Thiết bị đóng mạch máu Obtura

trong việc cầm máu sau thủ thuật can thiệp đường đùi

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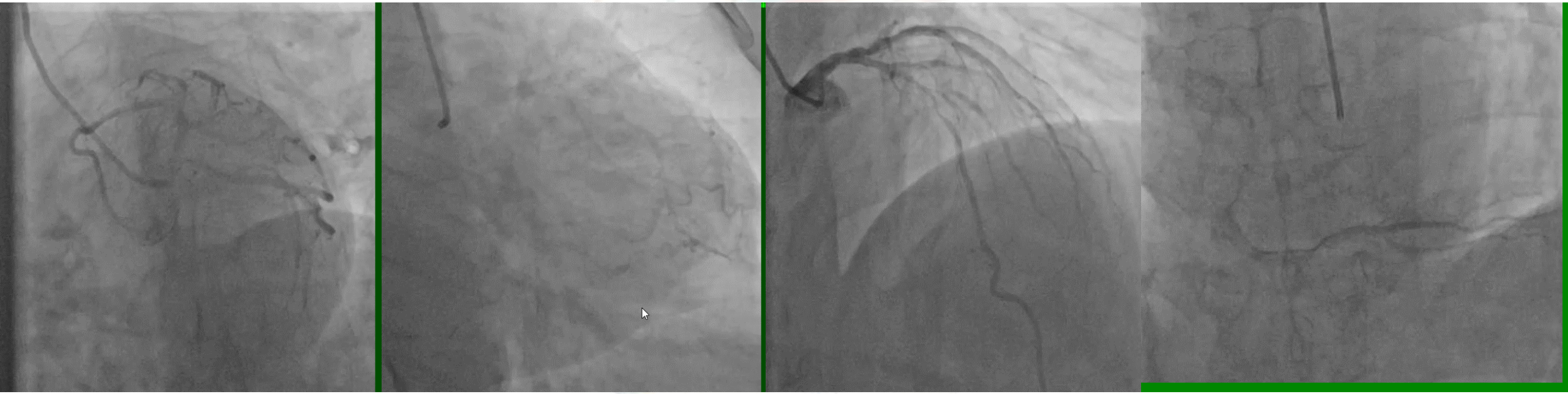
Case report

- Female, 64 ys
- Diagnosis: NSTEMI
- History: Diabetes, Hypertension, Lipid disorder
- Angiogram: severe stenosis of proximal LAD I, D1 with moderate calcium.
- Plan: PCI of LAD via R-DRA, 6F EBU

