2022

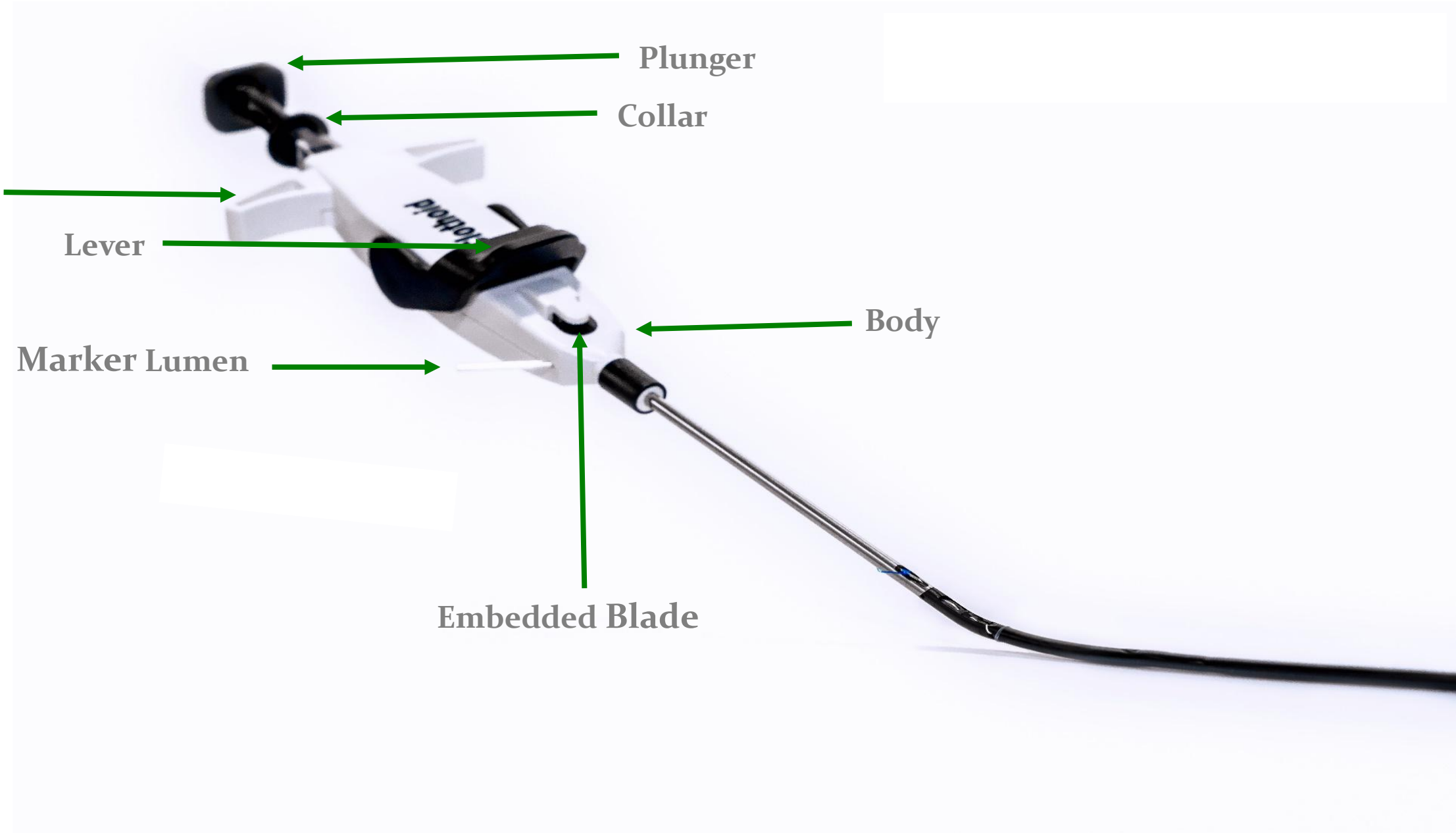
Clothoid

INNOVATIVE
& PRACTICAL

Overview

The Clothoid Vascular Closure System is designed to deliver a single monofilament polypropylene suture to close femoral vessel puncture sites following diagnostic or interventional catheterization procedures.

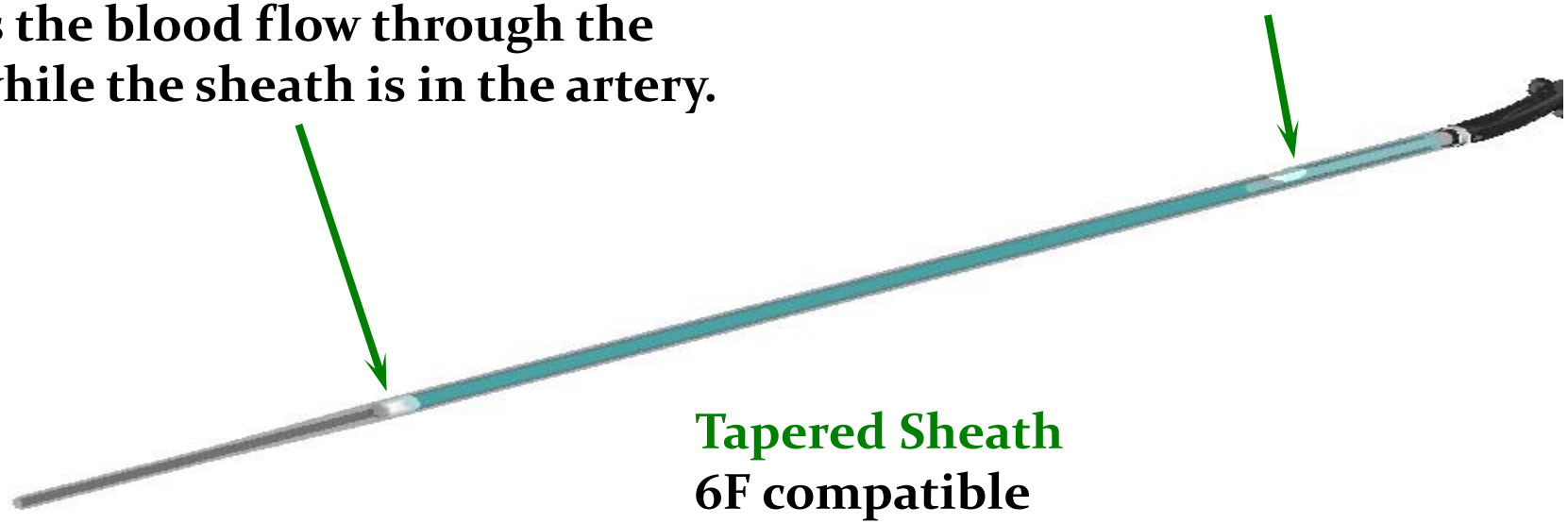
Body Components



Sheath

Guide Wire Exit Port
Directs the guide wire out of the sheath through the GW port

