



24p.d. Kraujagyslių uždarymo po kateterizacijos sistema

CORONARY | PERIPHERAL

FEMORAL ARTERIAL AND VENOUS ACCESS SITE MANAGEMENT

# THE PERCLOSE™ FAMILY OF PRODUCTS IN-SERVICE



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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Menu



Abbott

CORONARY | PERIPHERAL

## THE BENEFITS OF SUTURE-MEDIATED REPAIR



See Supplemental Safety Information (SSI) for additional information. AbbVie, the AbbVie logo and the V logo are trademarks of Abbott Laboratories. © 2021 Abbott. All rights reserved. SSI: 2021012545

Abbott

CORONARY | PERIPHERAL

## SYSTEM OVERVIEW



See Supplemental Safety Information (SSI) for additional information. AbbVie, the AbbVie logo and the V logo are trademarks of Abbott Laboratories. © 2021 Abbott. All rights reserved. SSI: 2021012545

Abbott

CORONARY | PERIPHERAL

## DETERMINE POST-CLOSE VS. PRE-CLOSE



See Supplemental Safety Information (SSI) for additional information. AbbVie, the AbbVie logo and the V logo are trademarks of Abbott Laboratories. © 2021 Abbott. All rights reserved. SSI: 2021012545

Abbott

CORONARY | PERIPHERAL

## 4 STEPS FOR SUTURE DEPLOYMENT



See Supplemental Safety Information (SSI) for additional information. AbbVie, the AbbVie logo and the V logo are trademarks of Abbott Laboratories. © 2021 Abbott. All rights reserved. SSI: 2021012545

Abbott

CORONARY | PERIPHERAL

## SUTURE MANAGEMENT AND LOCKING THE KNOT



See Supplemental Safety Information (SSI) for additional information. AbbVie, the AbbVie logo and the V logo are trademarks of Abbott Laboratories. © 2021 Abbott. All rights reserved. SSI: 2021012545

Abbott

CORONARY | PERIPHERAL

## TIPS AND TECHNIQUES



See Supplemental Safety Information (SSI) for additional information. AbbVie, the AbbVie logo and the V logo are trademarks of Abbott Laboratories. © 2021 Abbott. All rights reserved. SSI: 2021012545

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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0



# Perclose™ ProStyle™

## Suture-Mediated Closure and Repair System

This in-service for the Perclose™ ProStyle™ SMCR System also includes training on the Perclose™ ProGlide™ SMC System.



# Building upon the Perclose™ Legacy



11 MILLION+ REPAIRS†

The Perclose™ ProStyle™ SMCR System is the next generation design evolution of the proven and trusted Perclose ProGlide™ SMC System\*\*



† November 2020 Finance Report. Data on file at Abbott

\* On Nov. 8, 1993, the first (Perclose) patent was filed for the percutaneous suture vascular closure device.

The Perclose portfolio includes all percutaneous suture closure devices. Data on file at Abbott.

\*\* Perclose ProStyle SMCR System – Instructions for Use.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY.

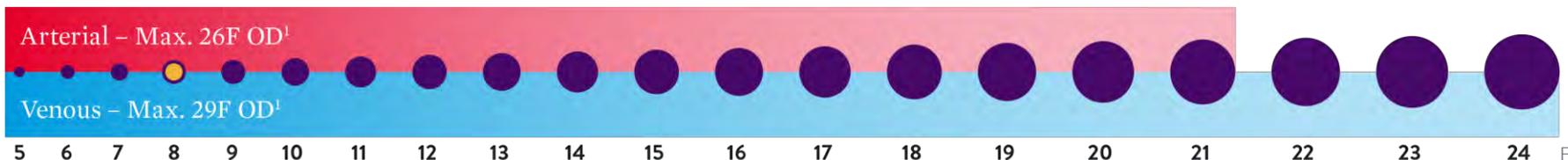
Check the regulatory status of the device in areas where CE marking is not the regulation in force

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Broadest Indication\*



Perclose™ ProStyle™ SMCR System has the broadest indication for the active closure and repair of both femoral arterial and venous access sites.



Skirta 5 – 24 F diametro punkcijas vietai užsiūti.

For Common Femoral Access Sites

		Max. OD <sup>1</sup>
Artery	5-21F <sup>2</sup>	26F
Vein	5-24F <sup>3</sup>	29F

## Common Femoral Artery:

- For sheath sizes > 8F, at least two devices and the pre-close technique are required.

## Common Femoral Vein:

- For sheath sizes > 8F, at least one device and the pre-close technique is required.

\*As compared to Angio-Seal<sup>†</sup>, ExoSeal<sup>†</sup>, FemoSeal<sup>†</sup>, InClosure<sup>†</sup>, MANTA<sup>†</sup>, Mynx<sup>†</sup>, PerQseal<sup>†</sup>, VASCADE<sup>†</sup>, Velox CD<sup>†</sup>, X-Seal<sup>†</sup>. 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 two devices and pre-close technique are required.

4. Perclose™ ProStyle™ SMCR System – Instructions for Use

**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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Built upon the Perclose™ Legacy



Galimybė kateterizuoti kraujagyslę toje pačioje vietoje iš karto po sistemos panaudojimo, manipuliacijų prietaisu  
Kraujagyslių uždaroma su siūlo ir mazgo pagalba.

## REDESIGNED.

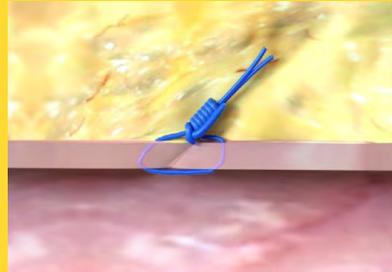
### Perclose™ ProStyle™

Suture-Mediated Closure and Repair System



Perclose™ ProStyle™ SMCR System is the next generation Perclose™ device redesigned with increased needle strength, enhanced usability, and a more intuitive deployment experience compared to earlier Perclose™ generations.<sup>1,2</sup>

## REPAIR.



Perclose™ devices achieve immediate and durable hemostasis via suture-mediated repair giving confidence of a secure close<sup>1</sup>, while preserving access sites for immediate re-access<sup>1</sup>, and enabling primary intention healing to begin.<sup>3</sup>

## RECOVER.



The Perclose™ ProStyle™ SMCR System can enhance the patient experience by providing earlier patient mobilization, shortened hospital length of stay<sup>4,5</sup>, and a reduced risk of access site-related complications.<sup>6,7</sup>

1. Perclose™ ProStyle™ SMCR System - Instructions for Use. 2. Data on file at Abbott. 3. 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. Advances in Skin & Wound Care: Healing by Intention. Salcido, Richard. 2017. 4. Based on arterial access data. 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. 6. Perclose ProGlide™ Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018. 7. 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.

**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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0



# Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

# THE BENEFITS OF SUTURE-MEDIATED REPAIR



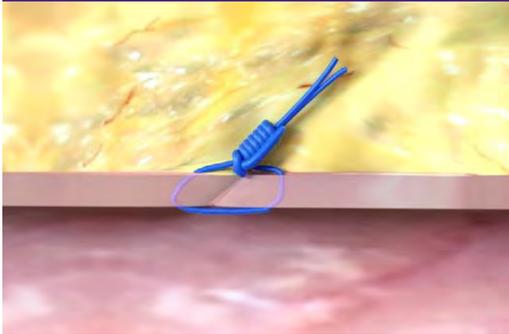
# Suture-Mediated Repair Enables Primary Healing



## DON'T JUST CLOSE. REPAIR.

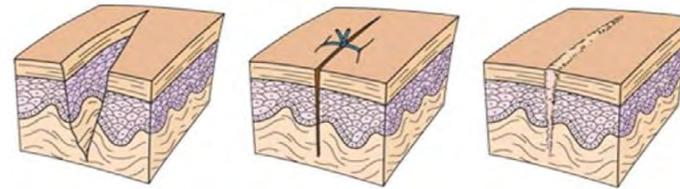
Perclose™ ProStyle™ SMCR System achieves rapid hemostasis of femoral arterial access sites by approximating the edges of the vessel wall with a surgical suture<sup>1</sup> promoting primary intention healing<sup>2</sup> with less scarring<sup>3</sup> and reduced time to hemostasis, ambulation, and discharge<sup>4,5</sup>.

### SUTURE-MEDIATED REPAIR



### PRIMARY INTENTION HEALING

Primary Wound Healing with Suture-Mediated Repair



Clean Incision

Early Suture

“Hairline” Scar

1. Perclose™ ProStyle™ SMCR System - Instructions for Use. 2. 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. *Advances in Skin & Wound Care: Healing by Intention*. Salcido, Richard. 2017. 3. Mercandetti, Michael. *Wound Healing and Repair*. Medscape. WebMD, 02 April 2019. Web. January 15, 2020. 4. Based on arterial access data. 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.

**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

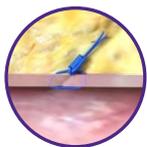
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Additional Benefits with Perclose™



## COMPLETE HEMOSTASIS CAN BE CONFIRMED WITH CONFIDENCE ON THE TABLE<sup>1</sup>

- Pre-tied polypropylene monofilament suture achieves rapid hemostasis by approximating the edges of the vessel wall.<sup>2</sup>
- Does not rely on any thrombogenic properties of collagen which could mask any potential underlying complications from view.



## MINIMAL INTRAVASCULAR FOOTPRINT PRESERVES ACCESS SITES

- Estimated 0.3% occlusion from two sutures in a 5mm ID vessel.<sup>2</sup>
- No reaccess restrictions, allowing for immediate reaccess if needed.<sup>1</sup>
- Minimizes inflammatory response and scarring.<sup>3</sup>

## SAFETY PROFILE OF PERCLOSE DEVICES REDUCES UNCERTAINTY AND RISK

- The ability to maintain guide wire access provides peace of mind with a “protected close”.<sup>1</sup>
- Option to use a “Pre-Close” Technique gives confidence knowing the sutures are already in place before the index procedure begins.<sup>1</sup>



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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

1. Perclose™ ProStyle™ SMCR System - Instructions for Use. 2. Data on file at Abbott. 3. Mercandetti, Michael. Wound Healing and Repair. Medscape. WebMD, 02 April 2019. Web. January 15, 2020

# Backed by Real-World Evidence



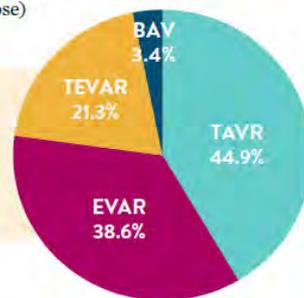
## REAL-WORLD EVIDENCE ON REPAIR OF LARGE-BORE ARTERIAL ACCESS

### 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

**TAVR:** Transcatheter Aortic Valve Replacement  
**EVAR:** Endovascular Aneurysm Repair  
**TEVAR:** Thoracic Endovascular Aneurysm Repair  
**BAV:** Balloon Aortic Valvuloplasty

#### 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

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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