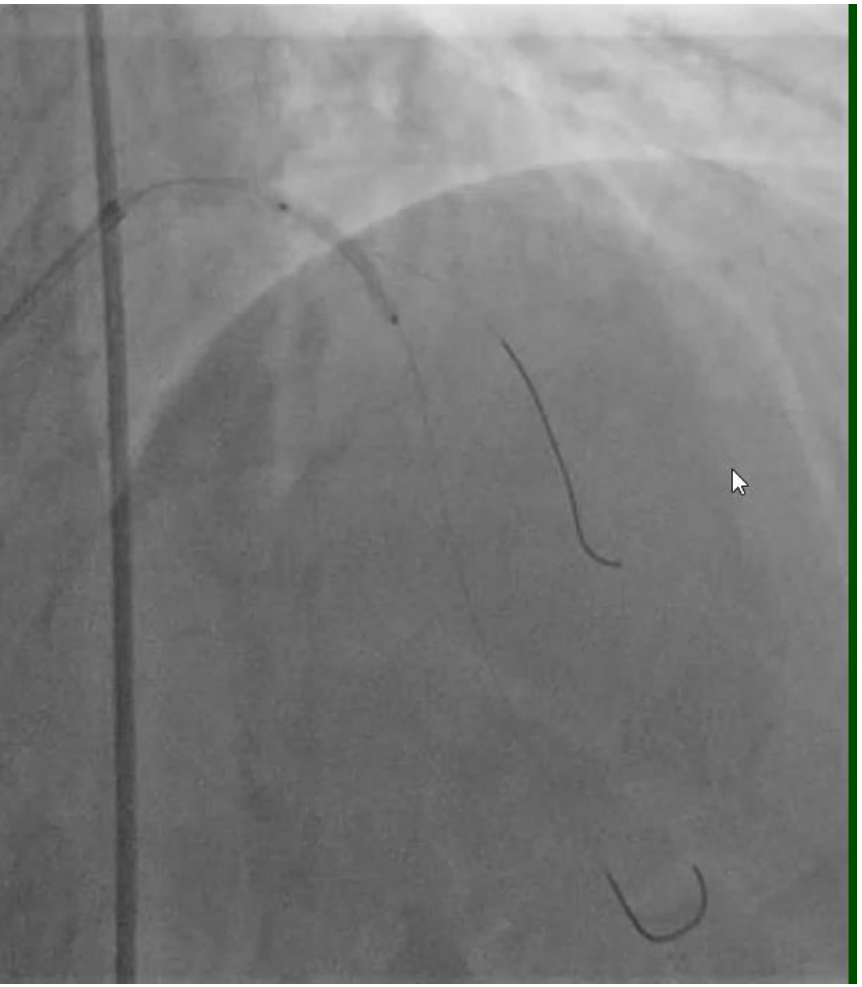
Angiogram

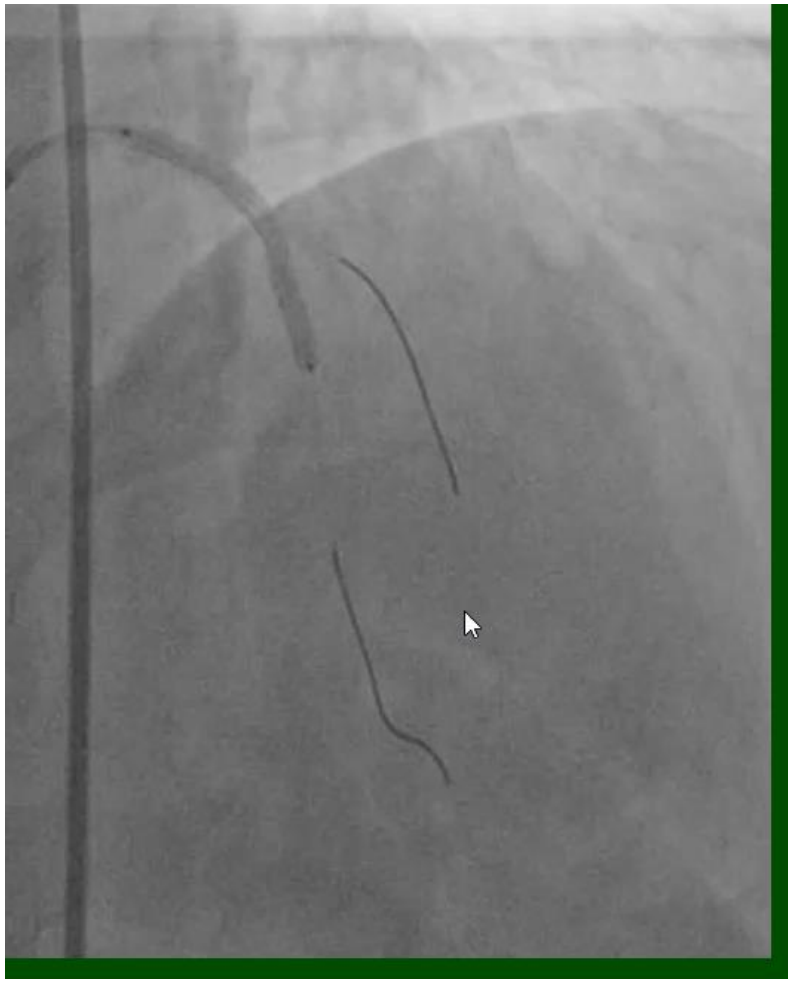


PCI

EBU 3.5 6F can not engage LMCA

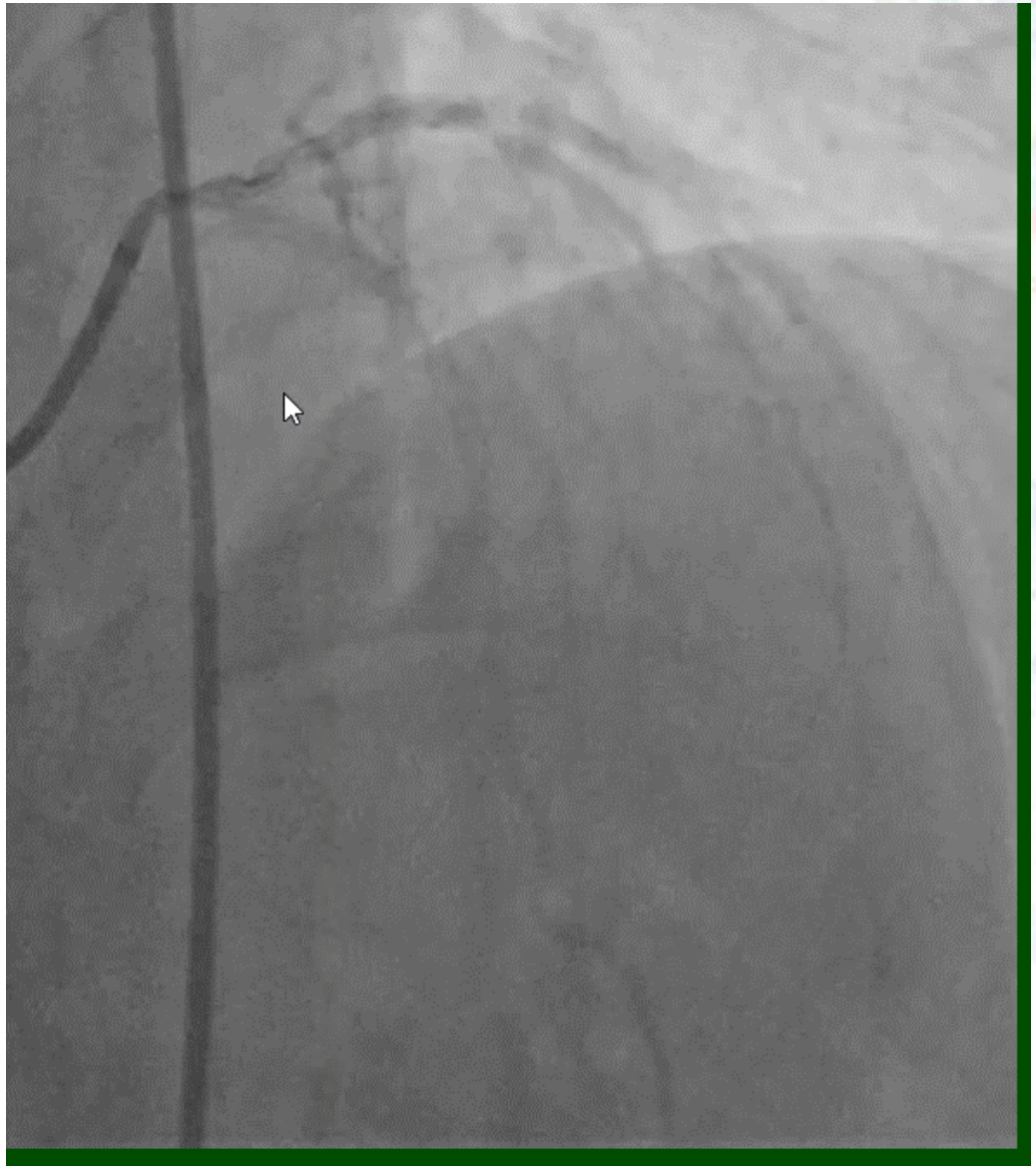
PCI via Femoral Access





2 wire were andvanced to LAD and D1 distally
Provisional technique was done with 3.0x33 mm on LAD I-II.

Final Angiogram

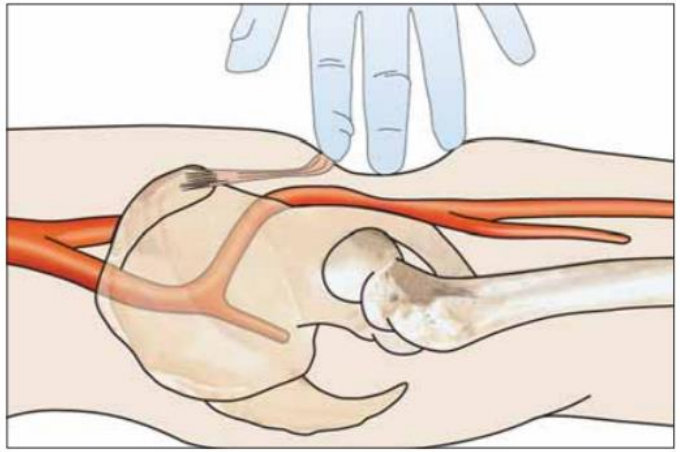


Hemostasis Definition

- Meaning to yield motionlessness or **stopping of blood**

Manual Compression – Why is it still around?

- Requirements
  - Applicable to most patients
- Strengths
  - Familiar technique



- **Weaknesses**

Vessel Closure Goals

- Minimize bleeding
- Avoid vascular access site complications
- Early ambulation
- Decrease patient discomfort
- Reduce length of stay
- Reduce acuity of care

Some key selection criteria to consider for VCD

- Access Site
- Procedure Type
- Vessel Size
- Patient Characteristics
- Anticoagulation Status
- Hemostasis Timing
- Operator Experience
- Patient Comfort
- Complication Rates
- Device Features
- Cost and Accessibility
- Post-Procedure Monitoring

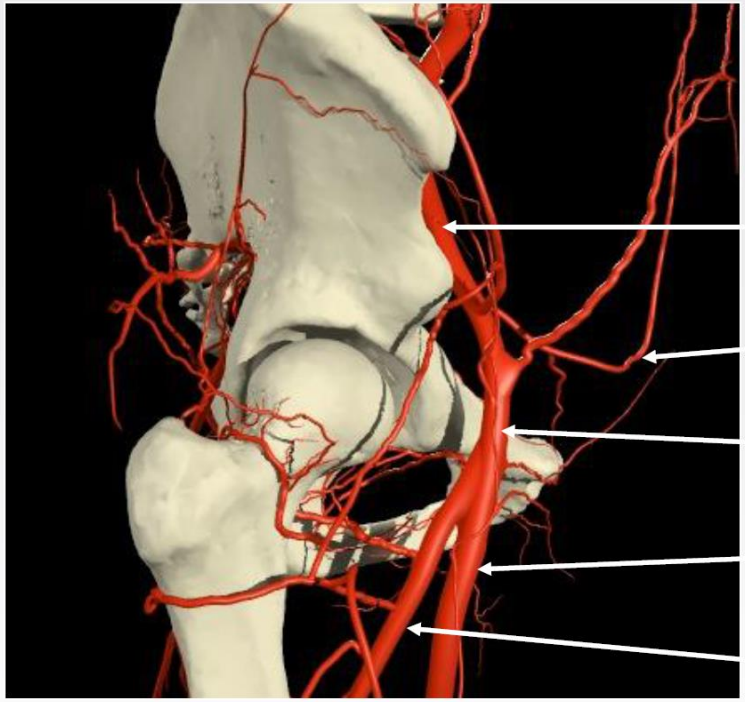
Global Market Segmentation

- Passive
  - **Collagen Plugs: Angioseal, Obtura.**
  - Sealant or Gel-Based Devices: Mynx
  - Compression Assist Devices: Radiostop, safeguard (Merit Med)
- Active
  - Suture-Mediated Devices : Perclose Proglide
  - Clip-Based Devices : Starclose
- External Hemostatic Devices

