


Ark Cannulation Training

Device Overview and Training Guide for Cannulation

Confidential Information 413-016-0001v7







413-016-0001



Agenda

Ark Introduction Access Evaluation Establishing Vascular Access Post Dialysis

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-  Introduction to the Ark
-  Access Evaluation: Ask, Look, Listen, Feel
-  Feel the Ark and Identify its Parts
-  Establishing Vascular Access and Potential Occurrences
-  Post Dialysis
-  Caution Statements, Training Activity and Q&A

Ark Introduction



Ark Introduction

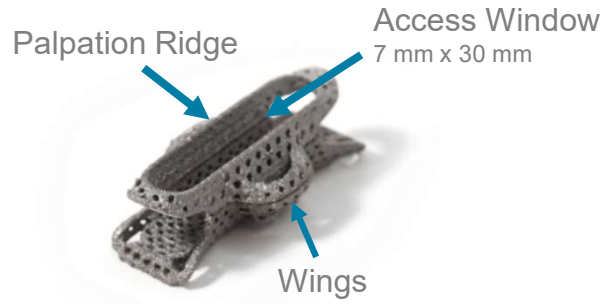
Access Evaluation

Establishing Vascular Access

Post Dialysis

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- ✓ Easy target for cannulation
- ✓ Protects the patient's access
- ✓ Accommodates access site rotation and buttonhole technique



Access Evaluation



Ark Introduction

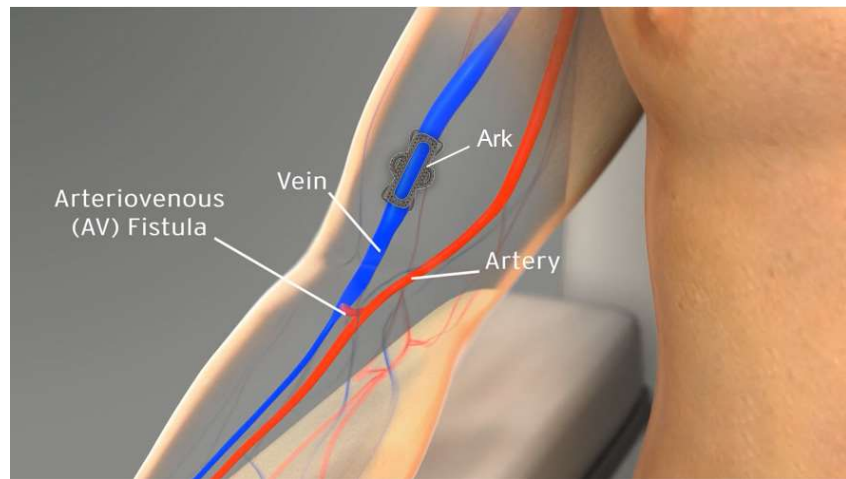
Access Evaluation

Establishing Vascular Access

Post Dialysis

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ASK
LOOK
LISTEN
FEEL



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Ask the Patient



Ark Introduction

Access Evaluation

Establishing Vascular
Access

Post Dialysis

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- Ask the patient about their access and their Ark.
- Review post-op surgical report
 - Good communication between the dialysis clinic and the surgeon can be very helpful
- Each patient should have:
 - Patient implant card with date of implantation and serial number
 - Bracelet with QR code that opens additional information about the Ark



Patient Name Provider Details
 Implant Date
 voyagerbiomedical.com

MRI Conditional: up to 3.0T
 Max Spatial Gradient Field of 5720 G/cm
 SAR of <4 W/kg
 Please complete or affix stickers supplied with packaging

<input type="checkbox"/> Upper	REF
<input type="checkbox"/> Lower	
<input type="checkbox"/> For Push	LOT
<input type="checkbox"/> For Pull	

Voyager Biomedical
 114 Holmes Rd.
 Houston, Texas 77065
 PH: 713.741.0111
 voyagerbiomedical.com

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Look At The Patient's Access

