EP PROCEDURE HIGHLIGHT

Ventricular Tachycardia and Atrial Fibrillation Ablations

PHYSICIAN NAME AND BACKGROUND

Dr. Jackson Liang, DO
Cardiac Electrophysiologist
University of Michigan, Ann Arbor, MI
VA Ann Arbor Healthcare System

HOSPITAL AND EP LAB SIZE

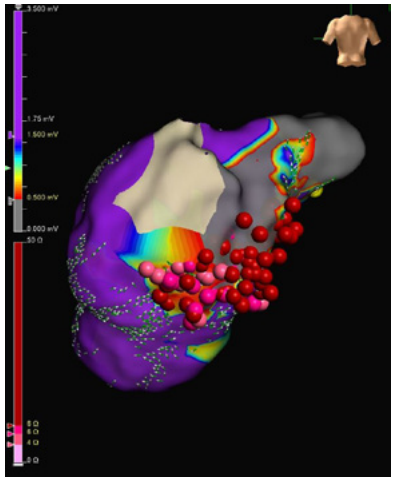
1,100 Beds and 6 EP Procedural Rooms at University of Michigan

106 Beds and 2 EP Procedural Rooms at VA Ann Arbor

CASE VOLUME

400 cases per year

Case images and hospital information provided by Dr. Jackson Liang



EnSite™ X Endocardial Normal Sinus Rhythm Voltage Map of the Left Ventricle with ablation lesions shown from a posterior-anterior (PA) View

5 QUESTIONS WITH DR. LIANG

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

A: I initially trained on Perclose ProGlide™ Suture-Mediated Closure during my EP fellowship, mainly closing large bore (>8Fr) arterial access sites and eventually transitioned to using the device for closing veins, too. When I arrived at University of Michigan, there was initially concern about the additional cost related to use of Perclose ProGlide™ for all venous accesses, especially since we already had dedicated sheath pullers who hold manual compression. However, a year into the COVID-19 pandemic, we went through a major protamine shortage and we were encouraged to use vascular closure devices including Perclose ProGlide™ since there is no need to reverse heparin with protamine when using this device. Many of my partners also learned how to use the device at that time. In addition to being able to continue treating patients during a pandemic during a protamine shortage, we were able to cut out at least 20 minutes from each case by skipping protamine and quickly noticed improvements in lab efficiency. Satisfaction levels of both patients and providers in the post-op area was noted to be markedly improved after vascular closure with Perclose™ devices. Therefore, many of my partners have continued to use the device even after the protamine shortage was over, and personally I no longer use protamine to reverse heparin for any patients.. Though I started with Perclose ProGlide™ initially, I'm now a Perclose™ ProStyle™ Suture-Mediated Closure and Repair (SMCR) System user. I especially love how with the new ProStyle™ device the hydrophilic surface allows for smoother vessel insertion (even with smaller bore accesses), and that the reinforced needles can now penetrate calcified vessels more effectively minimizing cuff misses.

Important Safety Information referenced within.

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

INDICATIONS

The Perclose™ ProStyle™ Suture-Mediated Closure and Repair (SMCR) System and the Perclose ProGlide™ Suture-Mediated Closure (SMC) System are 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 and the Perclose ProGlide™ SMC System are indicated for closing the common femoral vein in single or multiple access sites per limb. The Perclose™ ProStyle™ SMCR System and the Perclose ProGlide™ SMC System are 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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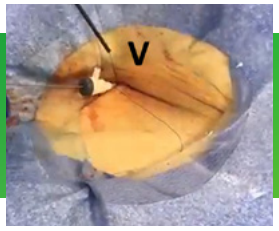
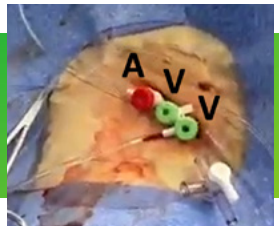
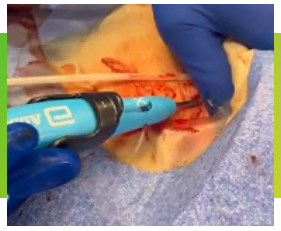
Case Images Using Perclose™ ProStyle™ SMCR System



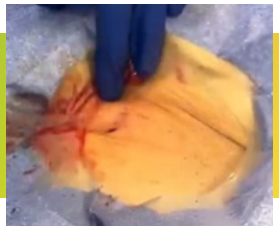
One venous (V) access site on the left groin pre-closed.



Three access sites on the right groin – one arterial (A) and two venous (V).



Arterial access and most caudal venous access sites post-closed. Most cranial venous access pre-closed.



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. LIANG (CONT.)

