Cordis **EXOSEAL**®

Vascular Closure Device

A Guide to Good Access and Closure

Transfemoral Access Closure Pocket Guide

Cordis

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Closure Procedure

This document is not intended to be used as a training guide. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device(s).

A Guide to Good Access and Closure

Introduction

Advance preparation by physicians followed by good access confirmed by femoral angiography is the formula for patients to derive the benefits of vascular access site closure over manual compression.

Compared to manual compression, vascular closure devices offer a reduction in time to hemostasis*, time to ambulation*, therefore helping to reduce the medical costs and optimize resource utilization. Vascular closure devices have been shown to be safe and effective*.

This booklet includes information on the following:

1. Femoral artery anatomy
2. Techniques for optimizing femoral artery access
3. Angiographic techniques for obtaining femoral artery access
4. Angiographic selection criteria for using the EXOSEAL™ Closure Device
5. Selected patient case presentations of appropriate and inappropriate candidates for puncture closure using vascular closure devices

* ECLIPSE Trial Wong et al JACC Cardiovasc Interv. 2009 Aug;2(8):785-93.

Femoral Arterial Anatomy

Anatomy of the Femoral Access Site

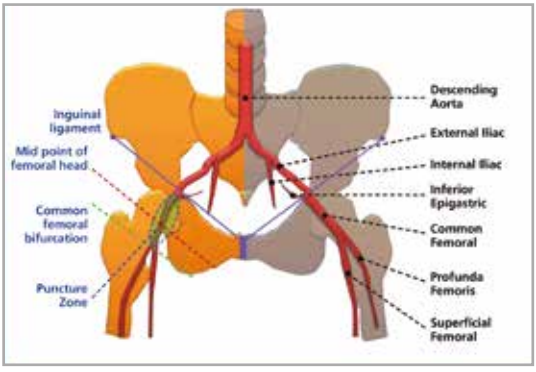
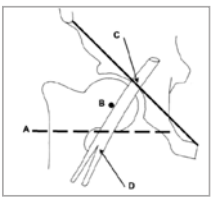


Image courtesy of Imad Nadra, BSc, MRCP, and Martyn Thomas, MD, FRC

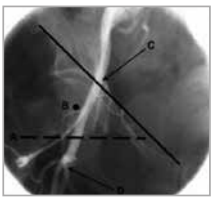
Techniques for Femoral Artery Access[1,2]

1. Position and drape patient on catheterization table[1]
   - Drape opening should permit access to the femoral artery
     - Especially important when draping obese patients
2. Confirm location of the femoral head using the Landmark technique[1, 2]*
   - Palpate the common femoral artery (CFA) and locate the anatomical landmarks of the anterior superior iliac spine and pubic symphysis to identify the level of the inguinal ligament
   - Puncture approximately 2 cm below the inguinal ligament at the level of the CFA
   - Use the Modified Seldinger Technique to direct the needle at a 30 – 45 degree angle
3. Access the femoral artery[1, 2]
   - Identify the femoral pulse
   - Insert access needle at 45° angle
   - Direct access needle to enter below the center line and toward the medial half of the femoral head
   - After sheath placement, perform femoral angiography in an ipsilateral view

Anatomy of the common femoral artery[3]



Angiography of the common femoral artery[3]



Images courtesy of Zoltan Turi, MD

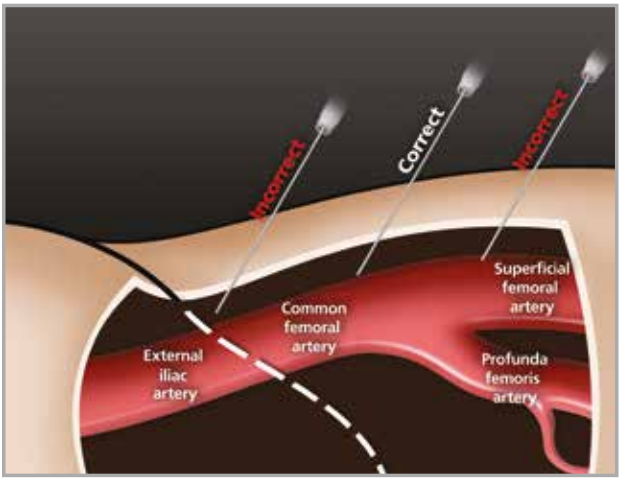
A = inferior border of the femoral head.
B = center of the femoral head.
C = transition between the external iliac artery and the common femoral artery.
D = bifurcation of the common femoral artery.

* Rashid MN and Bailey SR. Percutaneous femoral access and vascular closure devices. 2007. SIS yearbook.

Techniques for Femoral Artery Access

Modified Seldinger Technique

Use a 30° to 45° angle of needle entry into the common femoral artery



Angiographic Techniques for Obtaining Femoral Artery Access

- Contrast media injection through side arm of sheath
- Oblique projection to assess bifurcation location
  - Optional: caudal view is beneficial to low-access sheath entry
- Check points
  - Puncture location
  - Vessel size
  - Presence of disease

Angiographic Selection Criteria for Using the EXOSEAL® Closure Device[4]

V (Vascular access site)

- The sheath is in the common femoral artery

C (Caliber or size)

- ≥5 mm internal diameter

D (Disease/Deterrents)

- No or minimal atherosclerotic disease detectable from the arterial access site
- <50% luminal narrowing
- Typical vasculature or minimal tortuosity

