



MC-006101 Rev 0

Large Bore Femoral Arterial Access and Closure

Tips for Health Care Professionals

Conflict(s) of Interest

- [Enter conflicts here]

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Agenda

- The Challenge
- Anatomy
- Goal of Femoral Arterial Access
- Methods of Gaining Femoral Arterial Access
- Current Closure Devices
- Tips for Ideal Femoral Arterial Access and Closure

The Challenge

- To ensure that the femoral arterial access is in the desired location and to avoid hemostasis-related complications¹
- Bleeding risk can increase with sheath size and use of closure devices depends on optimal femoral arterial access, front wall stick, and minimal to disease free segments
- Sherev et al. found that 71% of all vascular access-site complications were due to low or high femoral artery puncture sites²

1. ADHIR SHROFF, MD, DUANE PINTO, MD, et al. Access and Hemostasis: Vascular Access, Management, and Closure: Chapter 2, Section 1: The Society for Cardiovascular Angiography and Interventions 2019

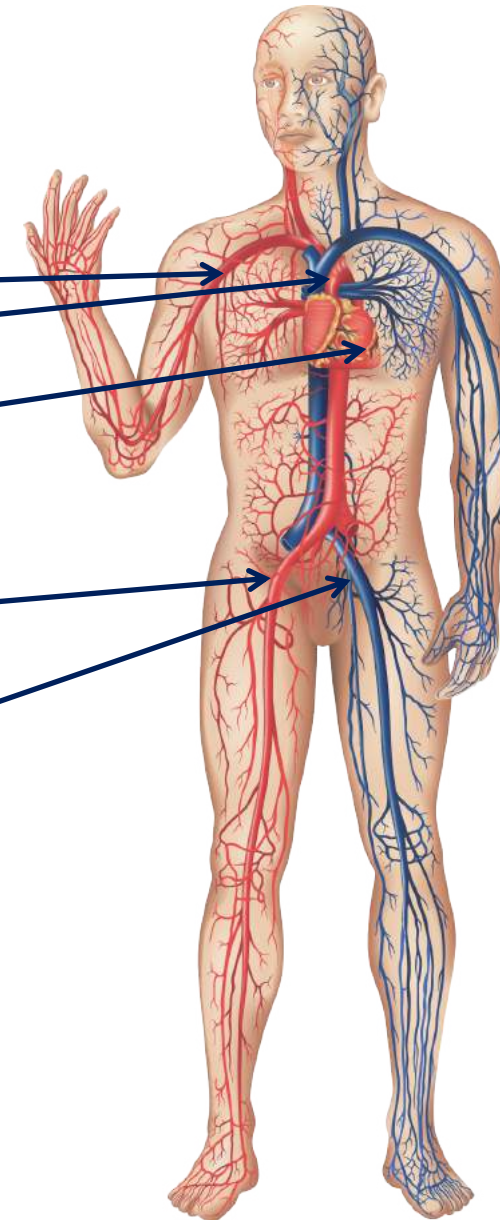
2. Shaun Bhatti, Richard Cooke, Ranjith Shetty and Ion S Jovin, et al. Femoral vascular access-site complications in the cardiac catheterization laboratory: diagnosis and management. *Interventional Cardiology* 2011. ISSN 1755-5310

