Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

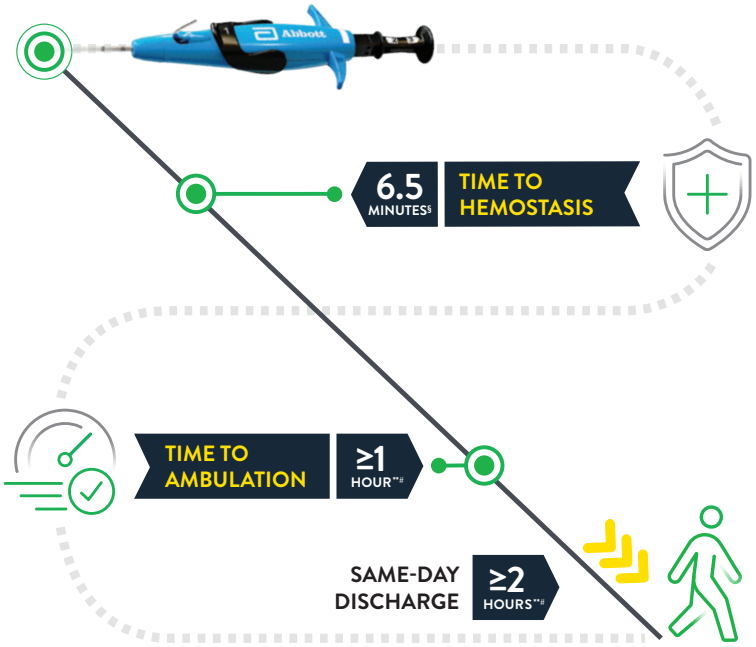
Experience unmatched versatility with the ONLY FDA-approved vessel closure device to close access sites for the latest generation Pulsed Field Ablation (PFA) Systems.*†

The global AFib crisis affects 37M+ patients today and is rising[1,2], leading to a critical need for improved EP Lab efficiency strategies.

PFA could significantly shorten AFib procedures vs. radiofrequency ablation (RFA) and cryoballoon ablation[3,4]

Considering adopting PFA for your practice to increase EP lab efficiency? Why not also streamline post-ablation care with the Perclose™ ProStyle™ SMCR System, the only FDA approved device suitable for closing access sites regardless of ablation type?*†

STREAMLINED POST-ABLATION CARE WITH PERCLOSE™ PROSTYLE™ SMCR SYSTEM



IMMEDIATE AND DURABLE HEMOSTASIS
with **>96%** freedom from major access site-related complications at 30 days[6]***

PATIENT MAY SIT UP IMMEDIATELY
with no lay flat restrictions[6]

AMBULATE IN 1 OR MORE HOURS
and send patient home same day in 2 or more hours**#

NO RE-ACCESS RESTRICTIONS[6]

SAFE AND EFFECTIVE
in closing multiple common femoral venous access sites per limb in over 1,000 combined patients◊

SUTURE-MEDICATED CLOSURE
with the broadest Indication in arterial and venous femoral access sites*
Arterial: 5-21F (Max, 26F OD)[5]
Venous: 5-24F (Max, 29F OD)[5]

State-of-the-art care deserves a state-of-the-art finish
Visit **EPvesselclosure.com**

Important Safety Information referenced on reverse.

INDICATIONS

The Perclose™ ProStyle™ Suture-Mediated Closure and Repair System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access sites of patients who have undergone diagnostic or interventional catheterization procedures.
The Perclose™ ProStyle™ SMCR System is indicated for closing the common femoral vein in single or multiple access sites per limb.
The Perclose™ ProStyle™ SMCR 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 arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required.
For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

Abbott

IMPORTANT SAFETY INFORMATION

℞ ONLY Perclose™ ProStyle™ Suture-Mediated Closure and Repair (SMCR) System

INDICATIONS
The Perclose™ ProStyle™ Suture-Mediated Closure and Repair System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access sites of patients who have undergone diagnostic or interventional catheterization procedures.
The Perclose™ ProStyle™ SMCR System is indicated for closing the common femoral vein in single or multiple access sites per limb.
The Perclose™ ProStyle™ SMCR 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 arterial sheath sizes greater than 8F, at least two devices and the pre-close technique are required.
For access sites in the common femoral vein using 5F to 24F sheaths. For venous sheath sizes greater than 14F, at least two devices and the pre-close technique are required.

