**Perclose ProGlide INDICATIONS:**

The Perclose ProGlide SMC 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 used without or, if required, with adjunctive manual compression. For access sites in the common femoral artery using 5F to 21F sheaths. For 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 sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

**MitraClip INDICATIONS:**

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

Important Safety Information Referenced Within

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The Use of the Perclose ProGlide® Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths

Saibai Kar, MD1; James Hermiller, MD2; Kyler Conn1; Yu Shu, PhD3; and Kunal Sankpat, MS4
1Cedars-Sinai Medical Center, Los Angeles, CA; 2St. Vincent Heart Center of Indiana, Indianapolis, IN; 3Abbott Vascular, Santa Clara, CA

ABSTRACT

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INTRODUCTION

METHODS

• Primary analysis population: subjects who received at least one ProGlide as primary intended femoral vein access-site closure device during the MitraClip index procedure (VCD usage per study site, see Figure 5). Baseline characteristics, see Table 1). Predefined subgroup analyses included:
  o ProGlide Alone (without any adjunctive methods other than [≤ 10 minutes] MC) vs ProGlide Plus (ProGlide plus secondary vessel closure method)
  o One ProGlide vs Two ProGlides

• Primary endpoint: rate of freedom from major femoral vein access-site related complications at 30 days post-procedure, compared to pre-defined clinical acceptance criteria (‘≤ 90%).
• Data were collected at baseline, during or up to 24F during or immediately post procedure, at hospital discharge, and at 30 days post procedure

• Trials: A total of 159 subjects from five (5) of the seven (7) high frequency VCD sites were included in this analysis. Two (2) high frequency VCD sites did not use any ProGlide for the femoral vein access-site closure. The subjects enrolled were a median age of 76 years, 53% were male, and presented with multiple comorbidities. The venous sheaths for the MitraClip procedure were placed through a French (F) sheath. The primary endpoint of the rate of freedom from major femoral vein access-site related complication at 30 days was 98.1% (95% CI [94.6%, 99.6%]), meeting the predefined acceptance safety criterion of 90%. Of the 159 cases in which ProGlide was used, 144 received 2 ProGlades and 15 received 1 ProGlide. In the ProGlide cohort, 69.2% (110/159) of the subjects received ProGlide alone or as the intended hemostasis method, 17.6% (28/159) achieved hemostasis with ProGlide plus MC, in 12.6% (20/159) a secondary closure method (subcutaneous stitch) was used along with ProGlide, and in 0.6% (1/159) ProGlide plus MC and a secondary closure method other than subcutaneous stitch was used. Hemostasis at the time of the procedure using ProGlide was achieved in an average time of 5.92 ± 6.19 minutes.
• Conclusion: The study results have demonstrated that the safety assessment of ProGlide met the predefined acceptance safety criterion. The use of ProGlide in the closure of large bore venous access sites was associated with a low 30-day major complication rate.

• The study cohort consisted of older men and women with a high rate of co-morbidities (Table 1)
• Most subjects were treated with two ProGlades (90.6% [144/159] versus one ProGlide, 9.4% [15/159]).
• The primary safety assessment met the pre-defined acceptance criterion (Figure 2).
• Access-related major complication ratio was 48 hours (1.3%) and 30 days low (1.9%) (Figure 3).
• Most of the complications occurred up to 48 hours (Figure 3).
• The majority of subjects (110/159 [69.2%]) were treated with ProGlide alone (Figure 4A).
• In the "ProGlide Alone" group, mean time to achieve hemostasis was 5.15 ± 6.05 min (Figure 4B).
• The annual ProGlide usage varied widely among the 5 clinical trial sites, ranging from 3.2 to 21.9 cases per enrollment year. Despite the low level of usage and experience, complication rates were low (Figure 5).

• This study was a prospective analysis of retrospectively collected data from the EVEREST II and REALISM continued access trials (EOAS-24F).
• The primary objective of this study was to evaluate the safety and performance of ProGlide in the closure of the venous access site in subjects treated with a large-caliber femoral vein sheath (24F).

