at the distal end. A marker lumen is contained within the barrel of the device with the intra-arterial port of the lumen positioned in the needle guide. Proximally, the marker lumen exits from the hub of the device. The marker lumen allows a pathway for back bleeding from the femoral artery and ensures proper device positioning. The barrel rotates independently from the central core and is designed to prepare the subcutaneous track. Barrel rotation is accomplished by depressing the interlocks exiting from the hub. The Prostar XL devices track over a standard 0.038" (or smaller) guide wire.

The Prostar XL PVS System consists of a 10F Prostar XL device and a Perclose[®] Knot Pusher. The Perclose Knot Pusher is designed to advance the tied knot to the arteriotomy. The Perclose Arterial Tamper is available as an accessory and may be used to augment hemostasis by positioning the knot over the artery surface.



The Prostar XL PVS System and accessories are depicted in Figure 1.

Prostar XL Percutaneous Vascular Surgical System

- A. Prostar Device
- B. Perclose Knot Pusher
- C. Perclose Arterial Tamper

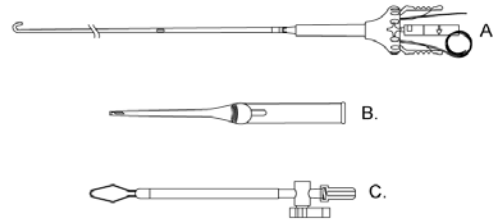


Figure 1

INDICATIONS FOR USE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

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

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

PRECAUTIONS

1. The Prostar XL 10F PVS device and accessories should only be used by physicians (or other healthcare professionals authorized by or under the direction of such physicians) after they have been trained in the use of the Prostar XL PVS System and accessories, *e.g.*, participation in a Prostar XL PVS System training program or equivalent.
2. Observe sterile technique at all times when using the Prostar XL PVS System. Employ appropriate groin management post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the artery.
4. Adequate knot security requires accepted surgical technique as warranted by surgical circumstances and the experience of the operator.
5. There are no reaccess restrictions if previous arteriotomy repairs were achieved with an Abbott Vascular Suture Mediated Device.
6. Do not insert the Prostar XL device into the femoral artery at an angle greater than 45 degrees to the longitudinal plane of the artery.



7. **Do not advance or withdraw the Prostar XL device against resistance until the cause of that resistance has been determined** (see CLINICAL PROCEDURE Device Placement section). **Excessive force used to advance or torque the Prostar XL device should be avoided as it may lead to significant arterial damage and/or breakage of the device, which may necessitate intervention and/or surgical removal of the device and arterial repair.**
8. If excessive resistance in advancing the Prostar XL device is encountered, withdraw the Prostar XL device over a 0.038" (or smaller) guide wire and reinsert the introducer sheath or use conventional compression therapy.
9. In the event suture breakage occurs after an initial knot has been tied, care should be taken to avoid excessive force if the reintroduction of the Prostar XL device or introducer sheath is required. Any resistance to introduction should result in advancement of an introducer sheath small enough to be introduced without undue force.
10. If significant blood flow is evident through or around the barrel of the Prostar XL device, do not deploy needles. Remove the Prostar XL device over a 0.038" (or smaller) guide wire and insert an appropriately sized introducer sheath.
11. Remove the Prostar XL sheath before tightening the suture. Failure to remove the sheath prior to tightening the suture may result in detachment of the tip of the sheath.
12. Do not attempt to re-deploy Prostar XL needles after the needles have been "backed-down" into the sheath (refer to the **TECHNIQUE FOR NEEDLE BACK-DOWN** section).
13. In the event bleeding from the femoral access site persists after the use of the Prostar XL device and accessories, use conventional compression therapy.

