

Perclose ProGlide

Suture-Mediated Closure System



DON'T JUST CLOSE.
REPAIR.

TO LEARN MORE, VISIT
WWW.ABBOTTVESSELCLOSURE.COM/INTL

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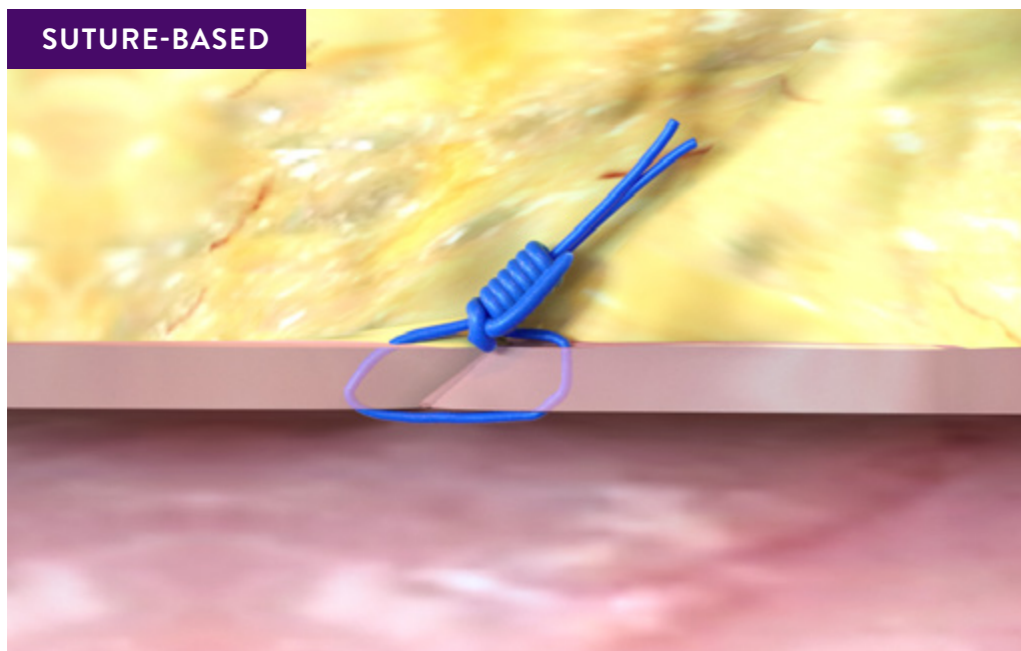


Abbott

DON'T JUST CLOSE. REPAIR.

Perclose ProGlide provides percutaneous surgical repair with a suture by delivering a secure, non-masking percutaneous repair. Perclose ProGlide promotes primary intention healing¹ with less scarring² and reduces time to hemostasis, ambulation, and discharge^{3,4}.

SUTURE-BASED

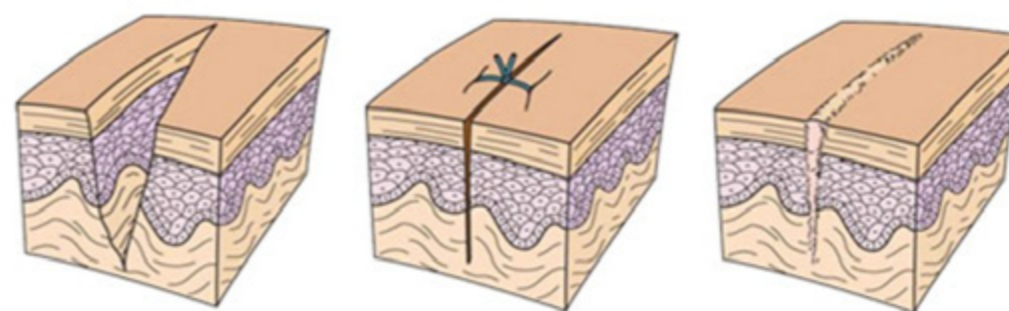


The use of Perclose ProGlide for repair of large-bore arterial access is associated with significantly lower blood transfusions, infections, mortality, and length of stay compared to cutdown⁵.

The use of Perclose ProGlide for large-bore venous access is also associated with low major access site-related complications⁶.