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

# 98.1% Freedom from major femoral vein access site-related complications



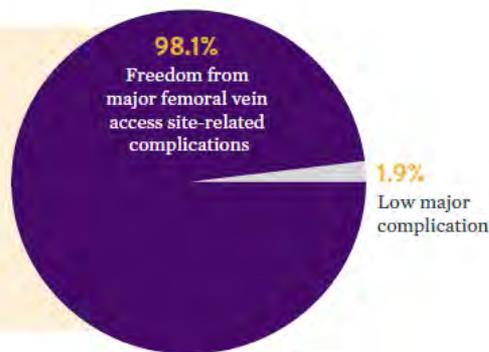
## CLINICAL EVIDENCE ON CLOSURE OF LARGE-BORE VENOUS ACCESS

### Perclose ProGlide Cohort in the REALISM<sup>®</sup> 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



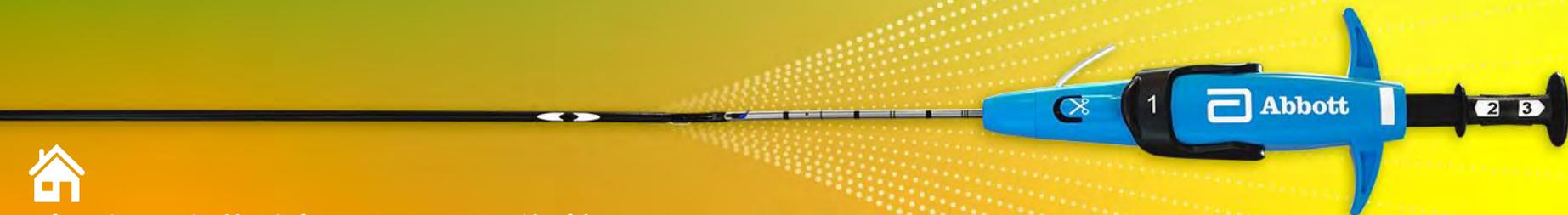
Low major complications at 30 days



# Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

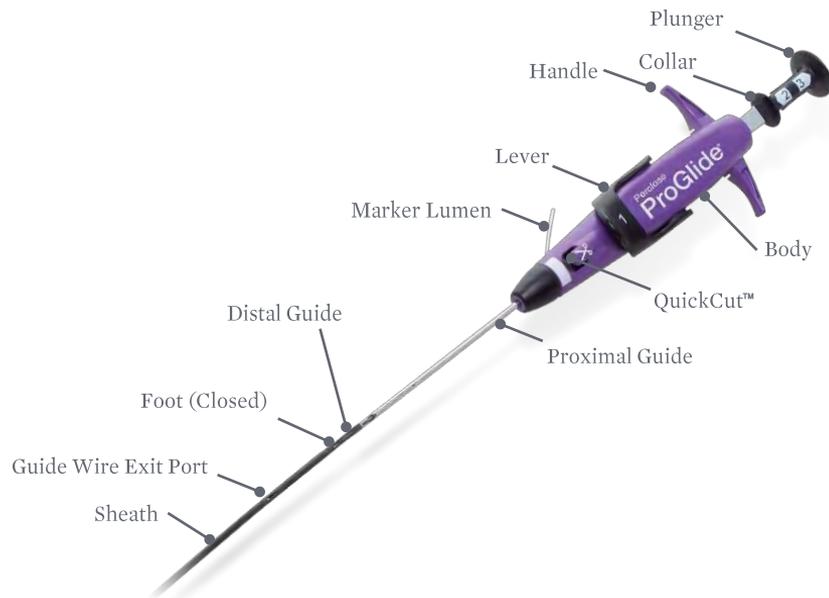
# SYSTEM OVERVIEW



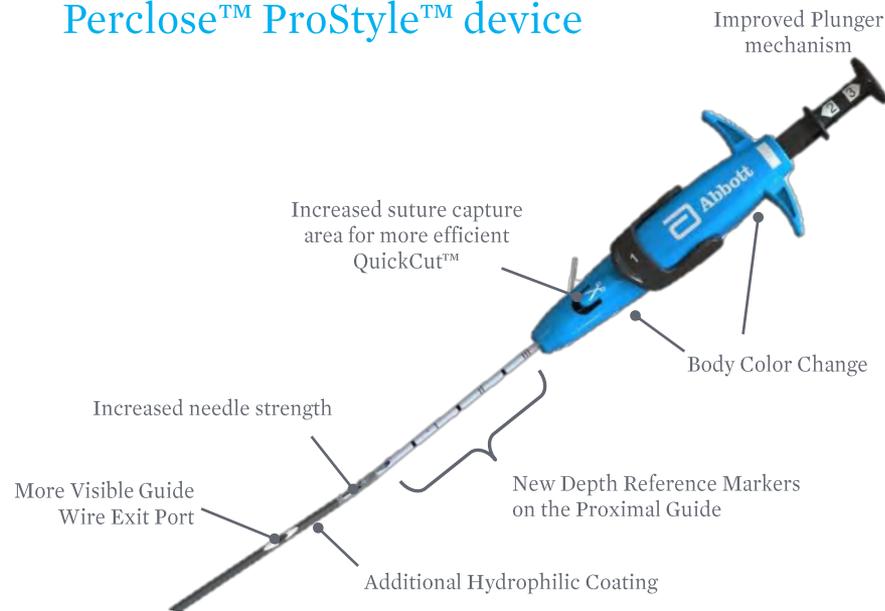
# Comparison of Perclose™ devices



## Perclose™ ProGlide™ device



## Perclose™ ProStyle™ device



Data on file at Abbott.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY.

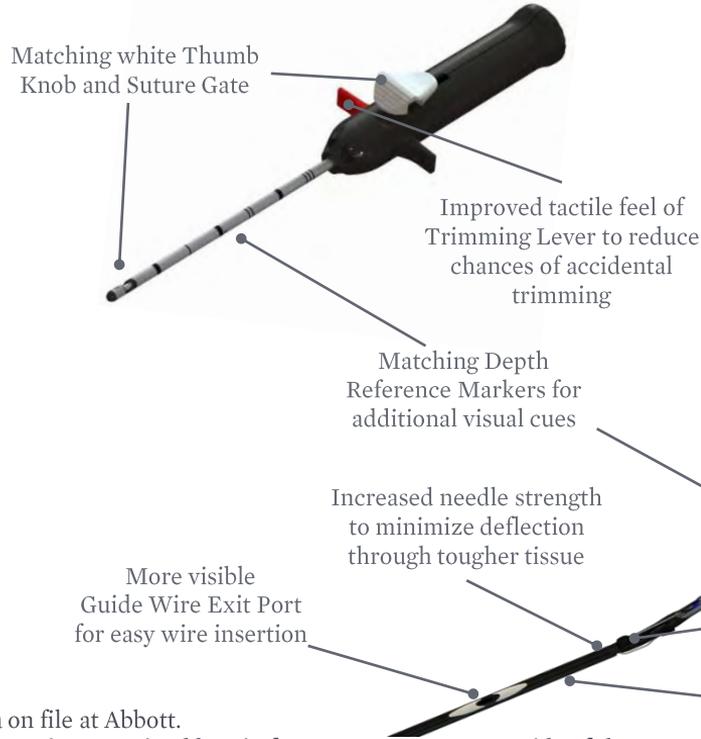
Check the regulatory status of the device in areas where CE marking is not the regulation in force

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Improvements made to Perclose™ ProStyle™ SMCR System



## Perclose™ ProStyle™ Suture Trimmer



## Perclose™ ProStyle™ Device

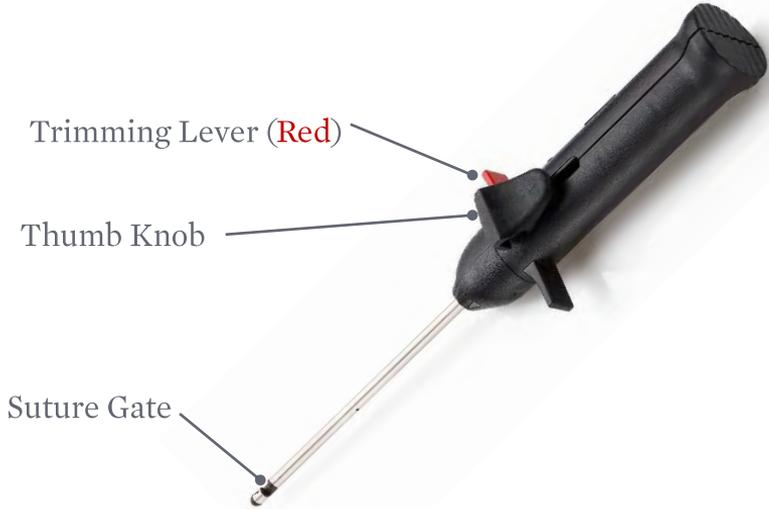


Data on file at Abbott.  
**Information contained herein for DISTRIBUTION outside of the U.S. ONLY.**  
Check the regulatory status of the device in areas where CE marking is not the regulation in force  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

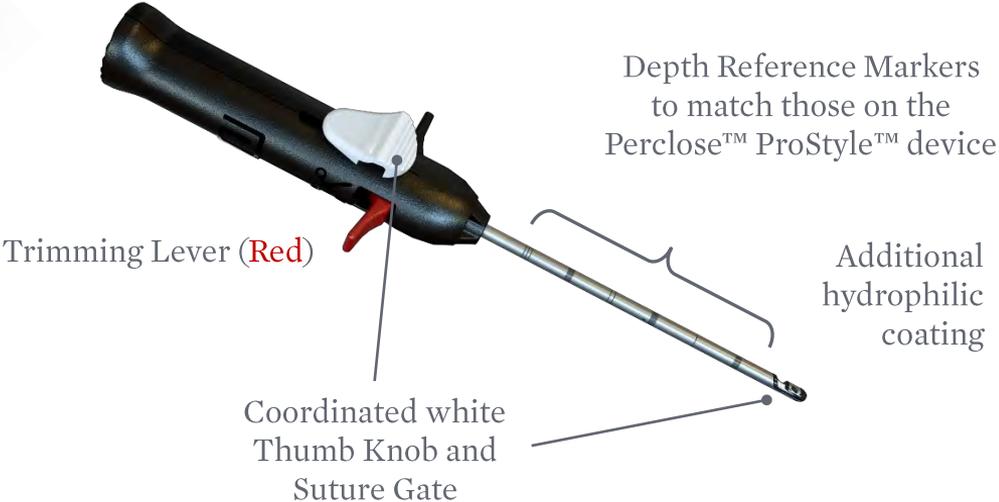
# Comparison of Perclose™ Suture Trimmers



## Original Perclose™ ProGlide™ Suture Trimmer

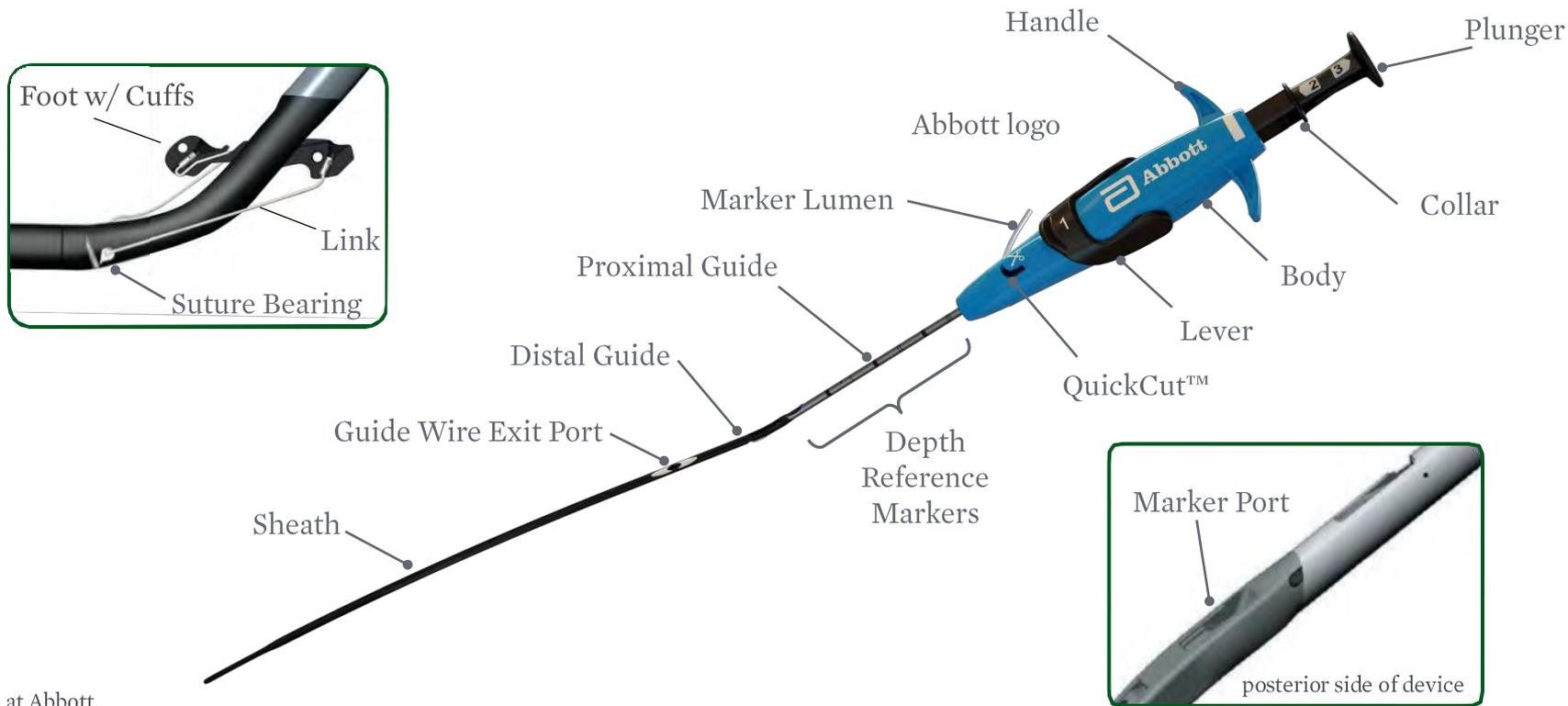


## Updated Perclose™ ProStyle™ Suture Trimmer



Data on file at Abbott.  
**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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Perclose™ ProStyle™ Device Components