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the Prostar XL 10F PVS System has not been established in the following patient populations:

- Patients with puncture sites at or above the inguinal ligament.
- Patients with puncture sites in the profunda femoris or superficial femoral arteries.
- Patients exhibiting hematoma, pseudoaneurysm or arteriovenous fistula prior to sheath removal.
- Patients with common femoral artery calcium, which is fluoroscopically visible.
- Patients with small femoral arteries (< 5 mm in diameter).
- Patients with a femoral artery stenosis greater than 50%.
- Patients with puncture sites in vascular grafts.
- Patients with antegrade punctures.
- Patients who are pregnant or lactating.
- Patients with bleeding diathesis or coagulopathy.
- Patients younger than 18 years of age.
- Patients with ipsilateral arterial access sites punctured and compressed within 48 hours of closure.
- Patients who are morbidly obese where less than one third of the access needle is above the skin line.

ADVERSE EVENTS

The Sutures To Ambulate and Discharge (STAND II) Trial was a multicenter, randomized controlled clinical trial involving 515 patients. The trial compared the Prostar Plus¹ PVS System to the conventional compression (*i.e.*, mechanical or manual) methods. All patients enrolled in the trial underwent a diagnostic or interventional procedure prior to randomization to the Prostar Plus System or compression. In this trial, 251 patients were randomized to the Prostar Plus System (227 patients were treated with the 8F and 24 patients were treated with the 10F) and 256 were randomized to compression. The adverse events that were observed during the trial are reported in the following **Table 1**.

¹ The Prostar XL PVS System is a design evolution of the Prostar Plus PVS System. The results of the STAND II trial are applicable to the Prostar XL PVS System because of the system similarities.

Table 1. Percentage of Patient Experiencing Adverse Events

(All patients enrolled in STAND II Trial; n = 515)

Study Arm	Prostar Plus All Sizes (n = 251)	Compression All Sizes (n = 264)	Δ, [95% CI]
Complications ‡ (per event basis)			
n (percent)			
Device Malfunction*	7 (2.8%)	n/a	-
Device Complication	2 (0.8%)	n/a	-
Vascular Repair**	3 (1.2%)	1 (0.4%)	0.8% [-2.0%, 4.1%]
Ultrasound Guided Compression**	2 (0.8%)	3 (1.1%)	-0.3% [-3.8%, 2.6%]
Transfusion**	0 (0.0%)	1 (0.4%)	-0.4% [-3.2%, 1.9%]
Infection Requiring IV Antibiotics**	2 (0.8%)	1 (0.4%)	0.4% [-2.3%, 3.5%]
Hematoma > 6 cm	6 (2.4%)	3 (1.1%)	1.3% [-2.2%, 5.2%]
AV Fistula	1 (0.4%)	1 (0.4%)	0.0% [-2.6%, 2.9%]
Nerve Injury	1 (0.4%)	0 (0.0%)	0.4% [-2.0%, 3.2%]
Pseudoaneurysm	3 (1.2%)	2 (0.8%)	0.4% [-2.6%, 3.8%]
Complications (per event basis)			
n (percent)			
Any Complication	15 (6.0%)¶	6 (2.3%)	3.7% [-0.7%, 8.7%]
8F	13 (5.7%)	4 (1.7%)	-
10F	2 (8.3%)	1 (4.0%)	-
Major Complication	6 (2.4%)	3 (1.1%)	1.3% [-2.2%, 5.2%]
8F	4 (1.8%)	2 (0.8%)	-
10F	2 (8.3%)	1 (4.0%)	-
No Major Complication	245 (97.6%)	261 (98.9%)	-
8F	223 (98.2%)	237 (99.2%)	-
10F	22 (91.7%)	25 (96.0%)	-

‡ Patients with hematoma < 6 cm not included [n = 4 (1.6%) Prostar Plus arm, n = 8 (3.0%) compression arm]; these patients did not experience adverse reactions related to hematoma < 6 cm.

* Patients experiencing device malfunction proceeded to successful closure without clinical sequelae; malfunction included suture breaks, 2 (0.8%); failed suture deployment, 1 (0.4%); failed sheath deployment, 3 (1.2%); failed needle deployment, 1 (0.4%).

** Indicates a major complication.

¶ Patients with any complication, including 1 (0.4%) patient requiring excision of the distal sheath tip from subcutaneous tissue and 4 (1.6%) patients with localized infection requiring oral antibiotics.