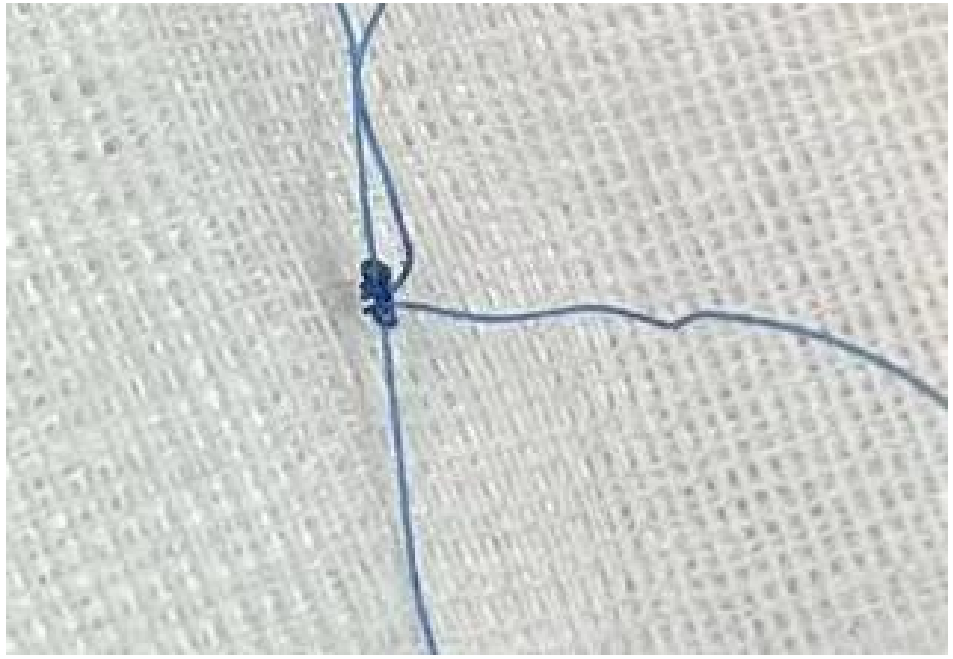
Hemostasis Valve
Restricts the blood flow through the sheath while the sheath is in the artery.

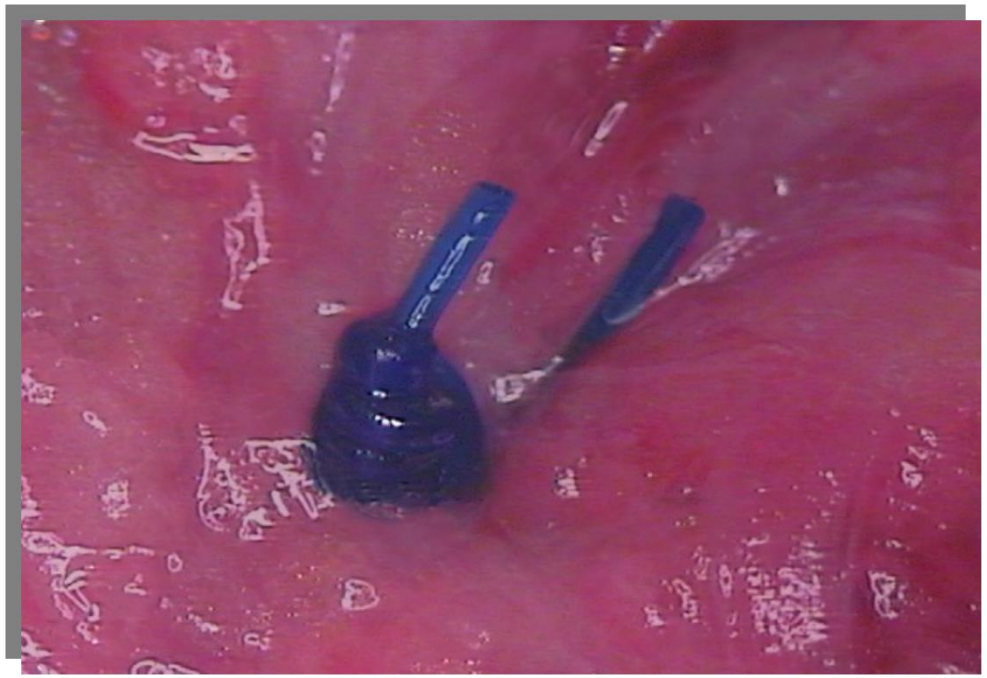


Tapered Sheath
6F compatible

Monofilament Suture

- Non-absorbable 3-0 polypropylene suture Suture of choice by vascular surgeons due to:
  - Minimized inflammatory response
  - High-knot tensile strength
  - Reduced perception of infection