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Anatomy

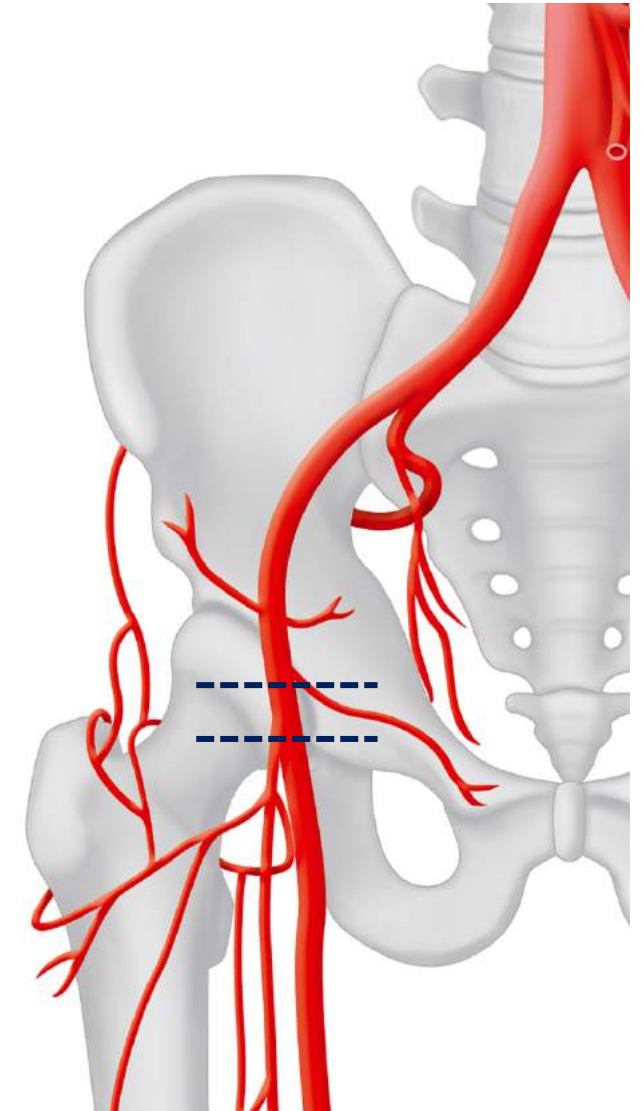
- Axillary/Subclavian
- Transaortic
- Transapical
- **Femoral (CFA) Transfemoral**
- Venous (CFV) Transcaval/septal



Anatomy¹

- Aligns with bottom-third to bottom-half of femoral head
- Avoids smaller, less suitable vessels
- Helps prevent retroperitoneal bleeding

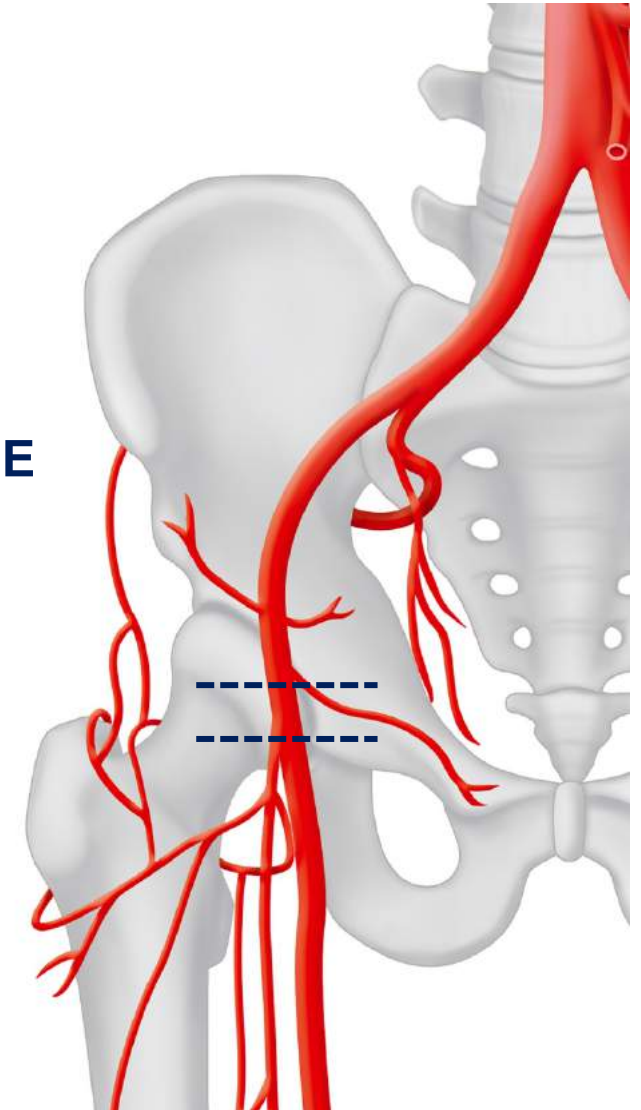
**Preferred
Femoral Arterial
Access Location**



Anatomy

- “Target Zone” is above the bifurcation and below the mid femoral head¹
 - That target decreases in size or must be adjusted based on high bifurcation or disease at desired femoral arterial access point
 - Manual control of the common femoral artery can be achieved by compression against the pubis or the femoral head depending on the vascular anatomy²

TARGET ZONE



1. Shaun Bhatti, Richard Cooke, Ranjith Shetty and Ion S Jovin, et al. Femoral vascular access-site complications in the cardiac catheterization laboratory: diagnosis and management. *Interventional Cardiology* 2011. ISSN 1755-5310
 2. Bangalore, Sripal, and Deepak L. Bhatt. “Femoral Arterial Access and Closure.” *Circulation*, vol. 124, no. 5, 2 Aug. 2011, doi:10.1161/circulationaha.111.032235.