Two deaths were reported in the STAND II Trial (one in each treatment arm). Both cases were reviewed and it was established that the cause of death was cardiac-related, not groin- or device-related. The following potential adverse reactions or conditions may be associated with the use of the PVS System: deep vein thrombosis, 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 limited 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*.

CLINICAL TRIAL

Prostar Plus² PVS Systems were evaluated in a multicenter, prospective randomized trial involving 515 post catheterization patients (71.0% male) at seven U.S. sites. Patients were randomly assigned with equal probability to the Prostar Plus PVS Device (n=251) and conventional compression (*i.e.* manual or mechanical) methods (n=264). The study 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 ambulation (patient walks ten feet). A major complication was defined as surgery or ultrasound-guided compression for vascular repair, surgery for nerve injury, groin-related blood transfusion or groin-related infection requiring prolonged hospitalization. The secondary endpoints were incidence of other complication, time to hemostasis, procedure success (achievement of hemostasis at the femoral artery access site and freedom from major complication using any closure method), and device success (acute success using the device only or the device plus adjunctive, non-arterial compression).

Patients having a catheterization procedure (55.1% interventional and 44.9% diagnostic) performed via the common femoral artery through a 6.5 to 10 French introducer sheath were eligible. Exclusion criteria included patients with bilateral arterial access sites punctured within 48 hours, pre-existing vascular complication, small femoral arteries (< 5 mm), femoral artery stenosis greater than 50%, fluoroscopically visible calcium, posterior wall puncture, bleeding diathesis or coagulopathy, anatomy which made successful Prostar Plus PVS Device placement unlikely and patients who were pregnant.

There were no significant differences between the two randomized groups with respect to age, major comorbidities, angina severity, peri-procedural medications, body size, or blood pressure. Although the gender representation was significantly different within the two groups (76.0% men for Prostar Plus patients vs. 67.0% for compression patients), this difference did not alter the safety and effectiveness results and the population, in both groups, remained representative of the overall population undergoing catheterization procedure. Arterial sheath sizes used (90.5% of patients, 8F or smaller and 9.5% larger than 8F) were comparable between treatment arms.

In suitable patients following 6.5 to 10F catheterization procedures, procedure success was achieved in 245 (97.6%) of 251 patients randomized to receive the Prostar Plus PVS System compared to 261 (98.9%) of 264 patients randomized to compression. Device success was achieved in 229 (91.2%) patients. The effectiveness of the Prostar Plus PVS System was assessed primarily by time to ambulation, which was defined as the elapsed time from the last angiogram to the time the patient walked 10 feet. Times to hemostasis and device success were secondary endpoints. The Prostar Plus PVS System resulted in significantly shorter times to hemostasis and ambulation compared to compression. **Table 2** presents the results by study arm with all Prostar Plus sizes combined (*i.e.*, 8F and 10F), while **Table 3** includes results by study arm separated by sheath size.

There was no statistically significant difference in the combined major complication rate between the Prostar Plus PVS Device (2.4%) and compression (1.1%). Univariable and multivariable modeling demonstrated that the Prostar Plus PVS treatment had no statistically significant association with the incidence of vascular surgery or with the combined major complications endpoint. In addition, this model showed that for all patients (Prostar Plus and compression) enrolled in the trial, time to ambulation was increased for those receiving abciximab (ReoPro).

² The Prostar XL PVS System is a design evolution of the Prostar Plus PVS System. The results of the STAND II Trial are applicable to the Prostar XL PVS System because of the system similarities.

Table 2. Principal Effectiveness Results for All Sizes

(All patients enrolled in STAND II Trial; n = 515)

Study Arm	Prostar Plus	Compression	Δ, [95% CI]
Effectiveness Measures ‡ (in hours)			
Randomized Patients	n = 251	n = 264	-
Time to Hemostasis	n = 248	n = 252	
mean ± S.D.	0.6 ± 1.8	5.4 ± 6.1	-4.8†
median [quartiles]	0.3 [0.2, 0.5]	4.0 [0.8, 7.1]	[5.7, -4.1]
Time to Ambulation	n = 248	n = 262	
mean ± S.D.	7.9 ± 11.1	15.8 ± 12.3	-7.9†
median [quartiles]	3.9 [2.0, 8.8]	14.8 [7.0, 19.9]	[-10.0, -5.9]
Device Success, n (%)	229 (91.2%)	-	-

‡ The number of patients listed under “Effectiveness Measures” is less than the total patients studied due to missing data for some patients.