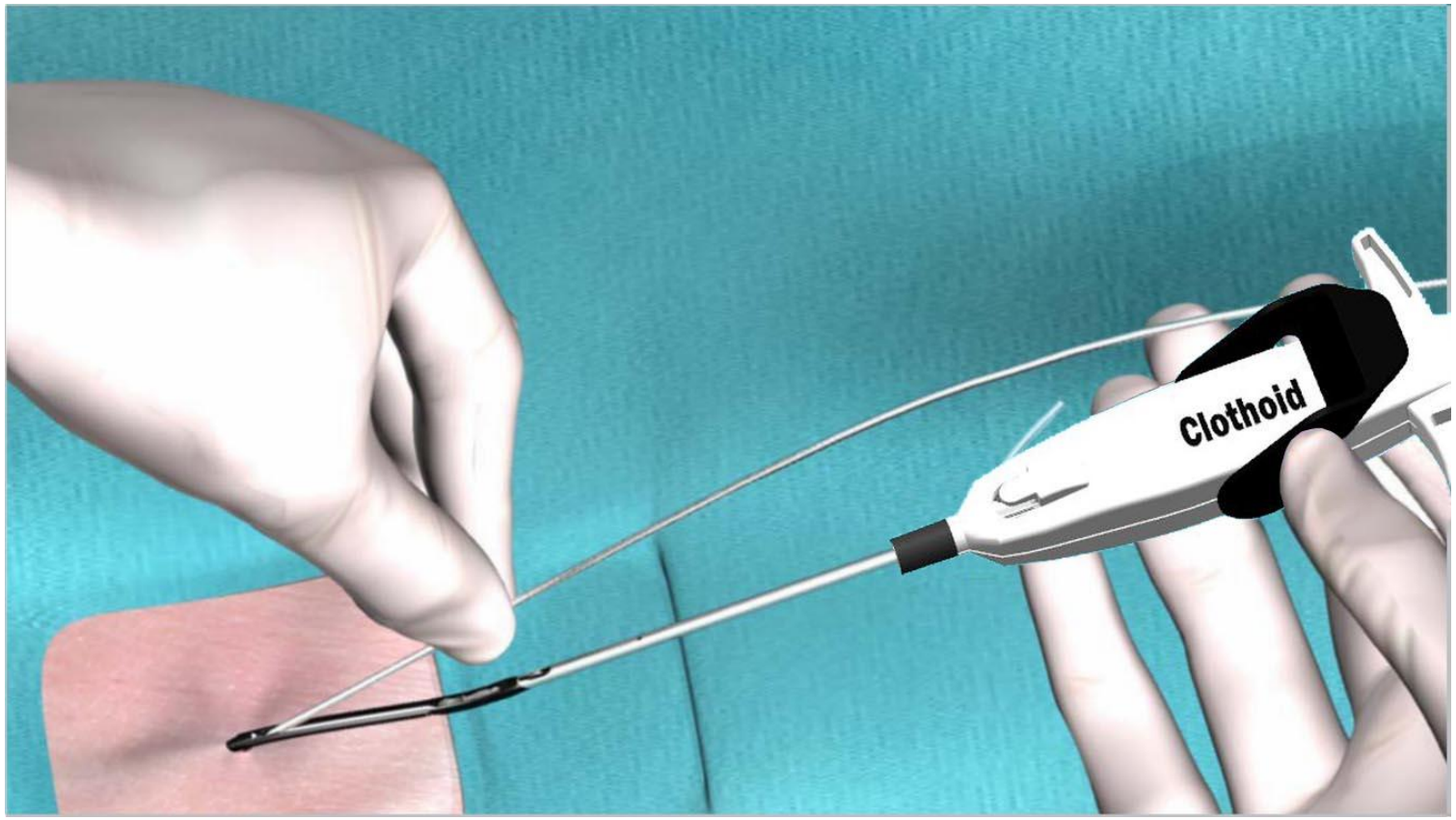
Clothoid Vascular Closure Device Surgical Technique

- **Device Preparation**
- ● Rinse the marked lumen with a heparin saline syringe.
- ● Observe the marked lumen patency for saline existence, proceed if saline flow is observed.

- **The following instructions detail the deployment sequence to close the access site of a catheterization procedure performed with a single device.**

Clothoid Vascular Closure Device Surgical Technique

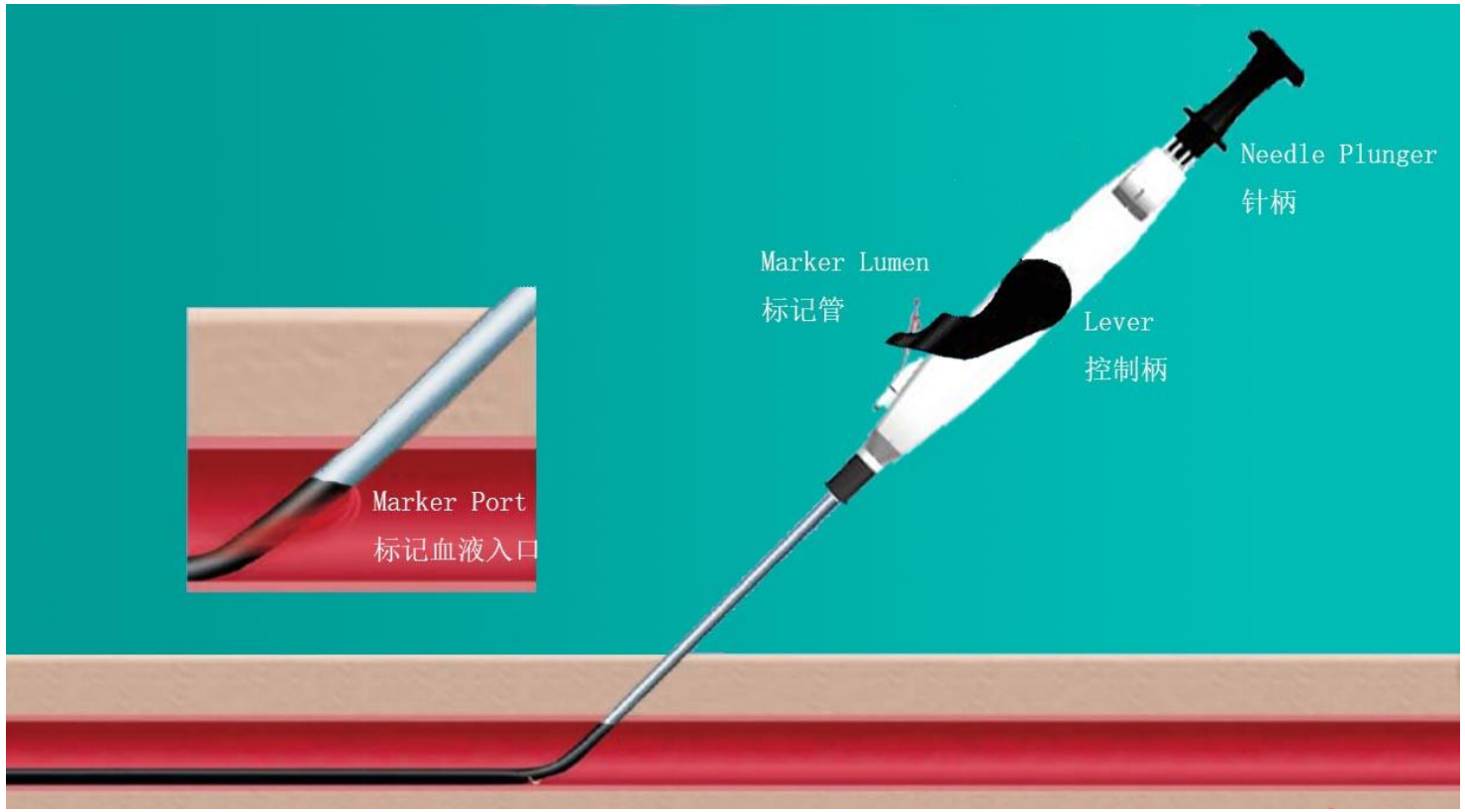
1. Place a 0.038" (or smaller) guidewire through the procedural (or introducer) sheath. Remove the procedural sheath while applying pressure on the groin to maintain hemostasis. Backload the device over the guidewire until the guide wire exit port of the device sheath is just above the skin line. Remove the guidewire before the exit port crosses the skin line.