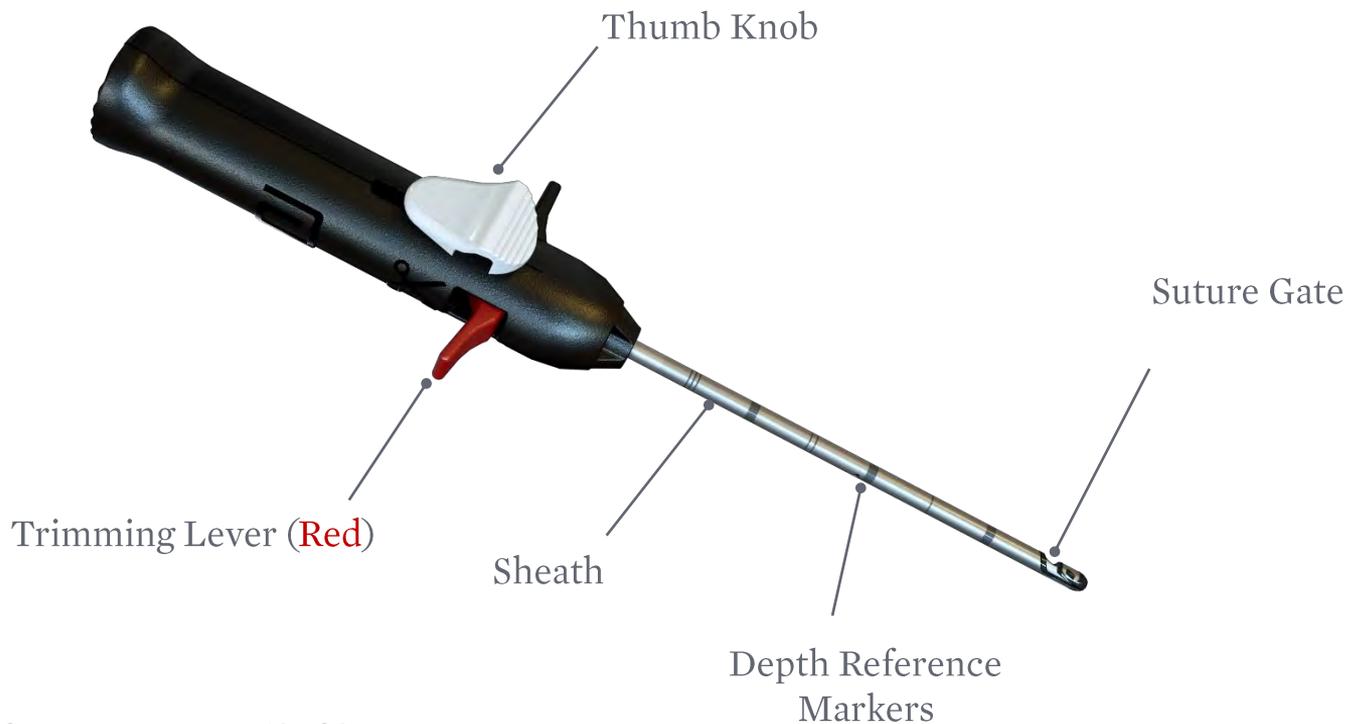
Data on file at Abbott.

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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Perclose™ ProStyle™ Suture Trimmer



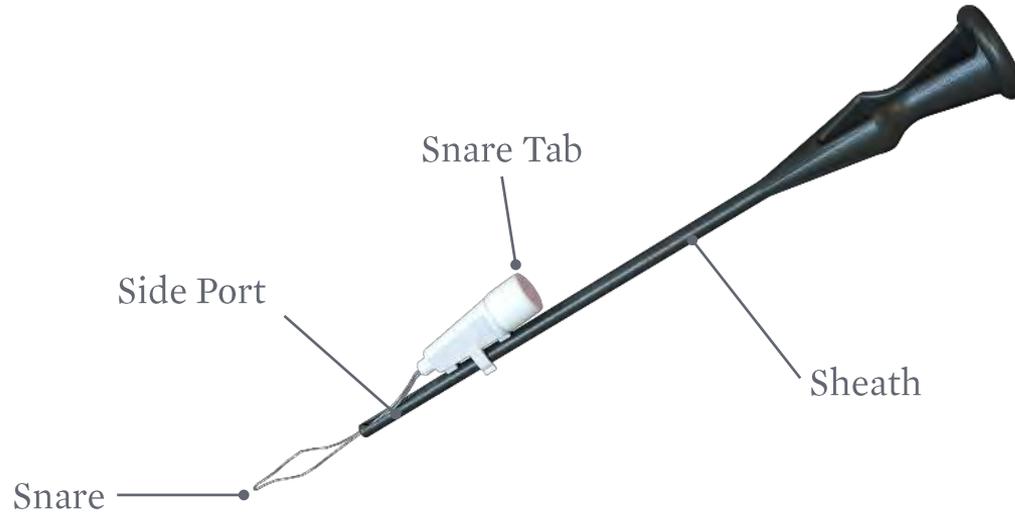
Data on file at Abbott.

**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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Perclose™ Snared Knot Pusher (SKP)



Data on file at Abbott.

**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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Matching Depth Reference Markers

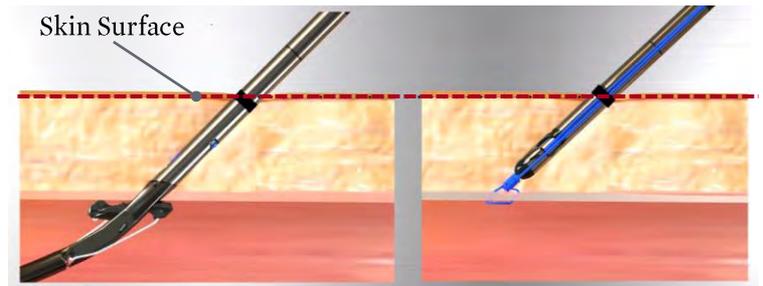
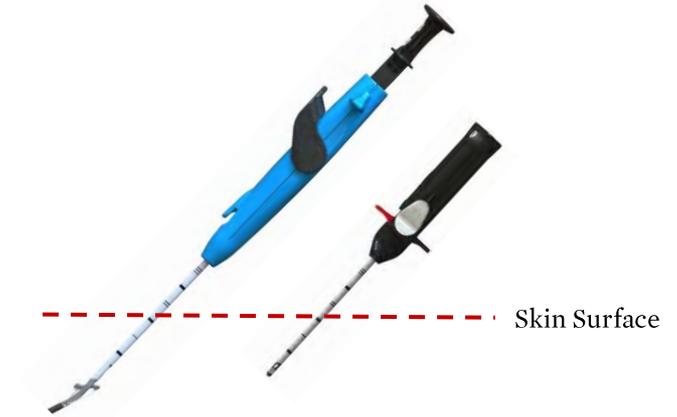


## USE OF DEPTH REFERENCE MARKERS (OPTIONAL)

- Depth Reference Markers on the device can be used to provide a visual estimation of the tissue tract depth during suture deployment
- There are corresponding Depth Reference Markers on the Perclose™ ProStyle™ Suture Trimmer that may also be used as a visual reference to approximate the depth while advancing the Perclose™ ProStyle™ Suture Trimmer.

### NOTE:

The depth reference markers are only to be used as a visual reference tool and are not intended to replace tactile feel during the advancement of the Perclose™ ProStyle™ Suture Trimmer into the tissue tract. Do not solely depend on these depth reference markers for approximating the tissue tract depth when advancing the Perclose™ ProStyle™ Suture Trimmer.



Information contained herein for DISTRIBUTION outside of the U.S. ONLY.

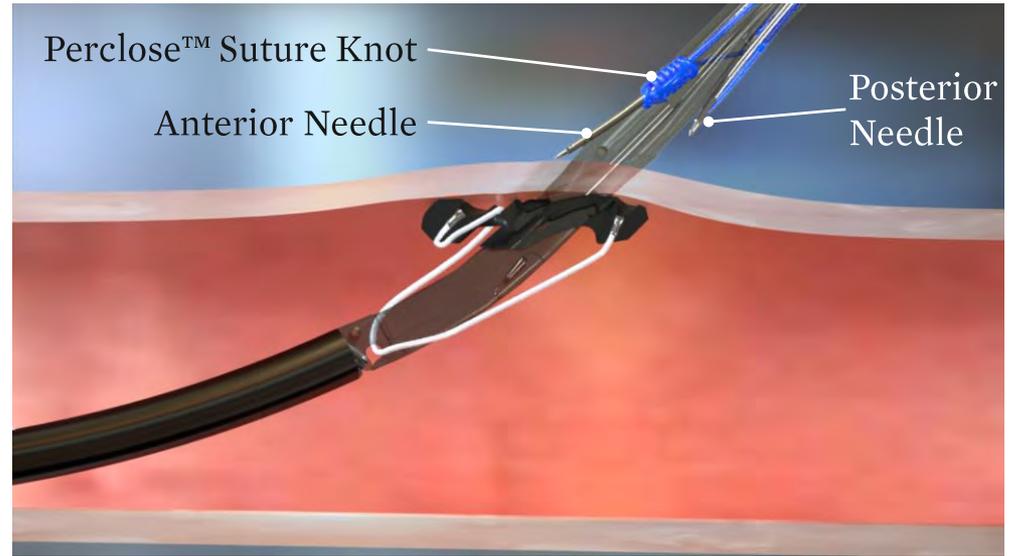
Check the regulatory status of the device in areas where CE marking is not the regulation in force

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Perclose™ Suture Properties



Each Perclose™ device delivers a single polypropylene monofilament suture with a pre-formed knot that is wrapped around the Anterior Needle and housed in the distal end of the Proximal Guide.



Data on file at Abbott.

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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Mechanism of Needles & Cuffs



## DEPRESSING PLUNGER

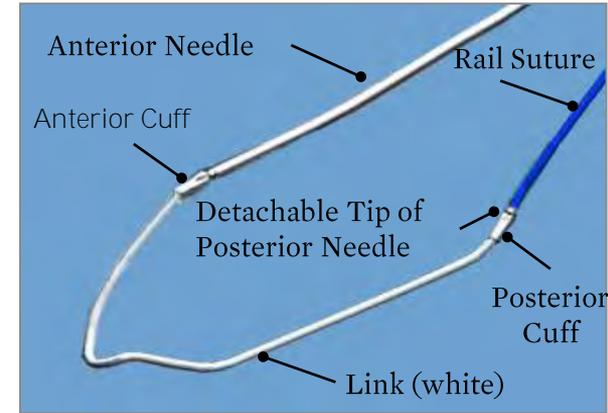
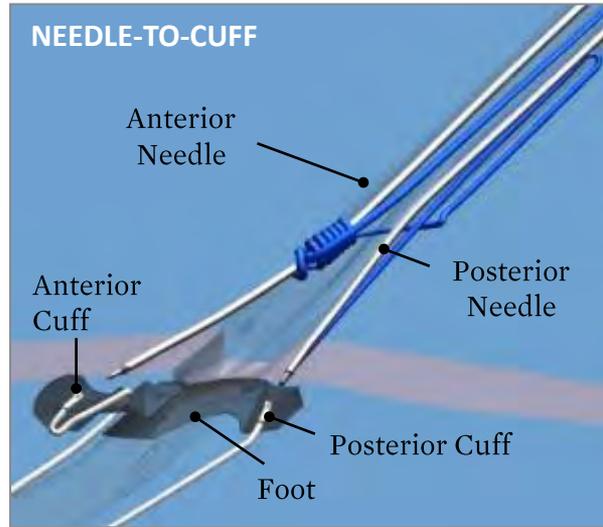
- Advances the Needles toward the Cuffs in the Foot