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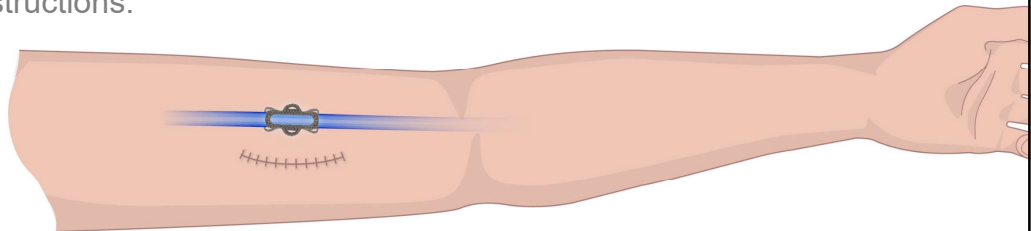
Access Evaluation

Establishing Vascular
Access

Post Dialysis

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- Look for post-op scars that may indicate Ark location
- Look to see if the Ark outline is visible under the skin
- Look at the access and examine for:
 - Any signs of Skin Erosion or Skin Breakdown especially around the Ark
 - If signs of skin erosion are present consult nephrologist for further instructions.



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Listen to the Patient's Access

Ark Introduction

Access Evaluation

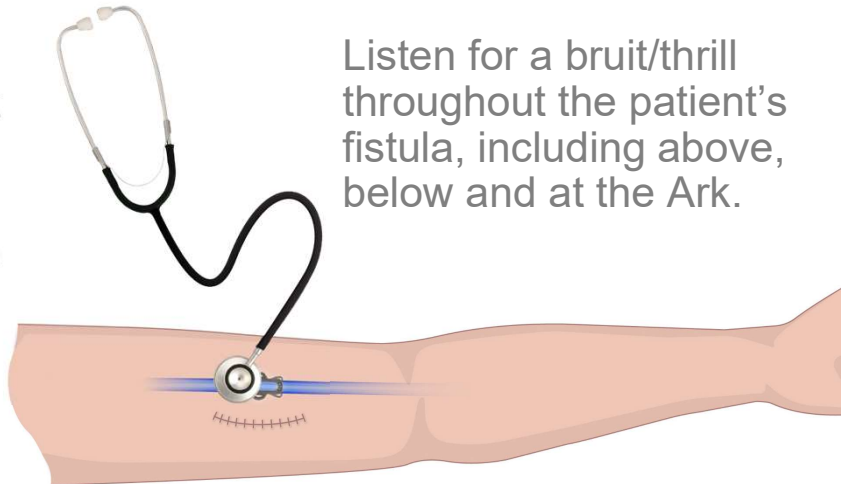
Establishing Vascular
Access

Post Dialysis


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ALUMINUM

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The Ark may affect the sound of the bruit when listening inside the Ark, so it is important to evaluate the entire fistula.



Listen for a bruit/thrill throughout the patient's fistula, including above, below and at the Ark.

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Feel the Patient's Access

Ark Introduction

Access Evaluation

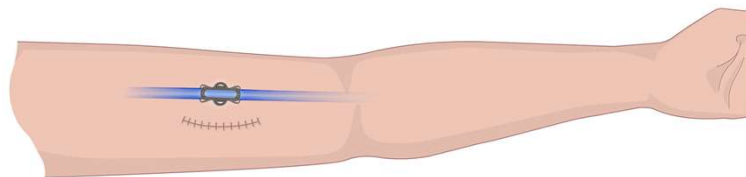
Establishing Vascular
Access

Post Dialysis


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ALUMINUM

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- Feel the entire fistula and assess
- Palpate the access to locate the Ark and its edges/ends
- Use your fingers to "see" the different parts of the Ark



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Feel: Identifying the Ark's Palpation Ridge