Clothoid Vascular Closure Device Surgical Technique

2. Continue to advance the device in the vessel until brisk pulsatile flow of blood is evident from the marker lumen.

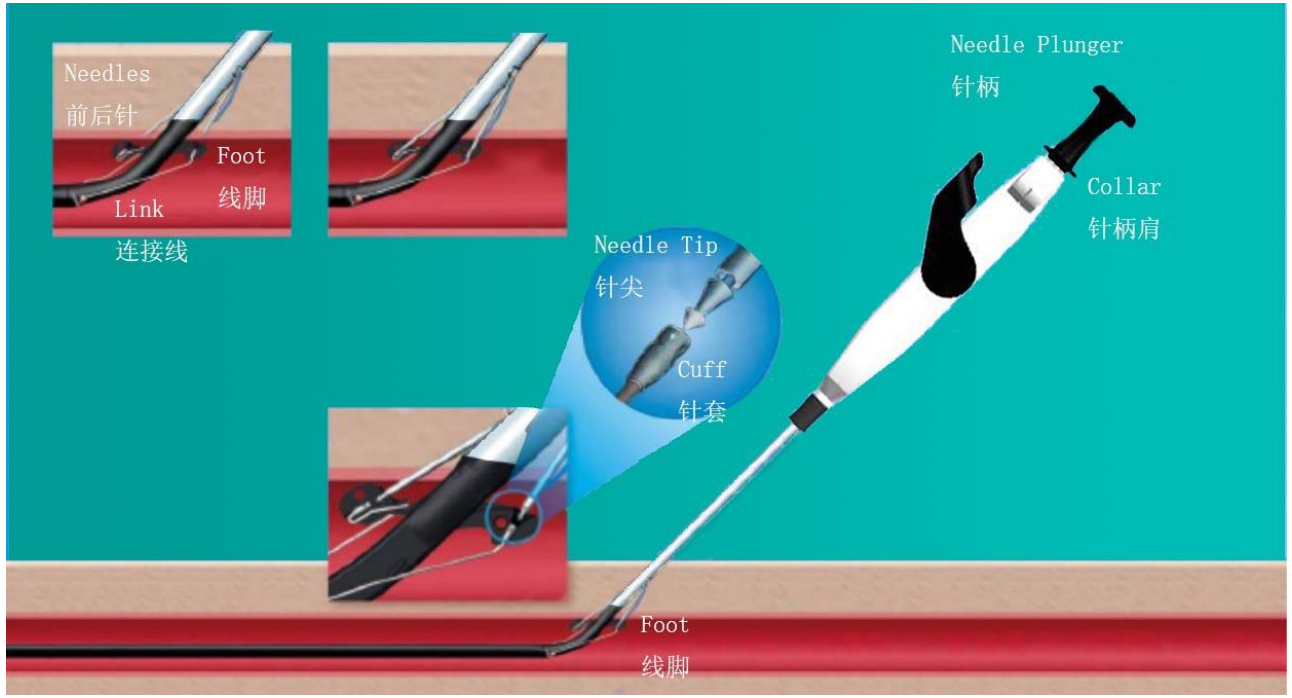
3. The device lever (marked #1) and logo should be facing the ceiling (12 o'clock). Position the device at a 45-degree angle. Deploy the foot by lifting the lever (marked #1) on the body of the device.



Clothoid Vascular Closure Device Surgical Technique

4. Gently pull the device back to position the foot against the vessel wall. After proper foot position is reached, in the artery blood marking will cease or be significantly reduced to a slight drip. In the vein, there may be no change in blood marking.

5. While maintaining device position, stabilize the device with one hand to maintain the gentle retraction and to ensure the device does not twist or move forward during deployment. Use your other hand to deploy needles by pushing on the plunger assembly until you visually confirm that the collar of the plunger makes contact with the proximal end of the body.