• 38 sites in EVEREST II and REALISM continued access trials with long-term data collection (≥ 12 months) of Abbott Vascular’s ProGlide® Suture Mediated Closure System in real-world conditions (NCT01940120).
• The primary endpoint was used to assess whether the ProGlide® Suture Mediated Closure System is effective and safe for patients undergoing large-volume cardiac procedures requiring cardiac catheterization, especially with the use of 24F sheaths.
• The study population included subjects with moderate to severe aortic regurgitation (75.5% of patients), with a median age of 69 years (range: 23-87 years).
• The study population consisted of 69.2% male and 30.8% female subjects, with a mean age of 69 years (range: 23-87 years).
• The study population consisted of 69.2% male and 30.8% female subjects, with a mean age of 69 years (range: 23-87 years).

• The primary endpoint analysis was performed on all subjects using ProGlide as the primary access closure device (ProGlide Alone) in the closure of the femoral vein access site.
• The primary safety endpoint analysis was performed on all subjects using ProGlide as the primary access closure device (ProGlide Alone).
• The primary safety endpoint analysis was performed on all subjects using ProGlide as the primary access closure device (ProGlide Alone).
• The primary endpoint analysis was performed on all subjects using ProGlide as the primary access closure device (ProGlide Alone).

• This study was funded by Abbott Vascular.

• Prospective analysis on retrospective data set
• Not a randomized trial
• No comparator group

The use of ProGlide in venous closure following the insertion of a 24F sheath was associated with a low 30-day major complication rate (98.1% freedom from major complications). All patients achieved hemostasis with ProGlide with or without additional methods. Additionally, 69.2% of patients achieved hemostasis with ProGlide alone in 5.15 mins. This analysis has demonstrated the safety and efficacy of the use of ProGlide in the closure of large bore venous access sites.


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This study was funded by Abbott Vascular.

Important Safety Information Related Within
INDICATIONS

The Perclose ProGlide SMC 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 used without or, if required, with adjunctive manual compression.

For access sites in the common femoral artery using 5F to 21F sheaths.

For access sites in the common femoral vein using 5F to 24F sheaths.

For arterial and venous sheath sizes greater than 8F, at least two devices and the pre-close technique are required.

CAUTION

Federal law restricts this 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 Vascular.

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 close the vessel is needed.

CONTRAINDICATIONS

There are no known contraindications to the use of this device. Attention is drawn to the WARNINGS and PRECAUTIONS sections.

WARNINGS

Do not use the Perclose ProGlide SMC device or accessories 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 device and accessories are 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 artery or vein.

Do not use the Perclose ProGlide SMC System if the puncture is through the posterior wall or if there are multiple punctures, 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 femoral artery or vein.

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.

4. Do not deploy the Perclose ProGlide SMC device at an angle greater than 45 degrees, as this may cause a cuff miss.

5. There are no reaccess restrictions if previous access site repairs were achieved with Abbott Vascular SMC devices.

6. If significant blood flow is present around the Perclose ProGlide SMC device, do not deploy needles. Remove the Perclose ProGlide SMC device over a 0.038” (0.97mm) (or smaller) guidewire and insert an appropriately sized introducer sheath.

7. When pushing the plunger assembly to advance the needles, stabilize the device to ensure the device does not twist or move forward during deployment. Twisting the device could lead to needle deflection resulting in a cuff miss. Do not use excessive force or repeatedly push the plunger assembly. 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 returning the foot to its original position (marked #4) down to the body of the device. Do not attempt to remove the device without closing the lever. Excessive force on the lever of the device 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 SMC device against resistance until the cause of that resistance has
been determined (see Section 11.3 Single SMC DEVICE PLACEMENT section). Excessive force used to advance or torque the Perclose ProGlide SMC 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 SMC device is encountered, withdraw the device over a 0.038” (0.97 mm) (or smaller) guidewire and reinsert the introducer sheath or use manual compression.

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. In using this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing damage due to application of surgical instruments such as clamps, forceps or needle holders.

13. During closure of access sites 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 device.

14. During closure of access sites using a procedural sheath > 8F, in the event that bleeding from the femoral access site persists after the use of the Perclose ProGlide SMC devices, the physician should assess the situation. Based on the physician assessment of the amount of bleeding use manual compression, compression assisted devices and / or a surgical repair to obtain hemostasis.