PRIMARY INTENTION

Primary Wound Healing With Suture Repair



Clean Incision

Early Suture

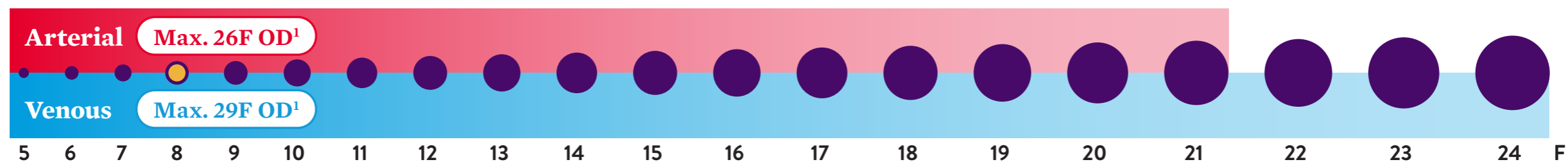
“Hairline” Scar

1. Primary intention healing occurs where vessel wall edges are brought together, adjacent to each other. This can be achieved with suture, stitches, staples, and clips.
2. Mercandetti, Michael. Wound Healing and Repair. Medscape. WebMD, 19 May 2017. Web. March 21, 2018.
3. Time to hemostasis, ambulation, and discharge applies to the arterial access.
4. Bhatt, Deepak L. et al. Successful “Pre-Closure” of 7Fr and 8Fr Femoral Arteriotomies With a 6Fr Suture-Based Device (The Multicenter Interventional Closer Registry). *American Journal of Cardiology* Vol 89. March 2002.
5. Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.
6. The Use of the Perclose ProGlide Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. Kar, Saibal; Hermiller, James; et al. CRT 2018.

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BROADEST INDICATION*

The Perclose ProGlide vascular closure system has the **broadest indication for both femoral arterial and venous access**



For Common Femoral Access Sites

		Max. OD ¹
Artery	5-21F ²	26F
Vein	5-24F ³	29F

*As compared to Angio-Seal, ExoSeal, FemoSeal, InClosure, MANTA, Mynx, PerQseal, Vascade, Velox CD, X-Seal. Data on file at Abbott.

1. Max. OD 26F/0.340 inches/8.62 mm; Max. OD 29F/0.378 inches/9.59 mm. Tests performed by and data on file at Abbott.

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

3. For venous sheath sizes greater than 8F, at least one device and pre-close technique are required.

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BROADEST INDICATION* FOR BOTH FEMORAL ARTERIAL AND VENOUS ACCESS

PARALLELS THE SURGICAL GOLD STANDARD

- Associated with significantly less blood transfusions, infections, mortality, and shorter length of stay compared to surgical cutdown¹
- Secure repair with pre-tied polypropylene monofilament suture
- Minimal intravascular footprint

PROMOTES VESSEL HEALING

- Minimized inflammatory response²
- No re-access restrictions after using Abbott vascular closure devices

GIVES IN-LAB CONFIDENCE

- Low access site-related complication^{1,3}, reduces time to hemostasis, ambulation, and discharge^{4,5}
- Suture repair can be challenged and confirmed on the table
- Ability to maintain wire access



*As compared to Angio-Seal, ExoSeal, FemoSeal, InClosure, MANTA, Mynx, PerQseal, Vascade, Velox CD, X-Seal. Data on file at Abbott.

1. Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.
2. Mercandetti, Michael. Wound Healing and Repair. Medscape. WebMD, 19 May 2017. Web. March 21, 2018.
3. The Use of the Perclose ProGlide Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. Kar, Saibal; Hermiller, James; et al. CRT 2018.
4. Applies to arterial access.
5. Bhatt, Deepak L. et al. Successful “Pre-Closure” of 7Fr and 8Fr Femoral Arteriotomies With a 6Fr Suture-Based Device (The Multicenter Interventional Closer Registry). *American Journal of Cardiology* Vol 89. March 2002.