CAUTION
Federal law restricts this medical 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. 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 repair the vessel is needed.

CONTRAINDICATIONS
There are no known contraindications to the use of this device.

WARNINGS
Do not use the Perclose™ ProStyle™ SMCR System 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™ ProStyle™ SMCR System is intended for single use only.
Do not use the Perclose™ ProStyle™ SMCR 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™ ProStyle™ SMCR 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 vessel.
Do not use the Perclose™ ProStyle™ SMCR System in arterial or venous access if the puncture is through the posterior wall or if there are multiple punctures in the same access site, since such punctures may result in a hematoma or retroperitoneal bleed.
Do not use the Perclose™ ProStyle™ SMCR 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 vessel.

PRECAUTIONS
1. Prior to use, inspect the Perclose™ ProStyle™ SMCR 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™ ProStyle™ SMCR 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 in arterial and venous access.
4. Do not deploy the Perclose™ ProStyle™ Device at an elevated angle against resistance as this may cause a cuff miss or device breakage.
5. There are no reaccess restrictions if previous arteriotomy / venotomy repairs were achieved with Abbott Medical SMC or SMCR systems.
6. If significant blood flow is present around the Perclose™ ProStyle™ Device, do not deploy needles. Remove the device over a 0.038" (0.97 mm) (or smaller) guide wire and insert an appropriately sized sheath.
7. Prior to depressing the plunger to advance the needles, stabilize the device by the body to ensure the foot is apposed to the vessel wall and the device does not twist during deployment. Twisting (torquing) of the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly depress the plunger. 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 opening the foot and returning the foot to its original position down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever 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™ ProStyle™ Device against resistance until the cause of that resistance has been determined. Excessive force used to advance or torque the Perclose™ ProStyle™ 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™ ProStyle™ Device is encountered, withdraw the device over a 0.038" (0.97 mm) (or smaller) guide wire and reinsert the introducer sheath or use manual compression.
11. Remove the Perclose™ ProStyle™ 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. Care should be taken to avoid damage to the suture from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.
13. For catheterization procedures using a 5F – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose™ ProStyle™ SMCR System to obtain hemostasis.
14. For catheterization procedures using a procedural sheath > 8F, use manual compression, compression assisted devices, surgical repair, and / or other appropriate treatment methods in the event that bleeding from the femoral access site persists after the use of the Perclose™ ProStyle™ SMCR System to obtain hemostasis.
15. For catheterization procedures using a procedural sheath > 8F, where the operating 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 vascular surgical intervention.
16. If the Perclose™ ProStyle™ Device is used to close and repair multiple access sites in the same vessel, space the access sites apart adequately to minimize sheath-device interference.

POTENTIAL ADVERSE EVENTS
Potential adverse events associated with use of vessel closure devices may include, but are not limited to, the following:
- Allergic reaction or hypersensitivity to device components
- Vascular access complications which may require transfusion or vessel repair, including:
  - Anemia
  - Aneurysm
  - Arteriovenous fistula
  - Bleeding / hemorrhage / re-bleeding
  - Bruising
  - Hematoma
  - Embolism
  - Inflammation
  - Intimal tear / dissection
  - Perforation
  - Pseudoaneurysm
  - Retroperitoneal hematoma / bleeding
  - Scar formation
  - Wound dehiscence
- Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias)
  - Atrial arrhythmias
  - Ventricular arrhythmias
- Femoral artery / venous complications which may require additional intervention, including:
  - Arterial / venous stenosis
  - Arterial / venous occlusion
  - Arteriovenous fistula
  - Intimal tear / dissection
  - Ischemia distal to closure site
  - Nerve injury
  - Numbness
  - Thrombus formation
  - Vascular injury
- Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post-procedure pulmonary embolism)
- Infection – local or systemic
- Pain
- Hemodynamic instability:
  - Hypotension / hypertension
  - Vasovagal episode
- Death
- Device complications
- Device failure
- Device malfunction