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Goal of Femoral Arterial Access (Credo)



Good Femoral Arterial Access = Good Closure

Goal of Femoral Arterial Access¹

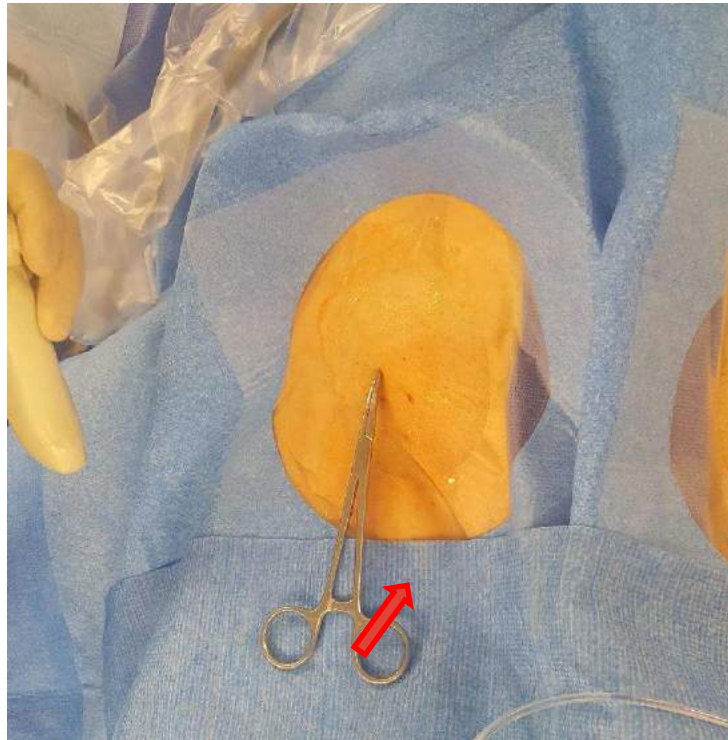
- Front wall of CFA (anterior stick)
- Above the PFA/SFA bifurcation
 - Below can increase risk for AV fistula and other bleeding complications
- Below the inguinal ligament / inferior epigastric artery
 - Preferably over the inferior half of the femoral head, and not through the ligament
 - If above, risk of retroperitoneal bleed can increase
- Away from calcification and disease
- Avoid small branches

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Method of Obtaining Femoral Arterial Access: Landmarks

- Visual and exam landmarks (skin fold and pulse palpation) unreliable



Based on skin fold
(note prior access)



Appropriate femoral arterial access
based on fluoroscopy and US
guidance

Methods of Obtaining Femoral Arterial Access: CTA and Fluoroscopy

- CTA images allow for pre-procedural FA access sight planning
- CTA overlay onto fluoroscopy is a novel technique to guide FA access



Methods of Obtaining Femoral Arterial Access: Road Mapping



Methods of Obtaining Femoral Arterial Access: Wire or Pigtail Marking



Method of Obtaining Femoral Arterial Access: Ultrasound

- **Ultrasound guidance by trained practitioners should be the first-line standard for central vascular access and arterial access procedures¹**
- Allows direct visualization of CFA stick and central front wall access
- Superior to fluoro for preventing low sticks (FAUST Trial)²
- Limitations of ultrasound include:
 - Morbidly obese harder to see
 - Imaging not always ideal and bifurcation not always obvious
 - Learning curve
 - Can stick too high
 - Fluoroscopy is complementary for detection of calcification so that it can be avoided

1. Christopher L. Moore, MD., et al. Ultrasound First, Second, and Last for Vascular Access; 2014 by the American Institute of Ultrasound in Medicine | J Ultrasound Med 2014; 33:1135–1142 | 0278-4297