## NEEDLE-TO-CUFF

- Capture mechanism aids in creating suture loop

## WHITE LINK

- Connects the two Cuffs for Suture passage



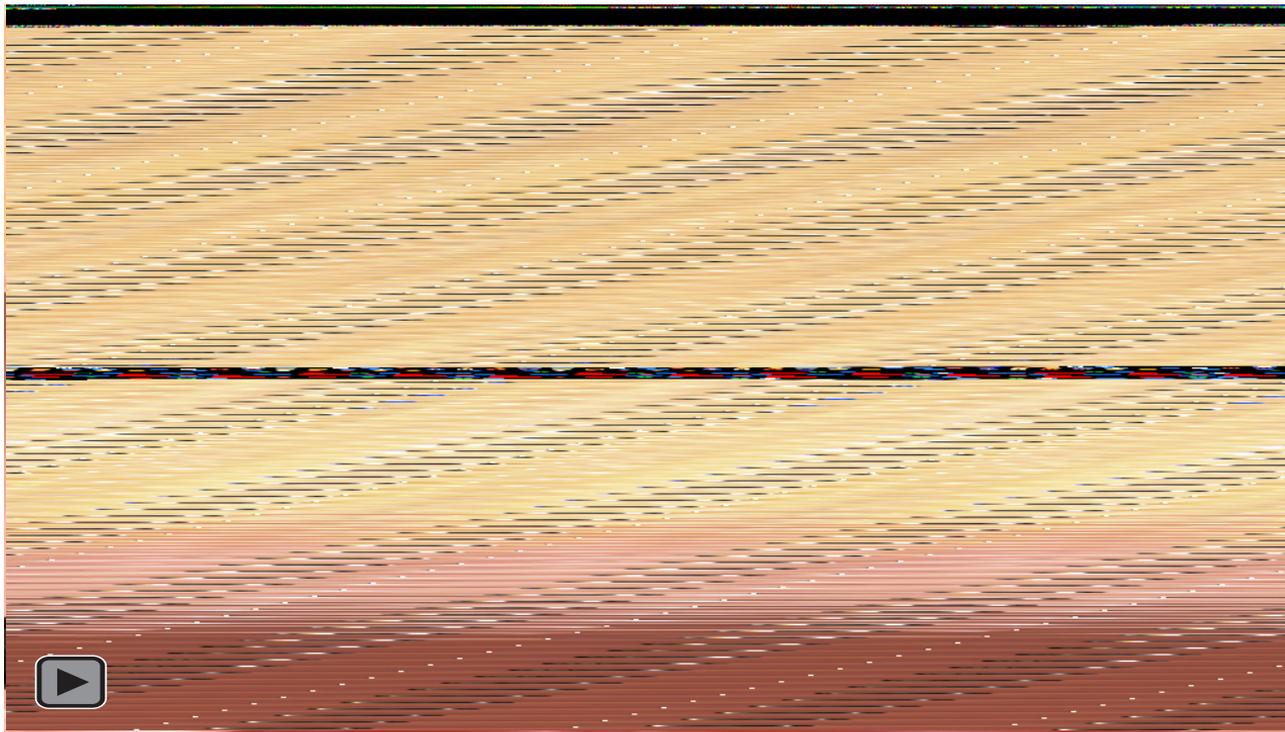
Data on file at Abbott.

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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Perclose™ ProStyle™ Knot Animation



Data on file at Abbott.

**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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0



# Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

# DETERMINE POST-CLOSE VS. PRE-CLOSE



Refer to Instructions for Use for additional information.

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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Determine Post-Close or Pre-Close Approach

	4 Key Steps to Suture Deployment	Suture Management
Post-close	<ul style="list-style-type: none"><li>• <b>AFTER</b> Index Procedure</li></ul>	<ul style="list-style-type: none"><li>• <b>AFTER</b> Index Procedure</li></ul>
Pre-close	<ul style="list-style-type: none"><li>• <b>BEFORE</b> Index Procedure</li></ul>	<ul style="list-style-type: none"><li>• <b>AFTER</b> Index Procedure</li></ul>

## POST-CLOSE TECHNIQUE (5-8F SHEATHS)

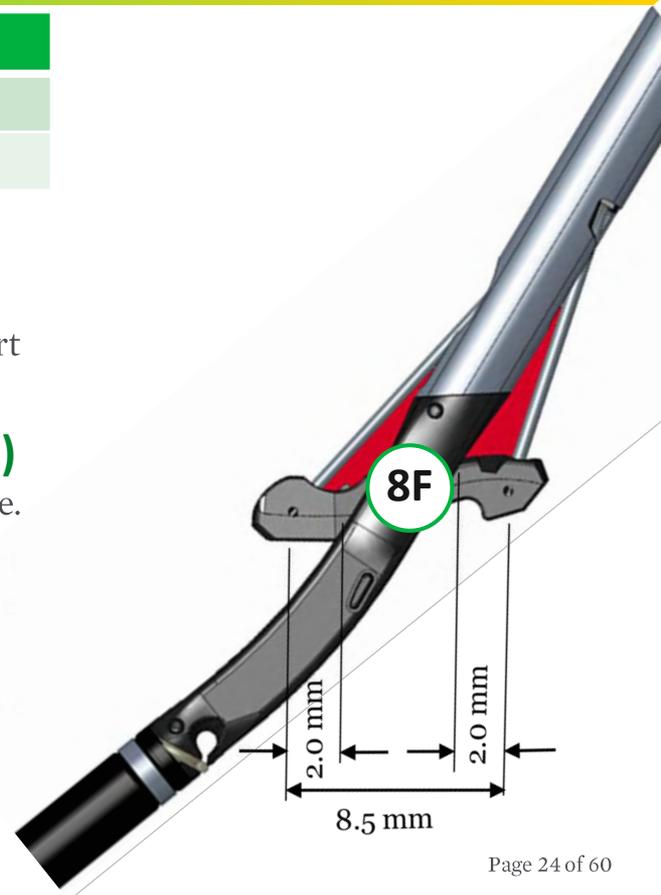
Perclose™ suture is placed around the access site **AFTER** the index procedure.

- Follow the 4 key steps to Suture Deployment, secure suture limbs, reinsert wire, remove device then proceed to Suture Management.

## PRE-CLOSE TECHNIQUE (REQUIRED FOR SHEATH SIZES > 8F)

Perclose™ suture is placed around the access site **BEFORE** the index procedure.

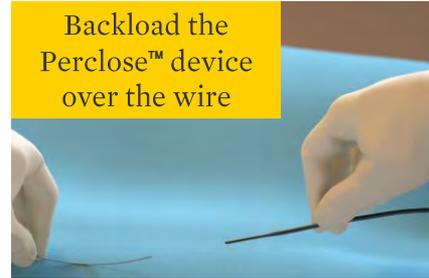
- Follow the 4 key steps to Suture Deployment, secure suture limbs, reinsert wire then remove device. Advance procedural sheath over the wire **BEFORE** the index procedure.
- **AFTER** index procedure, reinsert wire into the procedural sheath. Advance procedural sheath then proceed to Suture Management.



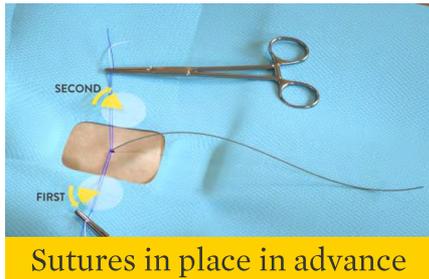
# Post-Close vs. Pre-Close Sequence



## POST-CLOSE TECHNIQUE:



## PRE-CLOSE TECHNIQUE:





# Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

# DEPLOYMENT STEPS



Refer to Instructions for Use for additional information.

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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Femoral Access and Puncture Best Practices

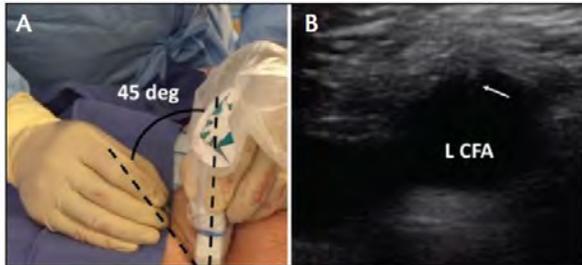


## BENEFITS OF USING ULTRASOUND<sup>1,2</sup>

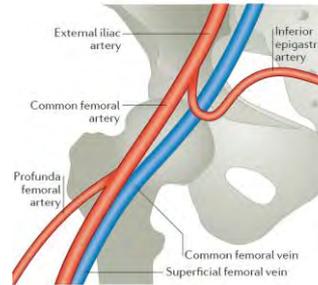
- Reduces time to obtain access
- Reduces the risk of puncturing the wrong vessel
- Reduced vascular complications
- Highlights presence of calcium
- Helps visualize the anterior and posterior walls of vessels

## IDEAL DEGREE OF ENTRY

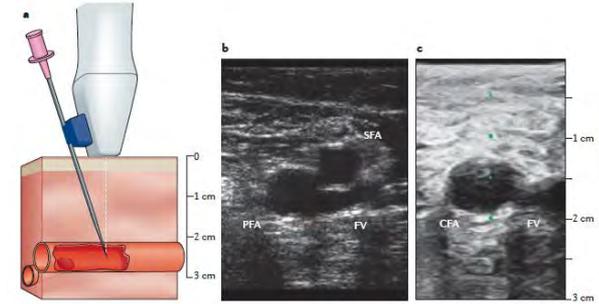
- Puncture the anterior wall of the common femoral artery or vein at an angle of approximately 45 degrees.<sup>3,5</sup>



Source: Singh G. Cardiac Interventions Today



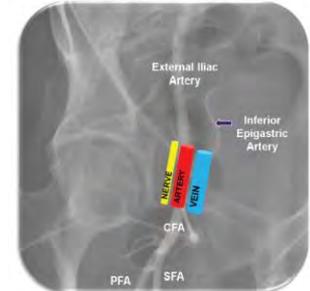
Source: Rao SV. Nature Reviews Cardiology 2013.



Source: Rao SV. Nature Reviews Cardiology 2013.

## FEMORAL ANGIOGRAM

- Prior to deployment of the Perclose™ ProStyle™ SMCR Device, perform a femoral angiogram to evaluate the access site for vessel size, calcium deposits, tortuosity, and for disease or dissections of the wall.<sup>4</sup>



Source: Bangalore S. Circulation 2011<sup>5</sup>

1. Azzalini, The Wise Radialists Guide to Optimal Transfemoral Access: Selection, Performance, and Troubleshooting. Cath Cardio Inter. 2017. 89: 399-407;
2. Rao SV, et al. Arterial access and arteriotomy site closure devices. Nat. Rev. Cardio 2016.
3. Singh G, et al. The Use of Ultrasound Guidance for Targeted Femoral Access, Cardiac Interventions Today – Sept/Oct 2015;
4. Perclose™ ProStyle™ SMCR System – Instructions for Use;
5. Bangalore S et al. Femoral Arterial Access and Closure. Circulation 2011.

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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Device Preparation



- Flush device through Marker Lumen with heparinized saline and observe the saline dripping out from the Marker Port
- Activate the hydrophilic coating on the Perclose™ ProStyle™ sheath with a little heparinized saline for smoother device advancement into the body
- Advance device over a 0.038" guide wire (or smaller)
- Remove wire when Guide Wire Exit Port is at skin level

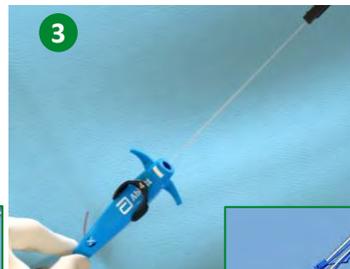
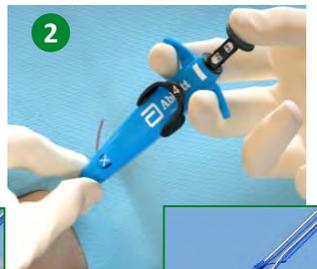


# Suture Deployment and Suture Management



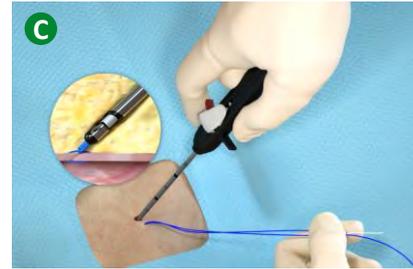
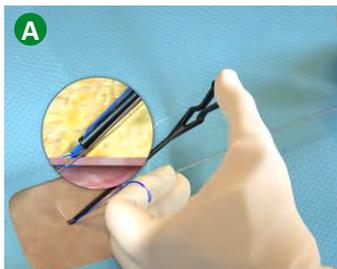
## 4 KEY STEPS TO SUTURE DEPLOYMENT

- 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

- 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 (Red) on Suture Trimmer



Refer to the Instructions for Use for additional information.



# Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

# 4 STEPS TO SUTURE DEPLOYMENT



Refer to Instructions for Use for additional information.

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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Step 1.

# Advance Device and Lift Lever (Open Foot)

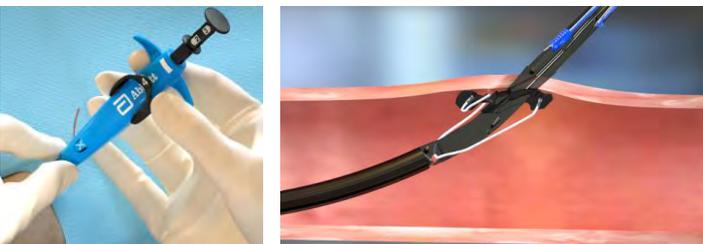


## ADVANCE THE PERCLOSE™ DEVICE

- With the logo at 12 o'clock, advance the Perclose™ device over a 0.038" (or smaller) guide wire until "mark" is observed from the Marker Lumen.\*
- Anticipate tactile sensation when Distal Guide enters the vessel.