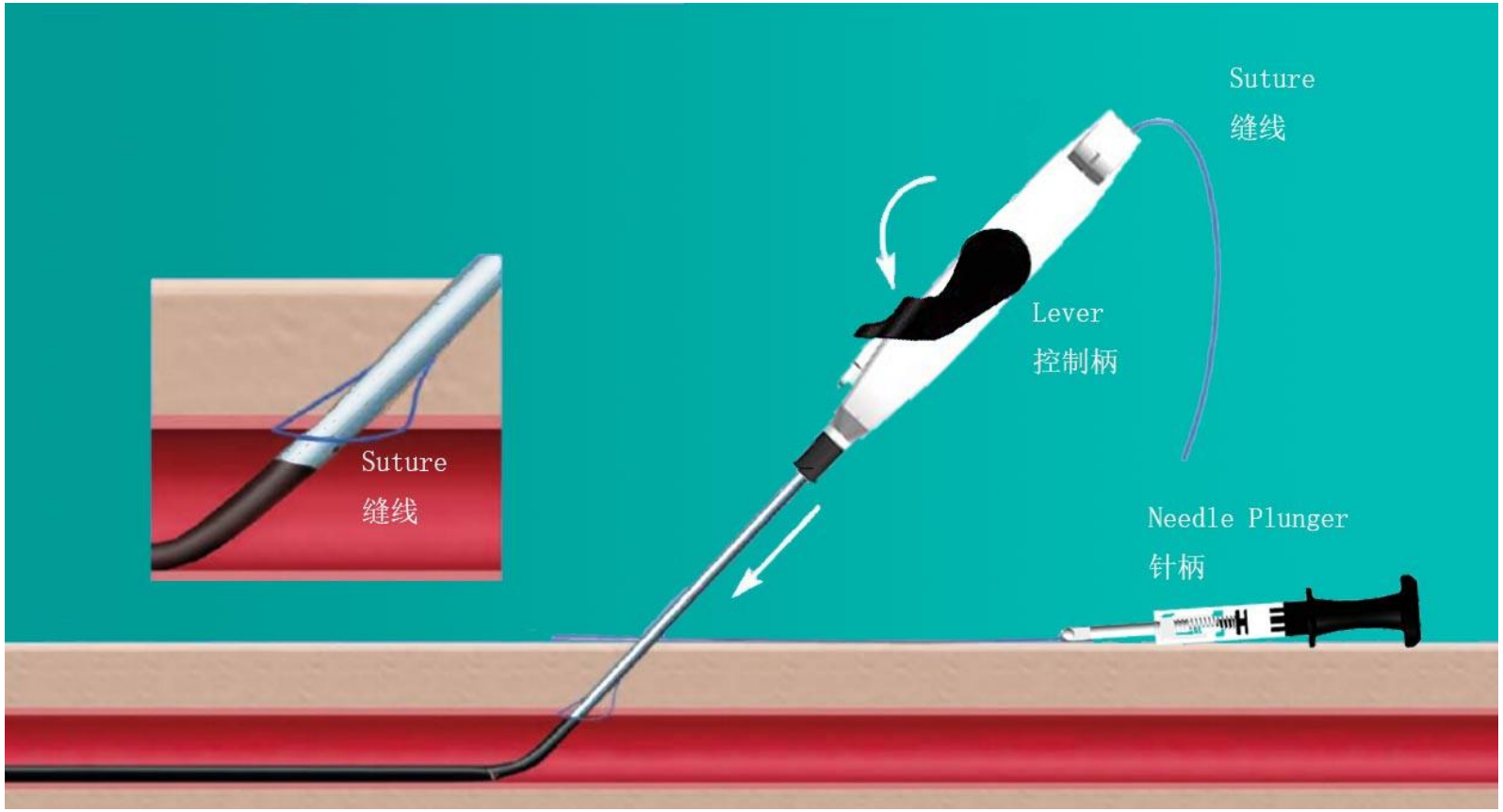


Clothoid Vascular Closure Device Surgical Technique

6. Using your thumb as a fulcrum on the handle, gently disengage the needles by pulling the plunger assembly back and completely remove the plunger and needles from the body of the device. Use the suture-trimming mechanism located on the body of the device to cut the suture from the anterior needle distal of the link.

Clothoid Vascular Closure Device Surgical Technique

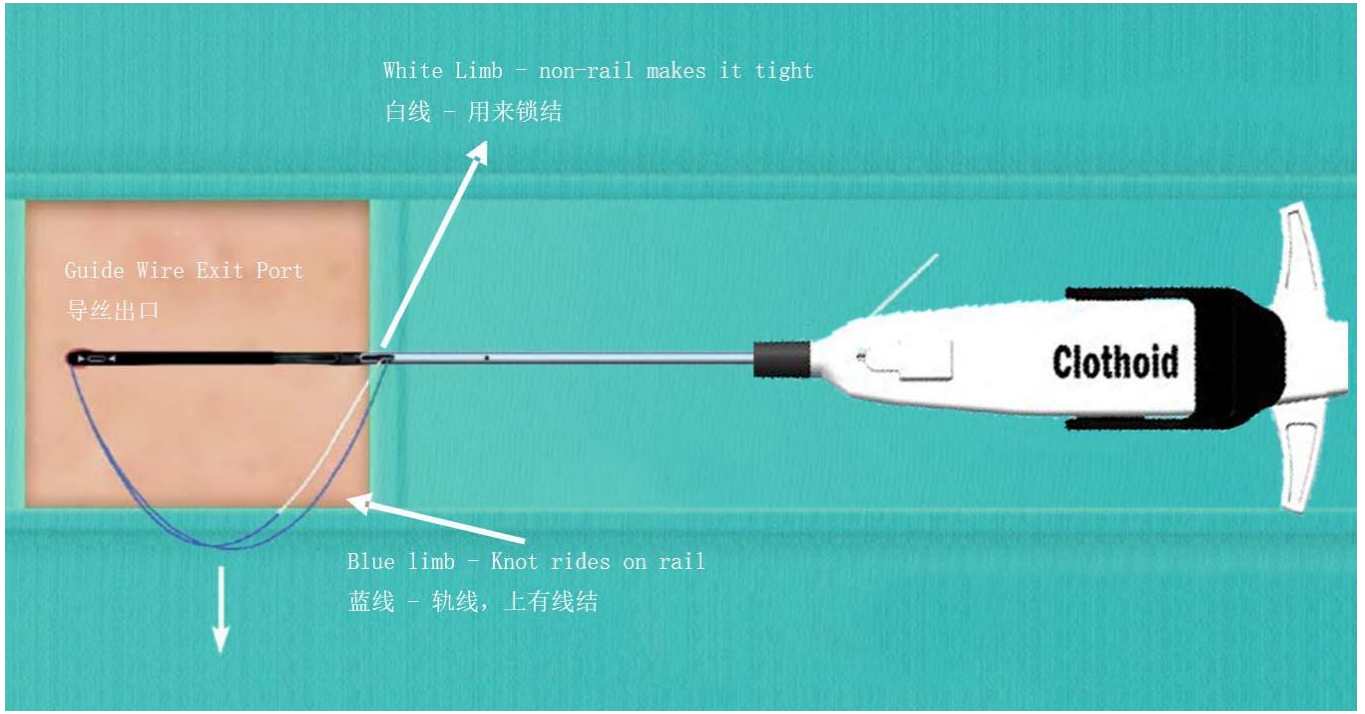
7. Relax the device and then return the foot to its original closed position by pushing the lever down to the body of the device.