2. Arnold H. Seto, MD., et al. Real-Time Ultrasound Guidance Facilitates Femoral Arterial Access and Reduces Vascular Complications FAUST (Femoral Arterial Access With Ultrasound Trial)

Method of Obtaining Femoral Arterial Access: Ultrasound

- Artery pulsatile and vein is compressible as shown in video below
- Vein is medial unless probe is upside down

CFA and compressible CFV

SFA



CFV

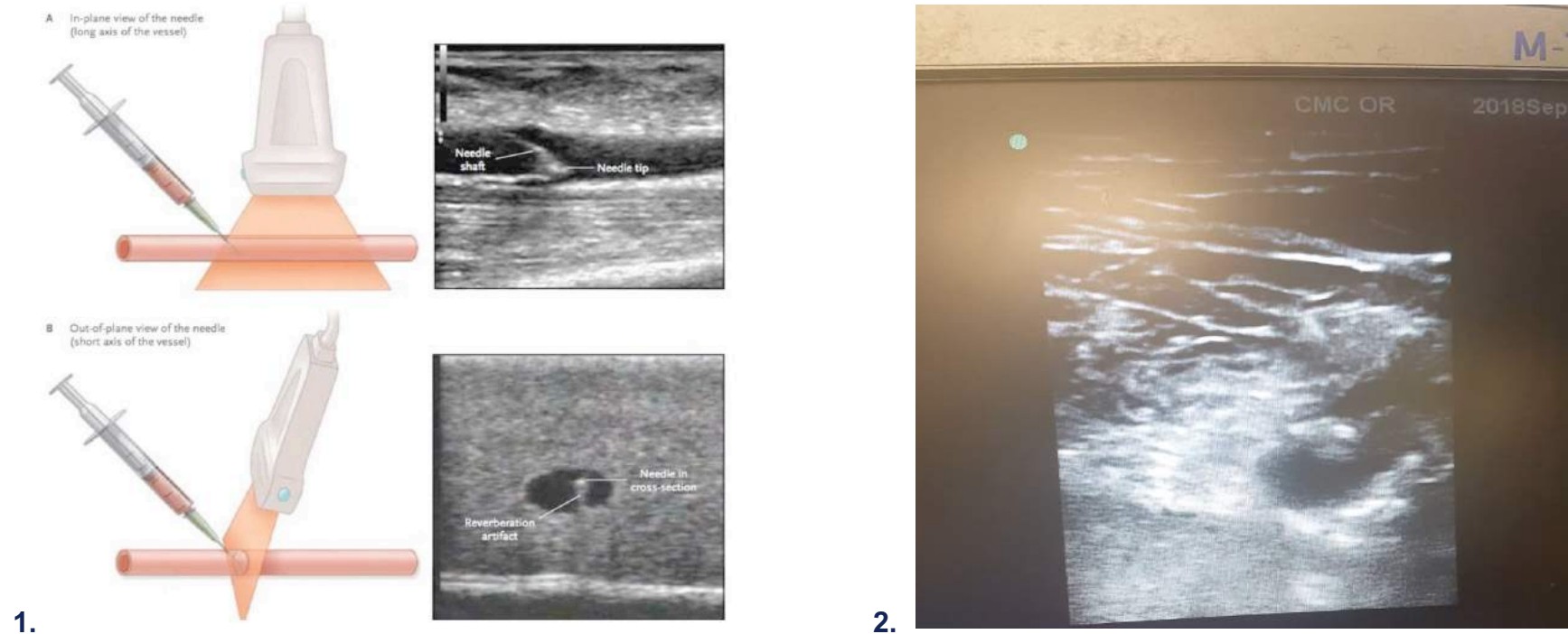
Method of Obtaining Femoral Arterial Access: Ultrasound