† Difference is statistically significant; p < 0.001.

Device Success = acute success using the device only or the device + adjunctive (non-arterial) compression.

Table 3. Principal Effectiveness Results by Sheath Size

(All patients enrolled in STAND II Trial; n = 515)

Study Arm	Prostar Plus 8F	Compression 8F	Prostar Plus 10F	Compression 10F
Effectiveness Measures (in hours)				
Randomized	n = 227	n = 239	n = 24	n = 25
Time to Hemostasis	n = 224	n = 228	n = 24	n = 24
mean ± S.D.	0.5 ± 1.8	5.0 ± 6.1	1.0 ± 1.9	8.5 ± 5.3
median [quartiles]	0.3 [0.2, 0.4]	3.6 [0.7, 6.8]	0.4 [0.3, 0.6]	6.7 [5.9, 8.7]
Time to Ambulation	n = 224	n = 237	n = 24	n = 25
mean ± S.D.	7.4 ± 11.4	15.1 ± 12.3	12.5 ± 6.9	22.4 ± 14.8
median [quartiles]	3.4 [1.8, 7.8]	14.0 [6.6, 19.9]	13.5 [6.2, 17.7]	17.9 [15.6, 20.3]
Device Success, n (%)	210 (92.5%)	-	19 (79.2%)	-

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of Prostar XL 10F PVS System. The techniques and procedures described are not intended as a substitute for the physician’s experience and judgment in treating any specific patients.

Examination and Selection of Products

1. Select the Prostar XL 10F device for closure of 8.5 to 10F sheath access sites.
2. The outer pouch packaging of the Prostar XL PVS System provides the sterile barrier. After careful inspection of the packaging to ensure there is no damage to the sterile barrier, carefully remove the device from the package.
3. Verify marker port patency by flushing the lumen with saline until the saline exits from the marker port. **Do not use the Prostar XL device if the marker lumen is not patent.**
4. Exercise care when using additional surgical instruments such as forceps, hemostats or needle holders during device handling, to reduce the possibility of accidental device breakage.

Arterial Puncture Considerations

1. Puncture the anterior wall of the common femoral artery at an angle of approximately 45 degrees.
2. Avoid sidewall or posterior wall femoral artery punctures.
3. Puncture locations are ideally located in the common femoral artery below the level of the inguinal ligament and above the common femoral artery bifurcation.

Prostar XL PVS Device Placement

1. Prior to Prostar XL device placement, perform a femoral angiogram through the introducer sheath to verify that the access site is in the common femoral artery.
2. Evaluate the femoral artery site for size, calcium deposits, and tortuosity, to avoid posterior wall suture placement and possible ligation of the anterior and posterior walls of the femoral artery.
3. While the introducer sheath remains in place, use a scalpel to slightly extend the incision and forceps to dilate subcutaneous tissue.
4. 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.
5. Carefully back-load the Prostar XL device over the guide wire until the guide wire exit port is just above the skin line. Remove the guide wire.
6. Unlock the hub by depressing the interlocks with your thumb and forefinger. Once the hub is unlocked, rotate the hub while gently advancing the barrel at a **45-degree angle**, or less.
7. A steady, continuous drip of blood from the dedicated marker lumen occurs when the Prostar XL device is properly positioned (see **Figure 2**). Marking from the lumen(s) containing suture(s) may occur but should not be used as the indicator for proper positioning and needle deployment.

Do not clamp the suture lumen with a hemostat or other instrument. Doing so will prevent suture deployment.