## FOR SINGLE DEVICE DEPLOYMENT

- Keep Logo at 12 o'clock (1 of 1 suture)
- Pull back device until tactile sensation is felt against the vessel wall and the "mark" is stopped or reduced.



\*In the artery, brisk pulsatile flow of blood can be expected. In the vein, the flow of blood may not be pulsatile or blood may only fill the Marker Lumen.

## FOR MULTIPLE DEVICE DEPLOYMENT

- 1st of 2 sutures: Rotate the device ~30° to the patient's right
- 2nd of 2 sutures: Rotate the device ~30° to the patient's left
- Lift Lever (#1 on the device) to open the Foot.
- Pull back device until tactile sensation is felt against the vessel wall and the "mark" is stopped or reduced.



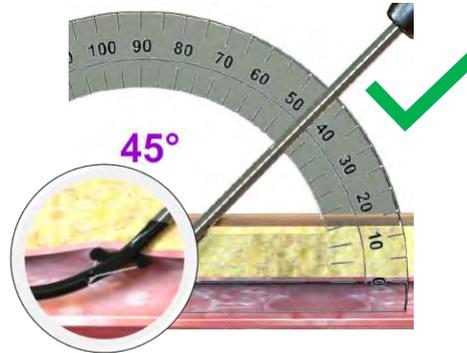
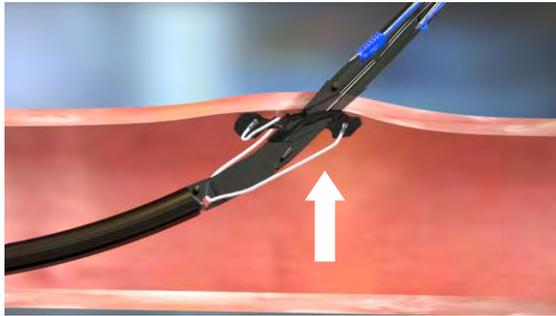
# Step 2. Depress Plunger (Deploy Needles)



Key Success Factor:

➤ Stabilize device at 45-degree angle & maintain gentle retraction

- Maintain gentle retraction against the vessel wall
- Stabilize device at 45° angle with left hand
- Depress black Plunger (#2 on device) until it meets the Perclose™ device Body (an audible click is heard)

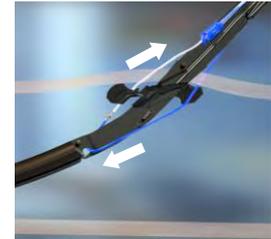
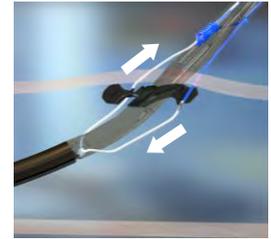
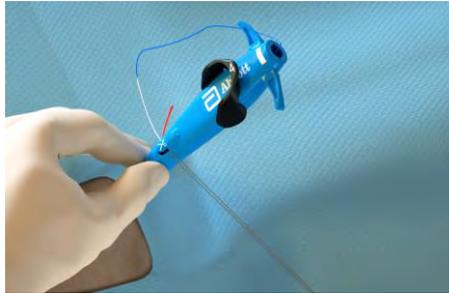


Information contained herein for DISTRIBUTION outside of the U.S. ONLY.  
Check the regulatory status of the device in areas where CE marking is not the regulation in force  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Step 3. Pull Back Plunger (Deploy Suture)



- Use your right thumb on the Handle to help remove the Plunger from the body of the Perclose™ device (#3 on device), and pull the Plunger back gently until the suture is taut.
- Afterwards, use the QuickCut™ to cut the suture



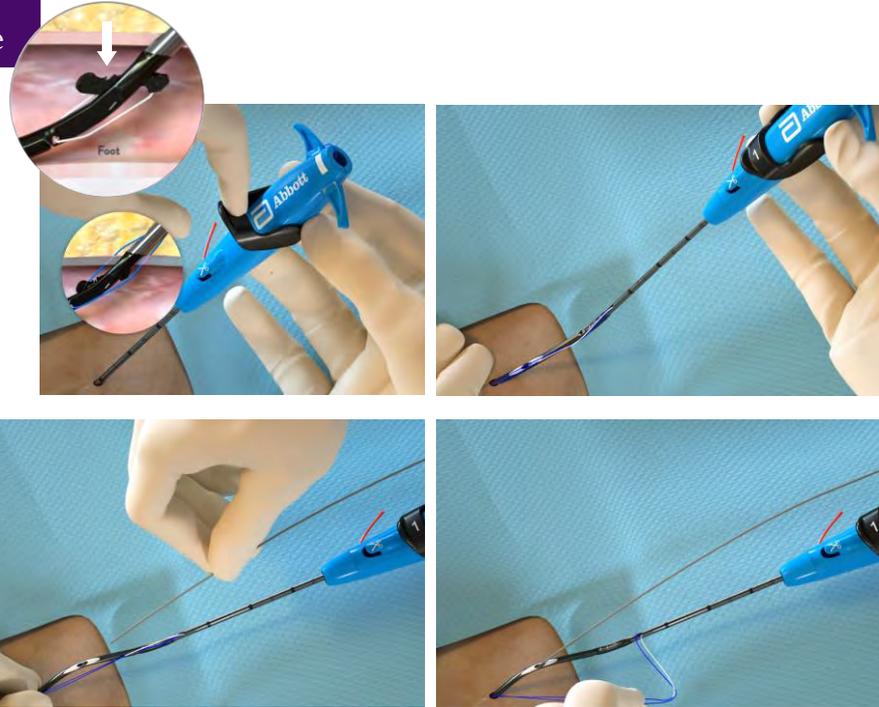
# Step 4. Lower Lever (Close Foot)



## Key Success Factor:

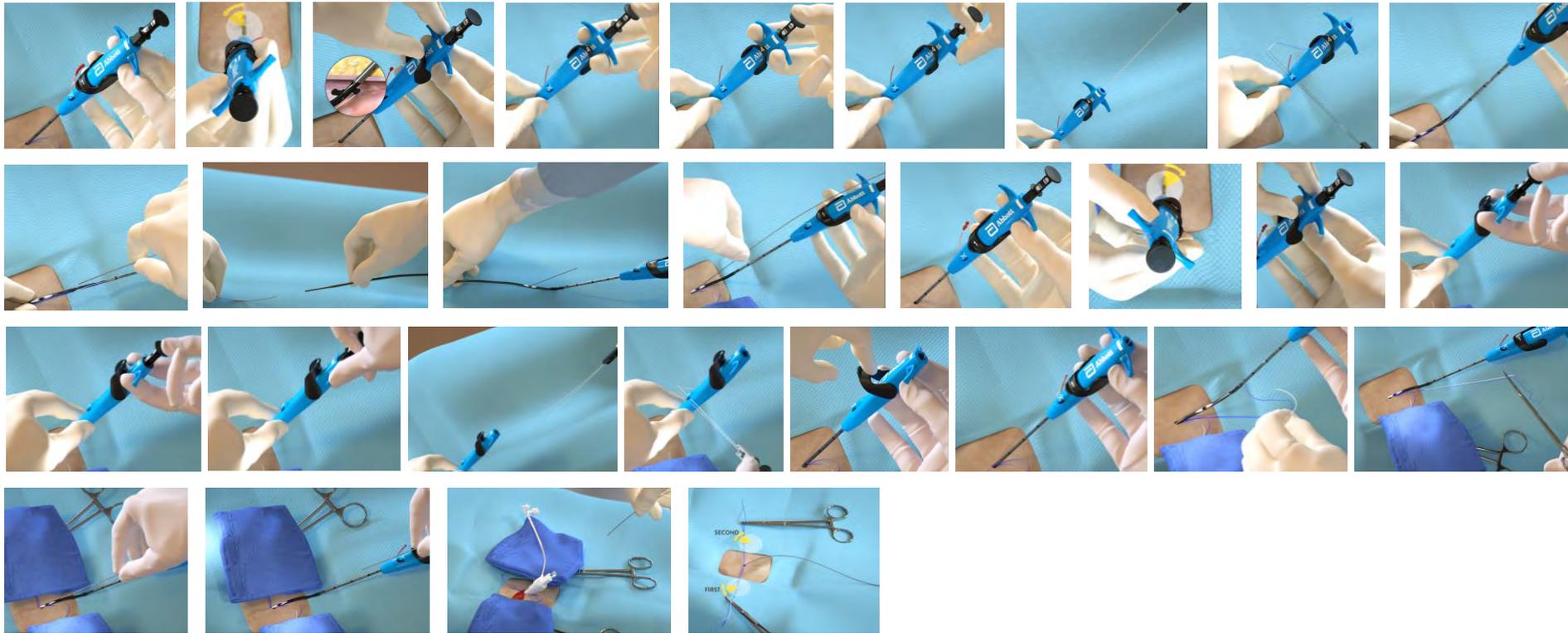
➤ Identify and secure suture limbs during and after index procedure

- Relax device by releasing traction on vessel wall.
- Lower Lever (#4 on device) to close the Foot.
- Deliberately retract the device to release suture from the Distal Guide.
- Reintroduce wire when the Guide Wire Exit Port is visible at the skin level.
- Pull BOTH suture limbs from the Proximal Guide until taut to remove any suture slack from the tissue tract.
- Secure both suture limbs together with a shodded hemostat or clamp under sterile towels as needed.
  - If start with 2 sutures, secure suture limbs to the patient's right side (1 of 2 suture) and to the patient's left side (2 of 2 suture).



Repeat Device Preparation & Steps 1-4 to deploy the second suture (2 of 2 suture) if needed

# Multiple Device Deployment Sequence



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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0



# Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

# SUTURE MANAGEMENT & LOCKING THE KNOT



Refer to Instructions for Use for additional information.

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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Suture Trimmer or Snared Knot Pusher



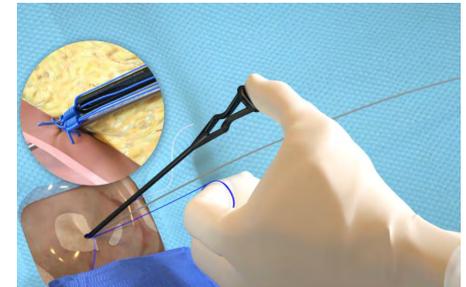
## PERCLOSE™ PROSTYLE™ SUTURE TRIMMER

- Advances the Suture Knot to tighten the suture and approximate the vessel wall
- The red Trimming Lever is used for subcutaneous suture trimming after the Suture Knot has been locked
- New Depth Reference Markers to gauge depth



## PERCLOSE™ SNARED KNOT PUSHER (SKP)

- An optional accessory that can be used for more tactile knot advancement
- The SKP's tapered profile can prove beneficial in more challenging anatomies



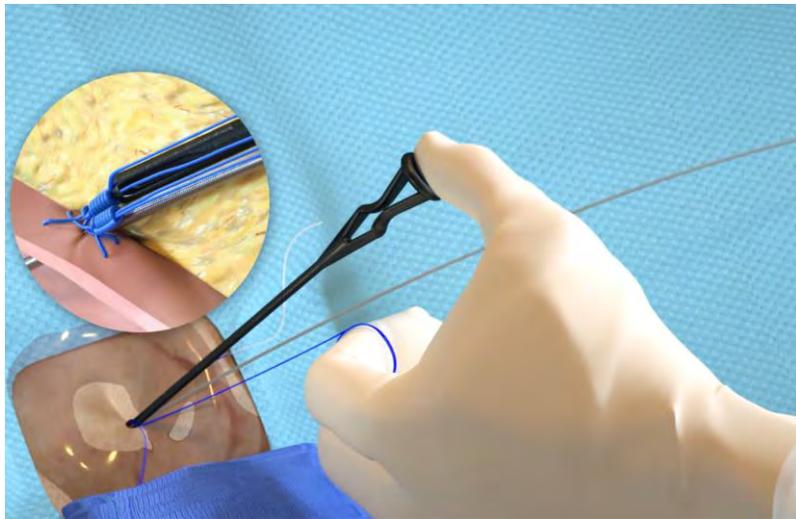
Information contained herein for DISTRIBUTION outside of the U.S. ONLY.  
Check the regulatory status of the device in areas where CE marking is not the regulation in force  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Single-Handed Technique for Knot Advancement