- Scanning proximal demonstrates the PFA/SFA transitioning to CFA



Method of Obtaining Femoral Arterial Access: Ultrasound

Accessing CFA with micro-puncture needle



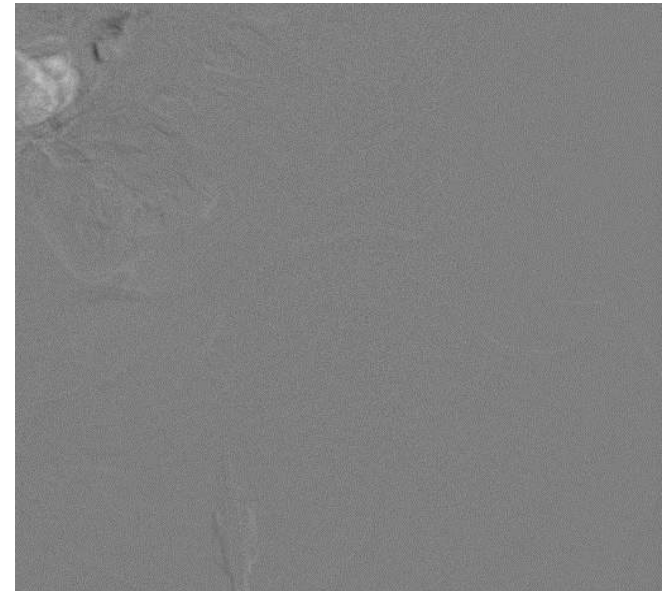
- Panel A shows a long-axis, “in-plane” view of the needle. Although it may be more difficult to keep the needle and structure of interest in view, the long-axis view is advantageous because it shows the entire needle, including the tip (ultrasound image at right). You can line up the center and see the needle compress the vessel centrally as it enters
- Panel B shows a short-axis approach, with the characteristic “target sign” of the needle in the vessel lumen.

1. Image source; Chris Moore, MD, et al AIUM PRACTICE GUIDELINES —Use of Ultrasound to Guide Vascular Access Procedures : IV. General Considerations for Ultrasound-Guided Vascular Access: A. Short-Axis (Out-of-Plane) Versus Long-Axis (In-Plane) Visualization (Figure 1) 2012.

2. Images courtesy of Michael Rinaldi et al **Getting Optimal Arterial and Venous Access for Large Bore Catheter Procedures** The Sanger Heart and Vascular Institute Carolinas Medical Center Charlotte, NC.

Method of Obtaining Femoral Arterial Access: Micro-puncture

- Using a very small needle to obtain initial access to vessels or organ cavities has the potential to reduce the risk of bleeding or organ injury¹
- 4F micro-puncture sheath angiography can confirm placement prior to committing (remove/brief hold/re-stick if inadequate)
- The smaller caliber needle may offer an advantage in terms of patient comfort²