*As compared to Angio-Seal‡, ExoSeal‡, Celt ACD‡, MANTA‡, Mynx‡, Vascade‡. Data on file at Abbott.
† At the time of publication.
§ Observed median time to hemostasis per patient level analysis in the duplex ultrasound (DUS) IDE Trial.
◊ Demonstrated in analysis of over 1,000 combined patients from a duplex ultrasound (DUS) IDE trial and three real-world investigator sponsored studies (ISS) Perclose™ ProStyle™ SMCR System Instructions for Use (IFU). Refer to IFU for additional information.
** After successful close with Perclose device(s) in patients who have undergone cardiac arrhythmia treatments with multiple common femoral venous access sites.
*** Observed in a duplex ultrasound (DUS) IDE trial and two real-world investigator sponsored studies.
# As per the IFU, patients who have undergone cardiac arrhythmia treatments with multiple access sites in a single femoral vein of one or both limbs may be ambulated one hour or more and may be eligible for same-day discharge two hours or more after successful closures with Perclose™ devices based on the judgment of the physician.
1. Lippi G, Sanchis-Gomar F, Cervellin G. Global epidemiology of atrial fibrillation: An increasing epidemic and public health challenge. Int J Stroke. 2021 Feb;16(2):217-221. doi: 10.1177/1747493019897870. Epub 2020 Jan 19. Erratum in: *Int J Stroke*. 2020 Jan 28;:1747493020905964. PMID: 31955707. **2.** Morillo, C. A., Banerjee, A., Perel, P., Wood, D., & Jouven, X. (2017). Atrial fibrillation: the current epidemic. Journal of geriatric cardiology: *JGC*, 14(3), 195–203. http://www.jgc301. com/en/article/doi/10.11909/j.issn.1671-5411.2017.03.011. **3.** Ekanem, E., Reddy, V. Y., Schmidt, B., Reichlin, T., Neven, K., Metzner, A., Hansen, J., Blaauw, Y., Maury, P., Arentz, T., Sommer, P., Anic, A., Anselme, F., Boveda, S., Deneke, T., Willems, S., van der Voort, P., Tilz, R., Funasako, M., ... Neuzil, P. (2022). Multi-national survey on the methods, efficacy, and safety on the post-approval clinical use of pulsed field ablation (MANIFEST-PF). Europace : European Pacing, Arrhythmias, and Cardiac Electrophysiology : *Journal of the Working Groups on Cardiac Pacing, Arrhythmias, and Cardiac Cellular Electrophysiology of the European Society of Cardiology*, 24(8), 1256–1266. https://doi.org/10.1093/europace/euac050. **4.** Reddy, Vivek Y., John W. Lehmann, Edward P. Gerstenfeld, Andrew S. Mugglin, Christopher W. Schneider, Anitha B. Achyutha, and Moussa Mansour. 2023. "A Randomized Controlled Trial of Pulsed Field Ablation versus Standard-of-Care Ablation for Paroxysmal Atrial Fibrillation: The ADVENT Trial Rationale and Design." *Heart Rhythm* O2 4 (5): 317–28. doi:10.1016/j.hroo.2023.03.001. **5.** Max. OD 26F/0.340 inches/8.62mm; Max. OD 29F/0.378 inches/9.59 mm. Data on file at Abbott. **6.** Perclose™ ProStyle™ Suture-Mediated Closure and Repair (SMCR) System Instructions for Use (IFU). Refer to IFU for additional information.

CAUTION: This product is intended for use by or under the direction of a physician.
Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *manuals.eifu.abbott* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.cardiovascular.abbott