Remember:
Good puncture leads to good closure

Good Access

1. Proximal to bifurcation of SFA and Profunda



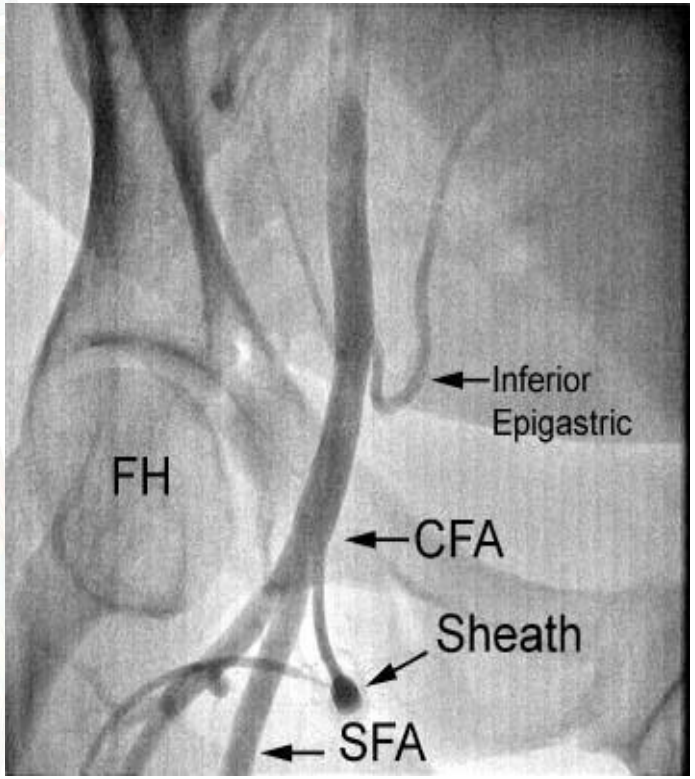
External iliac artery (EIA)

Inferior epigastric artery (IEA)

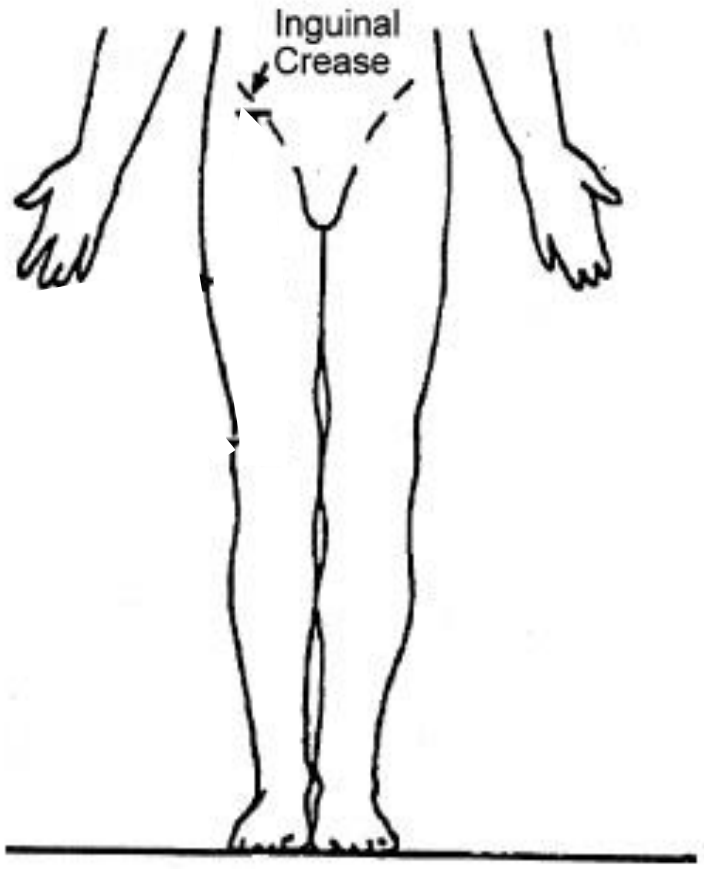
Common femoral artery (CFA)

Superficial femoral artery (SFA)

Deep femoral artery (Profunda)



External anatomical landmarks?

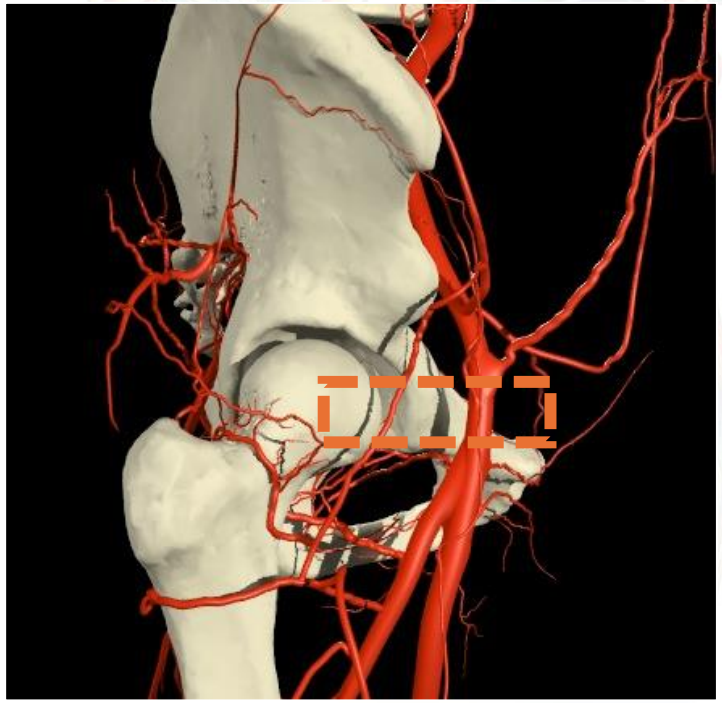


Inguinal Crease

Inguinal Skin

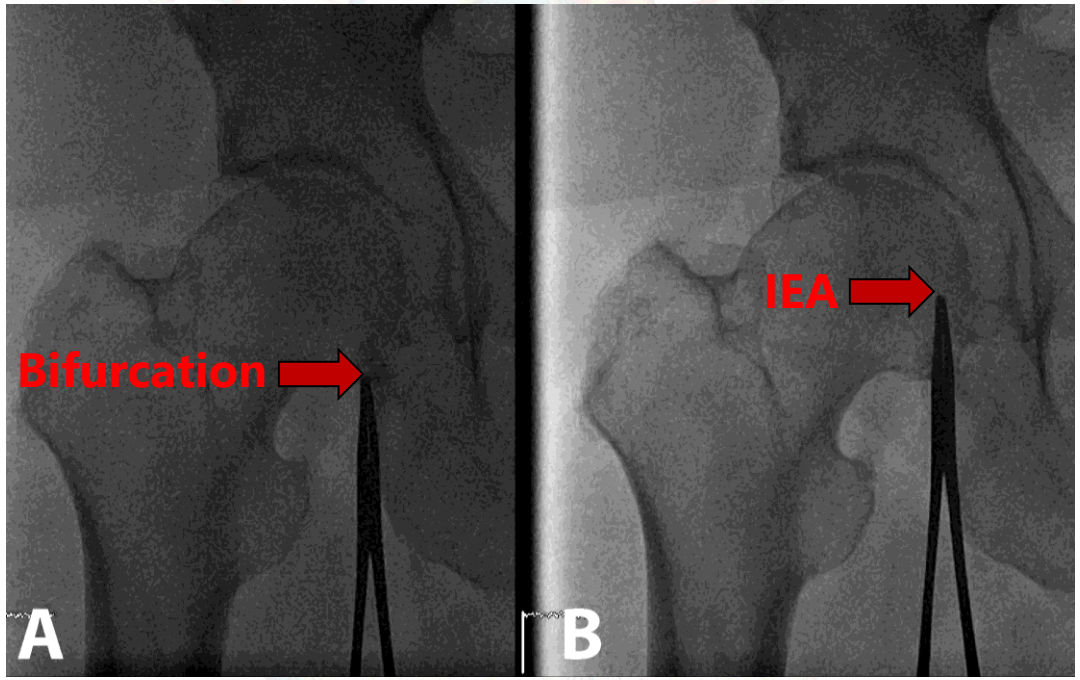
External anatomical landmarks is not reliable