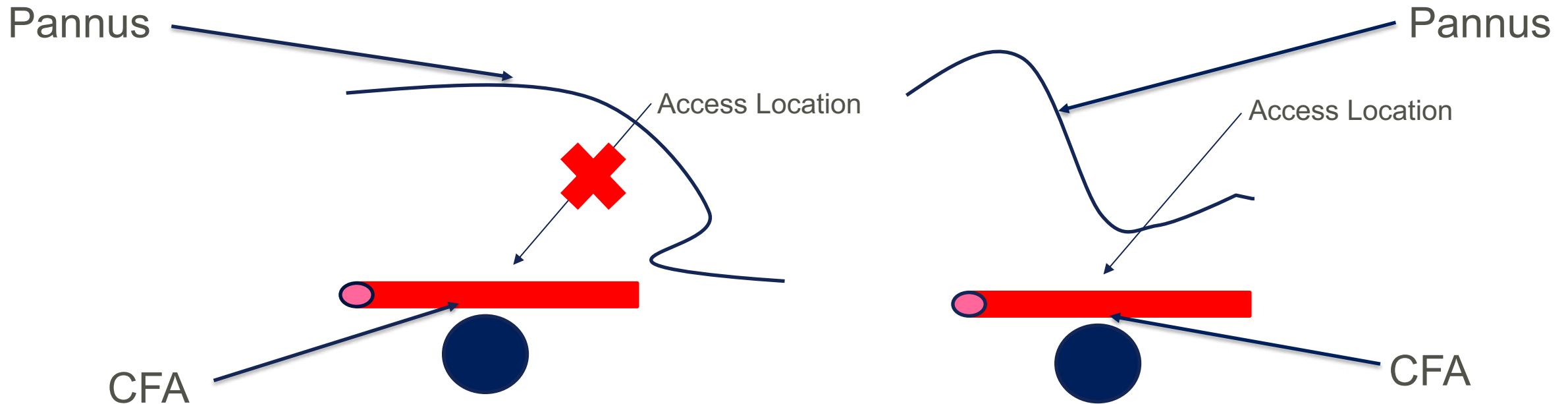


1. Shishir Murarka, MD,1 Mohammad Reza Movahed, MD, PhD2-4, et al. The Use of Micropuncture Technique for Vascular or Body Cavity Access: Vol. 15 No. 3 • 2014 • Reviews in Cardiovascular Medicine • 247
2. Arvind Gireesh, MD, FACC, Shahnaz Punjani, MD, Joseph Hannan, MD, FACC, Use of Micropuncture Needle in the Treatment of Pericardial Effusion by Pericardiocentesis; Volume 24 - Issue 10 - October 2016

Images courtesy of Michael Rinaldi et al **Getting Optimal Arterial and Venous Access for Large Bore Catheter Procedures** The Sanger Heart and Vascular Institute Carolinas Medical Center Charlotte, NC

Method of Obtaining Femoral Arterial Access: Obesity and Pannus

- Avoid access through pannus
- Push pannus up creating shortest tissue tract using fluoroscopic landmarks
- Dilate the tract deeply to allow pre-close knots to slide down easily



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Current Vascular Closure Devices: Suture Mediated

- **Perclose ProGlide® (Abbott)**
 - Arterial Access Closure Range: 5-21 Fr. with a maximum O.D. of 26 Fr.^{1a,b}
 - Pre-tied polypropylene monofilament suture¹
 - Pre-close technique where suture is placed around the arteriotomy at the beginning of the procedure and knot advancement is placed on hold until the procedure is complete¹
- **PROSTAR XL™ (Abbott)**
 - Arterial Access Closure Range: 8.5-10 Fr. with a maximum O.D. of 12 Fr.^{2a,b}
 - Uses two braided polyester sutures and four nitinol needles²
 - Vascular access can be maintained throughout deployment²

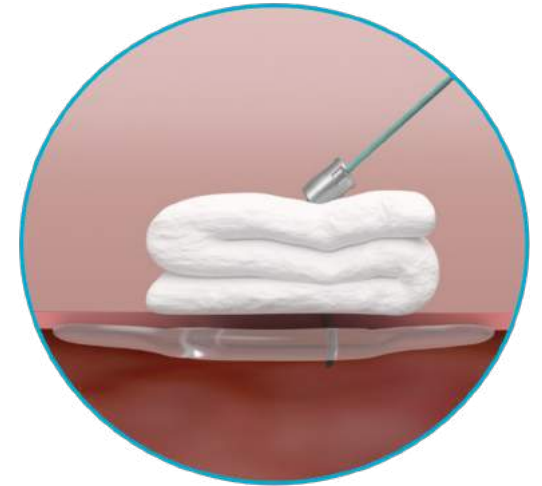
1. Perclose ProGlide® Suture-Mediated Closure (SMC) System Instructions for Use. Published 02/2018. <https://eifu.abbottvascular.com/content/dam/av/eifu-us/EL2105174%20Artwork.pdf>
 a. Max. OD 26F/0.340 inches/8.62 mm; Max. OD 29F/0.378 inches/9.59 mm. Tests performed by and data on file at Abbott.
 b. For sheath sizes greater than 8F, at least two devices and pre-close technique are required.

2. PROSTAR XL® Percutaneous Vascular Surgical System Instructions for Use. Published 10/2015. <https://eifu.abbottvascular.com/content/dam/av/eifu-us/EL2106469%20Artwork.pdf>
 a. <https://www.cardiovascular.abbott/us/en/hcp/products/peripheral-intervention/prostar-xl-percutaneous-vascular-surgical-system.html>. Website accessed 05/2019.
 b. The maximum closure size of this device is on the lower end of the range for large bore procedures.

Current Vascular Closure Devices: Collagen

The MANTA[®] Vascular Closure Device:

- Is the first commercially available biomechanical vascular closure device designed specifically for safe, effective, and reliable closure of large bore femoral arterial access sites following the use of 10-20 Fr. devices or sheaths (12-25 Fr. O.D.).¹
- Consists of a 14 Fr or 18 Fr. MANTA Closure Device, a 14 Fr. or 18 Fr. Sheath with Introducer, and an 8 Fr. Depth Locator.
- Has low complication rates for fast, reliable biomechanical closure with rapid hemostasis, potentially reducing costs.^{2a}



1. Data on file at Teleflex.

2. Data on file at Teleflex. The SAFE MANTA IDE Clinical Trial: MANTA[®] Device demonstrated a TTH of 24 seconds median time (65 seconds mean time) from deployment to hemostasis, which is lower than published rates for Perclose ProGlide where Perclose ProGlide demonstrated a TTH of 9.8 +/- 17 minutes (588 +/- 1,020 seconds). Study sponsored by Teleflex or its affiliates.