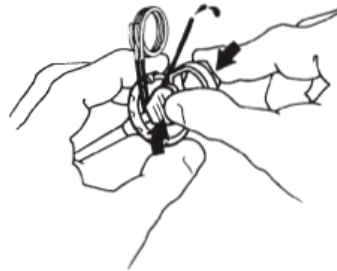


Figure 2

8. Lock the hub back in place.
 - 8.1. If a continuous drip of blood (luminal marking) from the dedicated marker lumen is not apparent, withdraw the device to expose the marker port. Flush the marker lumen to verify patency, and then continue to gently advance the Prostar XL device while rotating the barrel.
 - 8.2. If continuous marking is still not achieved, remove the Prostar XL device and follow conventional compression protocol, or replace the Prostar XL device with an appropriately sized introducer sheath.
 - 8.3. **Do not deploy needles until a continuous drip of blood is evident from the dedicated marker lumen.**

Needle Deployment

1. Confirm that the interlocks are re-engaged and correctly aligned with the locking indents in the hub (locked).
2. With left hand, hold the hub of the device in position at an **angle of 45 degrees** or less.
3. With the right hand, rotate the handle counterclockwise, to unlock the handle.

4. Ensure blood marking is maintained.
5. Pull the handle away from the hub to deploy the needles (see **Figure 3**).

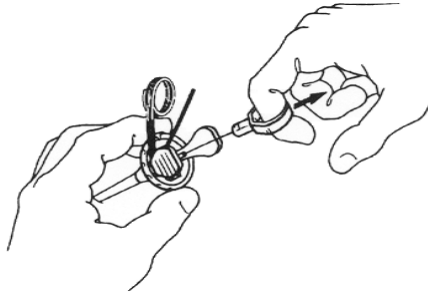


Figure 3

6. If resistance to rotating the handle is encountered, **do not attempt to deploy the needles**. Significant resistance is an indication that the hub is not properly positioned. Refer to the **TECHNIQUE FOR NEEDLE BACK-DOWN** section to ensure proper hub positioning.
7. **Do not clamp the suture lumen with a hemostat or other instrument. Doing so will prevent suture deployment.**
8. Continue to pull the handle until the needle tips emerge at the top of the barrel.
9. While steadily holding the device in position, confirm that all four needles are visible in the hub.
10. If significant resistance is encountered prior to needle tips emerging at the top of the barrel, or if all four of the needles are not deployed, terminate deployment. Refer to the **TECHNIQUE FOR NEEDLE BACK-DOWN** section to perform needle back-down procedure.
11. Using a hemostat, remove the posterior needle(s) followed by the anterior needle(s) using the funnel-shaped hub as a fulcrum to facilitate needle removal (see **Figure 4**). More force is required to remove the first needle than the remaining needle(s).

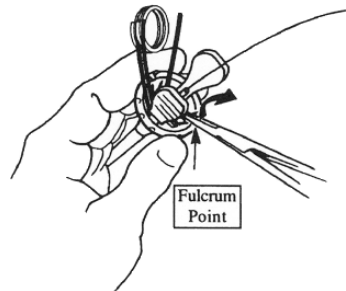


Figure 4

Suture Management

1. Once needles have been removed from the hub, remove slack in the suture(s) by pulling the suture ends to evenly matched lengths and tensioning until resistance is felt. Cut the suture ends close to the needles. Dispose of needles in accordance with hospital policy.
2. Withdraw the Prostar XL device until the guide wire port exits the skin line. Maintain access to the sutures exiting the hub during this step. Create a “bow string” effect with the exposed suture(s) by bending the Prostar XL device sheath away from the operator and applying tension to the suture ends exiting the hub (see **Figure 5**). This ensures that the sutures are not tied around the sheath and that guide wire access can be maintained until hemostasis is verified.

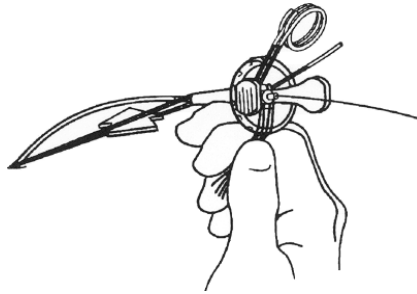


Figure 5

3. Grab the anterior suture ends (one white and one green) adjacent to the topside of the sheath and pull the suture ends through the distal end of the barrel. Place this pair of suture ends toward the patient's head.
4. Grab the posterior suture ends (one white and one green) adjacent to the underside of the sheath and pull the suture ends through the distal end of the barrel. Ensure that this pair of suture ends comes under the device and towards you. Place this pair of suture ends toward the patient's feet.
5. Identify the two ends of a single suture by color, and then tension the ends using a gentle seesawing motion.
6. Reinsert the 0.038" (or smaller) guide wire into the visible guide wire exit port.