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DEVICE OVERVIEW

PERCLOSE PROGLIDE

Guide Wire Exit Port – Allows for guide wire insertion and removal

Foot – Provides tactile confirmation of correct device position when open

Suture Knot – Biocompatible USP 3-0 Class I monofilament polypropylene suture

Marker Lumen – Provides visual confirmation of correct device positioning

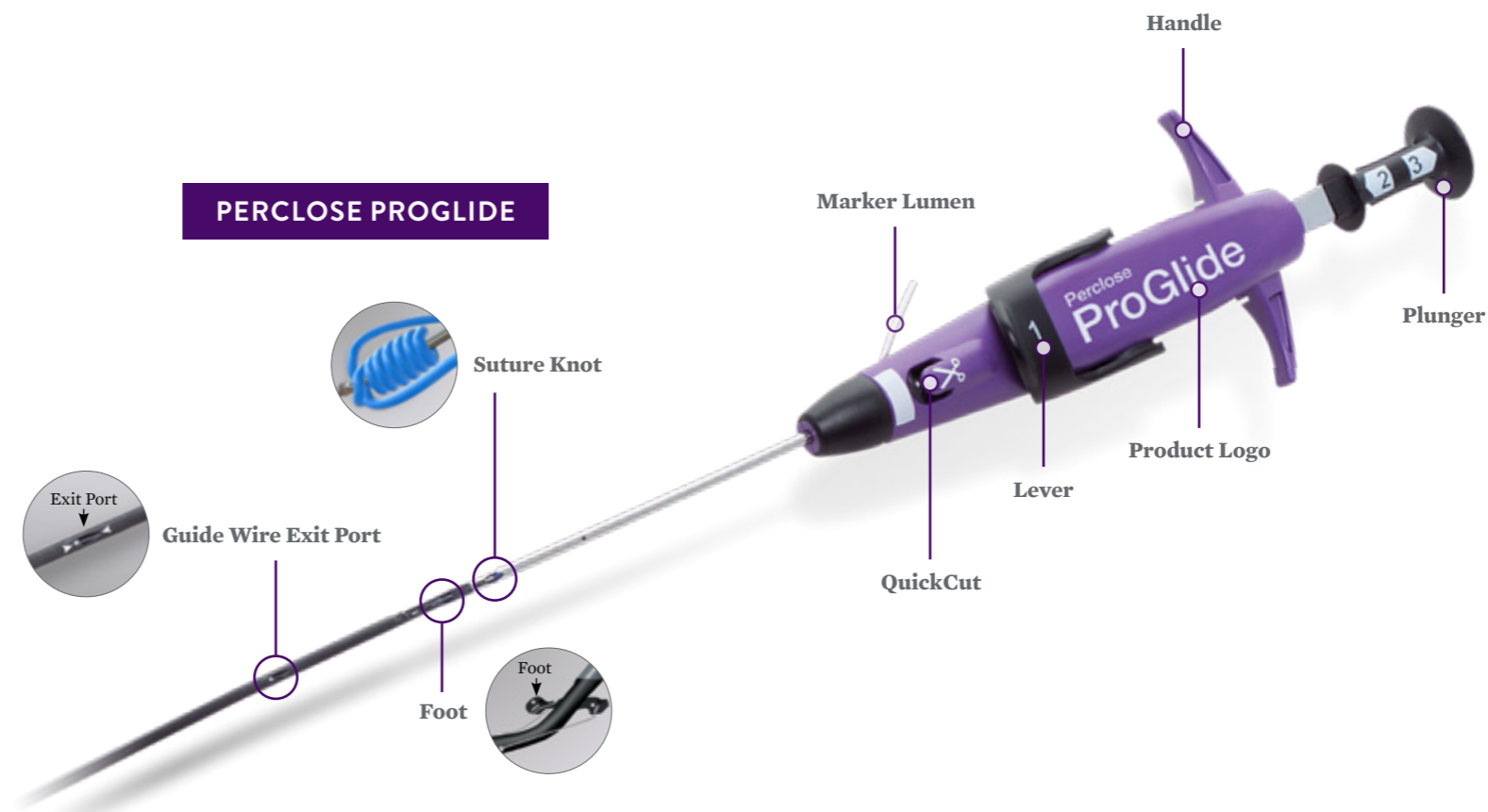
QuickCut – Allows for suture cutting