## USE A SINGLE-HANDED TECHNIQUE TO PROVIDE SLOW, INCREASING TENSION

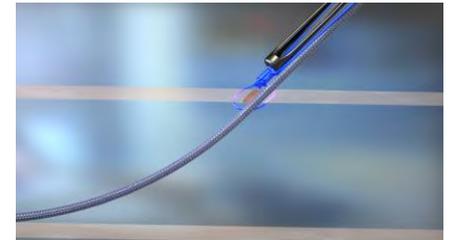
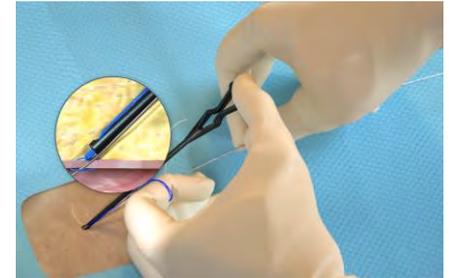
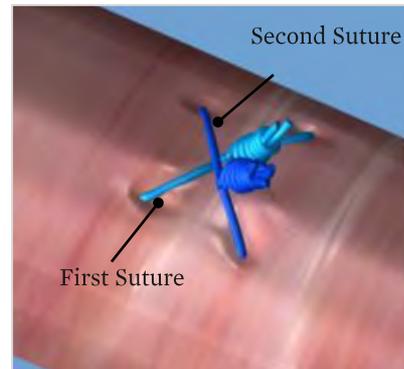
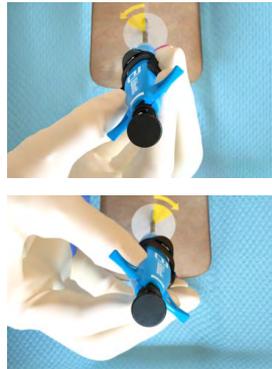
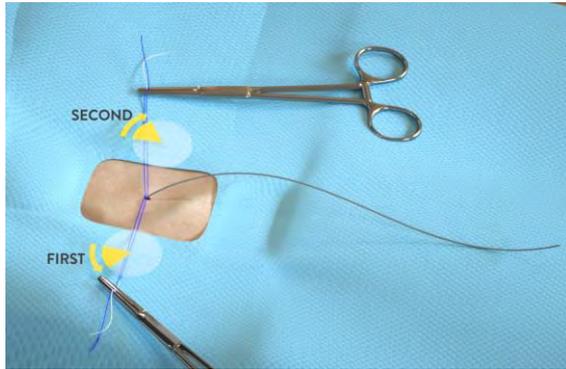
While maintaining tension on the rail suture limb, keeping the Perclose™ ProStyle™ Suture Trimmer and the rail suture limbs coaxial to the tissue tract and the thumb knob at 12 o'clock (facing the ceiling), advance the Perclose™ ProStyle™ Suture Trimmer on the rail suture limb coaxial to the tissue tract until the pre-tied suture knot is at the vessel surface.



# Advance Suture Knots in the Order Deployed

## Key Success Factors:

- In the order of deployment, advance Knot coaxial over wire using slow, consistent increasing tension
- Identify blue (rail) and white (non-rail) suture limbs
- Maintain wire access during Knot advancement



- Maintain guide wire access until any bleeding is controlled. Remove procedure sheath if needed.
- Use either the ProStyle™ Suture Trimmer or the Snared Knot Pusher to advance the suture knots using a Single-Handed Technique
- Advance each Knot coaxial over the wire while applying slow, consistent increasing tension to the blue (rail) suture limb.
- Assess hemostasis. If needed, follow Device Preparation & Steps 1-4 to deploy optional additional Perclose™ suture.

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

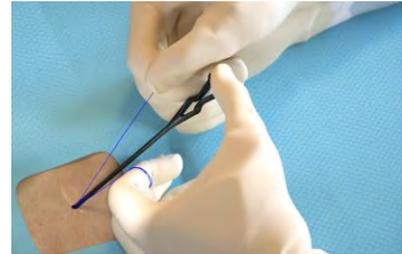
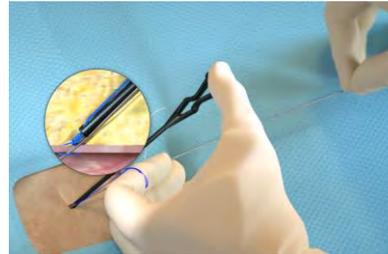
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Lock Knot & Trim Suture



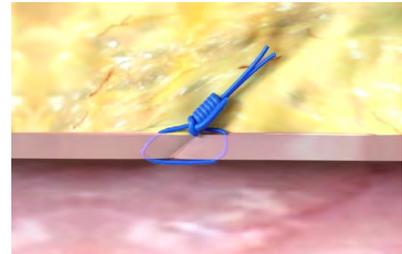
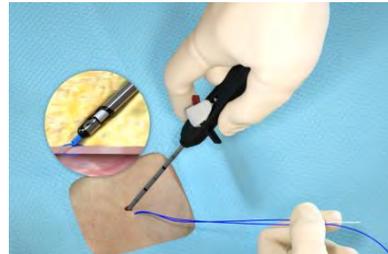
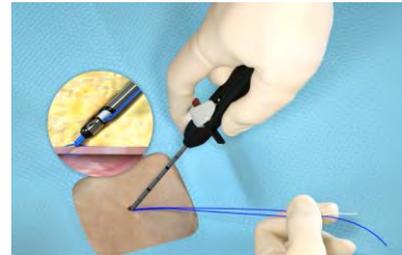
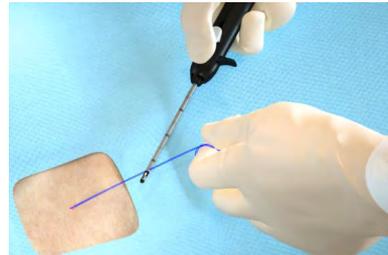
## LOCK KNOT

- If bleeding is controlled, remove guide wire.
- Pull white (non-rail) suture limb to lock Suture Knot while pulling blue (rail) suture limb using slow, consistent increasing tension.



## TRIM SUTURE

- Pull Thumb Knob on Suture Trimmer to open Suture Gate.
- Load BOTH suture limbs into Suture Gate before releasing the Thumb Knob.
- Keeping Thumb Knob facing the ceiling, advance Suture Trimmer coaxial to tissue tract.
- Pull Trimming Lever (**Red**) to trim suture limbs under the skin.





# Perclose™ ProStyle™

Suture-Mediated Closure and Repair System

# TIPS & TECHNIQUES

These Tips & Techniques apply to both the Perclose™ ProStyle™ SMCR System and the Perclose™ ProGlide™ SMC System.



Refer to Instructions for Use for additional information.

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  
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Tips and Techniques: Poor Arterial Flow

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System



Perclose ProGlide™  
Suture-Mediated Closure System

## POOR ARTERIAL FLOW

Brisk pulsatile flow  
from Marker Lumen



Slow drip from  
Marker Lumen



No flow



# Tips and Techniques: Poor Arterial Flow (Continued)

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System



Perclose ProGlide™  
Suture-Mediated Closure System

## POOR ARTERIAL FLOW/ NO FLOW/ RESOLUTION

### Marker Port against vessel wall

- Do not deploy Perclose™ devices with vessel diameters <5 mm

### Side wall stick

- Gently rotate device to move Marker Port off vessel wall

### Low blood pressure

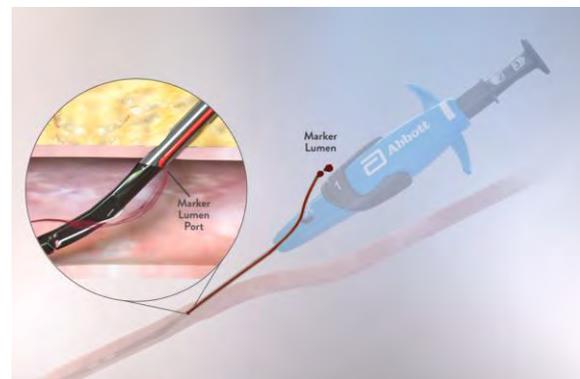
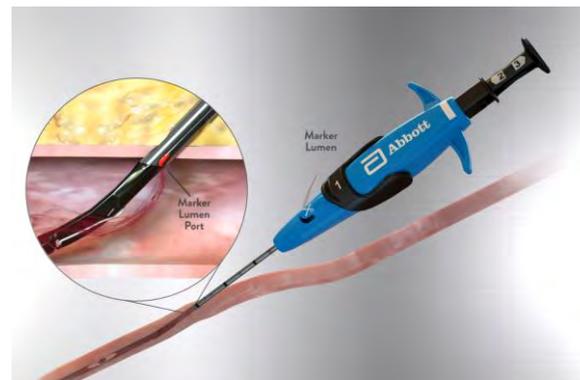
- Slow drip is acceptable if Perclose™ device position is confirmed

### Clot or tissue plugging Marker Port

- Retract device until Marker Port is above skin. Re-flush Marker Lumen and observe saline exiting the Marker Port

### Device not in vessel lumen

- Drip can occur when Marker Port is near vessel lumen but not completely in the vessel, especially with high blood pressure or 7/8F sheaths
- Continue advancing the Perclose™ device until brisk pulsatile flow is observed



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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Tips and Techniques: Poor Venous Flow

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System



Perclose ProGlide™  
Suture-Mediated Closure System

## POOR VENOUS FLOW



# Tips and Techniques: Poor Venous Flow (Continued)

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System

Perclose ProGlide™  
Suture-Mediated Closure System



## POOR VENOUS FLOW/ NO FLOW/ RESOLUTION

**No flow is possible and acceptable if device location is confirmed**

- Apply pressure on groin or lower abdomen
- Inject contrast through Marker Lumen
- Use ultrasound to confirm location of device
- Have the patient perform the Valsalva maneuver

**Marker Port against vessel wall**

- Small vessel diameter; if not 5 mm vessel, do not deploy

**Side wall stick**

- Gently rotate device to move Marker Port off vessel wall

**Low blood pressure**

- Slow drip is acceptable in vein

**Clot or tissue plugging Marker Port**

- Retract device until Marker Port is above skin. Re-flush Marker Lumen and observe saline exiting the Marker Port.

**Device not in vessel lumen**

- No flow can occur when Marker Port is near vessel lumen but not completely in the vessel
- Continue inserting device until slow drip occurs

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

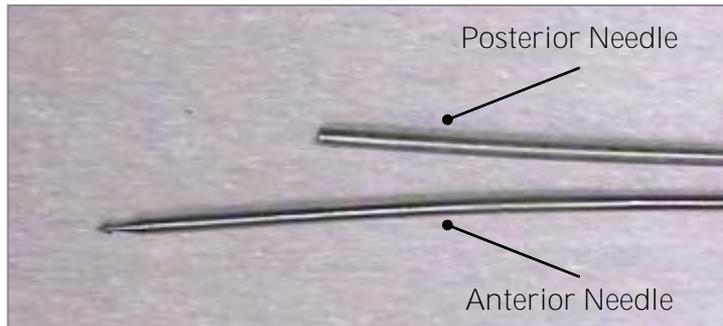
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Tips and Techniques: Cuff Miss

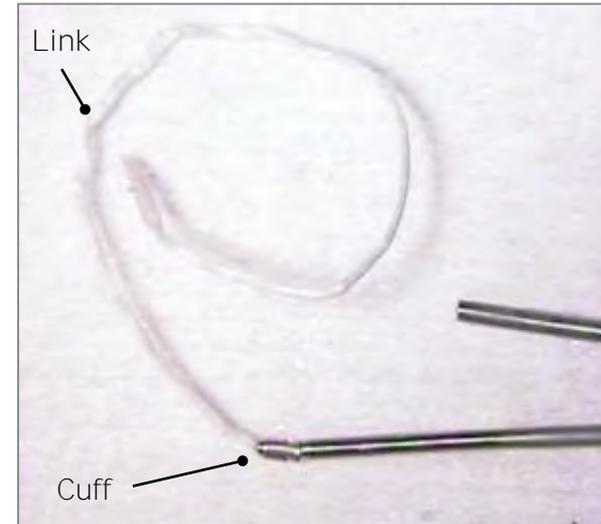


## CUFF MISS

- Plunger is withdrawn and no Suture is present  
The link may or may not be attached to Anterior Needle
- Tip(s) of Needle(s) did not lock with Cuff(s).



