Vascular Closure

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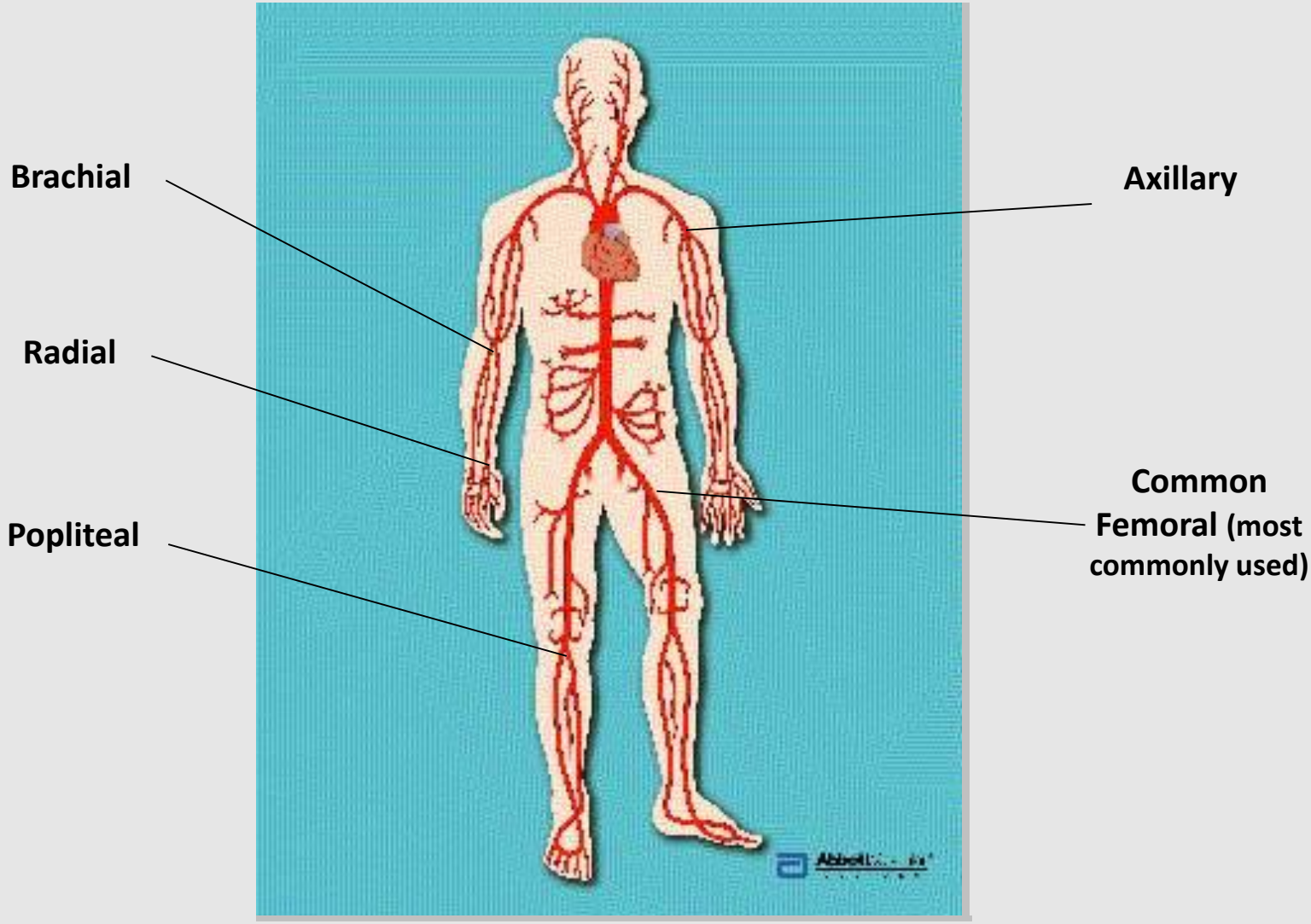
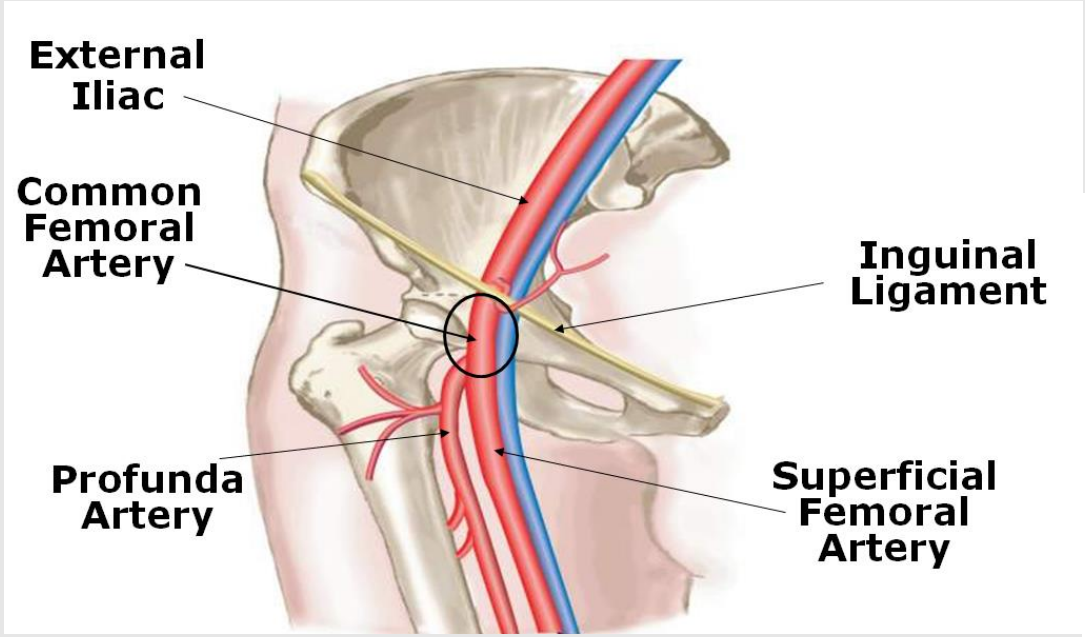
South Africa