Ark Introduction

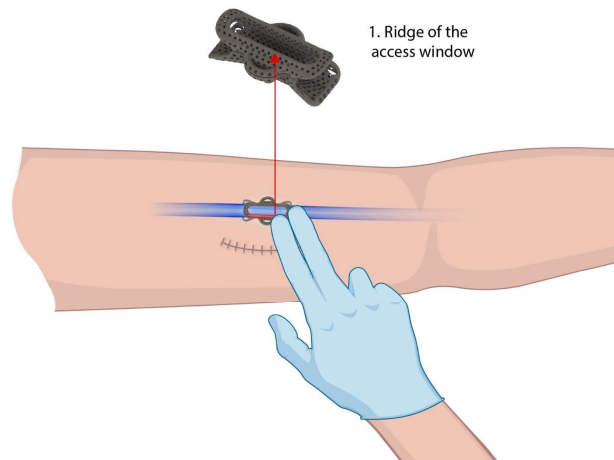
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- Feel for the ridge of the Access Window (highlighted in red)
- The palpation ridge is in the shape of an oval racetrack and marks the margins of the cannulation area



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Feel: Identifying the Ark's Access Window



Ark Introduction

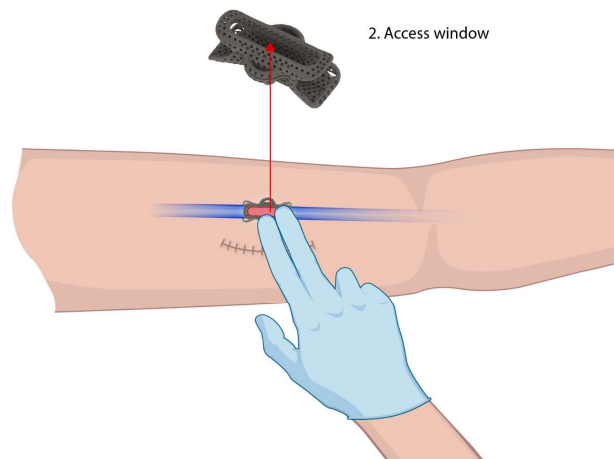
Access Evaluation

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- Once you identify the Palpation Ridge, feel for the Access Window (highlighted in red).
- Take note of any physical markers (i.e. scars, freckles, etc.) that can help locate the access window



Feel: Identifying the Wings of the Ark

Ark Introduction

Access Evaluation

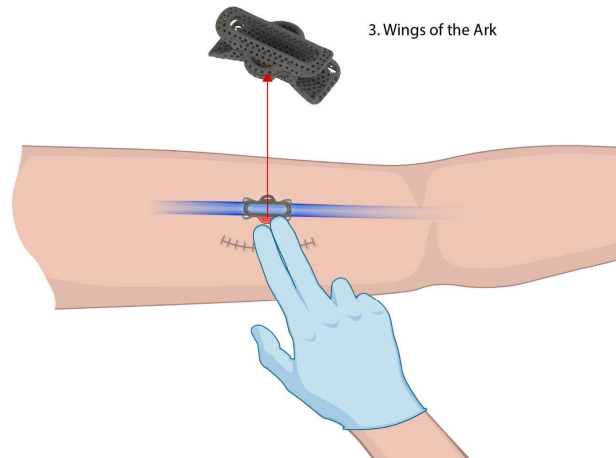
Establishing Vascular Access

Post Dialysis



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- Finally, identify the wings of the Ark (highlighted in red)
- The wings are different from the Palpation Ridge in length, shape and position.
- The wings can also help identify the orientation of the Ark if rotation is present.



Needle Rotation Accessory

Ark Introduction

Access Evaluation

Establishing Vascular Access

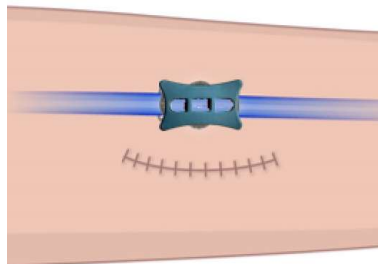
Post Dialysis



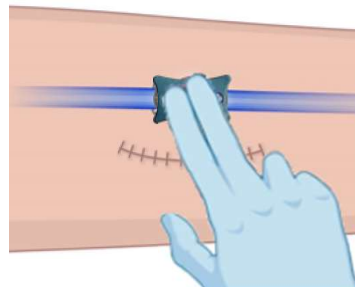
12

Cannulators may find this optional accessory helpful to practice rotation of the access site for Ark patients.