- Anatomical landmarks can be misleading
  - In 72-75% patients, bifurcation is proximal to skin crease
  - In 92.7% patients, point of maximal impulse is over the femoral head
- Under fluoroscopy, femoral head can be observed to identify good access point



Identify good access using fluoroscopy

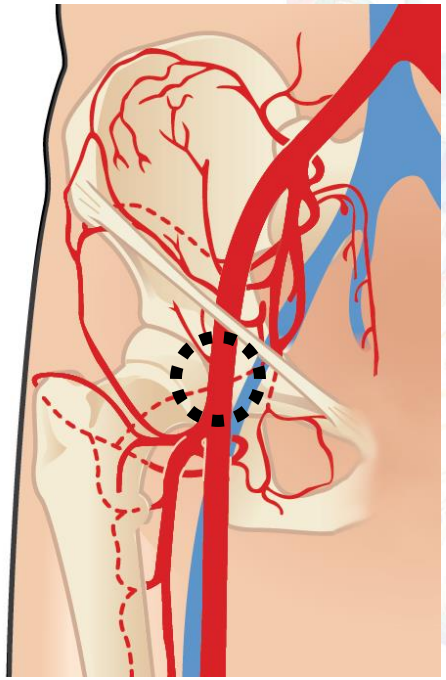
- Common femoral head
  - There is 98.5% success using fluoroscopy to help identify good access

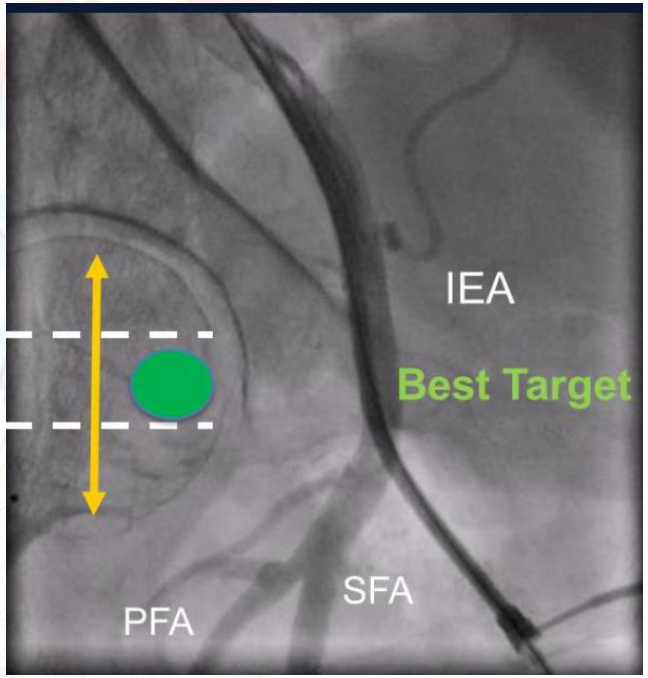


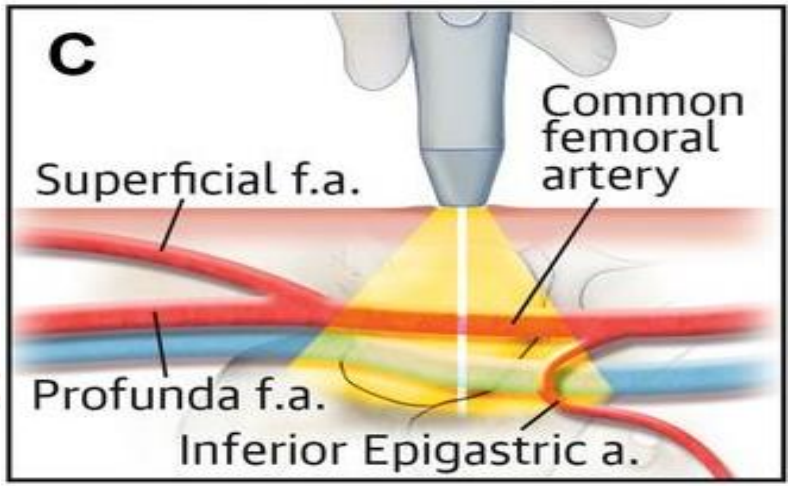
Fluoroscopy to identify the femoral is a recommended routine step for all femoral access procedures

Good Access: Key Points

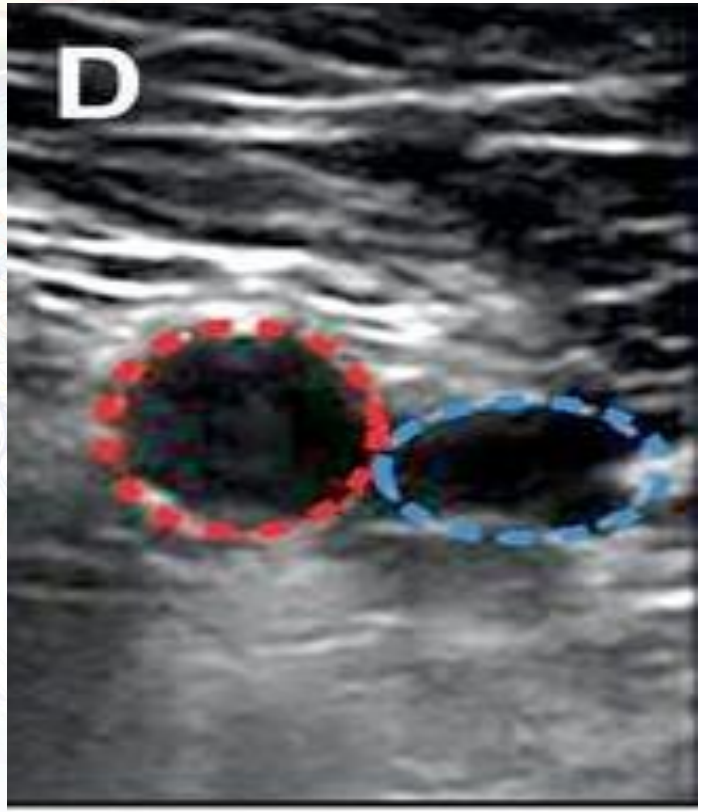
- Perform femoral angiography
- Puncture in the Common Femoral Artery (CFA)
  - Below the inguinal ligament (and IEA)
  - Above the bifurcation (of SFA and Profunda)