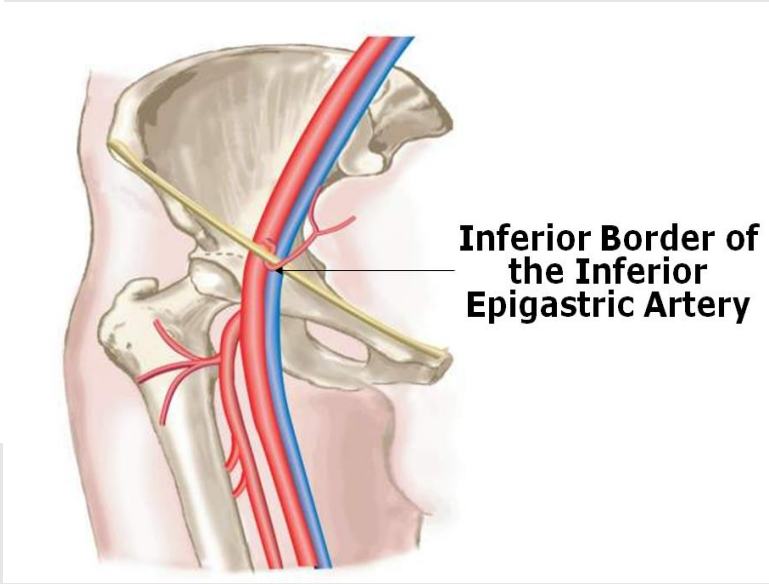
Arterial Access Site Locations



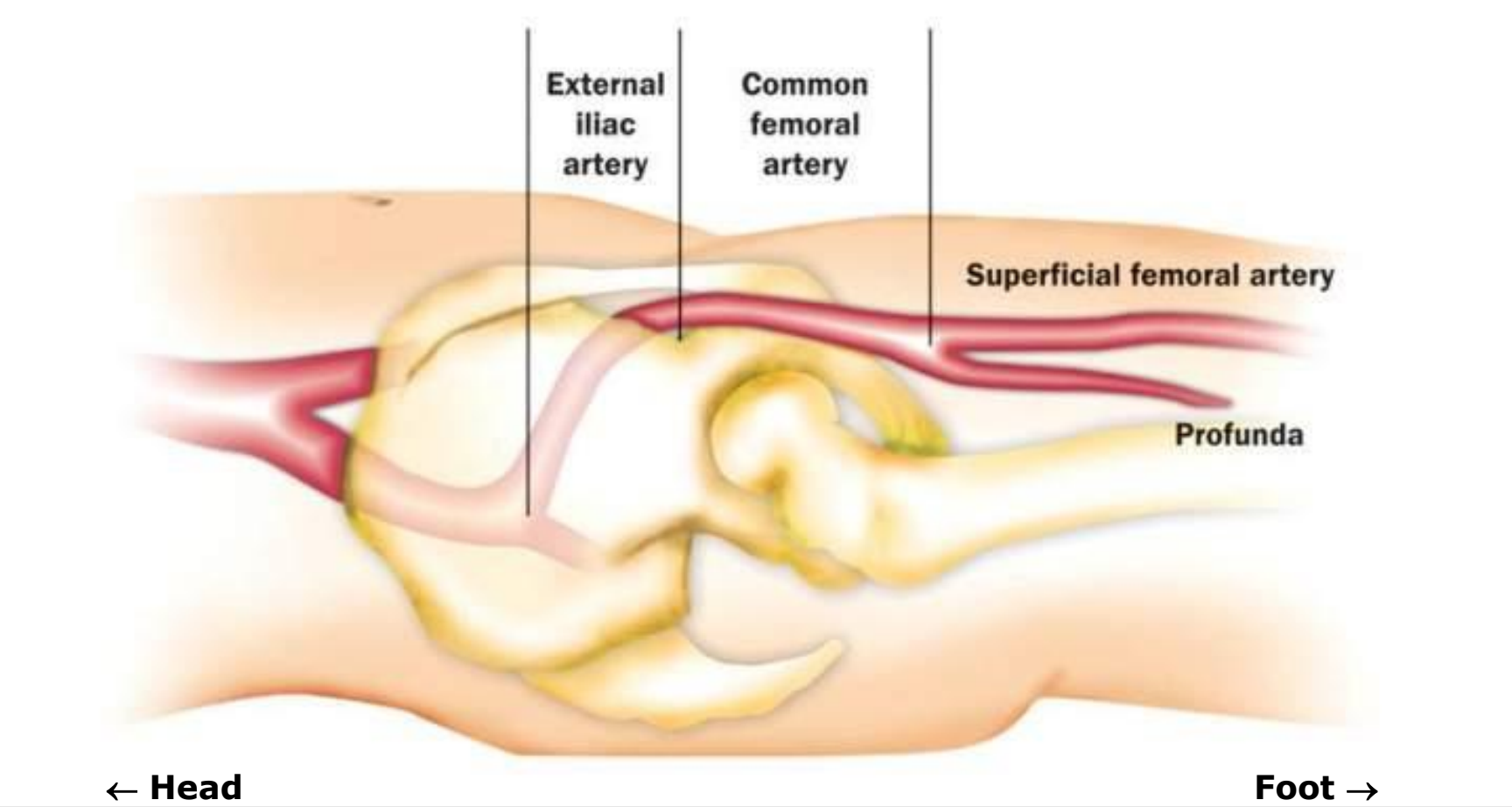
Femoral Access

- Puncture level
- View for femoral injection
- Timing of femoral injection

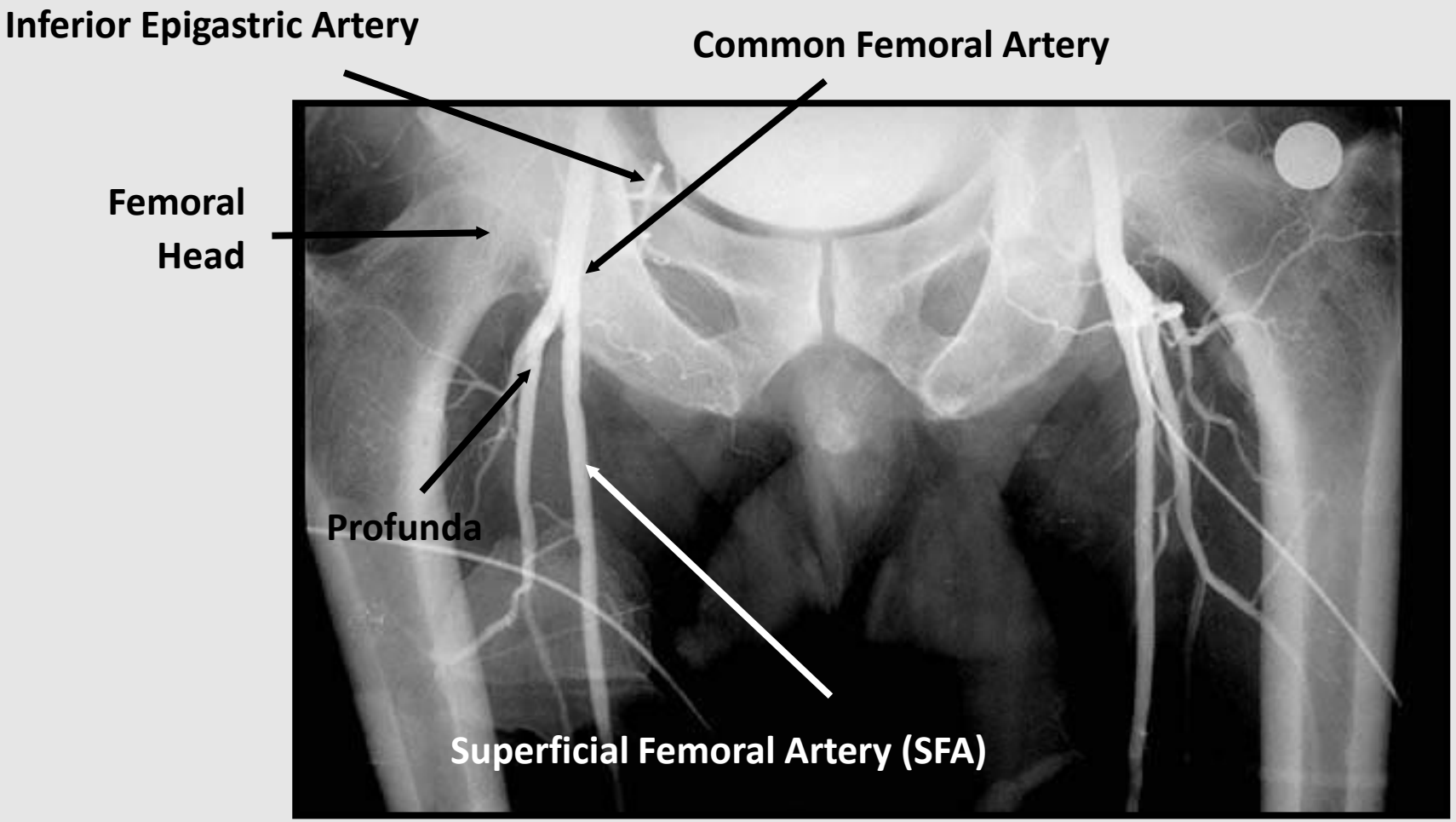




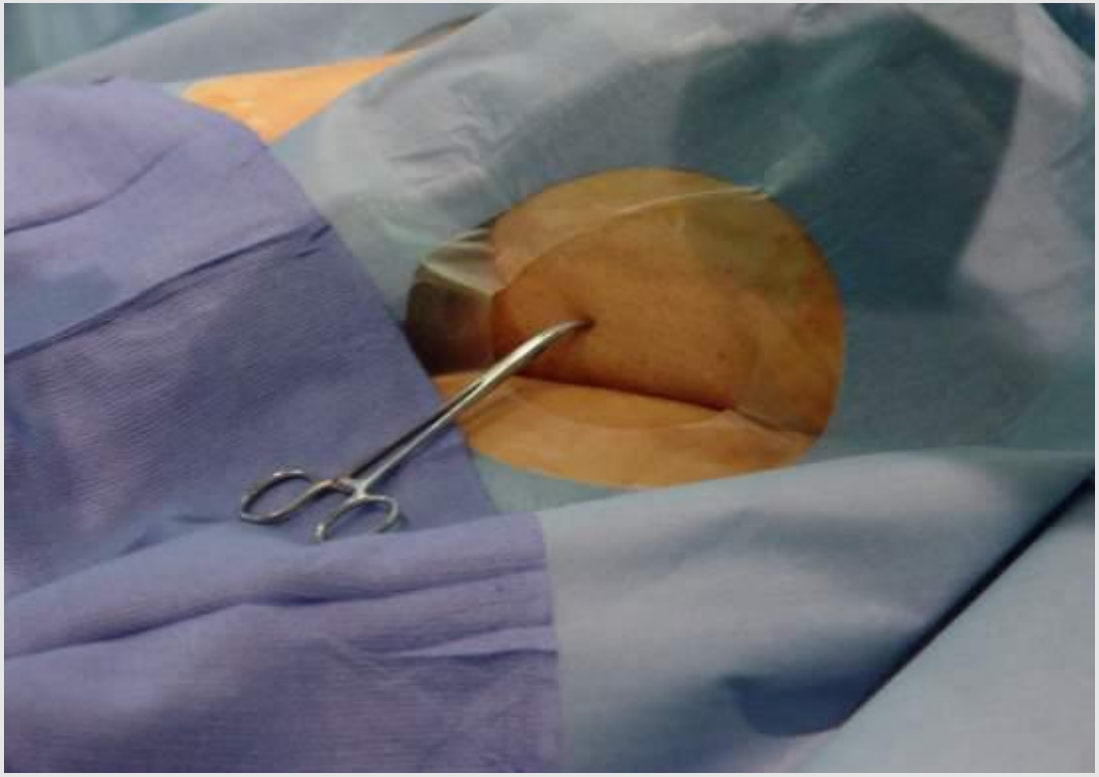
Femoral Anatomy – Lateral View

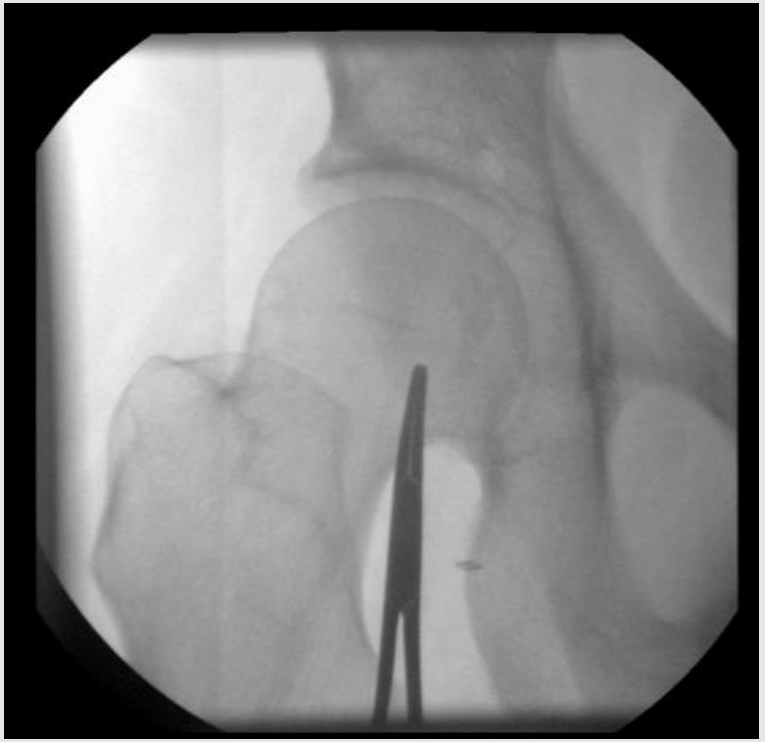


Common Femoral Artery Access



Locating Femoral Head

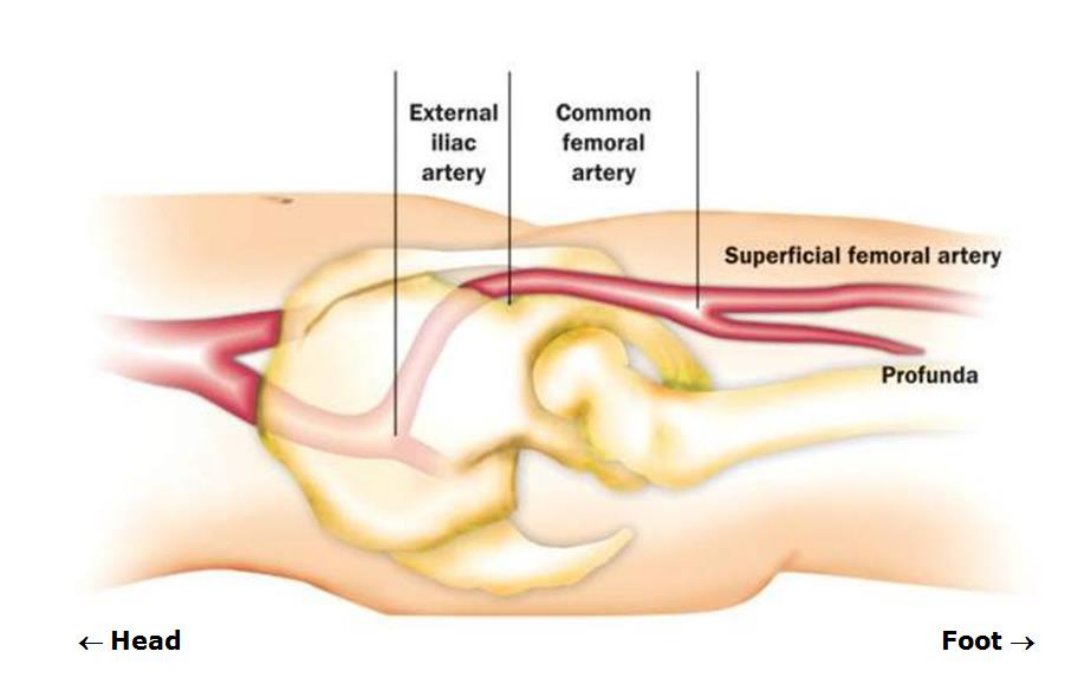




Recommended Approach

- Target the medial third of the femoral head as a reference point
- Target just below the horizontal mid-line of the femoral head

Perform Femoral Angio in Lateral View



In the lateral view one can:

- See exact sheath insertion point
- Note inferior epigastric reflection
- Visualise femoral bifurcation
- See where the artery dives posteriorly

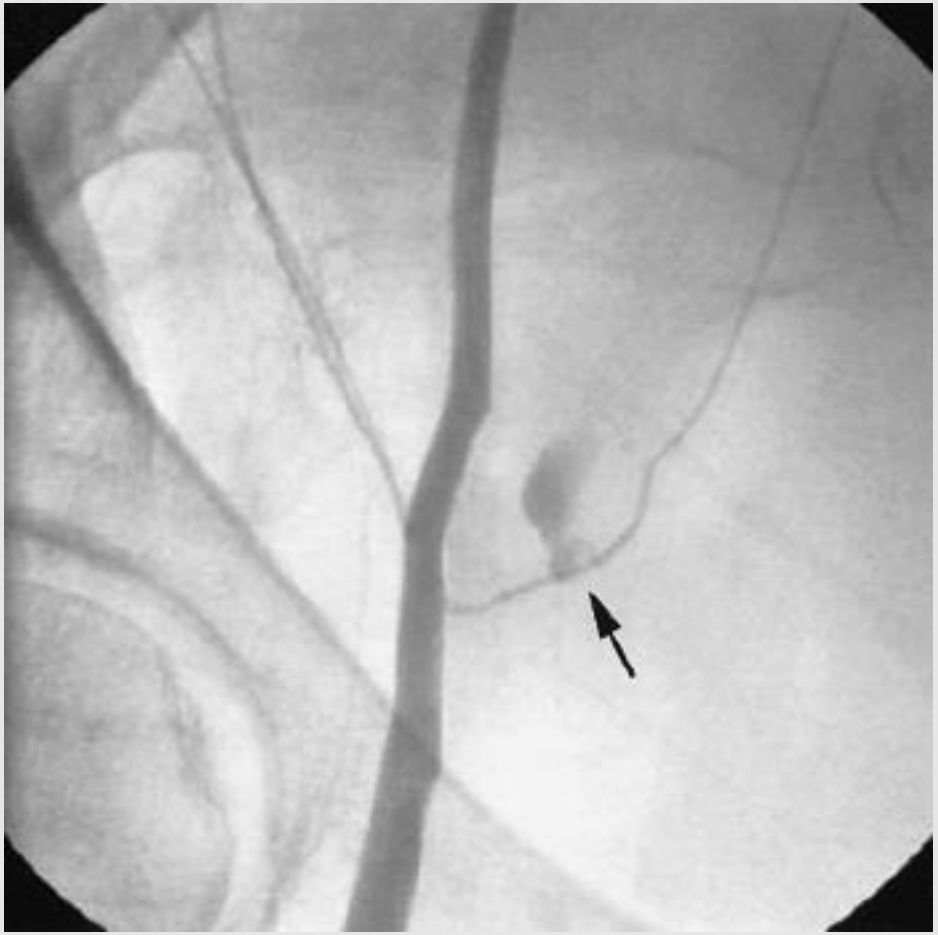
Role of Femoral Angiogram: LSD

- **L = Location**
  - Not too high or low
- **S = Size**
  - CFA > 4mm
- **D = Disease**
  - Peripheral vascular disease
  - Calcific vessels

Timing of femoral angiogram

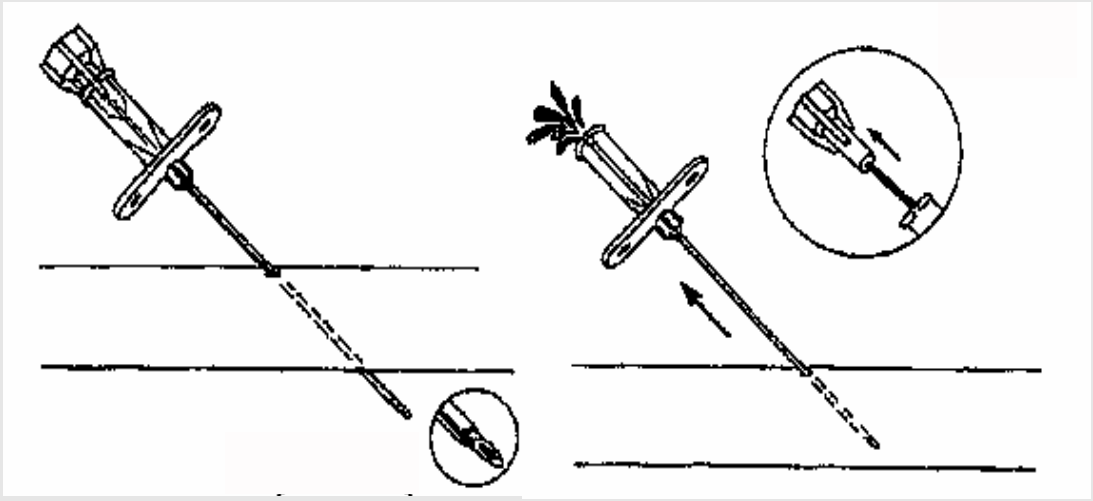
- At the beginning
  - Occult bleeding may stop during the procedure only to recur afterwards

Laceration of the inferior epigastric artery

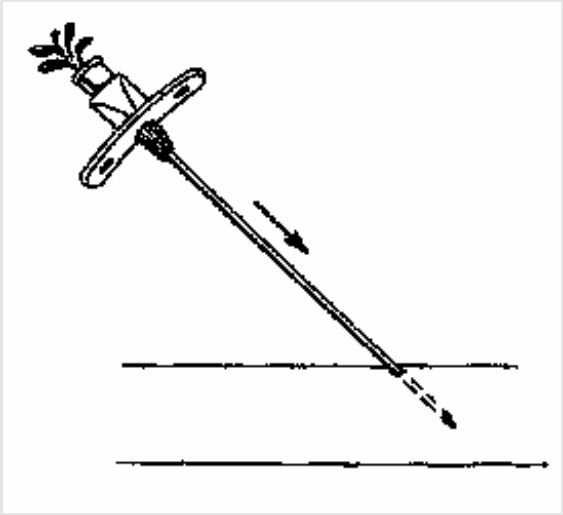


Silva et al, CCI 64: 212-222, 2005

Double-Wall Technique



Single-Wall Technique
(Modified Seldinger)