No Suture or link present



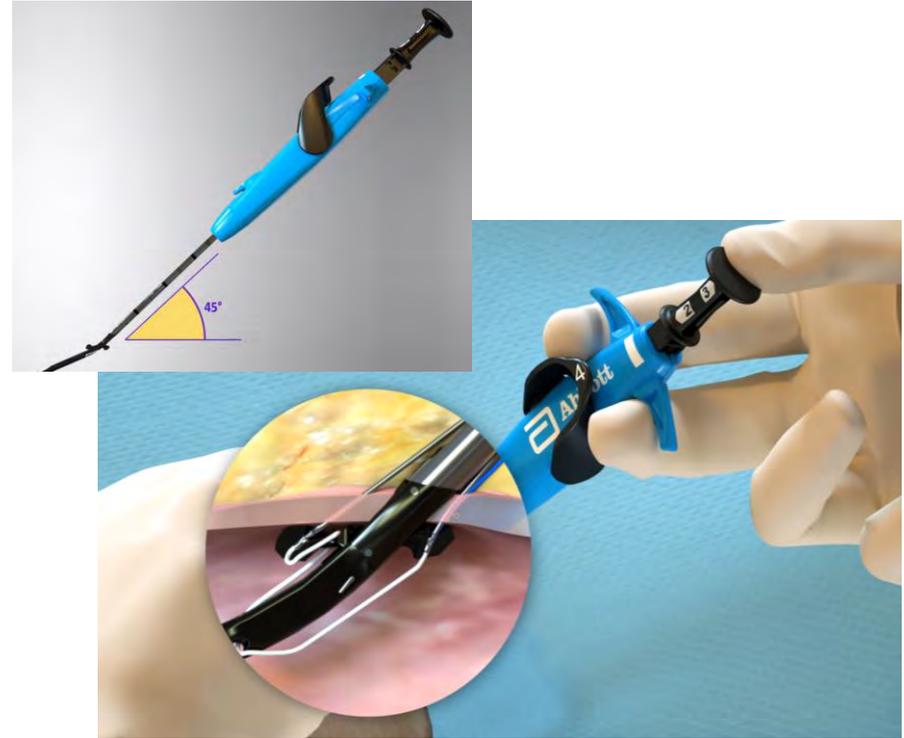
Cuff and link present, no Suture

# Tips and Techniques: Cuff Miss (Continued)



## POTENTIAL CAUSES OF A CUFF MISS

- Tissue too thick and the Needle(s) cannot lock with Cuff(s); certain anatomical conditions such as heavily calcified arteries or scarred tissue.
- Incomplete advancement of Plunger; black Collar on Plunger did not contact Body of Perclose™ device.
- Changing the angle, rotating or rocking the device may make the Needles more susceptible to deflection.
- Not stabilizing device or maintaining the device at 45° throughout deployment and retraction of Plunger/Suture.



# Tips and Techniques: Cuff Miss (Continued)

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System



Perclose ProGlide™  
Suture-Mediated Closure System

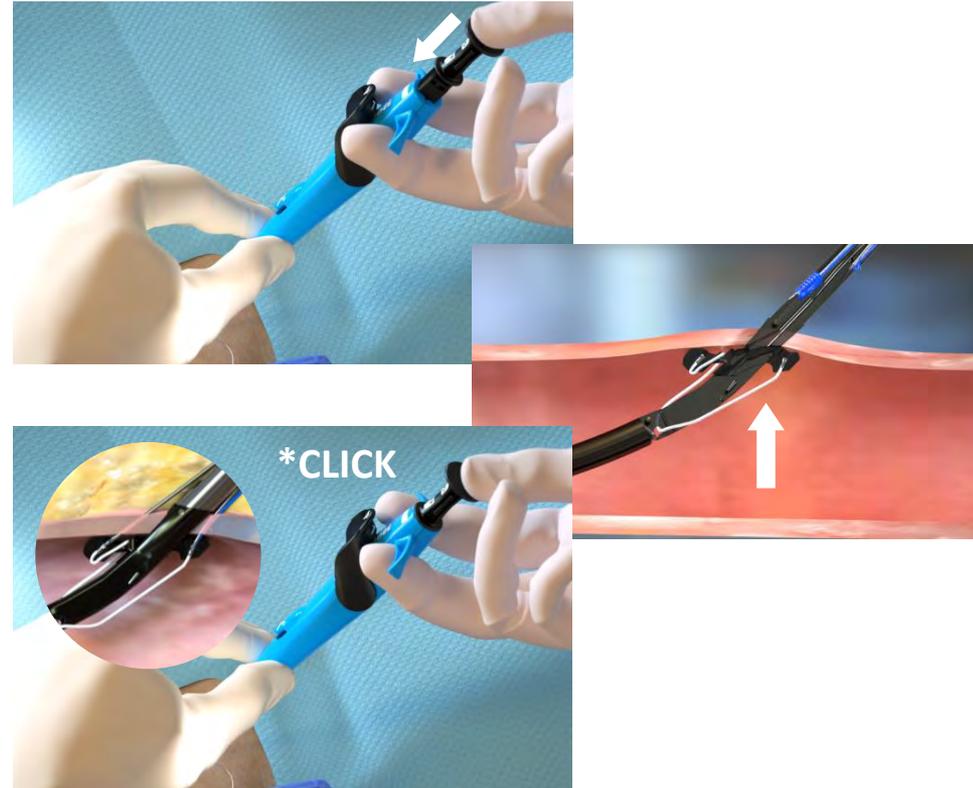
## CUFF MISS PREVENTION/ RESOLUTION

### Prevention

- Proper patient selection
- Deploy device at 45° angle
- Maintain gentle retraction against the vessel wall
- Stabilize device with left hand during Plunger deployment
- Ensure black Collar on Plunger contacts the device Body
- Maintain and stabilize the device at 45° angle throughout removal of Plunger/Needles and until Suture is fully retracted

### Resolution

- Insert wire and exchange for another device



# Tips and Techniques: Device Entrapment



## DEVICE ENTRAPMENT OBSERVATION

Difficult or unable to lower the Lever (close the Foot) and remove device after the Suture Deployment

## DEVICE ENTRAPMENT CAUSES AND PREVENTION

Potential Causes	Prevention
1. Separation of Proximal Guide & Distal Guide due to excessive pressure buildup during device advancement	<ul style="list-style-type: none"><li>If excessive resistance is felt during device advancement, <u>gently roll device medially and laterally</u> to ease device entry.</li></ul>
2. Separation of Proximal Guide & Distal Guide due to excessive device rotation prior to Step 1 (before Open Foot)	<ul style="list-style-type: none"><li><u>Only rotate device up to 30°</u> from the 12 o'clock position, especially in diseased non-compliant tissue conditions.</li></ul>
3. Separation of Proximal Guide & Distal Guide due to excessive device rotation after Step 1 (with Open Foot)	<ul style="list-style-type: none"><li>Complete device rotation, if necessary, before performing Step 1 (Open Foot).</li></ul>
4. Malfunction of Lever-Foot wire control mechanism due to excessive retraction force during suture deployment	<ul style="list-style-type: none"><li>Maintain <u>gentle retraction</u> against the vessel wall when depressing Plunger to deploy needles (Step 2).</li><li><u>Relax</u> device when lowering Lever (Step 4) to close the Foot.</li><li>Advance device slightly to restore marker flow, if necessary, before lowering the Lever.</li></ul>
5. Unable to close Foot due to tissue interference between Distal Guide and Posterior Foot	<ul style="list-style-type: none"><li>Stop device advancement once “mark” is observed from the Marker Lumen to ensure the Foot is open (Step 1) near or at the access site to minimize intraluminal travel during pull back for Step 2</li></ul>

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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Tips and Techniques: Foot Break



## FOOT BREAK CAUSES / OBSERVATIONS

### Potential causes during Plunger deployment (Step 2)

- Rotating / rocking the device or using excessive force during Plunger deployment
- Shallow (less than 45°) Plunger deployment angle

### Potential observations after Plunger removal (Step 3) and/ or device removal

- No suture or link present
- Just a link and no suture present
- Missing part of foot when the device is removed



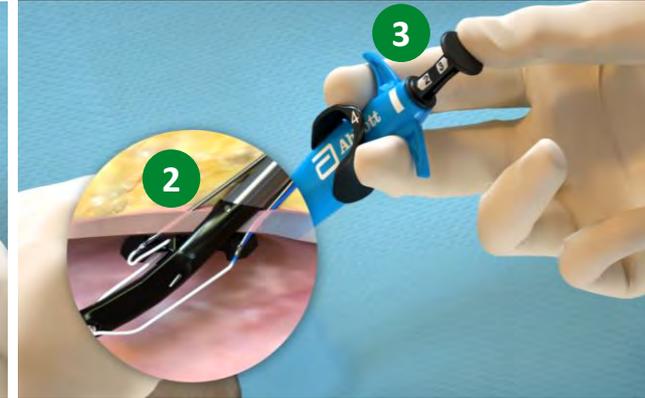
# Tips and Techniques: Foot Break (Continued)

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System



Perclose ProGlide™  
Suture-Mediated Closure System

## FOOT BREAK PREVENTION



1. Position the Perclose™ device at 45° angle and keep stable with the left hand during plunger deployment
  - The deployment angle may vary slightly depending on anatomy
2. Maintain **even and gentle tension** over the Anterior and Posterior Foot against the vessel wall
  - The key is to raise the device until pressure is evenly distributed across the Anterior and Posterior Foot
3. Press down on the Plunger with a **gentle, increasing pressure** to advance the Needles
  - The Needles are more susceptible to deflecting off calcification with higher plunger force and higher needle speed

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

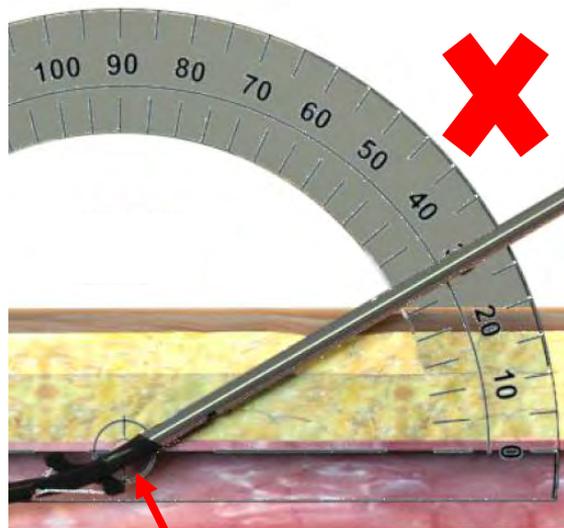
©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Tips and Techniques: Foot Break (Continued)



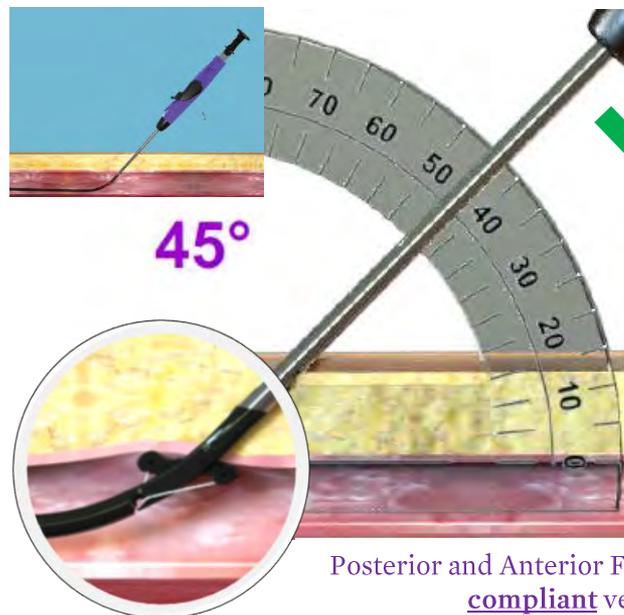
## DEPLOYMENT ANGLE DURING PLUNGER DEPLOYMENT (STEP 2)

Shallow Deployment Angle  
Sub-optimal in any tissue conditions



Potential gap between Posterior Foot and vessel wall  
increases chance for foot break and cuff miss