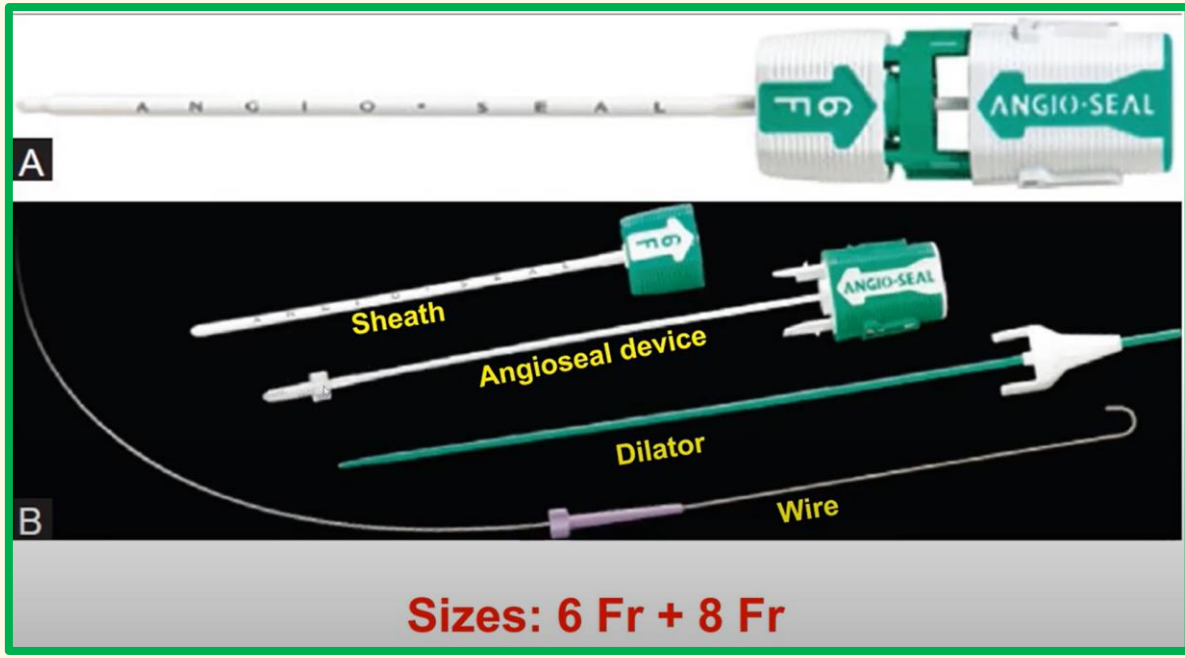
below bifurcation



above bifurcation

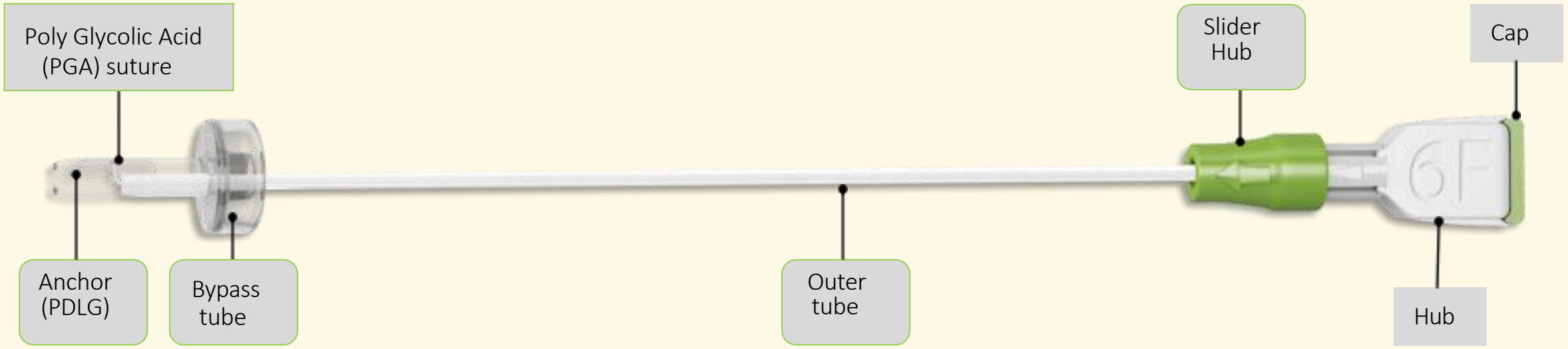
Sandoval et al. JACC Cardiovasc Interv. 2017;10:2233-41


obtura™
Vascular Closure Device
6F
CE


A
ANGIO·SEAL
6F
ANGIO·SEAL
B
Sheath
Angioseal device
Dilator
Wire
Sizes: 6 Fr + 8 Fr

Obtura™
Vascular Closure Device

Construction



Bio-Absorbable Implant Component

-Polymer anchor
-Type- 1 Bovine Collagen sponge
-Suture connecting Anchor and Collagen by self-tightening knot

Delivery Component

-Bypass tube that facilitates easy delivery system insertion through standard introducer sheath
-Dual Tube houses the suture ,Tamper tube and the locking and also act as device shaft

Obtura™
Vascular Closure Device

Features

3-Step Deployment

Unique 3- Step Deployment technique to reduce procedural time and blood Loss

No Exchange of Introducer Sheath

Specially Designed Obtura is compatible with the standard existing introducer sheath used during the interventional procedures leading to less blood loss

Rapid Hemostasis

Efficient Anchor- Collagen plug (Bovine type - I) sandwiches the arteriotomy and gives rapid hemostasis at puncture site

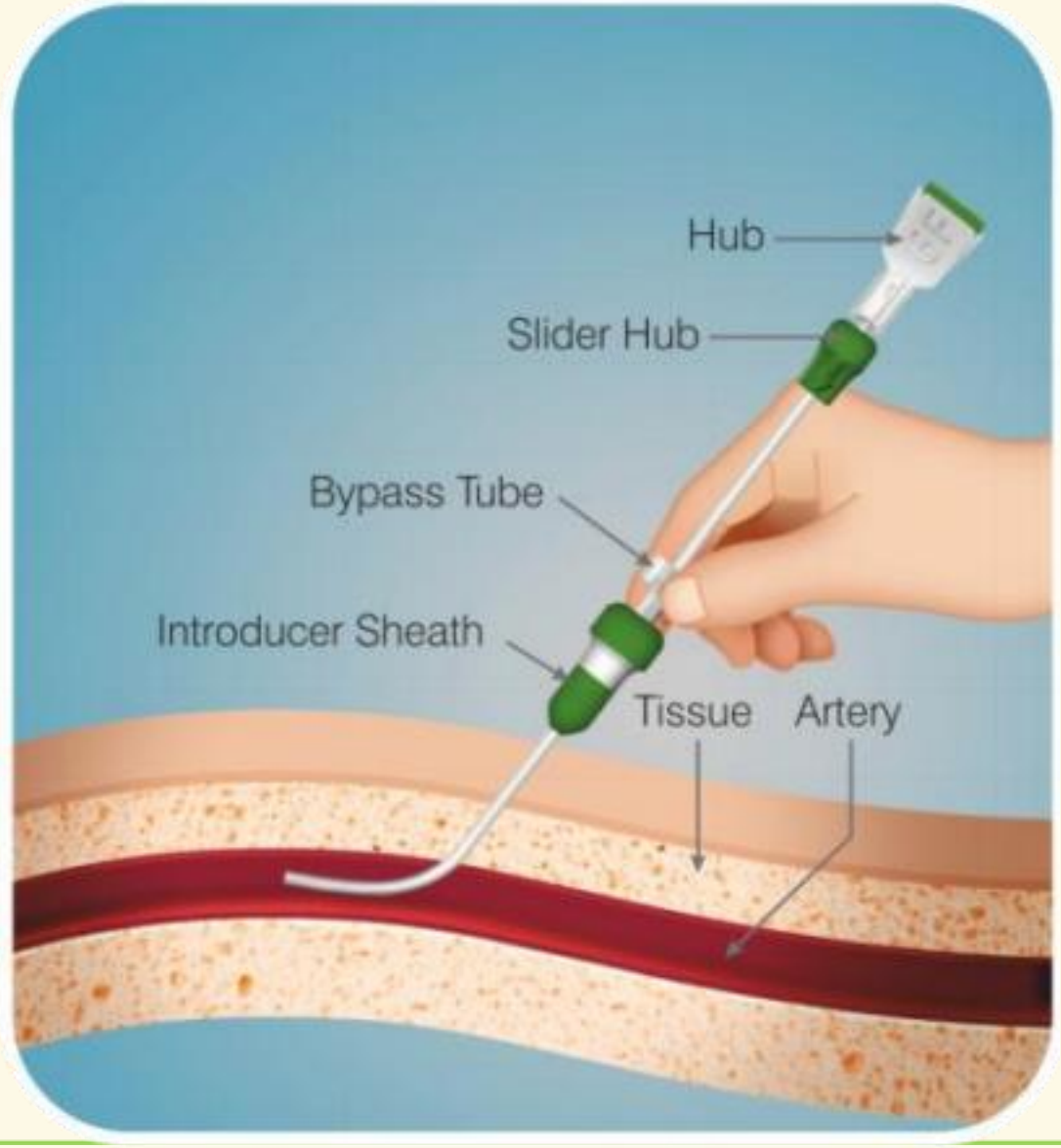
Rapid Absorption

Obtura facilities patient friendly sealing with the implant deployed at the puncture site which gets completely absorbed