Clothoid Vascular Closure Device Surgical Technique

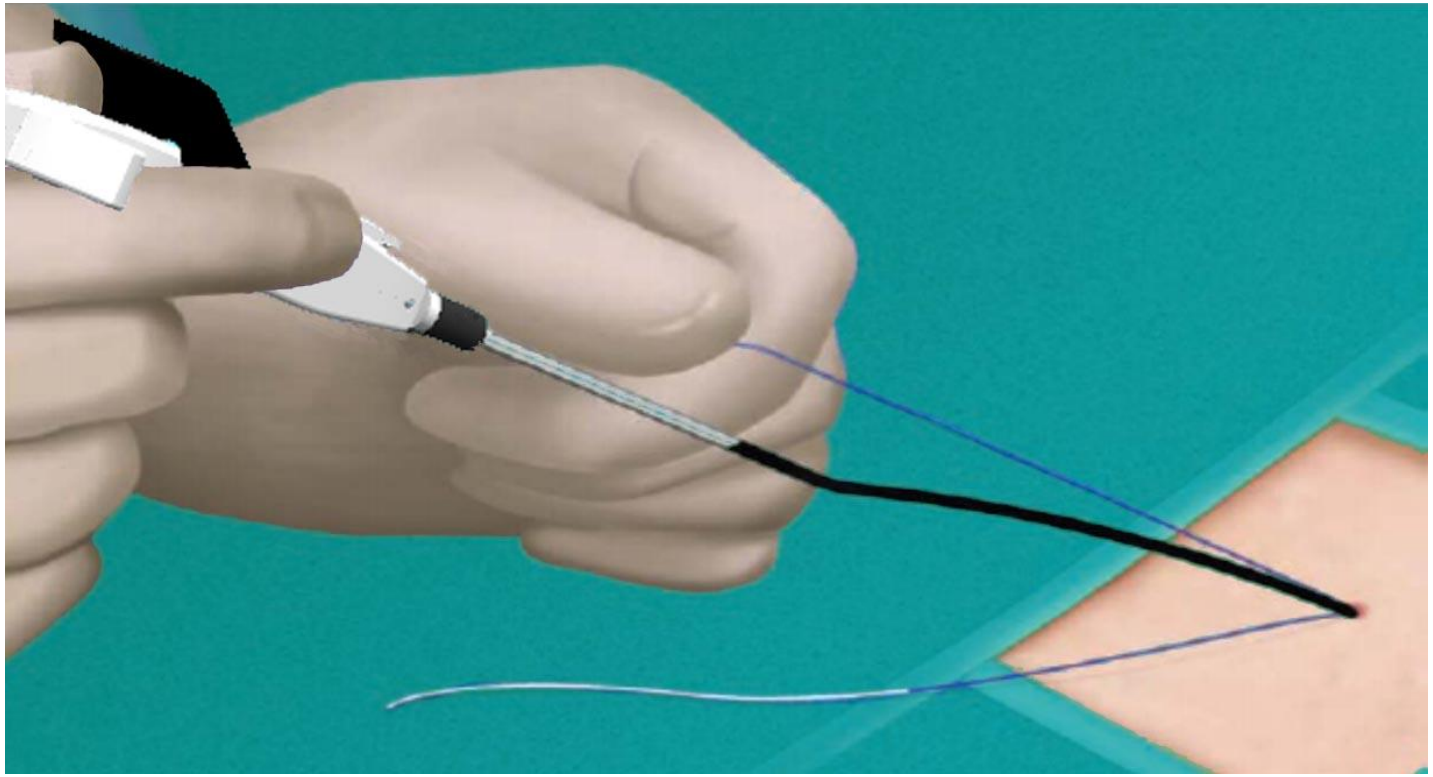
8. Retract the Clothoid Vascular Closure device to release the suture knot. Continue to gently withdraw the device until the guide wire exit port is visible above the skin line.

Slightly rotate the device until you can see the two suture limbs in the bend of the distal guide. Grasp the suture adjacent to the device sheath and pull the suture ends through the distal end of the proximal guide. The rail suture limb is blue and is the longer of the two suture limbs. This rail suture limb will be used to advance the knot. The shorter, non-rail suture limb is white tipped and will be used to lock the knot.



Clothoid Vascular Closure Device Surgical Technique

9. Securely wrap the rail (longer, blue) limb of the suture around your left forefinger, low close to the skin. Completely remove the device or the sheath from the artery, while simultaneously pulling gently on the rail limb.



Clothoid Vascular Closure Device Surgical Technique

10. With the rail (longer, blue) suture limb securely wrapped around your left forefinger, place the rail limb into the Suture Trimmer utilizing the following steps:

a) Retract the Thumb Knob on the Suture Trimmer with right hand.