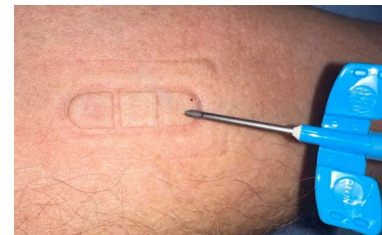
1. Once the Ark has been located and assessed, align the Accessory over the Access Window



2. Press down on the Accessory with mild to moderate pressure for 10-15 seconds



3. Remove the Accessory and palpate at the mark on the skin to ensure the Ark's Access Window is directly below



Feel: Ark Movement and Rotation



Ark Introduction

Access Evaluation

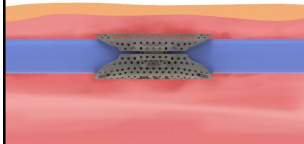
Establishing Vascular Access

Post Dialysis

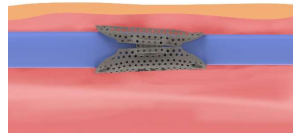
13

All of the below are **OK** with proper assessment!

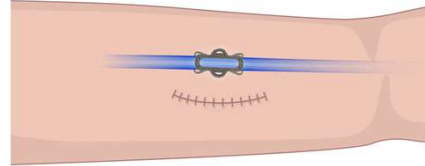
- Sign of separation: spongy/ squishy feeling



Even Separation



Uneven Separation



- Device separation or rotation inhibiting cannulation is **unacceptable**. If unable to cannulate, contact a nephrologist.

Determine Needle Type and Size



Ark Introduction

Access Evaluation

Establishing Vascular Access

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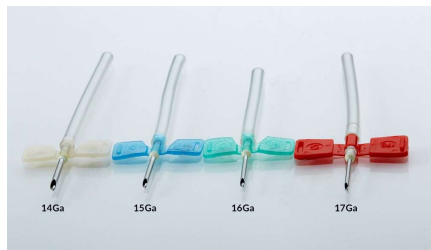
Follow dialysis clinic guidelines and protocol to select the proper needle



Buttonhole Needle



Routine Dialysis Needle

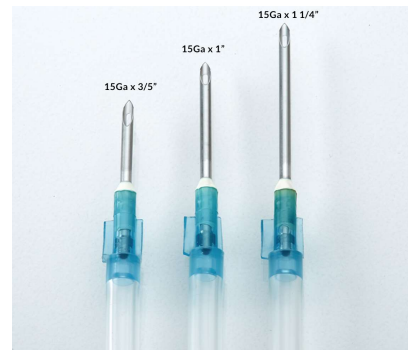


14Ga

15Ga

16Ga

17Ga



15Ga x 3/5"

15Ga x 1"

15Ga x 1 1/4"

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Establishing Vascular Access: Needle Insertion

Ark Introduction

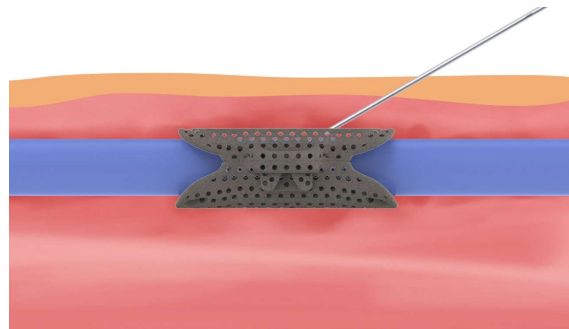
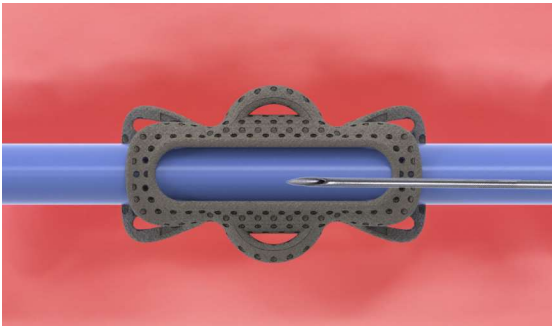
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The Ark does not require additional steps when cannulating compared to a fistula without a device; however, the angle of entry may need to be **slightly steeper**.