Closure Procedure - Step 1

Step 1

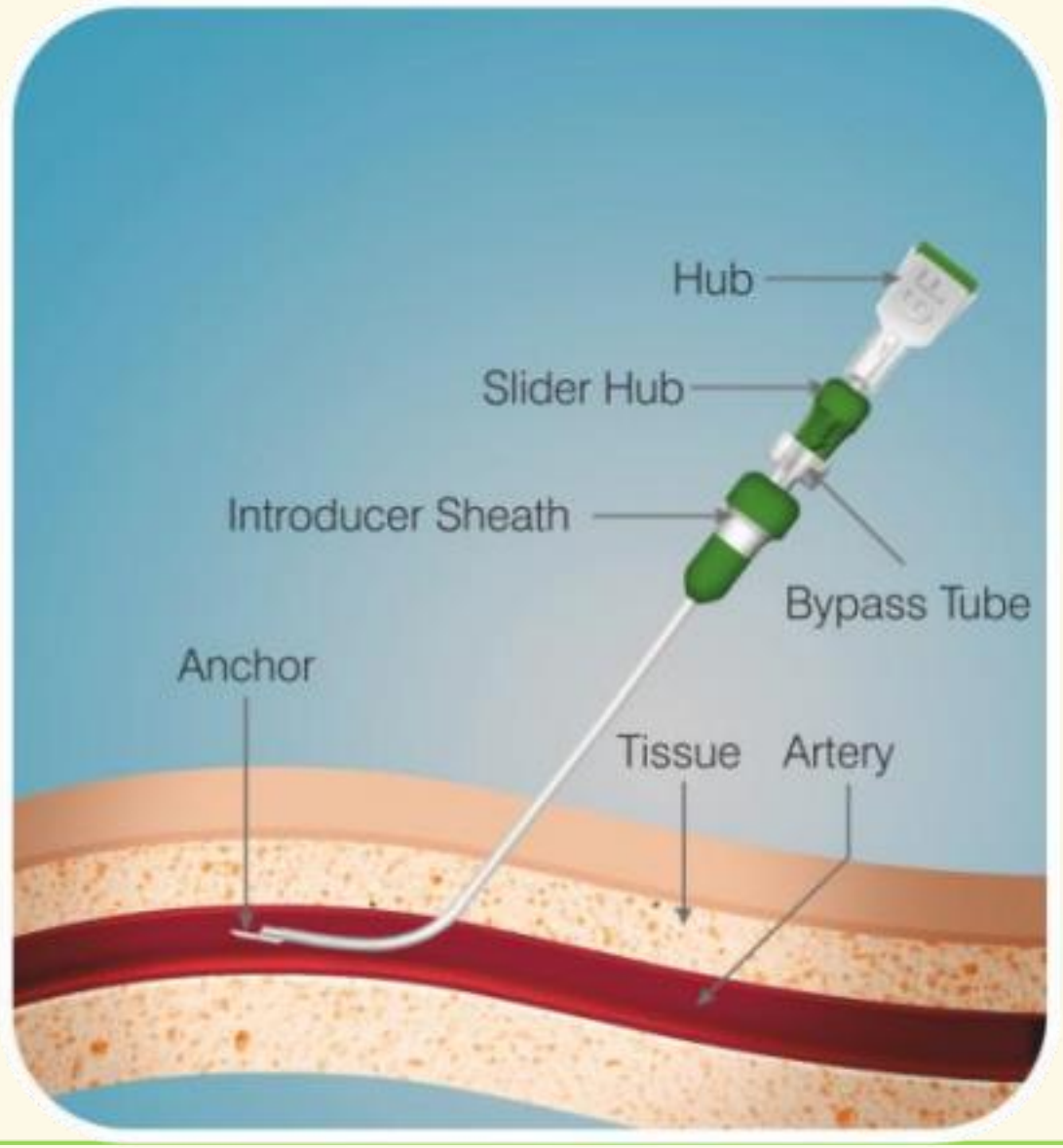
Hold the Obtura Vascular Closure Device at the Bypass tube between two fingers like a pen such that size indicator 6F/8F on hub and arrow mark on Slider Hub appears updwards and advance it into the introducer sheath.



Closure Procedure - Step 2

Step 2

Holding the slider hub with one hand , pull the hub until the black indicative market appears

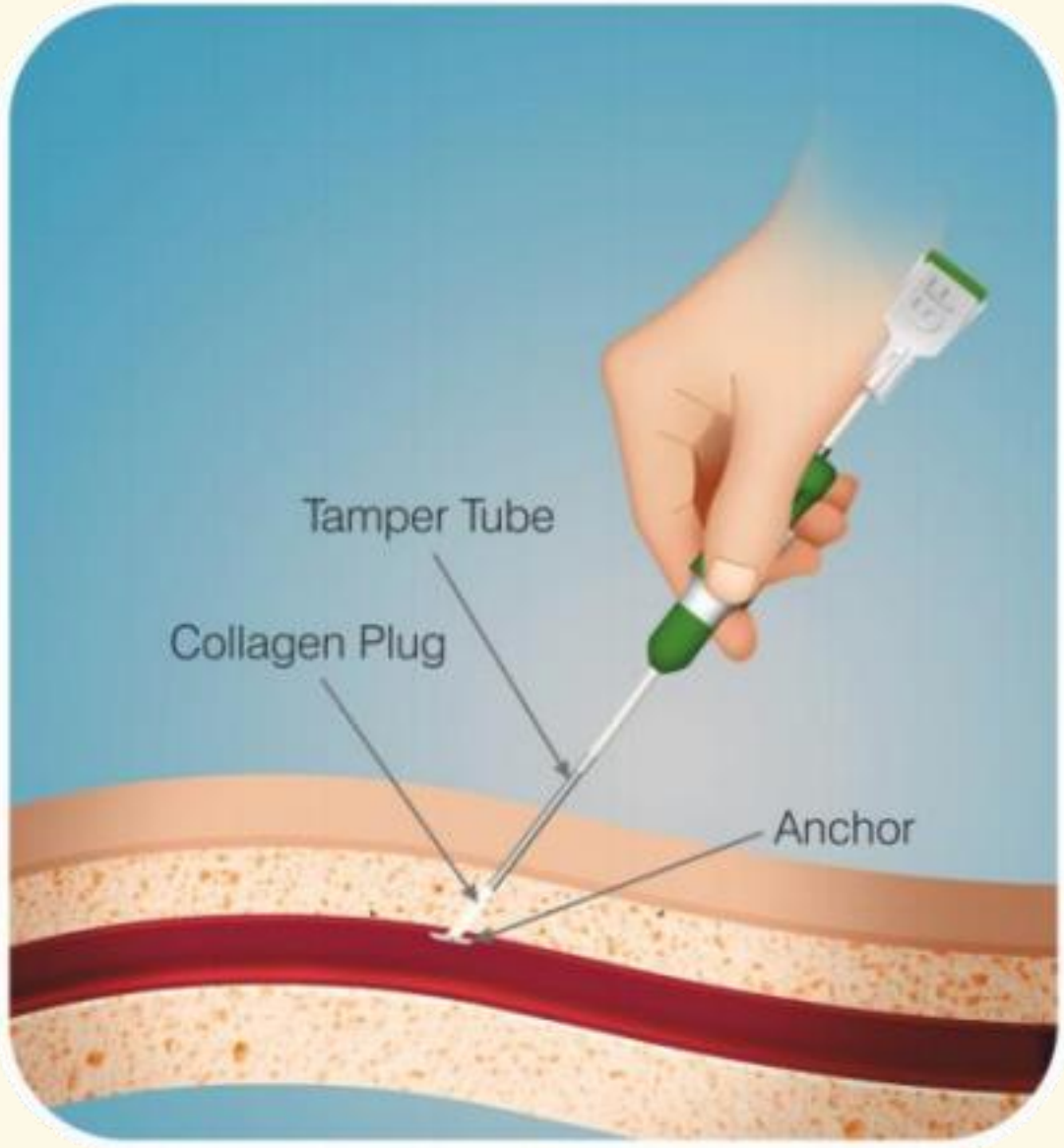


Closure Procedure - Step 3

Step 3

Hold the three components Hub- Slider Hub of the introducer sheath in the palm and retract the entire assembly along with the introducer sheath.

