EP PROCEDURE HIGHLIGHT

AFib Cryo-Ablation Procedure

PHYSICIAN NAME AND BACKGROUND

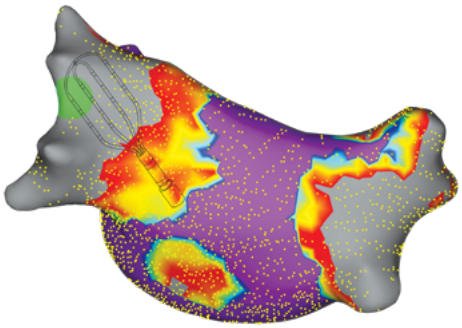
Dr. Rajdeep Gaitonde
Cardiac Electrophysiologist
Jewish Hospital and Baptist East
Medical Center, Louisville, KY

HOSPITAL AND EP LAB SIZE

462 Beds and 2 EP Procedural Rooms

CASE VOLUME

400+ Ablations Annually



EnSite™ X Endocardial Post Voltage Map of the Left Atrium shown from a posterior anterior (PA) view.

Case images and hospital information provided by Dr. Gaitonde

5 QUESTIONS WITH DR. GAITONDE

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

A: I initially became interested in Perclose™ ProStyle™ devices when thinking about the paradigm shift that occurred during COVID — namely transitioning towards same-day discharge for outpatient procedures including Atrial Fibrillation ablations, patients that traditionally were kept overnight or performing procedures on larger BMI patients who often require longer amounts of bedrest, I was looking to further minimize post procedure observation time. Therefore, being able to reduce bedrest from 3 or more hours to 1 hour and being able to raise the head of the bed to 30 degrees after confirming hemostasis seemed like a reset of everything we have traditionally done. I was also happy to hear that there is no ACT requirement to use Perclose™ devices, therefore I could avoid the common adverse reactions to protamine which can lead to increased morbidity and possibly mortality by not using protamine altogether and in the process save myself anywhere from 45 minutes to an hour waiting for an acceptable ACT in order to remove vascular access sheaths.

Important Safety Information referenced within.

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

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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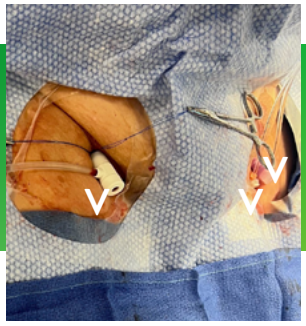
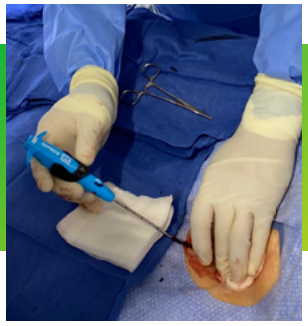
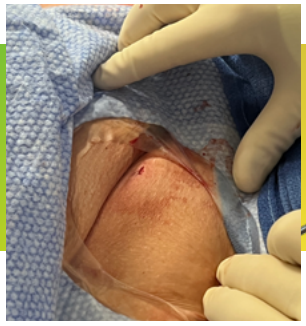
Case Images Using Perclose™ ProStyle™ SMCR System



Right Groin: 16F venous access site; pre-close technique.
Left Groin: 5F and 7F venous access sites; post-close technique.



Order of Post-Close Perclose™ ProStyle™ 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.

5 QUESTIONS WITH DR. GAITONDE (CONT.)

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

A: I am a very hands on and visual learner. Therefore, my rep and I spent a good amount of time deploying Perclose™ ProStyle™ devices on the wet model. My rep walked me through what the Perclose™ device was physically doing during each and every stage of the deployments steps and compared the process to a surgeon tying their own suture knot. The practice of deploying the Perclose™ ProStyle™ device coupled with the in-depth explanation of what I was doing at each step helped me to truly visualize and hence connect the dots and feel truly comfortable using and becoming truly a proficient user of Perclose™ ProStyle™.

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: During my previous life as an interventional fellow, I had used AngioSeal‡ before, but I questioned the practicality and safety of leaving foreign material in the lumen of the vessel. I was previously using the figure of eight closure to manage my access sites, but the bedrest time can be prolonged, especially when considering my larger BMI patients who sometimes would still be experiencing bleeding at the site even after 3 or more hours of bedrest. I had seen Perclose™ devices being used to close 14F access sites from Watchman procedures successfully, hence, I thought that this could be part of my armamentarium and use this in my practice to improve outcomes and patient care where I am using a 14F cryoablation catheter through a 16F support sheath and get the added benefit of less bedrest time, better patient satisfaction, and ultimately improved outcomes and patient care.

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5 QUESTIONS WITH DR. GAITONDE (CONT.)

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

A: On average, my Atrial Fibrillation Ablation procedures usually take less than 2 hours, but I am adding up to an hour of time to the procedure waiting for an acceptable ACT which ends up pushing back the next case start time which has a snowball effect for the rest of the operating day. When speaking about lab efficiency; if I am able to save 45 minutes to an hour for each case by using Perclose™ ProStyle™ devices, that can prove to be instrumental in making the day more efficient and improving every single facet of what we do including the satisfaction of the staff and ancillary staff because they can leave earlier. When I think about patient safety and improving their experience, I am pleased that I can avoid using protamine; therefore, dramatically reduce bedrest time from 3 or more hours to an hour, and that I can simultaneously raise the head of the bed to 30 degrees after confirmed hemostasis. All of these factors are significant for my patients as they feel better, especially considering that the vast majority have other comorbidities such as COPD, Pickwickian syndrome, pulmonary hypertension and respiratory distress from extubation.

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

A: When one is discussing improved patient satisfaction and a more efficient use of one's limited resources, that is something that impacts the economics of hospital administration and hospital healthcare. Suddenly, we don't have to keep patients longer and can truly get them through their procedure and post operative observation in a streamlined manner that is beneficial from a satisfaction as well as safety standpoint. Those patients with multiple comorbidities don't have to deal with having to lie flat for a prolonged period of time which can affect their ability to breathe and exacerbate other medical issues such as worsening musculoskeletal pain; that's a huge difference which impacts patient care that I can already see with my initial use of Perclose™ ProStyle™ devices. I think these factors illustrate how the use of existing technologies can create a paradigm shift and move the field of EP into a new frontier, where vascular closure is not simply for Interventional Cardiologists, but also for Interventional Electrophysiologists as well. I think this is revolutionary and helping to forge a new and better path and therefore a paradigm shift in how we practice Electrophysiology — how we do EP and how we do EP even better!

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IMPORTANT SAFETY INFORMATION

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

INDICATIONS

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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 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 posthospital 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) 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 (CONT.)

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, postprocedure 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.

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