Lever – Opens and closes the Foot

Product Logo – Indicates suture deployment position

Handle – For device stabilization

Plunger – Deploys the needles and suture



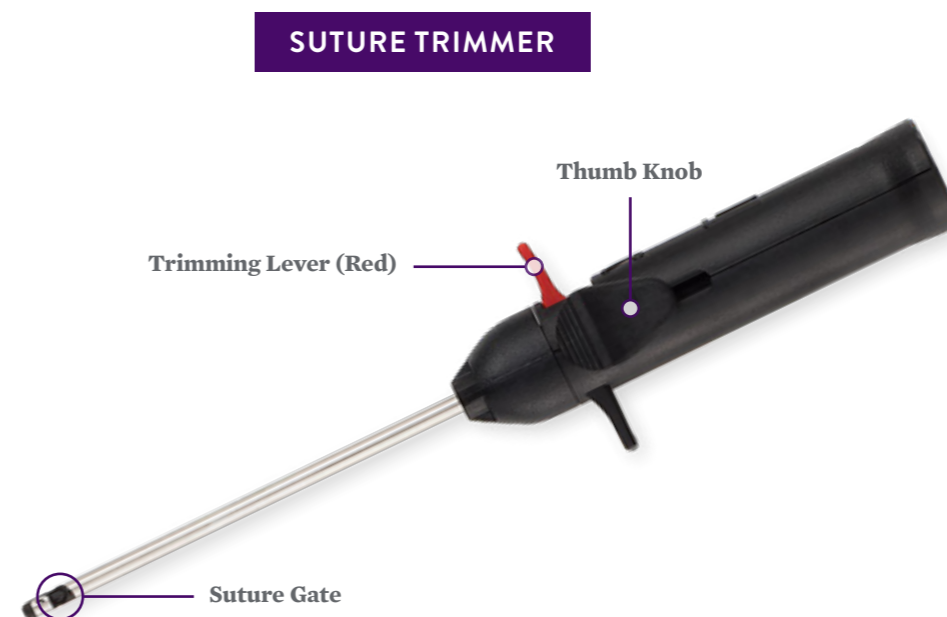
SUTURE TRIMMER

Suture Trimmer – Advances Suture Knot and allows subcutaneous suture trimming

Suture Gate – Open and close to capture suture

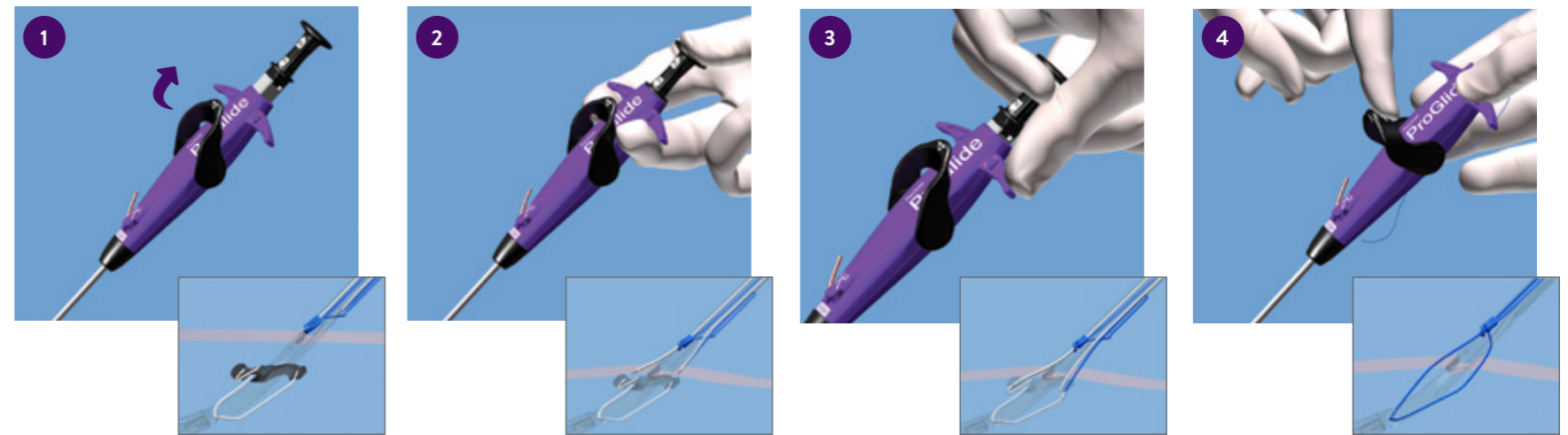
Trimming Lever (Red) – Pull to cut suture