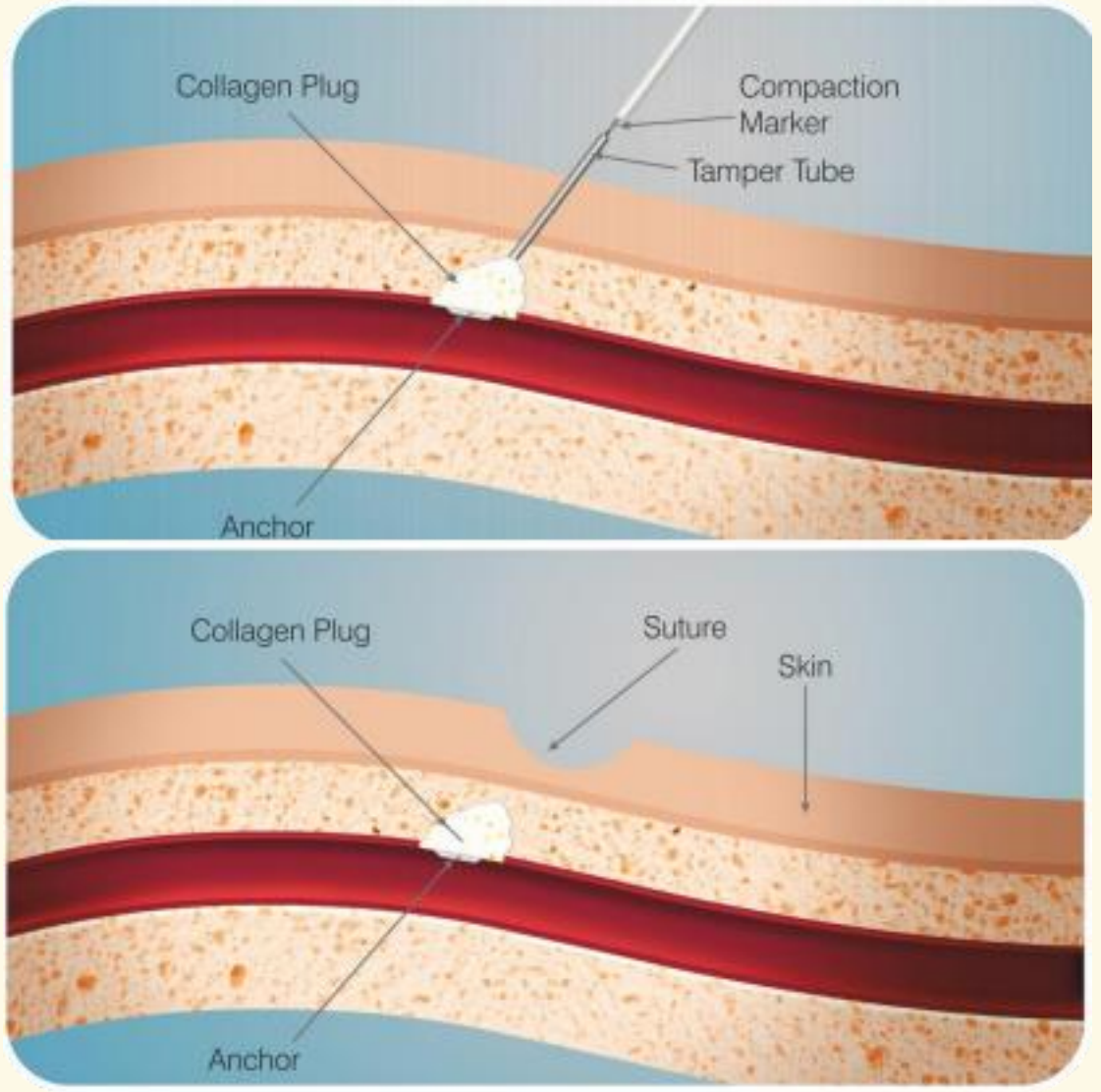
Keep a tension on suture



Obtura™
Vascular Closure Device

Deployment

- A complete seal is indicated when resistance is felt and Hemostasis is achieved.
- Cut the suture.
- Remove the tamper tube using aslight twirling upward motion.
- Gently pull upon the suture.
- Using asterile instrument, cut the suture below the skin level