Clinical Considerations for Puncture Closing Using the EXOSEAL® Closure Device

Access in the target zone of the femoral artery

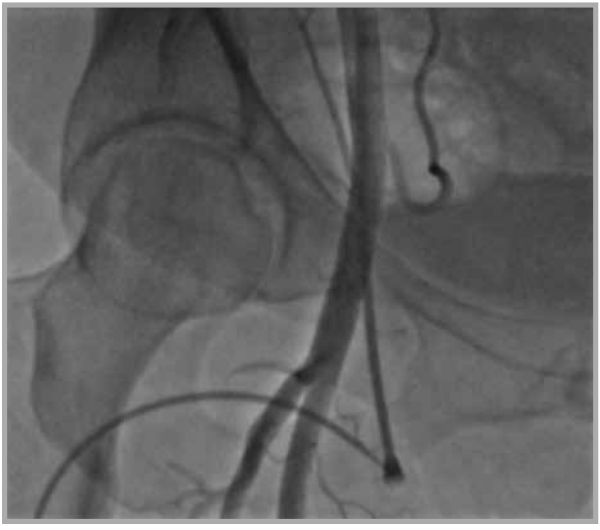


Image courtesy of Asoka Balaratna, MD

Clinical Considerations for Puncture Closing Using Vascular Closure Devices[1,4]

High Stick (Access at or above the inguinal ligament)

Right femoral angiogram shows high puncture into the external iliac artery. Procedure sheath positioned adjacent to the inferior epigastric artery branch, which can increase the risk for bleeding complication.

Image courtesy of Asoka Balaratna, MD

V (Vascular access site)[4]

- High stick: above the inguinal ligament in the external iliac artery

C (Caliber or size)[4]

- <5 mm internal diameter

D (Disease/Deterrents)[5]

- Prior femoral vascular surgery or vascular graft in region of access site or stent
- Fluoroscopically visible calcium, atherosclerotic disease, or stent <1 cm from the puncture site
- Pre-existing systemic or cutaneous infection
- Symptomatic leg ischemia
- History of bleeding or platelet disorder

High Stick–Associated Complications

- Inadvertent puncture[6]
- Retroperitoneal bleed[7]

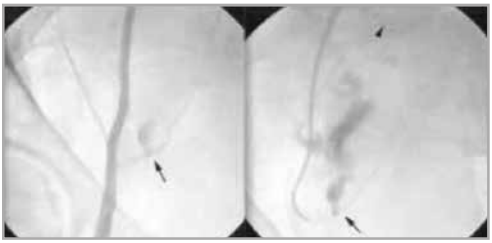


Image courtesy of Jose Silva, MD

Extravasation of contrast (see arrows) from perforated inferior epigastric artery.[8]

Arrowhead in image on right shows the tip of the guidewire in the distal portion of the inferior epigastric artery beyond the laceration.[8]

Clinical Considerations for Puncture Closing Using Vascular Closure Devices[4] (cont'd)

Low Stick (Access at or below distal femoral artery bifurcation)[9]

- Bifurcation
- Superficial femoral artery
- Profunda femoris artery

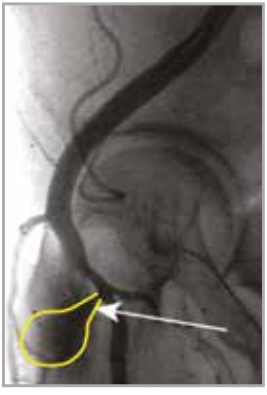
Image courtesy of Asoka Balaratna, MD

Right femoral angiogram shows suitable vessel and caliber; however, with low access of the superficial femoral artery, the risk for complications is increased.

Image courtesy of Zoltan Turi, MD

Right femoral angiogram shows low access via the profunda femoris artery. Vessel quality and caliber appear to be unremarkable; however, access below the common femoral artery increases the risk for complications.

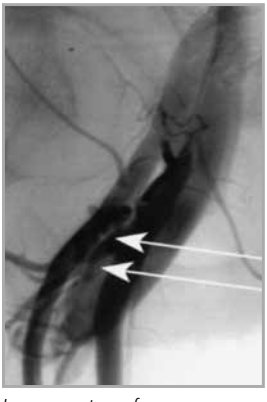
Low Stick–Associated Complications
Angiogram Showing Pseudoaneurysm[10]



From this anteroposterior angiogram a pseudoaneurysm (outlined in yellow with the neck marked by an arrow) is identified near the take-off of the left superficial femoral artery. Narrowing of the distal common femoral artery is also observed.

Image courtesy of Christoph Thalhammer, MD

Angiogram Showing Arteriovenous Fistula[10]



Anteroposterior angiogram shows arteriovenous fistula with contrast visible in the deep femoral artery (top arrow) and femoral vein (bottom arrow).

Image courtesy of Christoph Thalhammer, MD

Clinical Considerations for Puncture Closing Using Vascular Closure Devices (cont'd)

Lower Limb Ischemia

Image courtesy of Zoltan Turi, MD

This left transfemoral access image shows the sheath at the point of access to be nearly equivalent to the lumen size of the common femoral artery. Slow filling distal to the sheath is another indication that blood flow around the sheath is impeded. There is a risk of lower limb ischemia and thrombosis.

Variable Stick Techniques

- Double wall sticks (Seldinger technique)
- Multiple sticks
- Side wall sticks

Associated Complications

- Bleeding/hematoma
- Nerve injury
- Limb ischemia

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