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Potential Challenges of Vascular Closure Devices (VCDs)

- Low bifurcation stick
- High stick
- Significant Atherosclerotic Vascular Disease (ASCVD) of CFA
- Significant calcification of CFA
- Prior VCD use
- Severe angulation of sheath entry

Large Bore Femoral Arterial Access: Tips

- Essential to obtain access over the femoral head or pubis, depending on vascular anatomy, to allow for manual compression¹
 - The EIA cannot be compressed effectively, and puncture above the inguinal ligament is the main cause of iatrogenic retroperitoneal hematoma²
- **Essential to obtain access at the 12 o'clock anterior wall of the artery – no side wall sticks**³
 - If sidewall access, there is the potential for an increased risk of bleeding and pseudoaneurysm

1. Bangalore, Sripal, and Deepak L. Bhatt. "Femoral Arterial Access and Closure." *Circulation*, vol. 124, no. 5, 2 Aug. 2011, doi:10.1161/circulationaha.111.032235.

2. [Iacopo Barbetta, MD¹](#) and [Jos C. van den Berg, MD, PhD](#), et al Access and Hemostasis: Femoral and Popliteal Approaches and Closure Devices—Why, What, When, and How?: *Semin Intervent Radiol.* 2014 Dec; 31(4): 353–360. doi: [10.1055/s-0034-1393972](#)

3. ADHIR SHROFF, MD, DUANE PINTO, MD, et al Access and Hemostasis: Vascular Access, Management, and Closure: Chapter 2, Section 1: The Society for Cardiovascular Angiography and Interventions 2019

Large Bore Femoral Arterial Access: Tips¹

- Essential to obtain access at a 45-degree angle without any “Z-line” tracking through soft tissues
 - “Z-line” tracking could potentially increase risk of VCD failure
- Study CT and ultrasound to find area of free or minimal calcium to allow VCD to deploy properly
 - Severe calcium can potentially increase risk of dissection as well as poor apposition to the vessel wall and trapping the toggle in the vessel upon withdrawal

Large Bore Femoral Arterial Access: Tips

- US guidance should be used routinely for vessel access
 - Routine use can improve competency
- Should be used in conjunction with CTA images if available and correlated with fluoroscopy
- If imaging is inadequate, adjuvant techniques (road mapping and wire marking) can be useful
- Micro-puncture as primary access needle
- It's not just about a technique – **it's about an outcome** (Target Zone CFA access, front wall puncture, disease free segment)
- Use all tools available to assist in successful closure
 - Pre-procedural CTA correlation, US, selective fluoroscopy +/- road mapping/wire marking, micro-puncture access and micro-sheath angiography

Large Bore Femoral Arterial Access: Tips

- Take the time to learn how to use VCDs
- Commit to a VCD and gain expertise with it
- Follow the guidelines for use and perform femoral angiograms post deployment (utilize digital subtraction angiography (DSA))
- VCDs may fail; Be vigilant and recognize potential complications
- Be prepared in advance; have necessary tools in the room as well as bailout techniques

Any Questions?

Thank You

Thank You

INDICATIONS FOR USE: The MANTA Vascular Closure Device is indicated for closure of femoral arterial access sites while reducing time to hemostasis following the use of 10-20F devices or sheaths (12-25F OD) in endovascular catheterization procedures.

CONTRAINDICATIONS: There are no known contraindications to the use of this device.