Thumb Knob – Slide to open and close Suture Gate



FOUR KEY STEPS TO SUTURE DEPLOYMENT

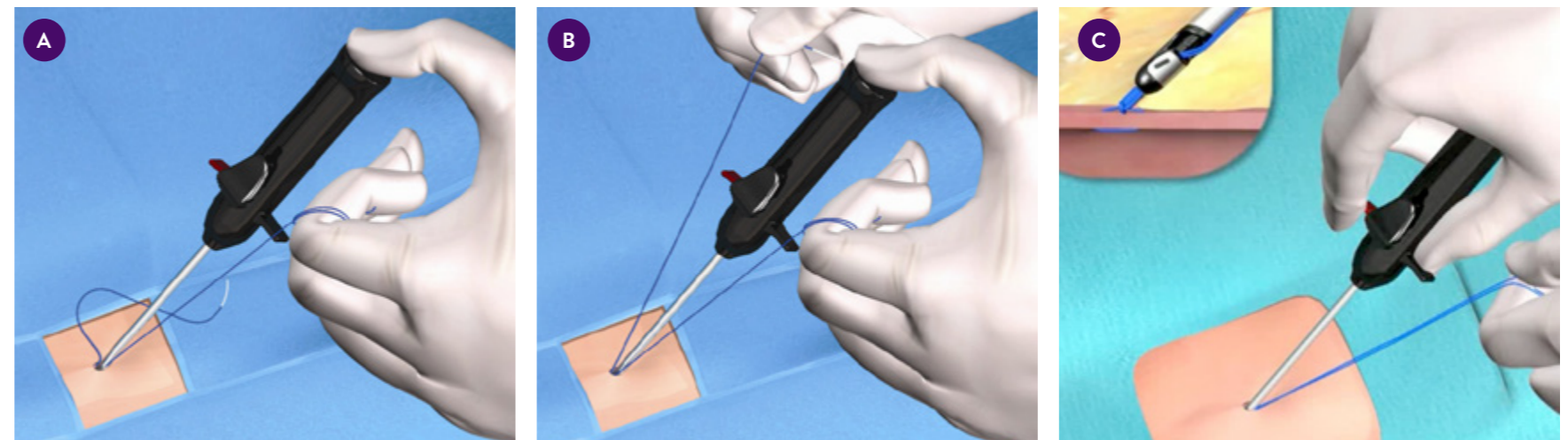
- 1 Advance device and lift Lever (open Foot)
- 2 Maintain retraction and depress Plunger (deploy Needles)
- 3 Pull back Plunger (deploy Suture)
- 4 Lower Lever (close Foot)



SUTURE MANAGEMENT

Suture Trimmer – Advances Suture Knot and trims Suture

- A Capture blue (rail) suture limb in Suture Gate and advance Suture Knot
- B Lock Suture Knot by pulling white (non-rail) suture limb
- C Trim suture limbs by pulling Trimming Lever



Refer to the **Instructions for Use** for additional information.

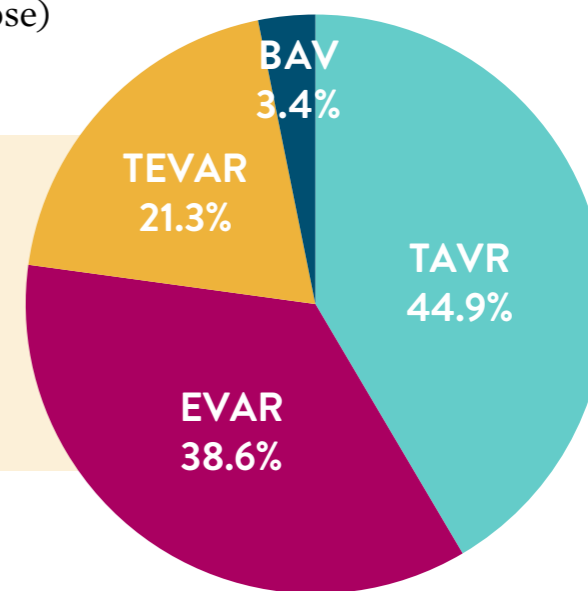
REAL-WORLD EVIDENCE ON REPAIR OF LARGE-BORE ARTERIAL ACCESS

Perclose ProGlide vs. Surgical Cutdown

The Perclose ProGlide vs. Surgical Cutdown retrospective study was designed to compare clinical outcomes and complication rates among patients undergoing closure of large-bore arterial access using Perclose ProGlide (Perclose) vs. Surgical Cutdown (Cutdown) in a real-world setting.