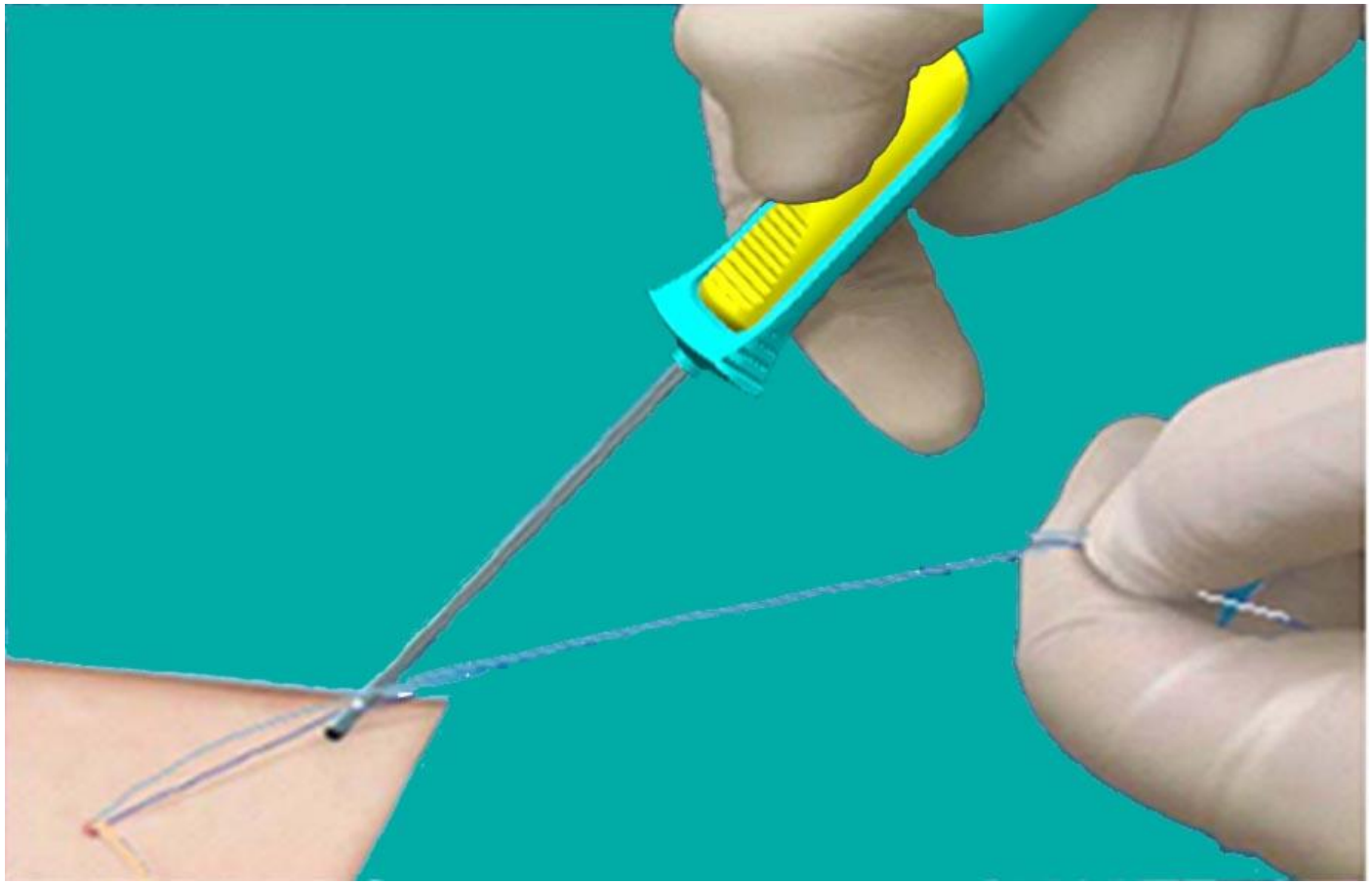
b) Place the Suture Trimmer under the suture limb making an “x” or a “cross” between the suture limb and the mid-point of the Suture Trimmer.

c) Slide the Suture Trimmer back to load the suture into the Suture Gate located at the distal end of the Suture Trimmer.

d) Keeping the Thumb Knob retracted, turn the Suture Trimmer coaxial to the suture and then release the Thumb Knob to capture the suture in the Suture Gate. Releasing the Thumb Knob before the suture is coaxial to the Suture Trimmer can cause the suture to be caught within the sliding mechanism at the distal tip and damage the suture.

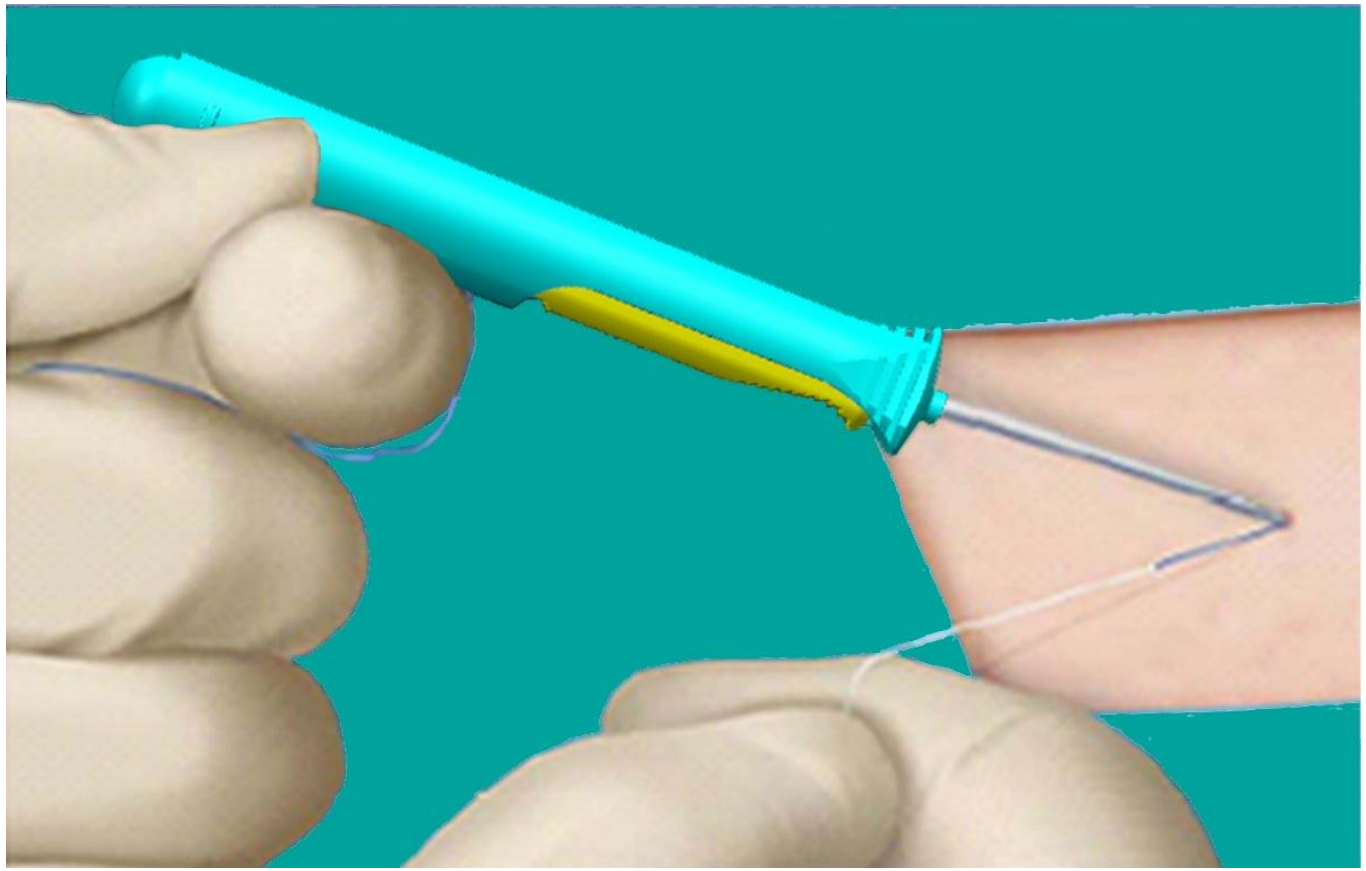
Clothoid Vascular Closure Device Surgical Technique