WARNINGS: 1) Do not use if the puncture site is proximal to the inguinal ligament or above the most inferior border of the epigastric artery (IEA), as this may result in retroperitoneal bleeding. 2) Do not use in patients with severe calcification of the access vessel and/or common femoral artery stenosis resulting in a vessel <5mm in diameter for the 14F MANTA or <6mm in diameter for the 18F MANTA, or >50% diameter femoral or iliac artery stenosis. 3) Do not use in patients with severe peripheral vascular disease, as evidenced by severe claudication when ambulating <100 feet, weak or absent pulses in the affected limb, or ABI <0.5 at rest. 4) Do not use if the temperature indicator dot on package has changed from light gray to dark gray or black. 5) Do not use if the package is damaged or any portion of the package has been previously opened. 6) Do not use if the items in the package appear damaged or defective in any way. 7) Do not REUSE or RESTERILIZE. The MANTA Device is single use only. The MANTA Device contains bioresorbable materials that cannot be reused or re-sterilized. Reuse or re-sterilization may cause degradation to the integrity of the device, leading to device failure which may result in patient injury, illness, or death. 8) Do not use the MANTA Device where bacterial contamination of the procedure sheath or surrounding tissues may have occurred, as this may result in infection. 9) Do not use if the MANTA delivery system becomes kinked. 11) Do not inflate a contralateral balloon in the femoral or iliac artery during MANTA Sheath exchange or the MANTA Closure procedure. 12) Do not use MANTA if there has been a femoral artery puncture in same vessel within the prior 30 days, recent femoral artery puncture in same groin that has not healed appropriately, and/or recent (<30 days) vascular closure device placement in same femoral artery. 13) Do not use if the puncture site is at or distal to the bifurcation of the superficial femoral and profunda femoris artery, as this may result in the (a) anchor catching on the bifurcation or being positioned incorrectly, and/or (b) collagen deposition into the vessel. 14) Do not use if there is difficult dilation from initial femoral artery access (e.g., damaging or kinking dilators) while step dilating up to the large-bore device. Difficult dilation of the puncture tract due to scar tissue may lead to swelling of surrounding tissue, thus compromising the accuracy of the puncture depth determined during the puncture location procedure. 15) Do not use if sheath insertion is in a vessel other than the femoral artery. 16) Do not use if there is marked tortuosity of the femoral or iliac artery. 17) Do not use if the patient has marked obesity or cachexia (BMI >40 kg/m² or <20 kg/m²). 18) Do not use if the patient has post-procedure blood pressure >180 mmHg that cannot be lowered prior to access site closure. 19) Do not use in patients who cannot be adequately anticoagulated for the procedure. 20) Do not use the MANTA Device in patients with known allergies to bovine products, collagen and/or collagen products, polyglycolic or polylactic acid polymers, stainless steel or nickel.

PRECAUTIONS: 1) The MANTA Device should only be used by a licensed physician or healthcare provider trained in the use of this device. 2) This device contains a small radiopaque stainless-steel lock that is implanted in the puncture tract. See MRI information in these instructions for use and patient implant card. 3) In the event that bleeding from the femoral access site persists after the use of the MANTA Device, the physician should assess the situation. Based on the physician assessment of the amount of bleeding, use manual or mechanical compression, application of balloon pressure from a secondary access site, placement of a covered stent, and/or surgical repair to obtain hemostasis.

POTENTIAL ADVERSE EVENTS: The following potential adverse events related to the deployment of Vascular Closure Devices have been identified: 1) Ischemia of the leg or stenosis of the femoral artery. 2) Local trauma to the femoral or iliac artery wall, such as dissection. 3) Retroperitoneal bleeding as a result of access above the inguinal ligament or the most inferior border of the epigastric artery (IEA). 4) Perforation of iliofemoral arteries, causing bleeding/hemorrhage. 5) Thrombosis formation or embolism. 6) Nerve damage or neuropathy. 7) Other access site complications leading to bleeding, hematoma, pseudoaneurysm, or arterio-venous fistula, possibly requiring blood transfusion, surgical repair, and/or endovascular intervention. Potential Adverse Events associated with any large bore intervention, including the use of the MANTA Vascular Closure Device, include but are not limited to: Arterial damage; Arterio-venous fistula; Bradycardia; Compartment syndrome; Death related to the procedure; Deep vein thrombosis; Ecchymosis; Edema; Infection at the puncture site which may require antibiotics or extended hospitalization; Inflammatory response; Late arterial bleeding; Oozing from the puncture site; Pressure in groin/access site region; Vessel laceration or trauma; Wound dehiscence.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Please see the instructions for use for complete product information.

For more information, please visit [teleflex.com](https://www.teleflex.com).

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