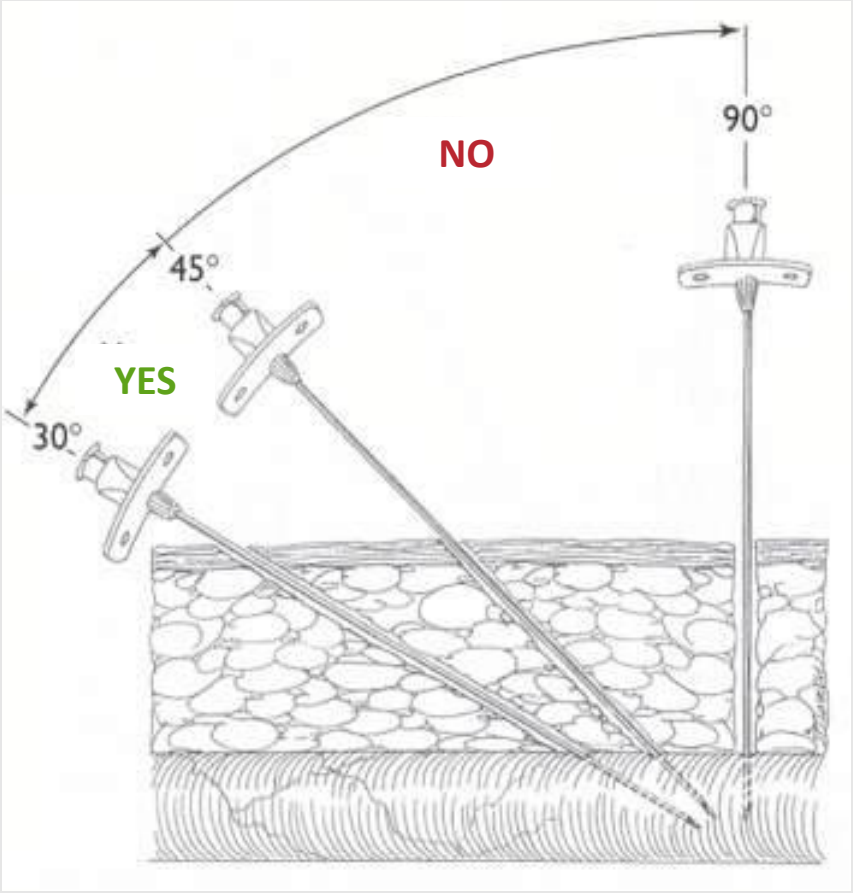
Retrograde Femoral Artery Access

Retrograde

- Against the arterial blood flow

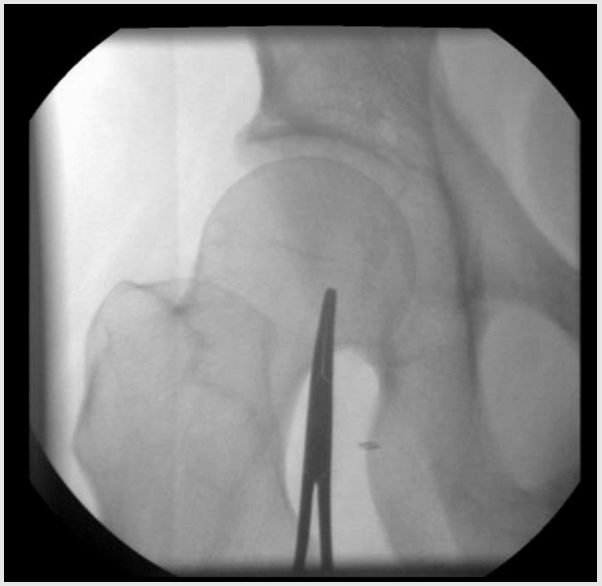
Level of entry

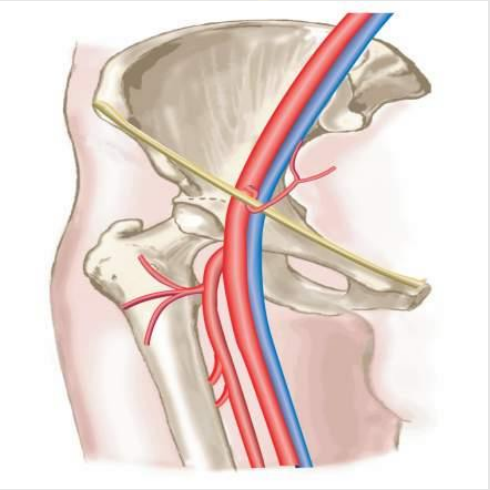
- Guided by palpable femoral pulse
  - Infra-inguinal position
  - Needle to vessel angle should be 30 – 45°
  - Facilitates guidewire passage into the target vessel
- Other guidance options
  - Ultrasound
  - Bony landmarks
  - Pigtail from opposite side
    - For large bore catheters



Summary: Approach to Femoral Puncture

- Identify landmarks
- Visualize femoral head
- Puncture just below and medial the center of the femoral head
- Perform femoral angiogram at the beginning of the procedure in lateral projection
- Visualize the Inferior Epigastric Artery and the femoral bifurcation





Patient Considerations

Favours closure devise use	Be careful using a closure device
Obese patients	Peripheral vascular disease
Coagulopathy	Small vessels
Chronic obstructive pulmonary disease	
Musculoskeletal problems	
Older patients	
Patients unable to cooperate	
Young active patients	

Anatomic Considerations

- Low or bifurcation stick
- High stick
- Significant disease of CFA
- Significant calcification of CFA
- Prior VCD use
- Severe angulation of sheath entry

Access location and anatomy where VCDs should not be used

Bifurcation stick

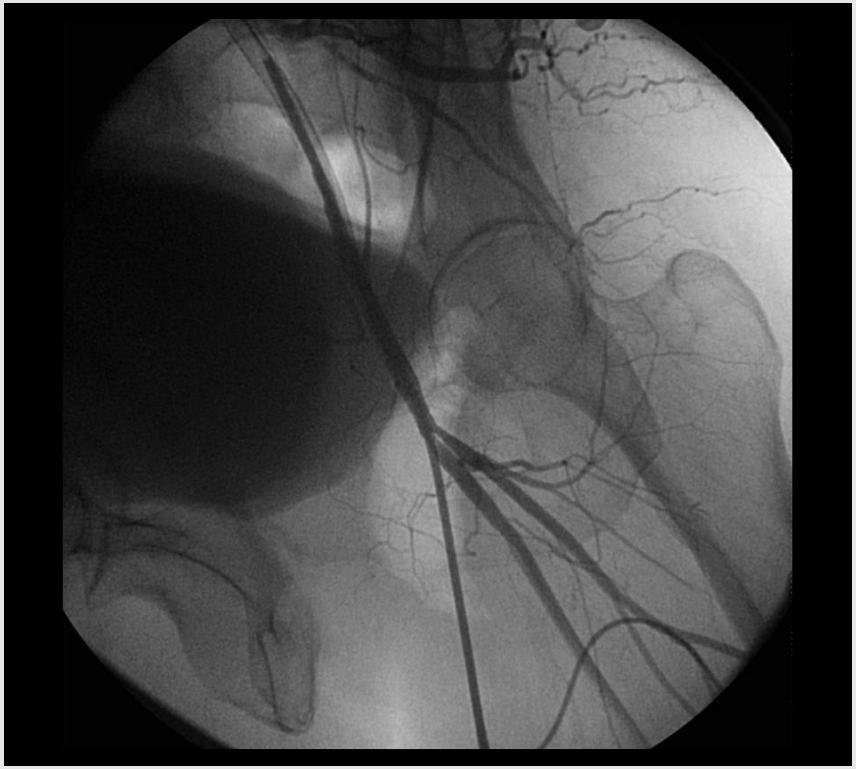
High stick

Lateral

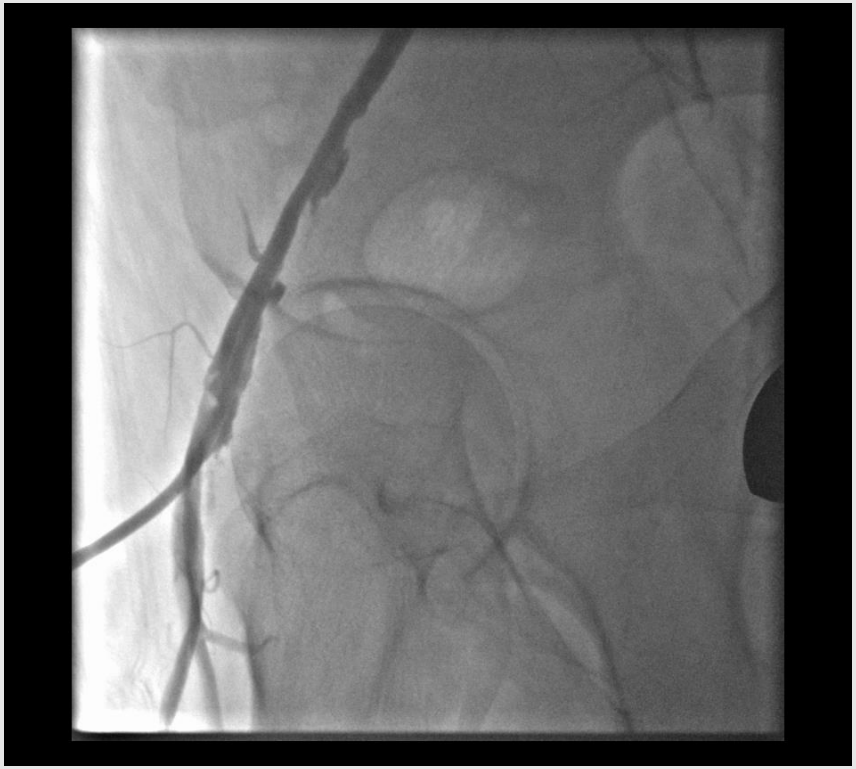
AP

Factors that influence outcome of VCD use

Small caliber vessel



Severe PVD



Procedural Considerations

- Anticoagulant and anti-platelet agents
- Location of stick
- Sheath size
- Time to sheath removal
- Need for repeat procedures

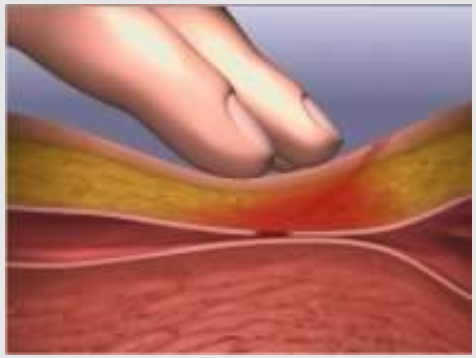
Achieving Haemostasis

Ideal Closure Device Characteristics

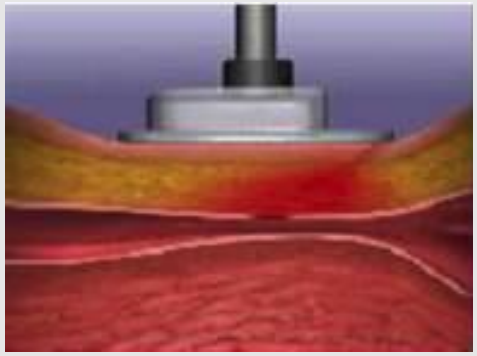
- Immediate haemostasis even in anti-coagulated patients
- Secure – no late bleeding
- Easy and reliable to use
- No complications
- Comfortable and allows immediate movement and ambulation
- Able to use in all clinical situations, including patients with peripheral disease
- Allows re-access of recently closed site