11. Once the suture is loaded correctly, the Suture Trimmer should slide easily.



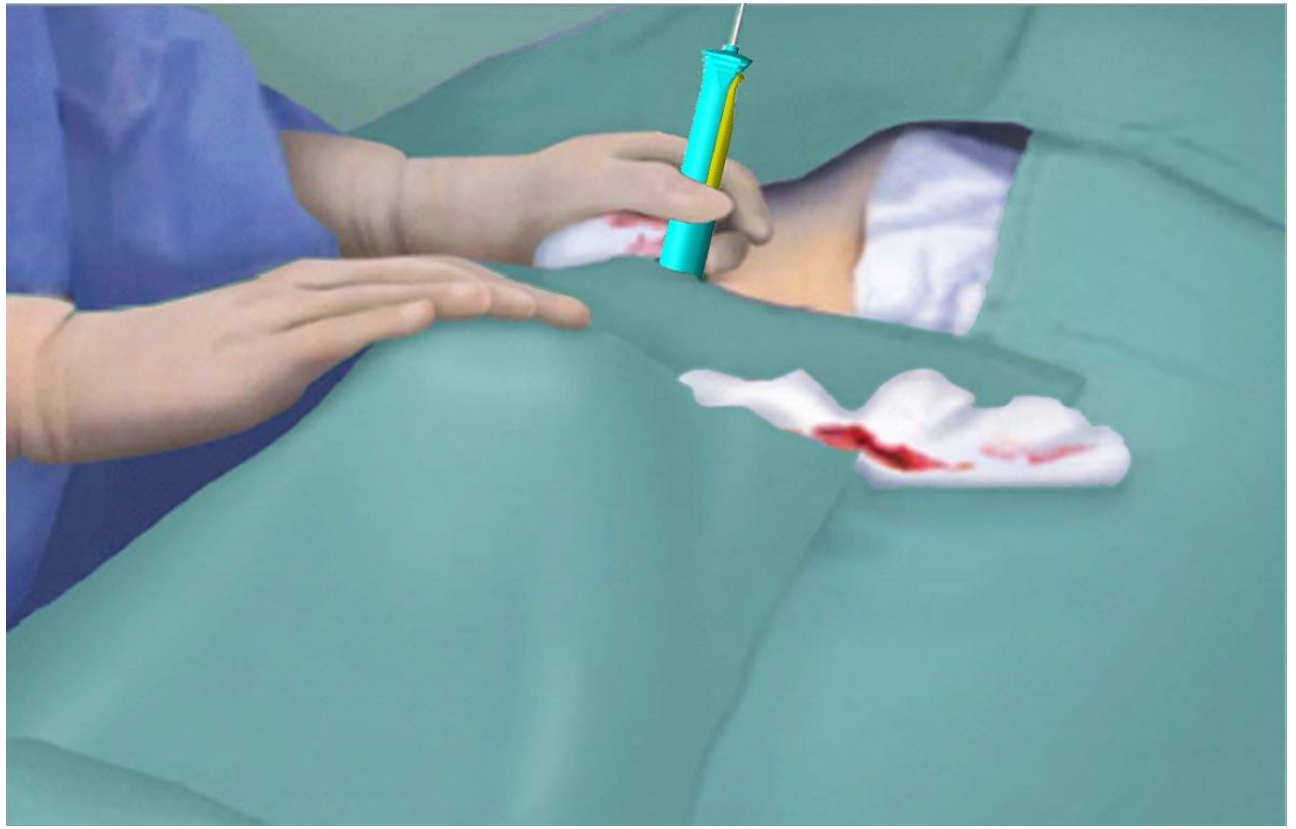
Clothoid Vascular Closure Device Surgical Technique

12. With the Suture Trimmer held in position and keeping the rail suture limb taut, tighten the knot by gently pulling the non-rail (shorter, white tipped) suture limb, keeping it coaxial to the tissue tract.



Clothoid Vascular Closure Device Surgical Technique

13. Confirm the security of the knot by having the patient cough and / or bend his / her leg. (Active testing for hemostasis is only for 5F – 8F sheaths. Only visually confirm hemostasis for sheath closure greater than 8F). Patients may be able to move freely in bed without head of bed or leg restrictions if the close is successful.



Clothoid Vascular Closure Device Surgical Technique

14. Once hemostasis is achieved, use the Suture Trimmer to trim the sutures below the skin.