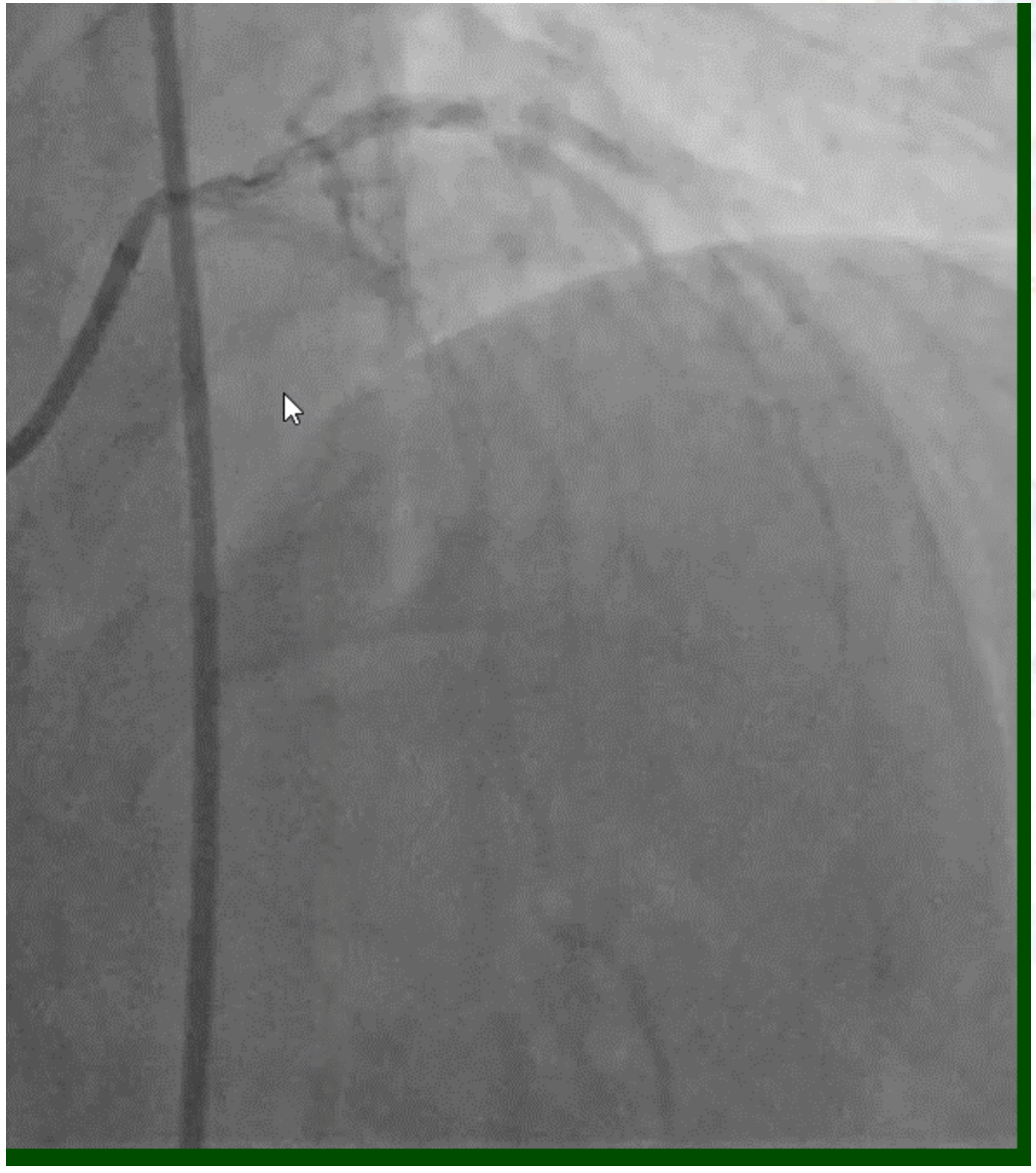


Obtura™
Vascular Closure Device

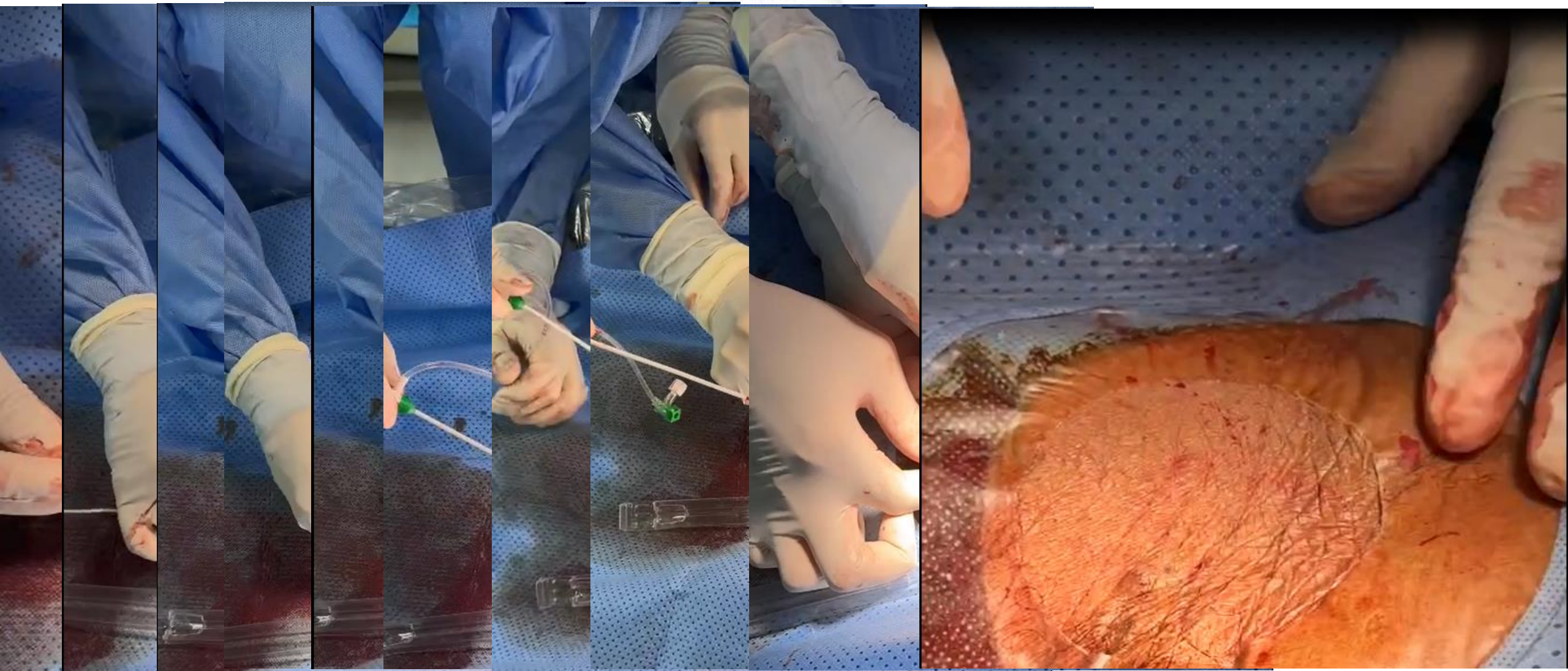
Technical specifications

Parameter	Specification
Device Size	6F and 8F
Device Total Length	205 ±10 mm
Device Effective Length	155 ±10 mm
Device Absorbable Material	Anchor - Poly(D,L-lactide-co-glycolide) (PDLG), Suture - Poly Glycolic Acid (PGA) and Collagen plug - Bovine type - I
Complete Degradation Period	90 Days
Device Size Compatibility	6F device compatible with 6F & 7F Introducer Sheath 8F device compatible with 8F & 9F Introducer Sheath
Absorption Profile	The Plug exhibits partial to advanced absorption at 45 - days, with complete absorption between 60 and 90 days post-implant

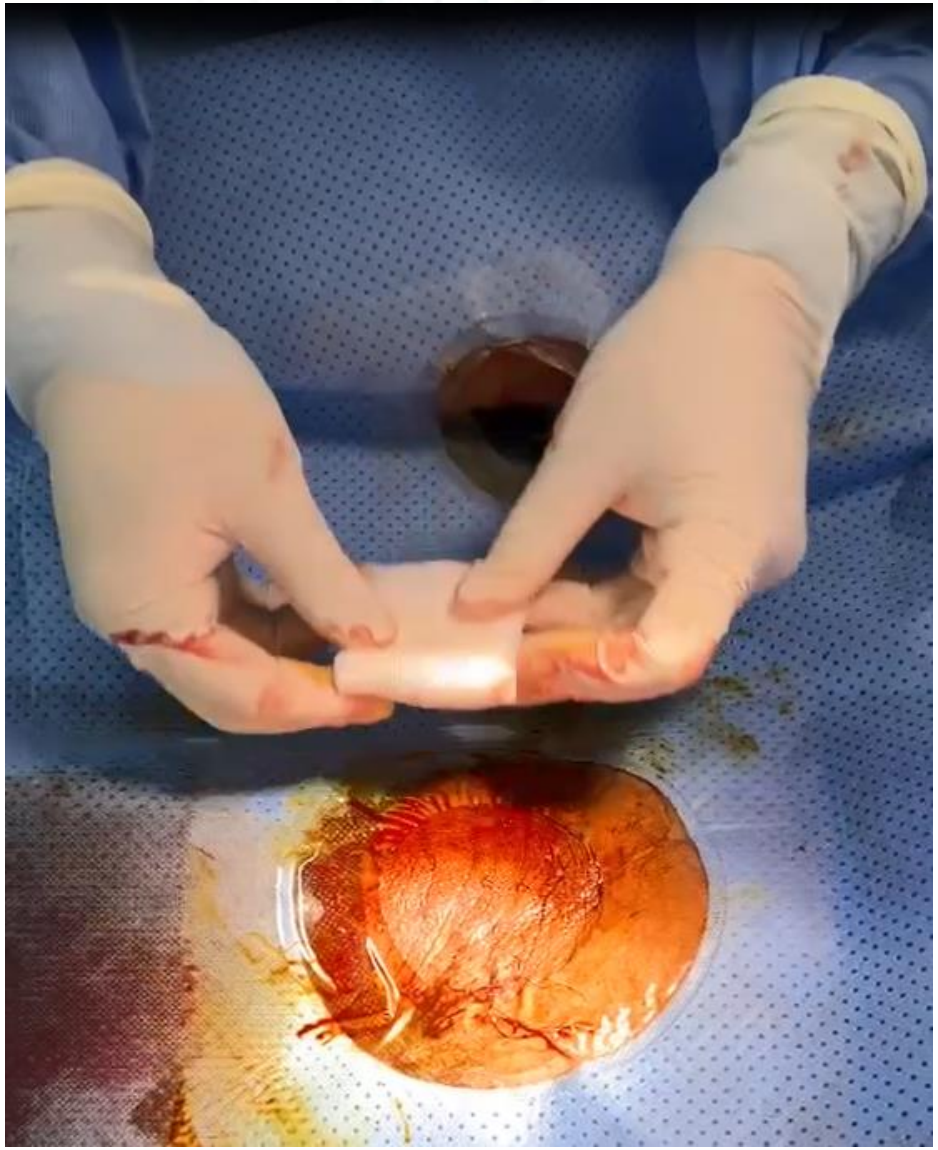
Common Femoral Artery



Step by step use Obtura



Final result



THANK YOU FOR YOUR ATTENTION