Methods of Achieving Hemostasis

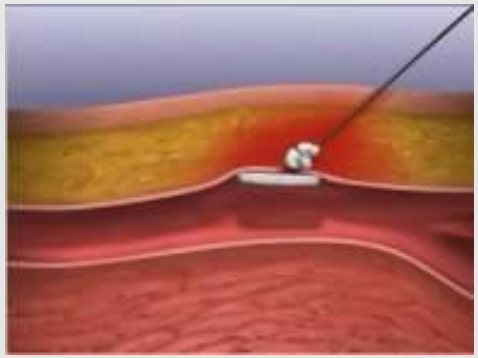
Manual Compression



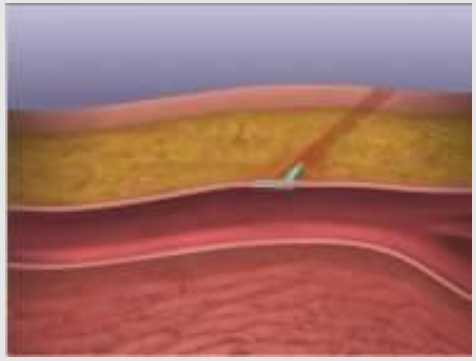
Assisted Compression



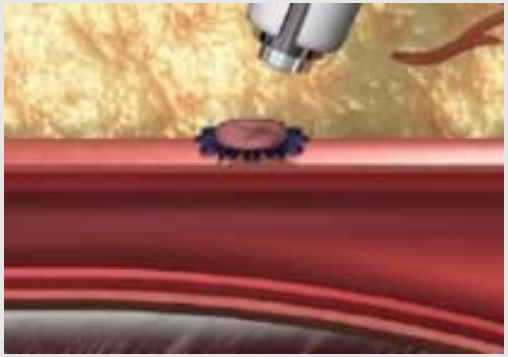
Collagen-Based



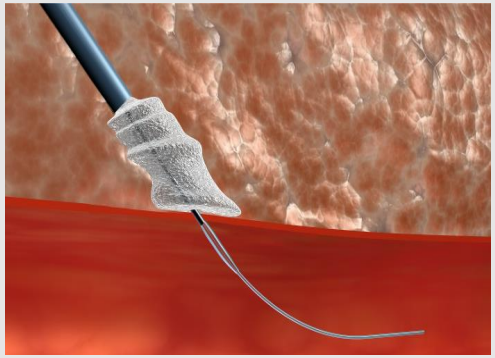
Suture-Based



Nitinol Clip-Based



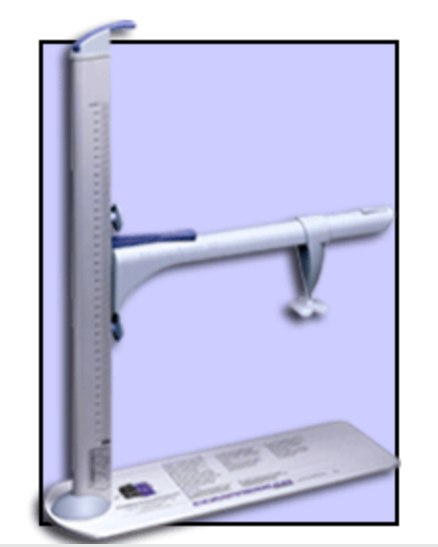
Extravascular PEG



Relative Advantages of methods

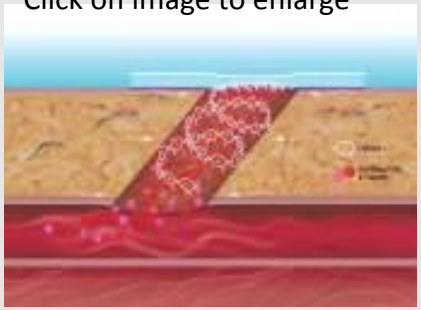
	Manual	Collagen	Suture	Nitinol clip	Extravascular PEG
Easy to do	-	+	- -	-	-
Early ambulation	- - -	+	+	+	+
Sheath Size limit	10F	9F	26F	8F	8F
Painless	- - -	+	- -	+	+++
Less intensive nursing	- - -	+	+	+	+
Nothing intraluminal	+++	-	+	+	++
Reaccess	+	+	++	+	+++
Wire can remain	- -	- - -	+++	- - -	++
OK with high stick	- - -	+++	+	+	-
Small femoral	+	-	-	-	+
OK with ++ calcium	++	+	-	-	-

Assisted Manual Compression



CompressAR® System
(Advanced Vascular Dynamics)

Click on image to enlarge



Chito-Seal™ Topical Hemostasis Pad
(Abbott Vascular)

Closure Technology

Active vs Passive

- ACTIVE:

  Mechanical approximators are active

  (ie. Angio-Seal, Perclose, Starclose)

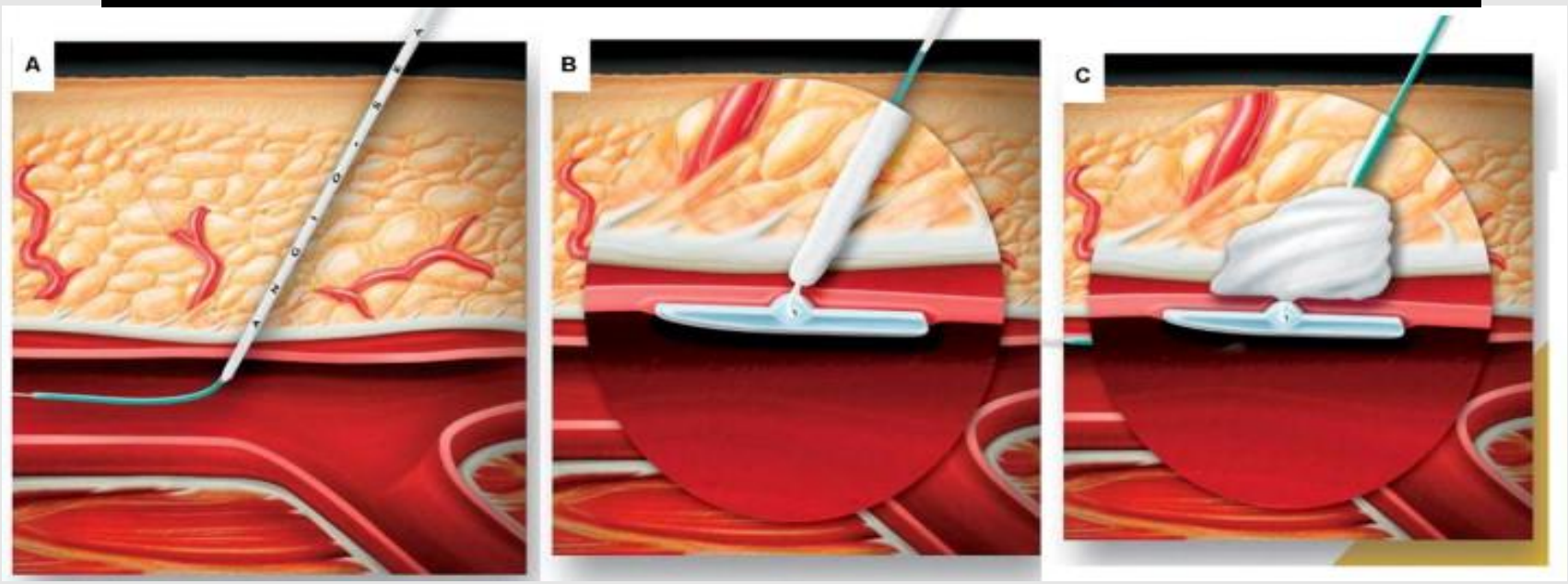
- PASSIVE:

  Cardiva Catalyst, Mynx

Intraluminal Vs Extraluminal

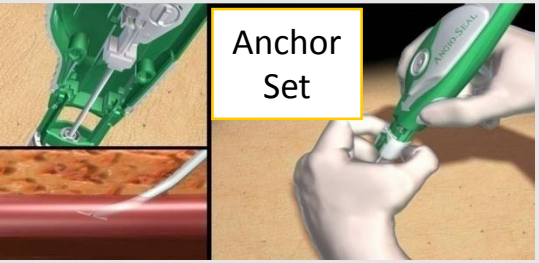
- Mynx and StarClose are Extraluminal

Angioseal



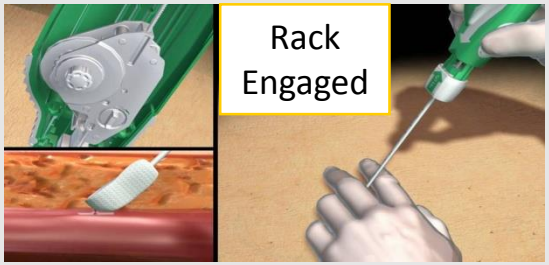
Angioseal Evolution

Automated Compaction



Gear Mechanism

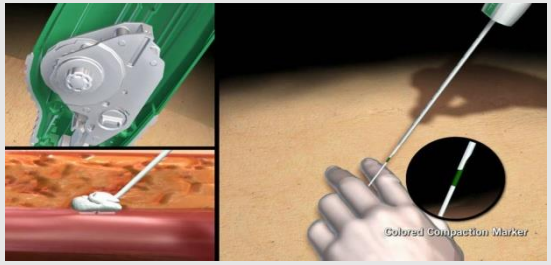
Designed with precision engineering to rotate as the device is pulled back by the user. Accurately manages the compressive sealing force.
"Standardized Deployment"



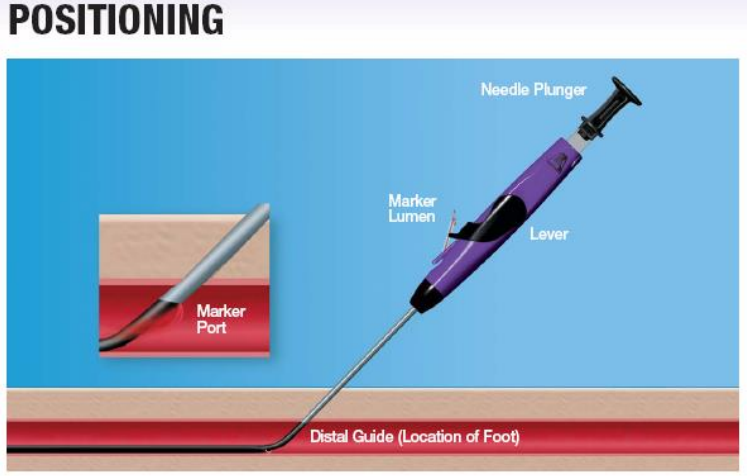
Rack

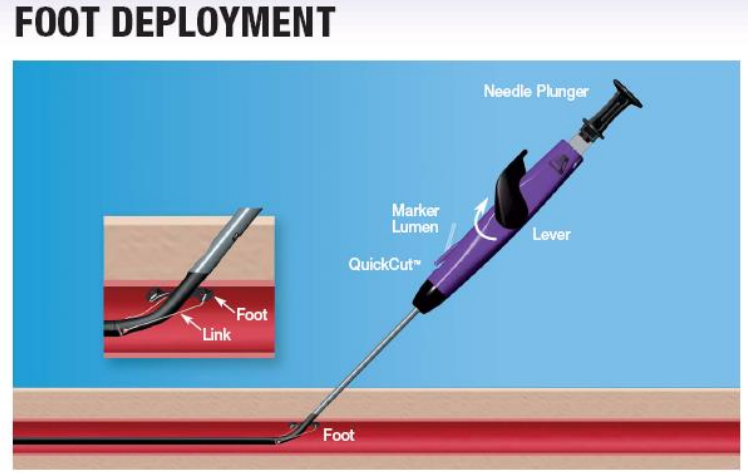
Precisely engineered for forward movement while user pulls back on the device. This forward movement guides the compaction tube forward.
"Automated Collagen Compaction"