Knot Advancement

1. Identify the green suture ends. Place one green suture end in each hand.
2. Gently tension the suture to create a longer suture end. (The short end will be your rail limb of suture, for the green knot).
3. Tie a sliding, self-locking surgical knot using the green suture.
4. Lay the green suture aside.
5. Identify the white suture ends. Place one white suture end in each hand.
6. Gently tension the suture to create a longer suture end. The short end will be your rail limb of suture, for the white knot.
7. Tie a sliding, self-locking surgical knot using the white suture.
8. Securely wrap the white rail suture around your left index finger. Saturate the suture with saline. Gently pull on the white rail suture first, keeping the suture coaxial to the tissue tract. Completely remove the device from the artery, leaving the guide wire in the artery.
 - 8.1. Do not compress the femoral access site while withdrawing the Prostar XL device from the tissue tract. Applying excessive force to the Prostar XL sheath, due to site compression, during removal of the device may result in a needle guide break. Please refer to **NEEDLE GUIDE BREAK PROCEDURE** section for further instruction.
 - 8.2. Do not tighten the suture around the sheath. Tightening the suture around the sheath during Prostar XL device removal may result in a needle guide break. Please refer to **NEEDLE GUIDE BREAK PROCEDURE** section for further instructions.
9. Saturate the sutures with saline. Load the rail suture into the Knot Pusher and continue to advance the knot forward to the arteriotomy (see **Figure 6**).



Figure 6

10. With the rail suture limb securely wrapped around the left forefinger, place the Knot Pusher under the left thumb to assume a single-handed position to complete knot advancement.
11. Do not tension the non-rail suture to tighten the knot.
12. Remove the Knot Pusher from the tissue tract and from the suture without using the thumb knob.
13. Lay the white suture down, being sure to separate the rail and non-rail ends.
14. Repeat steps 8-13 with the green suture.
15. If hemostasis has been achieved, remove the guide wire from the patient. Continue with step 17.
16. If hemostasis has not been achieved:
 - 16.1. Repeat steps 8-14.
 - 16.2. Exchange the Prostar XL device with an appropriately sized introducer sheath. Care should be taken to avoid excessive force if the reintroduction of another introducer sheath is required. To avoid resistance, use an introducer sheath small enough to be introduced without undue force, but large enough to maintain hemostasis.
 - 16.3. Apply conventional compression therapy.
17. Once again, securely wrap the white rail suture around your left index finger.
18. Load the white rail suture into the Knot Pusher and advance to the level of the arteriotomy.
19. With the rail limb securely wrapped around the left forefinger, place the Knot Pusher under the left thumb to assume a single-handed position and to complete knot advancement.
20. With the Knot Pusher in place, tighten the knot by gently pulling on the white non-rail suture.
21. Remove the Knot Pusher from the tissue tract and from the suture with out using the thumb knob.
22. Repeat these same steps 17-21 with the green suture.
23. If hemostasis is not complete, repeat the single-handed position for 20 seconds. After 20 seconds gently pull on the non-rail suture to tighten the knot. (Repeat first with the white suture and next with the green suture). **Do not apply excessive pressure to the Knot Pusher or suture.**
24. The Arterial Tamper accessory may be used if acceptable hemostasis is still not achieved:
 - 24.1. Thread the exposed suture ends through the snare.
 - 24.2. Unlock the snare handle by turning it counterclockwise.
 - 24.3. Pull the snare through the Arterial Tamper with the snare handle. The snare will exit with the suture from the proximal end of the Arterial Tamper.
 - 24.4. Gently advance the Arterial Tamper over the tensioned suture until it applies direct pressure to the access site.
 - 24.5. Keeping the stopcock lever facing to the patient's right ensures that the beveled tip is appropriately oriented to the arterial surface.
 - 24.6. The Arterial Tamper may be secured in place by tensioning the suture and rotating the stopcock lever 90 degrees in the counterclockwise direction.