15. During closure of access sites using a procedural sheath > 8F, in those cases where the implanting 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.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with use suture mediated closure devices may include, but are not limited to, the following:

- Anemia
- Arterial stenosis / occlusion
- Arteriovenous fistula
- Bleeding / hemorrhage
- Bruising / hematoma
- Death
- Deep vein thrombosis
- Device entrapment
- Device failure / malfunction / misplacement
- Diminished pulses distal to closure site
- Embolism
- Hypotension / hypertension
- Infection / sepsis
- Inflammation
- Intimal tear / dissection
- Ischemia distal to closure site
- Nerve injury
- Numbness
- Pain
- Perforation
- Pseudoaneurysm
- Pulmonary embolism
- Retroperitoneal hematoma / bleeding
- Thrombus formation
- Vascular injury
- Vasoconstriction / vasospasm
- Vasovagal episode
- Wound dehiscence
**INDICATION FOR USE**

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 2+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

**CONTRAINDICATIONS**

The MitraClip Clip Delivery System is contraindicated in DMR patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

**WARNINGS**

- **DO NOT use MitraClip outside of the labeled indication.** Treatment of non-prohibitive risk DMR patients should be conducted in accordance with standard hospital practices for surgical repair and replacement.
- MitraClip is intended to reduce mitral regurgitation. The MitraClip procedure is recommended to be performed when an experienced heart team has determined that reduction of MR to ≤2+ is reasonably expected following the MitraClip. If MR reduction to ≤2+ is not achieved, the benefits of reduced symptoms and hospitalizations, improved quality of life, and reverse LV remodeling expected from MitraClip may not occur.
- The MitraClip Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use unique precautions for biohazards and sharps while handling the MitraClip System to avoid user injury.
- Use of the MitraClip System could be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning/re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death.
- Inspect all product prior to use. DO NOT use if the package is opened or damaged.

**PRECAUTIONS**

- **Patient Selection:**
  - Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:
  - 30-day ITS predicted operative mortality risk score of:
    - ≥2% for patients deemed likely to undergo mitral valve replacement or
    - ≥6% for patients deemed likely to undergo mitral valve repair
  - Porcelain aorta or extensively calcified ascending aorta
  - Frail (assessed by in-person cardiac surgeon consultation)
  - Hostile chest
  - Severe liver disease/cirrhosis (MELD Score ≥ 12)
  - Severe pulmonary hypertension (systolic pulmonary artery pressure ≥ 30 mmHg)
  - Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery (IMA) at high risk of injury, etc.

**POSSIBLE COMPLICATIONS AND ADVERSE EVENTS**

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip procedure:

- Allergic reaction (anesthetic, contrast,_Tefarin, nickel alloy, latex) Anemia or pseudo-anemia
- Arrhythmias: Atrial fibrillation, Atrial septal defect requiring intervention, Arterio-venous fistula Bleeding: Cardiac arrest, Cardiac perforation, Cardiac tamponade, Pericardial Effusion, Chordal entanglement/rupture, Coagulopathy, Conversion to standard valve surgery, Death, Deep venous thrombus (DVT), Dislodgement of previously implanted devices, Diastasis: Drug reaction to anti-platelet/anticoagulation agents/contrast media, Dyskinesies: Dyspnea, Edema: Emboli (air, thrombus, MitraClip Device), Emergency cardiac surgery, Endocarditis: Esophageal Irritation, Esophageal perforation or stricture, Failure to deliver MitraClip to the intended site, Failure to retrieve MitraClip System components, Fever or hyperthermia, Gastrointestinal bleeding or infarct, Hemotomas, Hemolysis, Hemorrhage requiring transfusion, Hypotension/hypertension, Infection, Injury to mitral valve complicating or preventing future surgical repair, Lymphatic complications, Mitral stenosis, Mitral valve injury, Major system organ failure, Myocardial Infarction, Nausea/vomiting, Pain, Pneumonia, Pulmonary embolism, Pulmonary hypertension, Renal insufficiency or failure, Respiratory failure/atelectasis/pneumonia, Septicemia, Shock, Anaphylactic or Cardiogenic, Single leaflet device attachment (SLDA): Skin injury due to contact with radiation, Stroke or transient ischemic attack (TIA), Urinary tract infection, Vascular trauma, dissection or occlusion, Vessel spasm, Vessel perforation or laceration, Worsening heart failure, Worsening mitral regurgitation, Wound dehiscence.

Prior to use, please reference the instructions for use at www.abbottvascular.com/ifs for more information on indications, contraindications, warnings, precautions, and adverse events.

Caution: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at eifu.abbottvascular.com or at Manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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

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