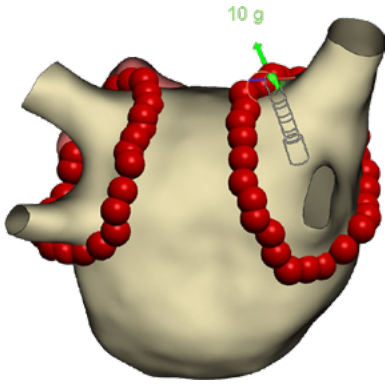
Perclose™ ProStyle™
Suture-Mediated Closure and Repair (SMCR) System

EP PROCEDURE HIGHLIGHT
AFib RF Ablation Procedure

PHYSICIAN NAME AND BACKGROUND:
Dr. Sri Sundaram, MD, FHRS, FACC
Cardiac Electrophysiologist
Porter Adventist Hospital, Denver, CO

HOSPITAL AND EP LAB SIZE:
3 EP Labs

ABLATION VOLUME:
~750 Ablations Per Year



Pulmonary Vein Isolation (PVI) performed using TactiFlex™ Ablation Catheter, Sensor Enabled™

Case images and hospital information provided by Dr. Sundaram.

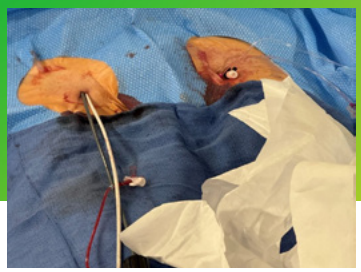
5 QUESTIONS WITH DR. SUNDARAM

Q: Why did you become interested in using Perclose™ ProStyle™ devices for AF cases?

A: During the pandemic, bed space in hospitals became limited and reserved for treating those with COVID-19. This limited the ability to perform elective procedures and placed an emphasis on discharging patients the same day. Prior to the pandemic, approximately 10% of all patients were discharged within the same day, while during the pandemic the same-day discharge rate rose to approximately 80% of patients. Perclose™ ProStyle™ gave my lab the ability to discharge more of our patients because we were able to quickly confirm hemostasis on the table while the patient was still in the Cath Lab. This helped me feel confident in ambulating them in 2 hours and send them home the same day in 2-4 hours.

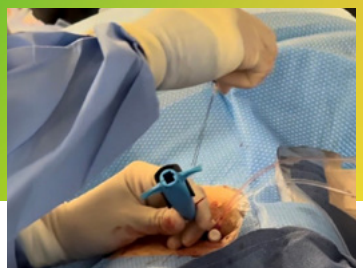
Case Images post AFib Ablation Procedure Using Perclose™ ProStyle™ SMCR System

Ultrasound guided access for all sheaths



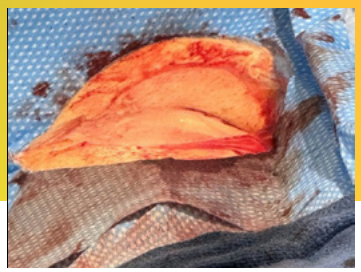
Left Groin:
8.5F & 10F venous access sites

Right Groin:
8.5F & 8.5F venous access sites



Order of Post-Close Perclose™ ProStyle™ device deployment:

Cranial-to-Caudal



Immediate hemostasis achieved for both groins. If closure is successful with Perclose™ ProStyle™ SMCR System, patient can sit up without head of bed or leg restrictions.

Important Safety Information referenced within.

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.

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5 QUESTIONS WITH DR. SUNDARAM (CONT.)

Q: How did you learn to use Perclose™ ProStyle™ devices?

A: Having excellent rep support to walk you and your staff through the deployment steps a few times on an acrylic block or wet model is helpful before performing a closure on a live patient. I found the numbered steps on the actual Perclose™ ProStyle™ device extremely helpful when deploying the device. Although there is a learning curve, I would say that it only took about 5 cases as a physician and 10-15 cases for my scrub techs and nurses to feel proficient at deploying the Perclose™ ProStyle™. Based upon some initial internal quality tracking data, we experienced a 96% success rate with Perclose™ ProStyle™ after two and a half weeks.

Q: What vessel closure methods did you use prior to adopting Perclose™ ProStyle™ devices? Why do you think Perclose™ ProStyle™ devices are a better choice for you now?

A: I've experienced a failure rate of approximately 25% with figure of eight closures, especially amongst my larger BMI patient group. With manual compression and figure of eight, we would sometimes get bleeding hours later or after ambulation. The additional time of bedrest after a bleed required more in-hospital time and led to patients not being able to be discharged same day. I don't experience as large of a failure rate while using Perclose™ ProStyle™ amongst any patient body type.

Q: What role do Perclose™ ProStyle™ devices play in improving the patient experience and lab efficiency in your practice?

A: Since Perclose™ ProStyle™ devices allow me to check for hemostasis right away and allow me to let my patients sit up immediately, I get fewer complaints about back pain, and my patients are typically happier with the option to be able to go home the same day as the procedure. My nursing staff is also much happier that they are able to have patients sit up as soon as they are awake. My staff has experienced a shorter ambulation time for my patients and fewer groin complications. The qualitative benefits my patients and I have been experiencing led me to explore potential quantitative benefits, and at AP HRS, I was able to present a poster on how same-day discharge has a cost savings of approximately $3000 per patient.

Q: How do you see Perclose™ ProStyle™ devices playing a role in the future of your EP practice?

A: Closing with Perclose™ ProStyle™ helps to facilitate same-day discharge with my ablation cases and Perclose™ ProStyle™ will continue to be used in my practice. Because of the broad indication for Perclose™ ProStyle™, it will also have a large role to play in the larger bore procedures such as LAAO, leadless pacemakers, and PFA. I like that with one stock keeping unit (SKU), I can cover all my vessel closure needs, no matter what procedures I'm performing. The hospital likes having to deal with just one SKU, too.

Important Safety Information referenced within.

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IMPORTANT SAFETY INFORMATION

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

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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.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

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

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. Photos on file at Abbott.

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