- 24.7. When hemostasis has been achieved, rotate the stopcock lever clockwise until the suture moves freely.
- 24.8. The Arterial Tamper can now be withdrawn.
- 25. In the event bleeding from the femoral access site persists after use of the Prostar XL PVS System and Arterial Tamper, use conventional compression therapy.
- 26. Once hemostasis is achieved, trim the sutures below the skin.

TECHNIQUE FOR NEEDLE BACK-DOWN

The following describes a safety feature (“needle back-down”) that permits the physician to return the needles into the sheath. This feature provides the option of exchanging the Prostar XL device with another Prostar XL device or an introducer sheath so that the patient may be treated with conventional compression therapy.

1. If resistance to counter-clockwise rotation of the handle is felt, **do not attempt to deploy the needles**. Check that the interlocks are correctly aligned with the locking indents in the hub. The star on the edge of the hub should be centered directly between the interlocks.
2. If needles are not easily deployed, back the needles down into the sheath prior to removal of the device.
3. Manually remove the coiled sections of the suture lumens to uncover the suture loops.
4. Use a hemostat to grasp the pull rod close to the hub. Advance the pull rod 1 cm into the core (see **Figure 7**) and then gently pull the slack out of the uncovered suture loops.

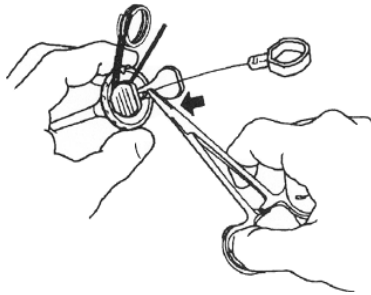


Figure 7

5. Repeat step 4 until the handle snaps into position on the proximal end of the device.
6. Pull back on the suture loops exiting the suture lumens to ensure that all slack in the sutures has been removed.
7. Prior to device removal, use fluoroscopy to verify the needles have been returned into the needle guide. **The needle tips should be as close as possible to the proximal edge of the radiopaque sheath ring before removal of the Prostar XL device.**
8. Perform the same needle back-down procedure in the event that all needles are not deployed. **DO NOT REMOVE ANY DEPLOYED NEEDLES.**
9. Do not attempt to re-deploy the Prostar XL device after the needles have been “backed-down”. Replace the Prostar XL device with another Prostar XL device, an introducer sheath, or utilize conventional compression therapy.

SUTURE BREAKAGE

1. If sutures are inadvertently tangled or removed prior to knot tying, discard the suture material and remove the Prostar XL device over the guide wire. Use another Prostar XL device to complete the procedure.
2. In the event suture breakage occurs prior to completing the initial knot, discard the suture material and remove the device over the guide wire. Use another Prostar XL device to complete the procedure.
3. In the event suture breakage occurs after the initial knot has been tied, the Arterial Tamper may be used to augment hemostasis. The broken suture may be discarded and another Prostar XL device may be introduced or the introducer sheath may be replaced. If replacement of the introducer sheath is attempted, care should be taken to avoid excessive force during introduction. Any resistance to introduction should result in advancement of an introducer sheath small enough to be introduced without undue force, but large enough to maintain hemostasis.



NEEDLE GUIDE BREAK PROCEDURE

In the event that the Needle Guide of the Prostar XL device breaks, the following describes a safety procedure that allows the physician to remove the Prostar XL device from the patient without surgical intervention.