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Potential Occurrences: Establishing Vascular Access

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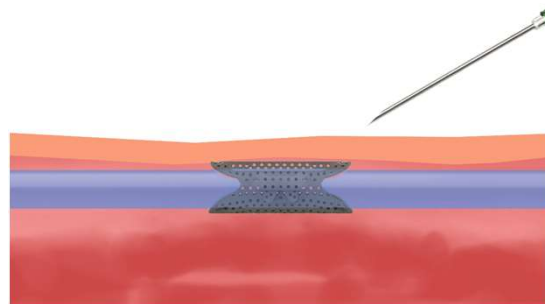
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Needle can come into contact with the back wall. This is not a problem and can occur during normal cannulation. Simply pull back very slightly, adjust the angle and advance needle.



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Potential Occurrences: Establishing Vascular Access

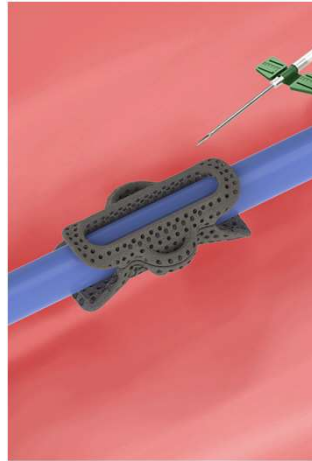
Ark Introduction

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Needle
contacts the
top of device

Adjust needle
as needed to
achieve access

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Potential Occurrences: Establishing Vascular Access

Ark Introduction

Access Evaluation

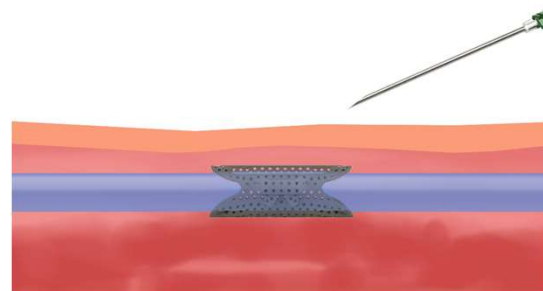
Establishing Vascular
Access

Post Dialysis

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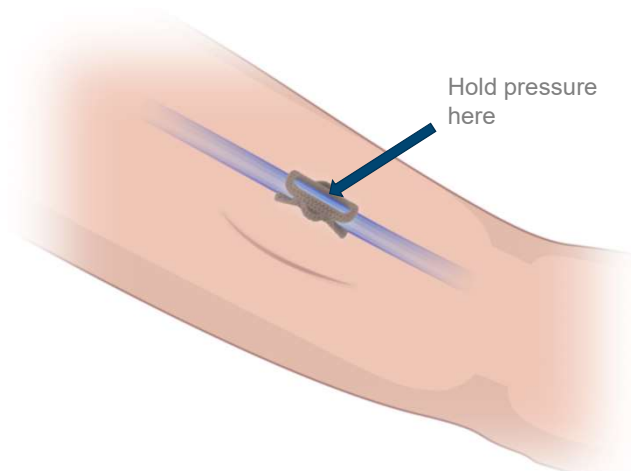
Needle is inserted but there is no flashback

- Follow similar steps for achieving access as a normal surgical fistula, just remember the Ark may require a **steeper cannulation angle**.
- Confirm that the depth of your cannulation is sufficient
- Confirm that you have gone through the Access Window



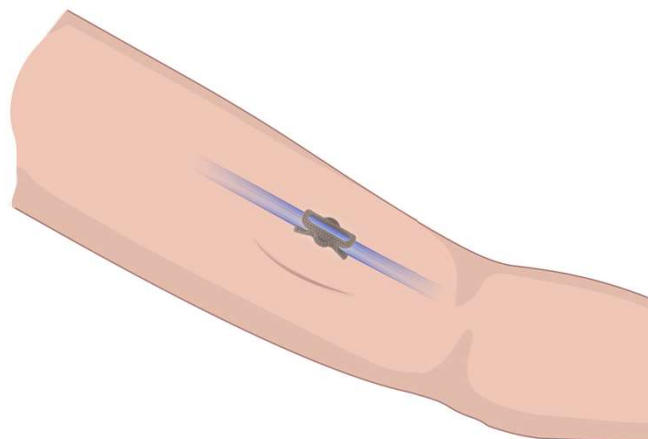
Post Dialysis

- Once dialysis treatment is complete, follow institutional protocols for removing needle and holding pressure and/or hold pressure for 10 minutes after bleeding has stopped, whichever is greater.