At least a 45° Deployment Angle  
Ideal in healthy compliant tissue conditions



Posterior and Anterior Foot appose evenly to  
compliant vessel wall



# Tips and Techniques: Foot Break (Continued)

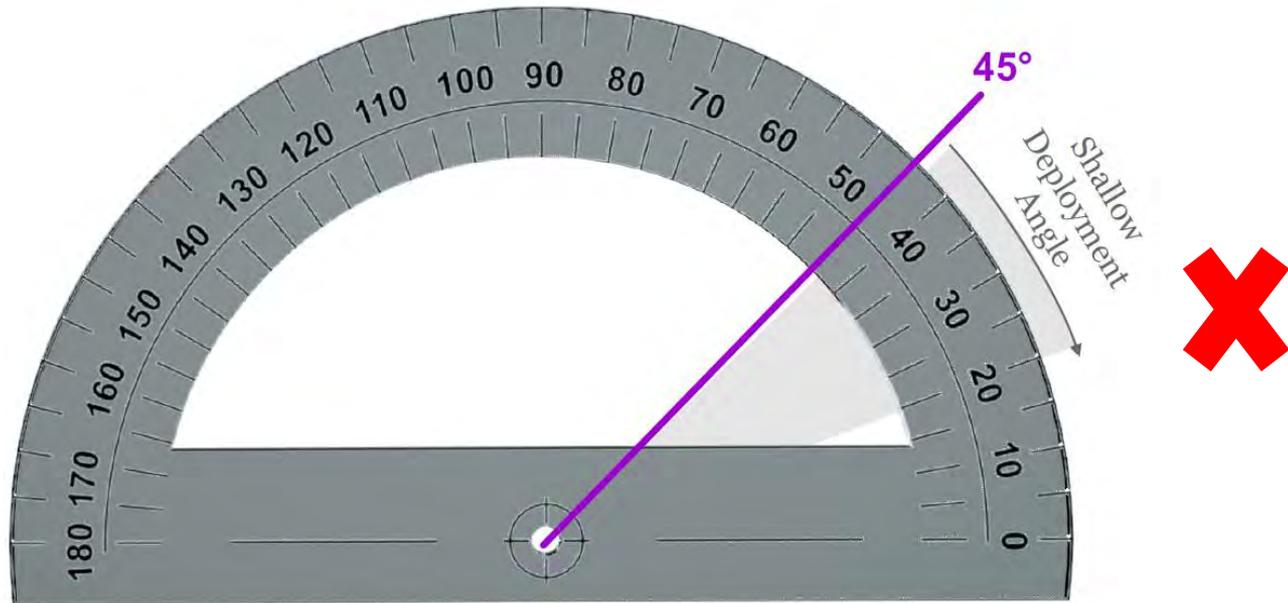
Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System

Perclose ProGlide™  
Suture-Mediated Closure System



## EXERCISE: USE AN ACTUAL DEVICE, OBSERVE THE DIFFERENT FOOT DEPLOYMENT ANGLES

Note: Best if protractor is viewed on a small screen or print out



# Tips and Techniques: Foot Break (Continued)

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System



Perclose ProGlide™  
Suture-Mediated Closure System

## FOOT BREAK PREVENTION

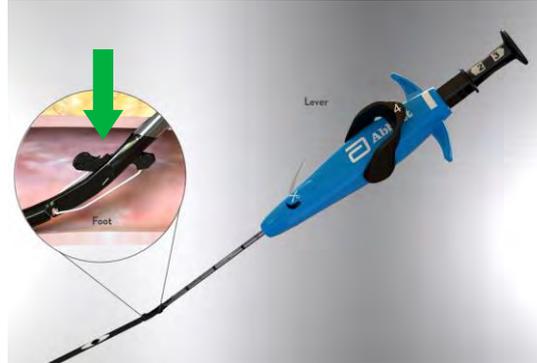
- Avoid challenging anatomical conditions such as heavily calcified arteries, scarred groins, etc.
- Avoid using excessive force, especially when the Lever is lifted (with the Foot plate open)



## DEVICE REMOVAL

Before attempting to remove the device:

- RELAX the device
- Push the Lever down to return Foot to the closed position



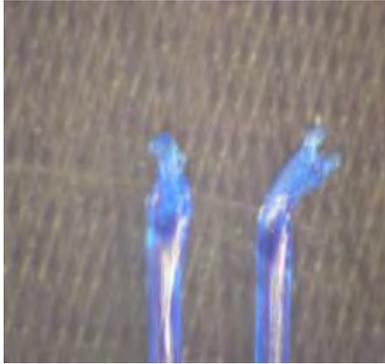
# Tips and Techniques: Suture Break

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System

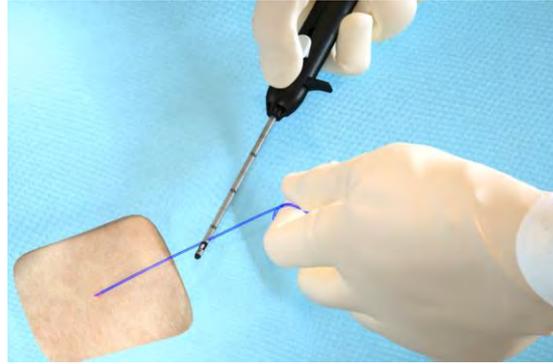
Perclose ProGlide™  
Suture-Mediated Closure System



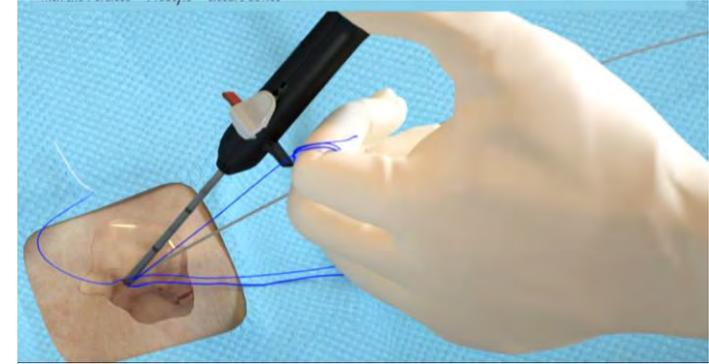
## SUTURE BREAK CAUSES/ PREVENTION



- Suture may look thin and elongated
- Rail or non-rail limbs can break



- Load Suture at mid-point of Suture Trimmer (Do not load at tip)
- Keep Thumb Knob retracted until Suture limbs drop into Suture Gate (Do not close Suture Gate on the suture)



- Keep Thumb Knob toward ceiling (Do not rotate Suture Trimmer)
- Keep suture limbs coaxial to Suture Trimmer and tissue tract at all times
- Do not pull laterally or medially on suture limbs
- Apply slow, consistent increasing tension (Avoid quick, jerky movements)

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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Tips and Techniques: Suture Break (Continued)

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System



Perclose ProGlide™  
Suture-Mediated Closure System

## SUTURE BREAK RESOLUTION

### If the device is still in place

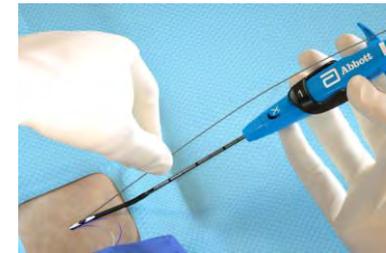
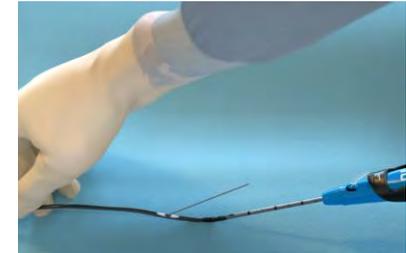
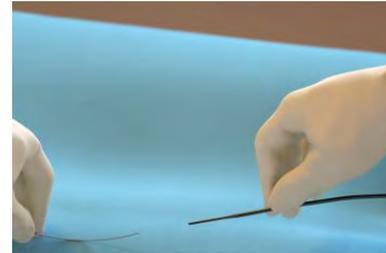
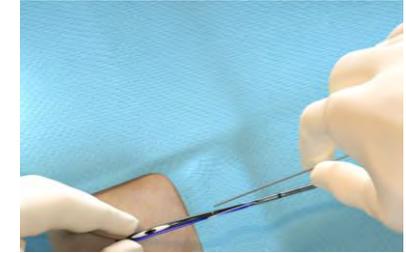
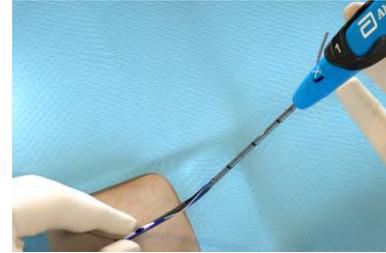
- Insert wire and exchange for another Perclose™ device

### If closing over the wire

- Insert and deploy another device

### If device is already removed and no wire access, assess hemostasis

- Manual compression may be necessary, depending on when and where the suture broke



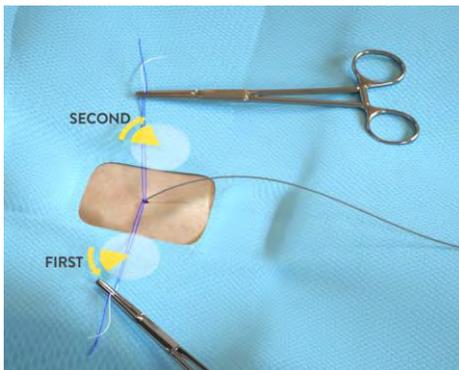
# Tips and Techniques: Lack of Hemostasis

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System

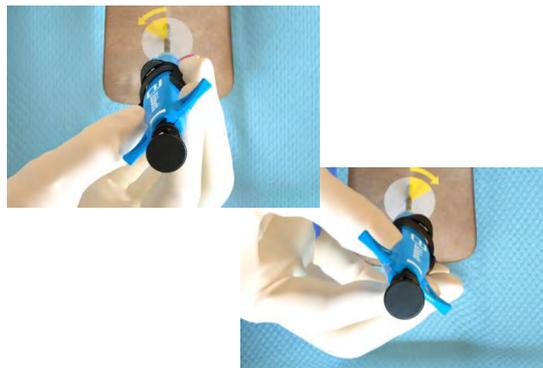
Perclose ProGlide™  
Suture-Mediated Closure System



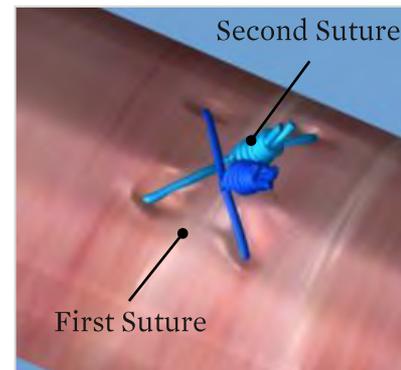
## LACK OF HEMOSTASIS – DUE TO INCORRECT ORDER OF KNOT ADVANCEMENT



Advance Sutures in the order of deployment.



First Suture deployed is on the “bottom” or closest to the vessel. If Second Suture is tightened out of order, it may result in tangled Sutures and/or the inability to tighten the First Suture successfully.



After initial knot advancement of all Sutures, continue to tighten and lock each knot in the order deployed.

Tightening and locking the Second Suture before the First Suture is completely secure can result in an incomplete or “partial” close.

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

©2021 Abbott. All rights reserved. MAT-2012545 v3.0

# Tips and Techniques: Lack of Hemostasis (Continued)

Perclose™ ProStyle™  
Suture-Mediated Closure and Repair System

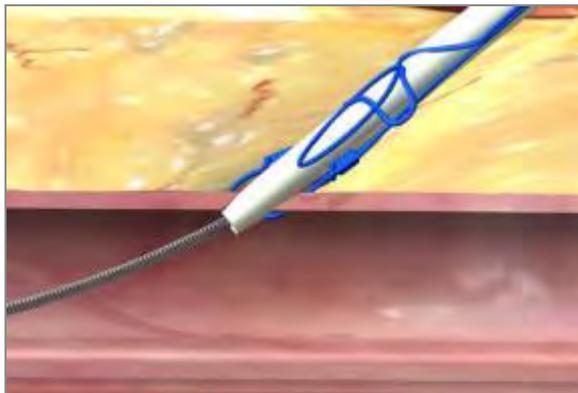


Perclose ProGlide™  
Suture-Mediated Closure System

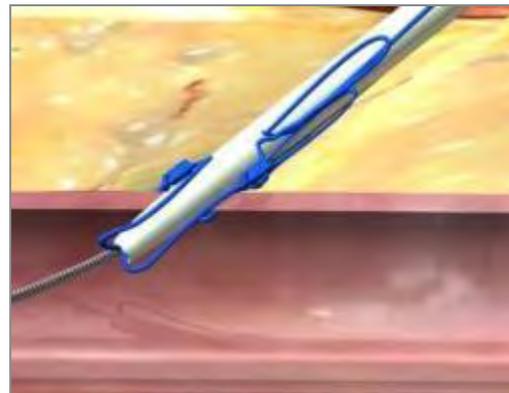
## LACK OF HEMOSTASIS – DUE TO TANGLED SUTURES



After Suture Deployment, a clamp is immediately placed on the Suture limbs. A gentle retraction is placed on the clamp until the Suture is taut. This removes all Suture slack from the tissue tract.



If Suture slack is not removed, the Sutures can become tangled or pushed into the vessel during insertion of procedural sheaths and device exchanges.



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 [eifu.abbottvascular.com](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

**Information contained herein for DISTRIBUTION outside 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**

Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

™ Indicates a trademark of the Abbott Group of Companies.

‡ Indicates a third-party trademark, which is property of its respective owner.

[www.cardiovascular.abbott](http://www.cardiovascular.abbott)

©2021 Abbott. All rights reserved. MAT-2012545 v3.0



**Abbott**