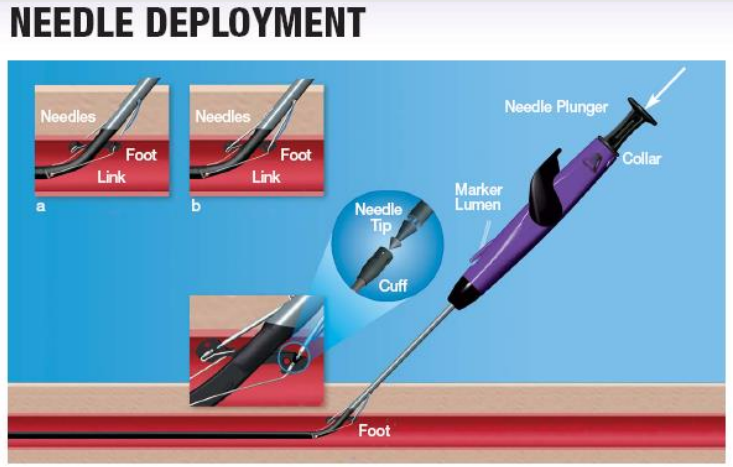
Ease of use

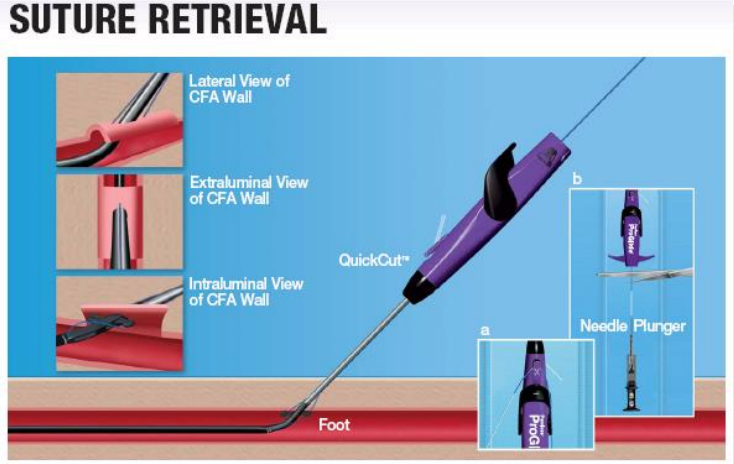


Perclose ProGlide



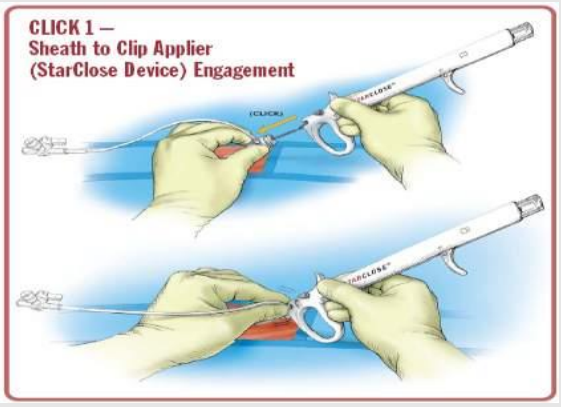


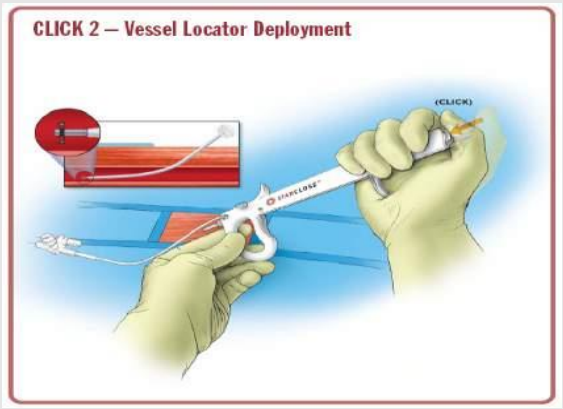


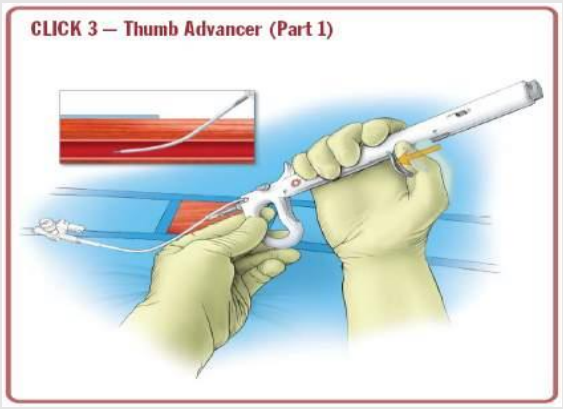


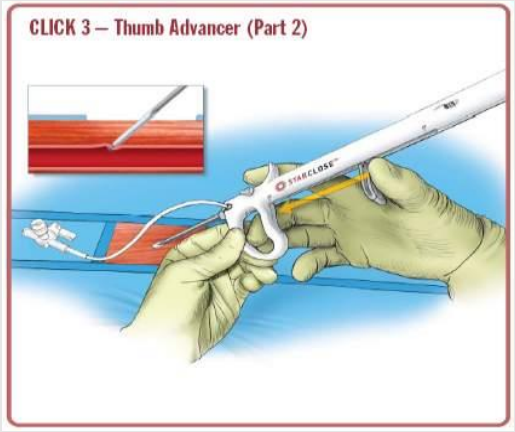
VCD of choice for large sheath closure

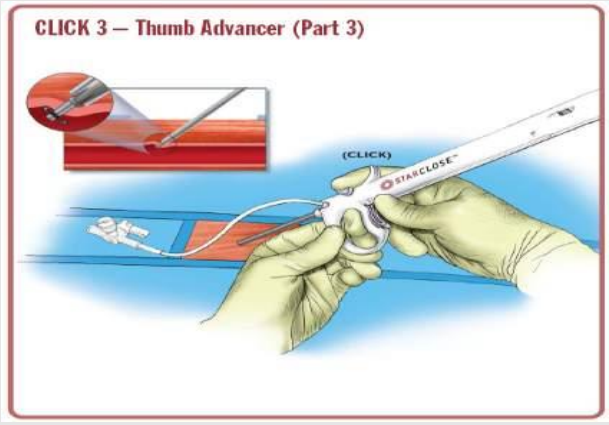
StarClose

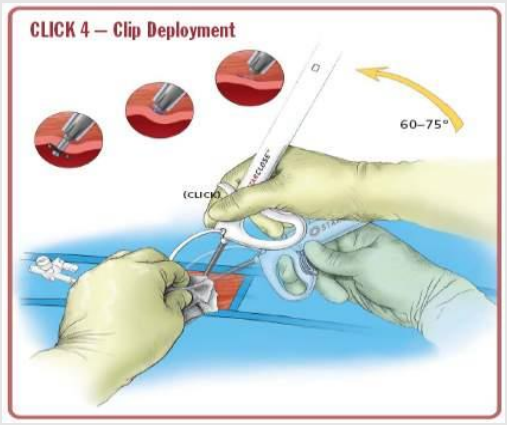

CLICK 1 –
Sheath to Clip Applier
(StarClose Device) Engagement


CLICK 2 – Vessel Locator Deployment
(CLICK)

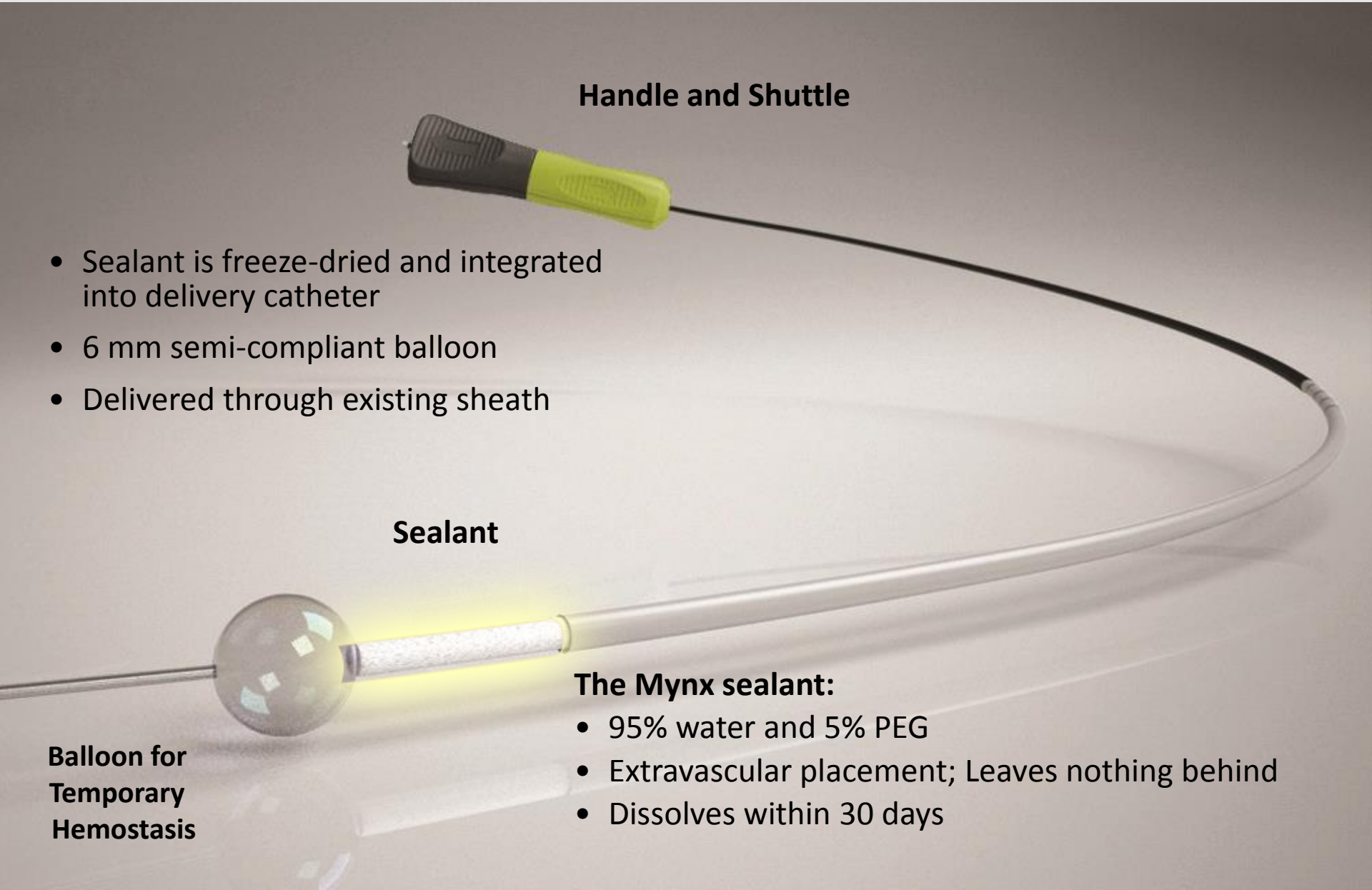

CLICK 3 – Thumb Advancer (Part 1)