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

A: I was first taught how to use the Perclose ProGlide™ device by my EP attendings during fellowship, as well as Abbott clinical representatives who educated me on how to deploy the device both on an acrylic block model and in a wet model. As with all procedures, there is a learning curve, but with appropriate education over the first few attempts, device deployment becomes quite straightforward. The numbered steps on the device are very helpful, and currently my success rates (and those of my EP fellow trainees) are >95% - even when closing multiple access sites in the same vessel.

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: Before using closure devices for venous access sites, we either held manual compression or used figure of eight sutures for hemostasis after venous access. One of my main issues with manual compression and even figure-of-eight sutures was late re-bleeds. Also, I had to keep my patients lying flat for hours, which often led to patient discomfort and need for back pain medications. Despite the fact that they just received potentially life-saving cardiac care, all some patients remembered was the groin pain from manual compression and the discomfort of having to lie flat for prolonged periods of time post-procedure. Using Perclose™ ProStyle™ eliminates all of these pain points. I can assess hemostasis on the table, and it really gives me confidence that I have hemostasis before the patient leaves the lab and I do not have to be worried about being called for late re-bleeds or having to interrupt anticoagulation.

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5 QUESTIONS WITH DR. LIANG (CONT.)

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

A: Using Perclose™ ProStyle™ has significantly improved the patient experience for my practice. There are no long manual compression holds, so groin pain isn't their #1 complaint when they come out of anesthesia. While we typically do 2 hours of bedrest before ambulation (to ensure patients have awaken completely from anesthesia), in patients with back pain who have issues lying flat, I am comfortable allowing them to sit up immediately as I am able to confirm hemostasis on the table immediately after device deployment. Since they can sit up, they can also go to the restroom themselves and do not need a Foley catheter – nobody likes a Foley catheter. Aside from the early ambulation, perhaps what my patients love most is being able to go home the same day. Personally, I love having the peace of mind to be able to discharge patients home early and not be worried about a late call about re-bleeding. From a lab efficiency point of view, not having to prolong anesthesia time while administering protamine, pulling sheaths, and holding manual compression saves us 20-30 minutes of time per procedure. With immediate hemostasis, 2 hour ambulation and 3-4 hour discharge of patients, Perclose™ ProStyle™ has allowed for rapid lab turnover and ability to do more cases per day.

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

A: With the increasing number of patients with atrial fibrillation and ventricular arrhythmias, combined with the recent HRS reimbursement cuts for EP ablation procedures, hospital systems and electrophysiologists are being increasingly pressured to do more and more cases per day. Venous and arterial closure with Perclose™ ProStyle™ allows for increased throughput of cases and facilitates early ambulation and same-day discharge. Furthermore, as larger bore venous accesses are being increasingly required for certain EP procedures (e.g. leadless pacemakers, cryoballoon ablation, left atrial occlusion devices), safe and effective utilization of vascular closure devices is becoming more important. Additionally, as patients often need multiple procedures, re-accessing of vessels may be problematic in patients treated with alternative closure devices. With Perclose™ ProStyle™, it is perfectly safe to re-access the same vessel immediately post-closure which is nice.

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IMPORTANT SAFETY INFORMATION

Rx 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 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.

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:

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IMPORTANT SAFETY INFORMATION (CONT.)

- 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

Rx ONLY Perclose ProGlide™ Suture-Mediated Closure (SMC) System

INDICATIONS

The Perclose ProGlide™ Suture-Mediated Closure System is indicated for the percutaneous delivery of suture for closing the common femoral artery and vein access site of patients who have undergone diagnostic or interventional catheterization procedures.

The Perclose ProGlide™ SMC System is indicated for closing the common femoral vein in single or multiple access sites per limb.

The Perclose ProGlide™ SMC 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 ProGlide™ SMC 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 ProGlide™ SMC System is intended for single use only.

Do not use the Perclose ProGlide™ 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 ProGlide™ 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. **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 ProGlide™ SMC 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 ProGlide™ SMC 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 ProGlide™ 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.
2. As with all catheter-based procedures, infection is a possibility. Observe sterile technique at all times when using the Perclose ProGlide™ SMC 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 ProGlide™ 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 ProGlide™ 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 ProGlide™ Device against resistance until the cause of that resistance has been determined. Excessive force used to advance or torque the Perclose ProGlide™ 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 ProGlide™ 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.

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IMPORTANT SAFETY INFORMATION (CONT.)

11. Remove the Perclose ProGlide™ 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 5 – 8F procedural sheath, use manual compression in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide™ SMC 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 ProGlide™ SMC 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 surgical intervention.
16. If the Perclose ProGlide™ 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 / rebleeding
  - 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 vascular.eifu.abbott or at medical.abbott/manuals 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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