Procedure for Needle Guide Break pre needle deployment:

1. Do not advance or withdraw the Prostar XL device against resistance until the cause of that resistance has been determined. **Advancing or withdrawing the Prostar XL device against resistance may cause the device to break.**
2. Note: though the guide will appear to be broken, the sheath remains attached to the device via the holder stop. The Prostar XL device has a redundant system that prevents the sheath from becoming completely detached from the device.
3. To remove a Prostar XL device with a Needle Guide Break that occurred during device insertion, evaluate if the Guide Wire Exit Port can be visualized above the skin.
4. If the Guide Wire Exit Port cannot be visualized:
 - 4.1. Manually remove the coiled sections of the suture lumens to uncover the suture loop.
 - 4.2. Pull back on the suture loops exiting the suture lumens to ensure that all slack in the sutures has been removed.
 - 4.3. Clamp the suture lumens with hemostats.
 - 4.4. Remove the device until the Guide Wire Exit Port is visualized.
5. Insert a 0.038" (or smaller) guide wire into the Guide Wire Exit Port and replace the Prostar XL device with another Prostar XL device, an introducer sheath, or use conventional compression therapy.

Procedure for Needle Guide Break post needle deployment:

1. Do not compress the femoral access site while withdrawing the Prostar XL device from the tissue tract. **Applying excessive force to the Prostar XL sheath, due to site compression, during removal of the device may result in a needle guide break.**
2. Do not tighten the suture around the sheath. **Tightening the suture around the sheath during Prostar XL device removal may result in a needle guide break.**
3. Do not advance or withdraw the Prostar XL device against resistance until the cause of that resistance has been determined. **Advancing or withdrawing the Prostar XL device against resistance may cause the device to break.**
4. Note: though the guide will appear to be broken, the sheath remains attached to the device via the holder stop. The Prostar XL device has a redundant system that prevents the sheath from becoming completely detached from the device.
5. To remove the Prostar XL device when a Needle Guide Break has occurred during device removal, evaluate if the Guide Wire Exit Port can be visualized above the skin.
 - 5.1. If the Guide Wire Exit Port cannot be visualized, apply similar and simultaneous backward tension to both the circular handle and the device hub.
 - 5.2. Remove the device until the Guide Wire exit Port is visualized.
 - 5.3. Insert a 0.038" (or smaller) guide wire into the Guide Wire Exit Port and replace the Prostar XL device with another Prostar XL device, an introducer sheath, or utilize conventional compression therapy.

POST PROCEDURE PATIENT MANAGEMENT

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



COMPLICATIONS

Potential complications resulting from procedures associated with the use of the Prostar XL 10F PVS System include, but are not limited to:

- Localized vessel wall trauma which may lead to surgical repair
- Arterial thrombus
- Deep vein thrombosis
- Pseudoaneurysm
- Hematoma
- Local infection
- Nerve injury
- Local pulse deficits or ischemia
- Blood loss that may lead to blood transfusion
- Local discomfort
- Wound dehiscence.

RECOMMENDATION FOR PATIENT AMBULATION

1. Patients may be ambulated after Prostar XL 10F PVS device procedures with normalized (150-180 seconds) Activated Clotting Times (ACTs).
2. Before considering early discharge, assess for the following clinical conditions:
 - Conscious sedation
 - Anticoagulation, antiplatelet or thrombolytic 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.

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, the 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.



HOW SUPPLIED

Prostar XL 10F Percutaneous Vascular Surgical System

List/REF 12322 (Box of 5)

Each system includes:

One (1) Prostar XL 10F Percutaneous Vascular Surgical Device

One (1) Perclose Knot Pusher

Accessories

Perclose Arterial Tamper

List/REF 12323 (Box of 5)

Perclose Knot Pusher

List/REF 12324 (Box of 5)

The Prostar XL 10F PVS System 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 cool, dry place. The Prostar XL device, individual accessories and immediate packaging do not contain latex.

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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		Latex Free
	Contents		Do not use product if packaging or sterile barrier has been previously opened or damaged.
	Number of units		Store in a cool location (room temperature).
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.		Keep dry
	Caution, refer to accompanying documents.		Manufactured by
	Sterilized using ethylene oxide		Distributed by



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5,417,699	5,527,322	5,613,974	5,746,755
5,779,719	5,797,929	5,792,152	5,860,991
5,902,311	5,921,994	6,036,699	6,117,145
6,206,893	6,355,050	6,517,553	
EP 673228	EP 727965	EP 910288	

Other patents pending.

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