CLICK 3 – Thumb Advancer (Part 2)


CLICK 3 – Thumb Advancer (Part 3)
(CLICK)


CLICK 4 – Clip Deployment
60–75°
(CLICK)

Mynx



- Sealant is freeze-dried and integrated into delivery catheter
- 6 mm semi-compliant balloon
- Delivered through existing sheath

The Mynx sealant:

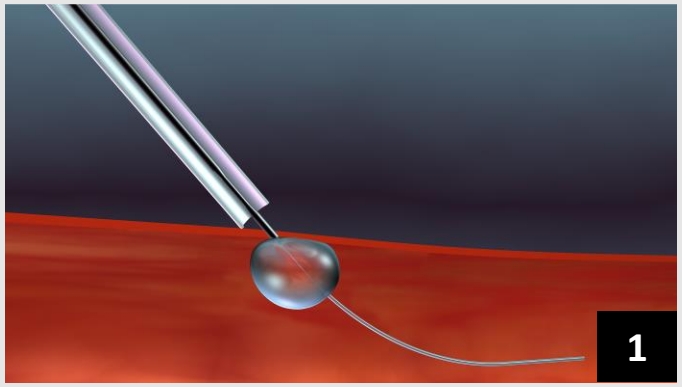
- 95% water and 5% PEG
- Extravascular placement; Leaves nothing behind
- Dissolves within 30 days

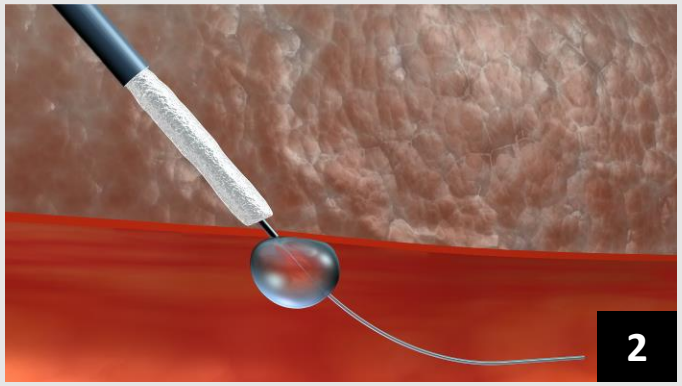
Procedure Overview

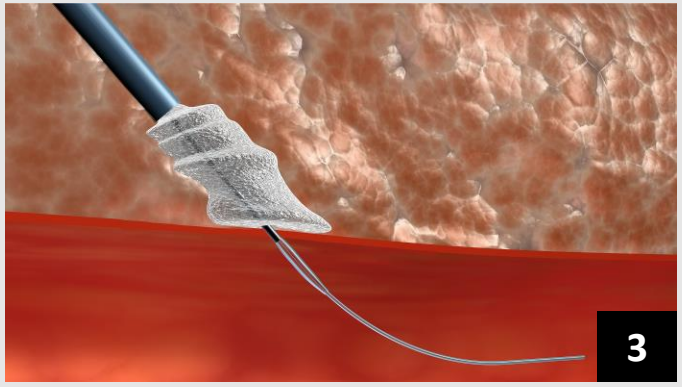
1. Insert Mynx into existing procedural sheath and inflate small semi-compliant balloon to create temporary hemostasis.

2. Deliver and unsleeve sealant, exposing it to blood and subcutaneous fluids, causing it to swell 3-4X.

3. Deflate balloon and remove device. Sealant is located on surface of arteriotomy.







Vascular Access Complications

What about Post-Cath Hypotension?

What can it be?

Bleeding
Bleeding
Bleeding

Subcutaneous Ooze

- Ooze: persistent slow bleeding from the skin puncture site after a percutaneous procedure
- Differentiating between capillary and arteriotomy bleeding
  - Challenge test the closure
  - Apply occlusive pressure over the arteriotomy
  - Pharmacology considerations
    - Injection of lignocaine with adrenaline
    - Hemostatic Patch / Pressure Dressing / Regular Manual Compression

Complications

- Haematoma
- Retroperitoneal Haematoma
- Pseudoaneurysm
- AV Fistula
- Infection
- Leg ischaemia

Haematoma

- Definition: collection of blood, as a result of hemorrhage from the vessel, within the soft tissues
- Difficult to quantify
- Not benign
- More common than hemorrhage or free bleeding

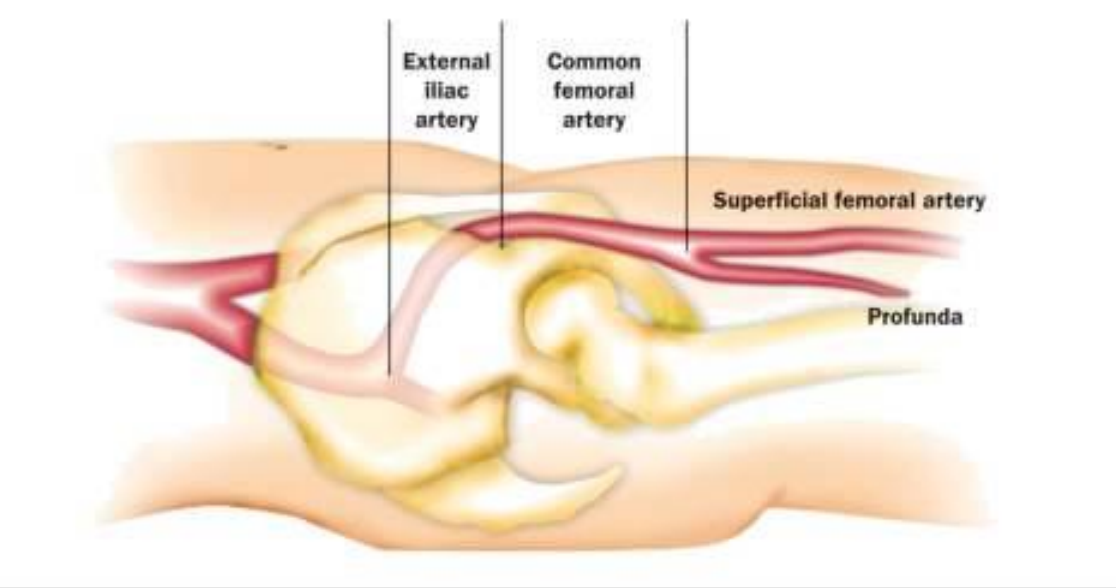
- Use manual compression
- Manage anticoagulation
- Can occasionally require reangio from the other side and occlusive balloon or covered stent or surgery

Incidence:
1-6%

Retroperitoneal Haematoma (Haemorrhage)

Definition: Bleeding into the free space behind the abdominal cavity

Incidence:
0.3-3%



Retroperitoneal Haemorrhage (RPH)

- The retroperitoneum can harbor a large volume of blood with few external manifestations; diagnosis is often made only after significant blood loss has occurred
- Failure to recognize a retroperitoneal bleed can have a fatal consequence
- Delay in recognition increases morbidity from blood loss, prolonged hypotension, need for further tests, procedures, or blood transfusions

Retroperitoneal Haematoma

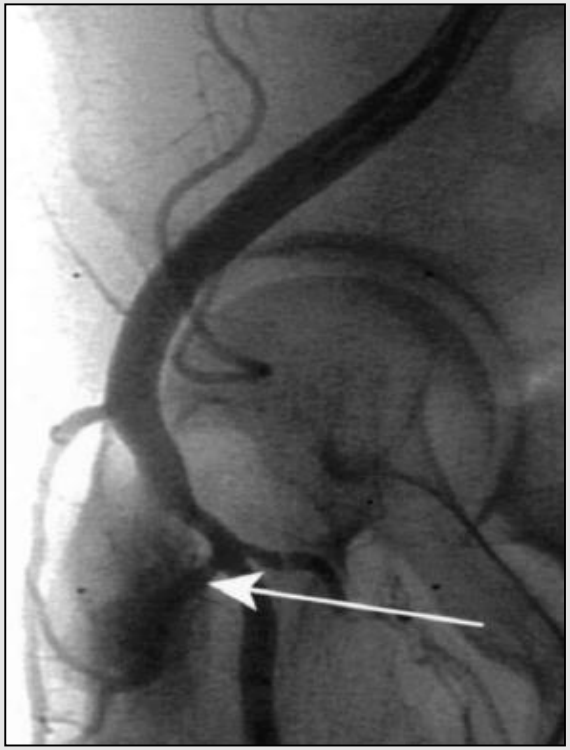
- Prevention
  - Identify patients at risk
    - High stick
    - Female
    - Low BSA
    - IIbIIIa
  - Careful femoral puncture

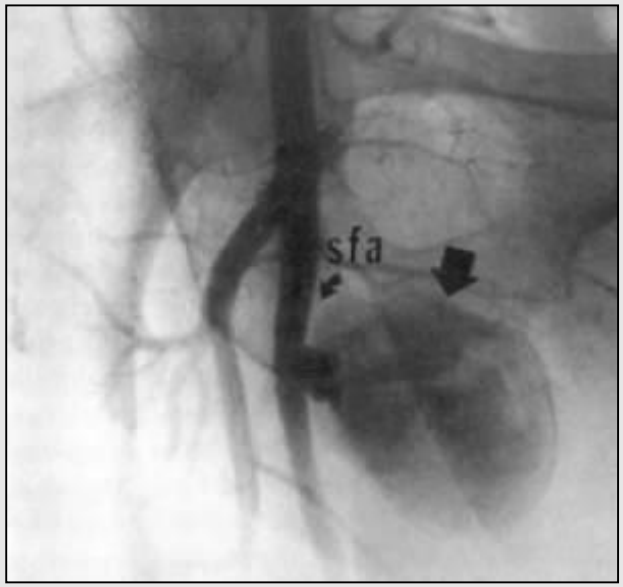
- Recognition
  - Similar to a vagal response!
  - Usually within 3 hours of procedure
  - Anaemia
  - Hypotension
  - Abdominal tenderness
  - Diaphoresis
  - Often there is no groin haematoma

- Treatment
  - Use manual compression independent of the closure device
  - Administer IV fluid and blood products as necessary
    - Most patients will settle within 2 hours
  - Occasionally requires surgery for bleeding or organ/nerve compression
  - Monitor patients for 4 hours

- Can occasionally require reangio from the other side and occlusive balloon or covered stent or surgery

Farouque HM, et al (2005). J Am Coll Cardiol 45:363-8.