Post Dialysis Considerations

- Check for thrill, bruit and verify hemostasis
- Dress the access site according to facility guidelines



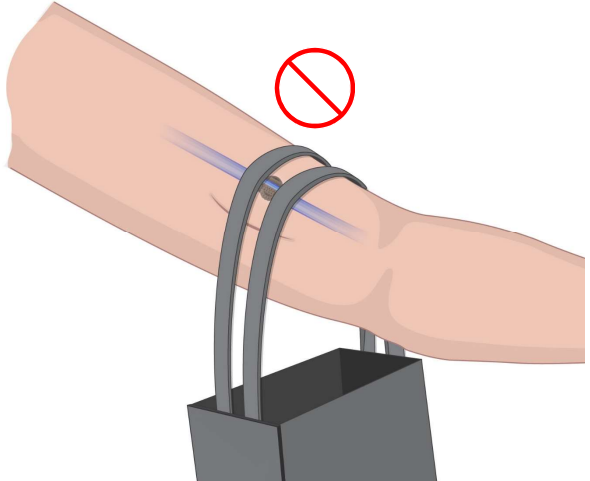
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Patient Education

Ark Introduction Access Evaluation Establishing Vascular Access **Post Dialysis**

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- The Ark has the same care requirements as a normal fistula
- Avoid physical trauma and prolonged pressure to the Ark area such as carrying a heavy purse or shopping bag over the Ark area.



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CAUTION STATEMENTS

Ark Introduction Access Evaluation Establishing Vascular Access **Post Dialysis**

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- **CAUTION:** Avoid tourniquet placement over or around the Ark area
- **CAUTION:** Consult a nephrologist or vascular surgeon if unable to identify or cannulate the access window
- **CAUTION:** The Ark bottom protects the back wall of the vessel from infiltration when cannulating; however, a needle advanced outside of the Ark may still result in back wall penetration
- **CAUTION:** Avoid excessive force or prolonged pressure.
- **WARNING:** Post dialysis risks include skin erosion due to excessive pressure at the puncture site. Inspect for skin erosion and treat as necessary
- **WARNING:** Only authorized and trained medical professionals who have read the instructions for use and been trained can implant and use the Voyager device.

Cannulation Activity

Cannulation Activities

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SCIENTIFICAL

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- Utilize cannulation aids to practice assessing and accessing the Ark device.

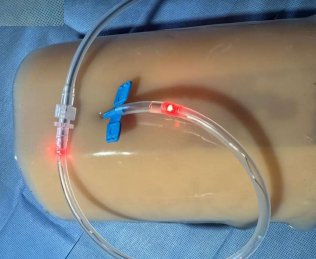
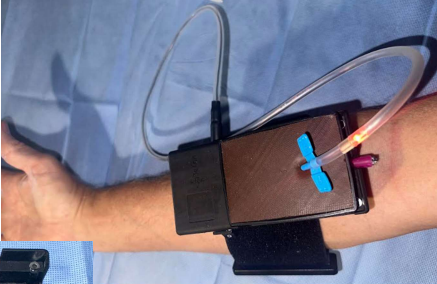


Image above shows 2 Ark tabletop cannulation model without skin layer

Image at right shows same model with skin layer in place.

Image above shows single Ark wearable cannulation model with skin layer in place. This model can be used with a partner

Image at left shows the same model without the skin layer in place

Resources



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For additional guidance, review 413-016-0002 Cannulation Training Video.



During the initial cannulation of the Ark device, a clinical representative is required to be present to provide support. Please reach out to clinicalsupport@voyagerbiomedical.com to get in contact with a clinical representative.

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