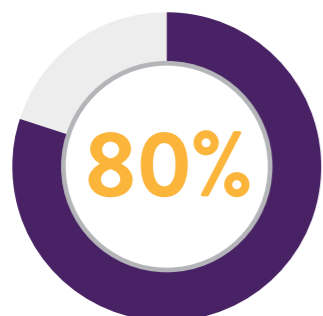
▶ KEY FINDINGS

The use of Perclose ProGlide for repair of large-bore arterial access is associated with significantly **lower blood transfusions, infections, mortality, and length of stay compared to Surgical Cutdown.**

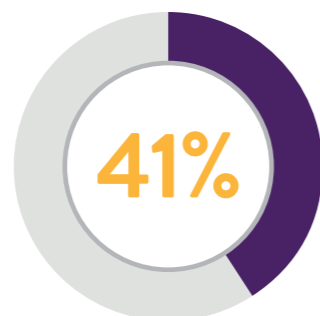


Patients may have had multiple procedures during index admission

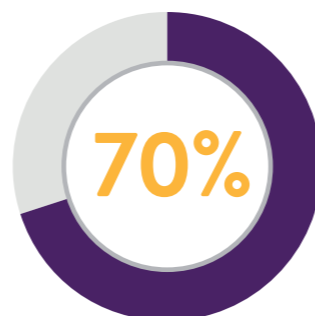
PERCLOSE PROGLIDE PATIENTS



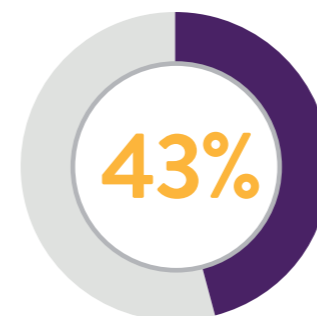
Less likely to require a blood transfusion



Less likely to have an infection



Less likely to die within 30 days post-procedure



Shorter hospital stay

Source: Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.

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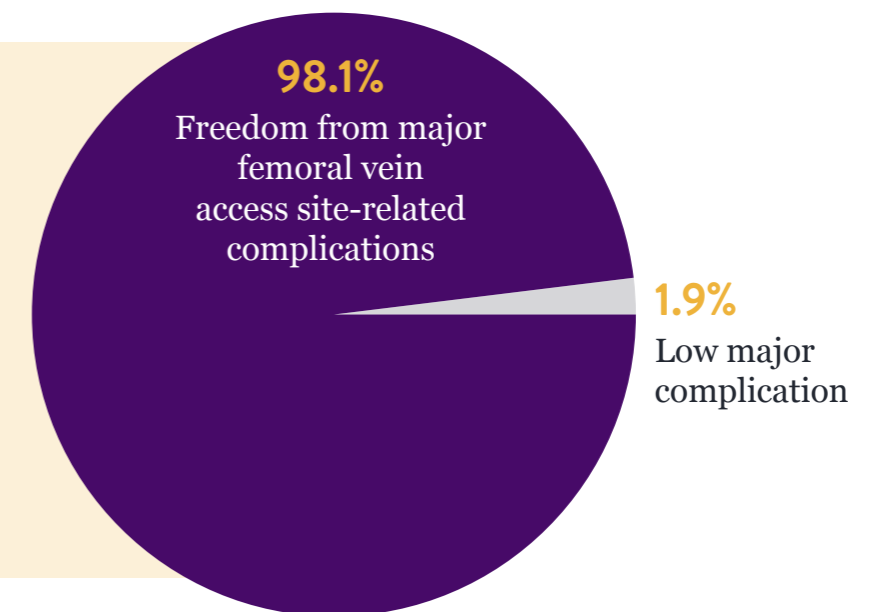
CLINICAL EVIDENCE ON CLOSURE OF LARGE-BORE VENOUS ACCESS

Perclose ProGlide Cohort in the REALISM* Clinical Trial

A prospective analysis was performed to evaluate the safety and effectiveness of Perclose ProGlide in closing large-sized venous access sites through a retrospective data collection. The prospective analysis included subjects in whom Perclose ProGlide was used as the primary method for large-bore venous access site closure during the MitraClip index procedure with a 24F vascular sheath.

▶ KEY FINDINGS

- Major complication was low at 1.9%
- Freedom from major femoral vein access site-related complications was 98.1% at 30 days
- Perclose ProGlide is safe and effective in the closure of venous access-site with up to 24F sheath



Low major complications at 30 days

*EVEREST II/REALISM Continued Access Registry Study.

Source: The Use of the Perclose ProGlide Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. Kar, Saibal; Hermiller, James; et al. CRT 2018.

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ORDERING INFORMATION

DESCRIPTION	STOCK NUMBER	UNITS PER PACKAGE	INCLUDES
Perclose ProGlide Suture-Mediated Closure System	12673-05	10	(1) Perclose ProGlide Suture-Mediated Closure Device (1) Suture Trimmer



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 efu.abbottvascular.com or at manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for **DISTRIBUTION outside of the U.S.** **ONLY.** Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott International BVBA

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