Pseudoaneurysm

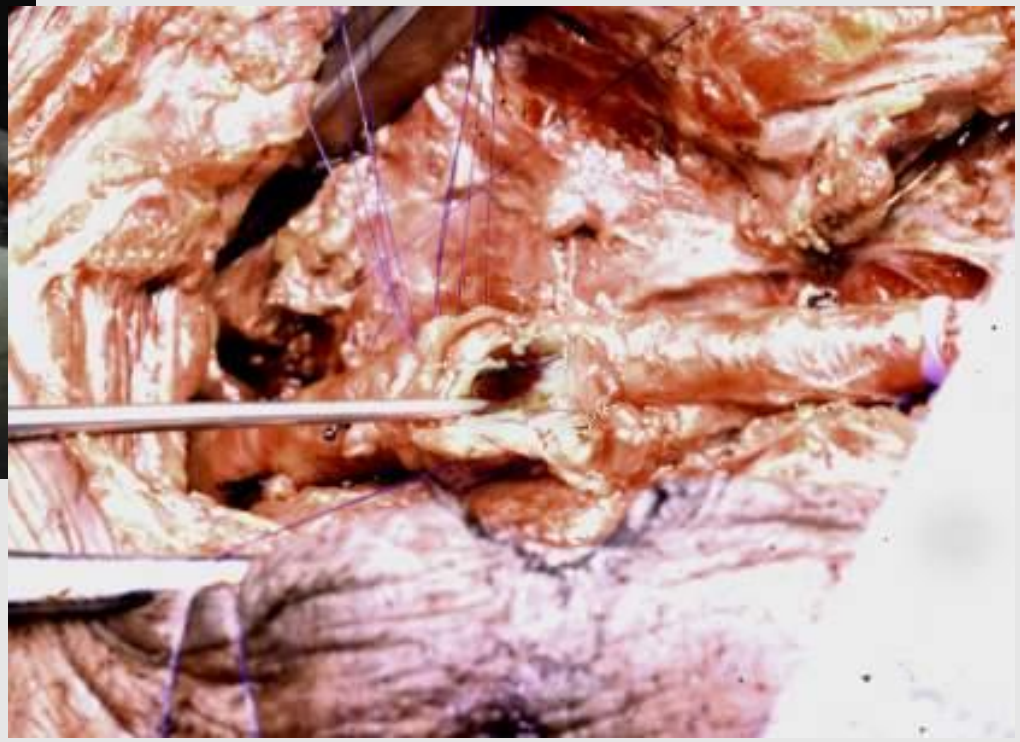
- **Definition:** A dilation of an artery with actual disruption of one or more layers of its walls with extravascular contained flow
- Can expand or rupture
- Painful
- Incidence - 0.5-1.0%
- Treatment
  - Ultrasound guided thrombin injection

Arteriovenous (AV) Fistula

- Predominantly asymptomatic
  - If large, may result in – High output CHF and limb ischemia
  - If small, stable or spontaneously resolve
- Due to
  - Large bore catheters
  - Aggressive anticoagulation
  - Poor access site location – associated with low access site SFA & Profunda
- Incidence 0.1%

Definition: Dilated connection between an artery and vein that allows blood to flow from the artery into the vein

Infection



Risk factors

- Diabetes
- Obesity
- Foreign body
- Sterile Technique Compromised
- Indwelling Sheath Time
- Poor patient hygiene

Incidence ≤ 0.25%

Ischemia – Thrombosis - Emboli

- Incidence < 1%

- Risk Factors
  - Large access catheter/small artery
  - Presence of peripheral arterial disease
  - Iatrogenic dissection
  - Thrombus within sheath

Wiley, J. Catheterization and Cardiac Interventions. 57:257-265, 2002.

Data

There is not one large randomized clinical trial of

closure device vs manual compression!!

Meta-analysis of 30 trials

	Relative risk of closure device vs compression	p
hematoma	1.14	0.35
bleeding	1.48	0.14
arteriovenous fistula	0.83	0.77
pseudoaneurysm	1.19	0.46
Surgical intervention	1.61	
transfusion	1.21	
Leg ischaemia	2.10	

E Riedmuller, M Nikfardjam, P Siostrzonek, M Mullner

There is a substantial learning curve with VCDs!

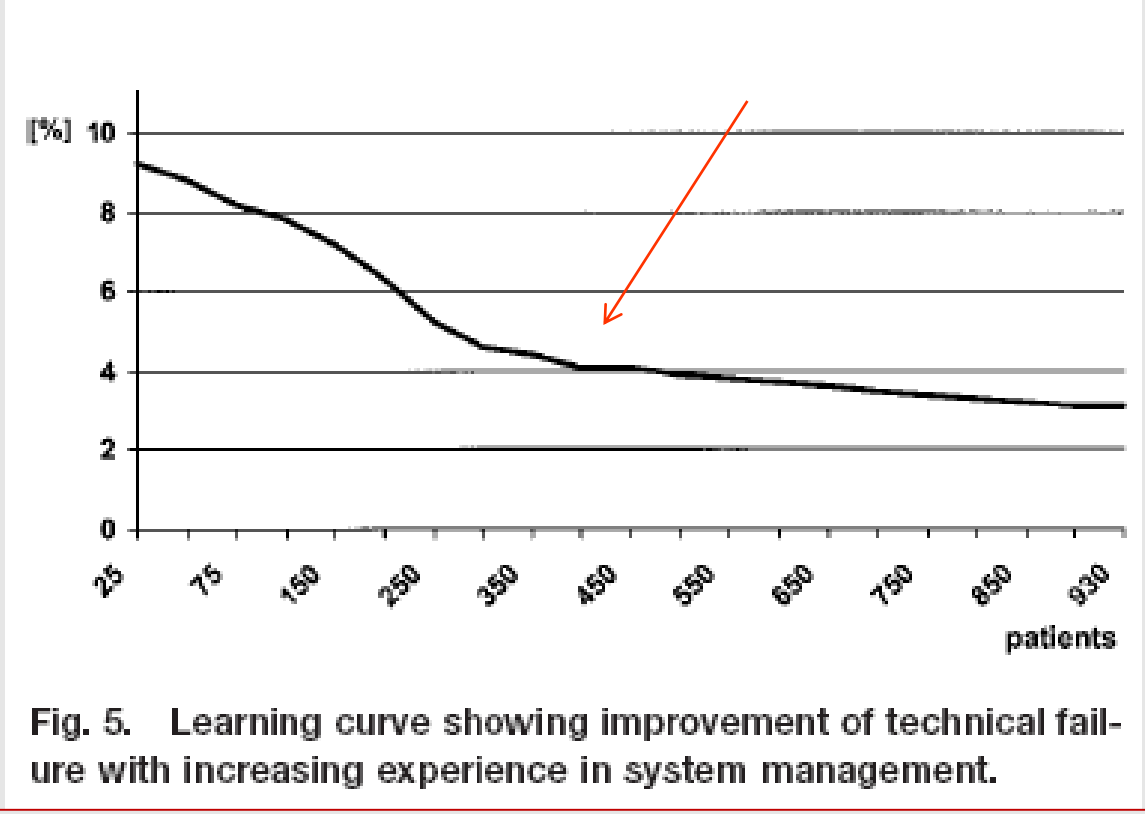


Fig. 5. Learning curve showing improvement of technical failure with increasing experience in system management.

Greater experience, multiple modifications of VCDs benefitting efficacy and safety!

Balzer et al CCI 2001; 53:174-181

Single Centre Experience

- 21841 patients
  - Closure device vs manual compression
- Any vascular complication
  - Closure device 1.3%
  - Compression 1.4%
- Odds Ratio
  - 0.86 for all procedures
    - 0.80 for diagnostic cath
    - 0.90 for intrventions

R. J. Applegate et al. Catheterization and Cardiovascular Interventions 67:556–562 (2006)

What to tell the patient

- **Access site care**
  - Keep access site clean and dry
  - Remove dressing within 24 hours post-discharge
  - Wash site daily with soap and water, standing
  - Reapply adhesive bandage after cleaning until skin is closed
  - Change dressing as needed
  - Oozing may occur

- **Activity restrictions**
  - The patient may resume normal activity in 2 days, including driving
  - Limit lifting to 5 kg for 7 days or until healed
  - You may shower 24 hours after the procedure
  - No bath or pool until skin is closed

Normal Patient Observations - Don’t worry

- Some soreness or discomfort for 7 days
- Some bruising that could last 14 days
- Formation of a small lump at the incision site that could last up to 6 weeks
- Mild oozing from incision site

Patients to Contact Physician if…

- Significant bleeding
- Increased swelling to the groin or leg
- Unusual pain in access site or leg
- Non-healing wound
- Increased redness
- Incision warm to touch
- Pain or swelling at the site
- Drainage other than blood
- Fever or chills

Question 1

For femoral access, this is an unacceptable method of locating the appropriate puncture site:

a. Ultrasound guidance
b. Flouroscopy of femoral head
c. The position of the skin crease
d. Use of bony landmarks

Question 2

Which method of vascular closure leaves some material inside the artery

a. Angio-Seal
b. Mynx
c. Manual compression
d. Starclose