WELCOME *To the*

2026 SYMPOSIUM

HeRO

(Hemodialysis Reliable Outflow)

Pros and Cons

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Disclosure

Speaker and consultant for Merit Medical – producer/seller of the HeRO graft



What's in a Name?

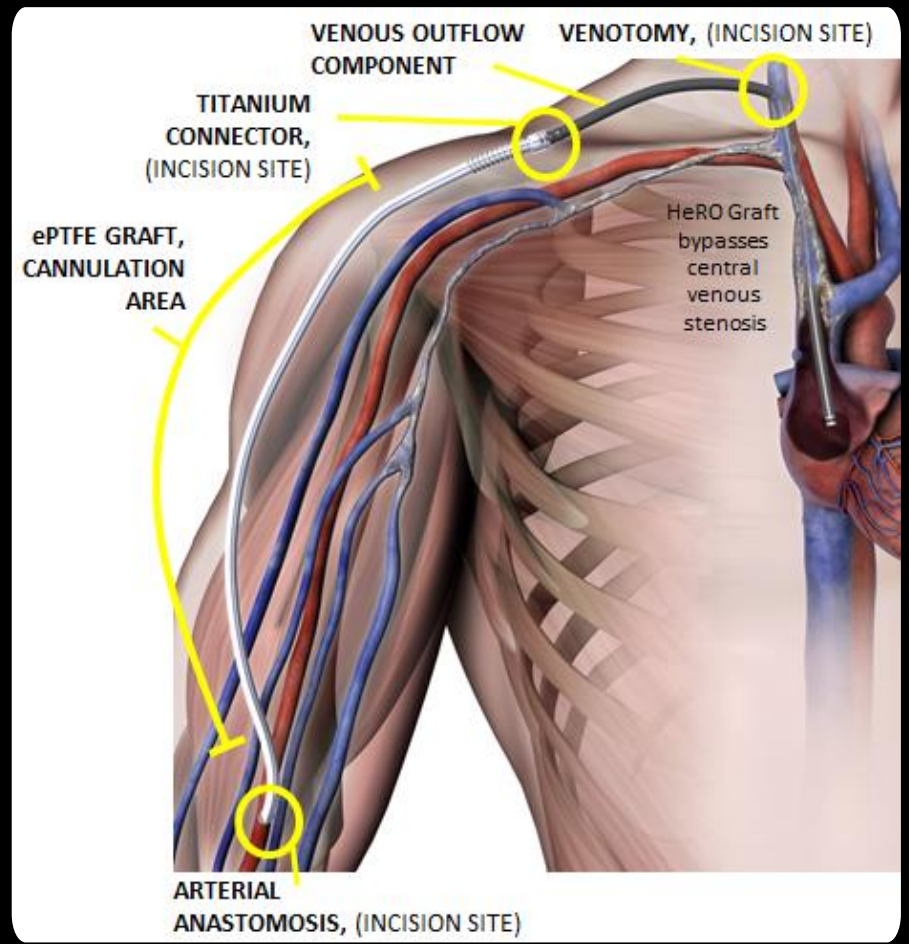
- Hemodialysis Reliable Outflow
- Graft is a graft is a graft . . . clotting, infection, steal, stenosis
- HeRO is a graft, BUT solves a very unique problem

What's Not?

- Solution for every challenging patient
- Superior to a functioning avf
- Freedom from issues

What is a HeRO?

Hemodialysis Reliable Outflow



HeRO (Hemodialysis Reliable Outflow) Graft is a vascular access device designed for *patients with central venous stenosis including those with failing fistulas or grafts due to central venous stenosis.*

It bypasses central venous stenosis and is recognized for its clinical utility in hemodialysis access.

It is especially useful in those catheter-dependent or approaching catheter-dependency

WHO NEEDS A HeRO?



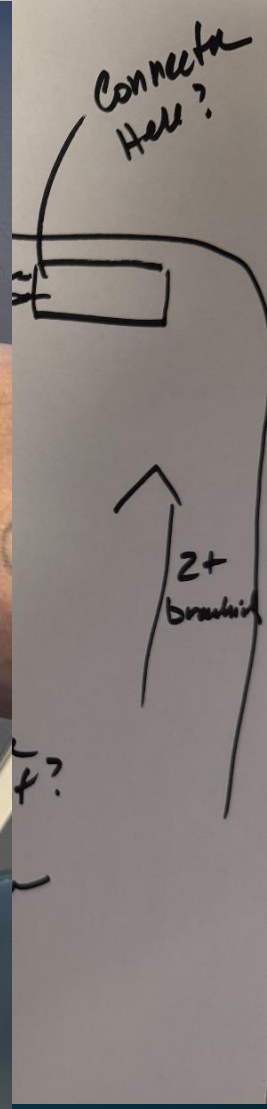
Who May Not?


R FLUORO PER 30 MIN STATISTIC
cc: SW59235251
2026-May-14
(not calbr


XR FLUORO PER 30 MIN STATISTIC
Acc: SW59235251
2026-May-14






Connector
Here?
2+
bruising

Where Does HeRO fit in the Treatment Algorithm?

Failing AVF or AVG due to **central venous stenosis**



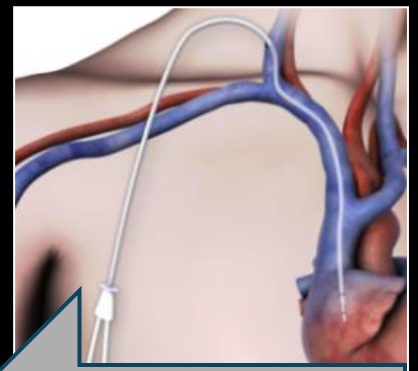
Fistula



Graft



HeRO Graft



Catheter-dependent patients

Catheter

HeRO Graft Candidates

STENTING?

- Failing fistulas or grafts due to central venous stenosis
- Catheter-dependent or approaching catheter-dependency

HeRO GRAFT

Versus catheters and other grafts

	HeRO Graft Gage, et al. EJVES[1,*]	HeRO Graft Nassar, et al. Semin Dial[2,*]	HeRO Graft Katzman, et al. JVS[3,*]	Catheter Literature	AV Graft Literature
Bacteremia Rates (Infections/1,000 days)	0.14	0.13	0.70	2.31[1,3,4]	0.11[2,4]
Adequacy of Dialysis (mean Kt/V)†	NA	1.6	1.7	1.29 - 1.46[4]	1.37 .62[2-4]
Cumulative Patency at 1 Year	91%	68%	72%^	37%[1,3,4]	65%[1-4]
Intervention Rate (per year)	1.5	2.2	2.5	5.8[1,3]	1.6 - 2.4[1,3]

†Note: Every 0.1 decrease in Kt/V increases the mortality rate by 7%[5] and is significantly (P<0.05) associated with 11% more hospitalizations, 12% more hospital days, and a $940 increase in Medicare inpatient expenditures.[6]

^8.6months

1) Gage et al., EJVES 2012. 2) Nassar et al., Semin Dial 2014. 3) Katzman et al., J Vasc Surg 2009. 4) Data on file. 5) Dhingra et al., Kidney Int 2001. 6) 2006 NKF KDOQI, Guideline 4.

HeRO® GRAFT

Key Benefits (versus CATHETERS!)

- **Fewer Infections:**
  69% reduced infection rate compared with catheters[1]

- **Superior Dialysis Adequacy:**
  1.7 Kt/V, a 16% to 32% improvement compared with catheters[1]

- **High Patency Rates:**
  Up to 87% cumulative patency at 2 years[1,2]

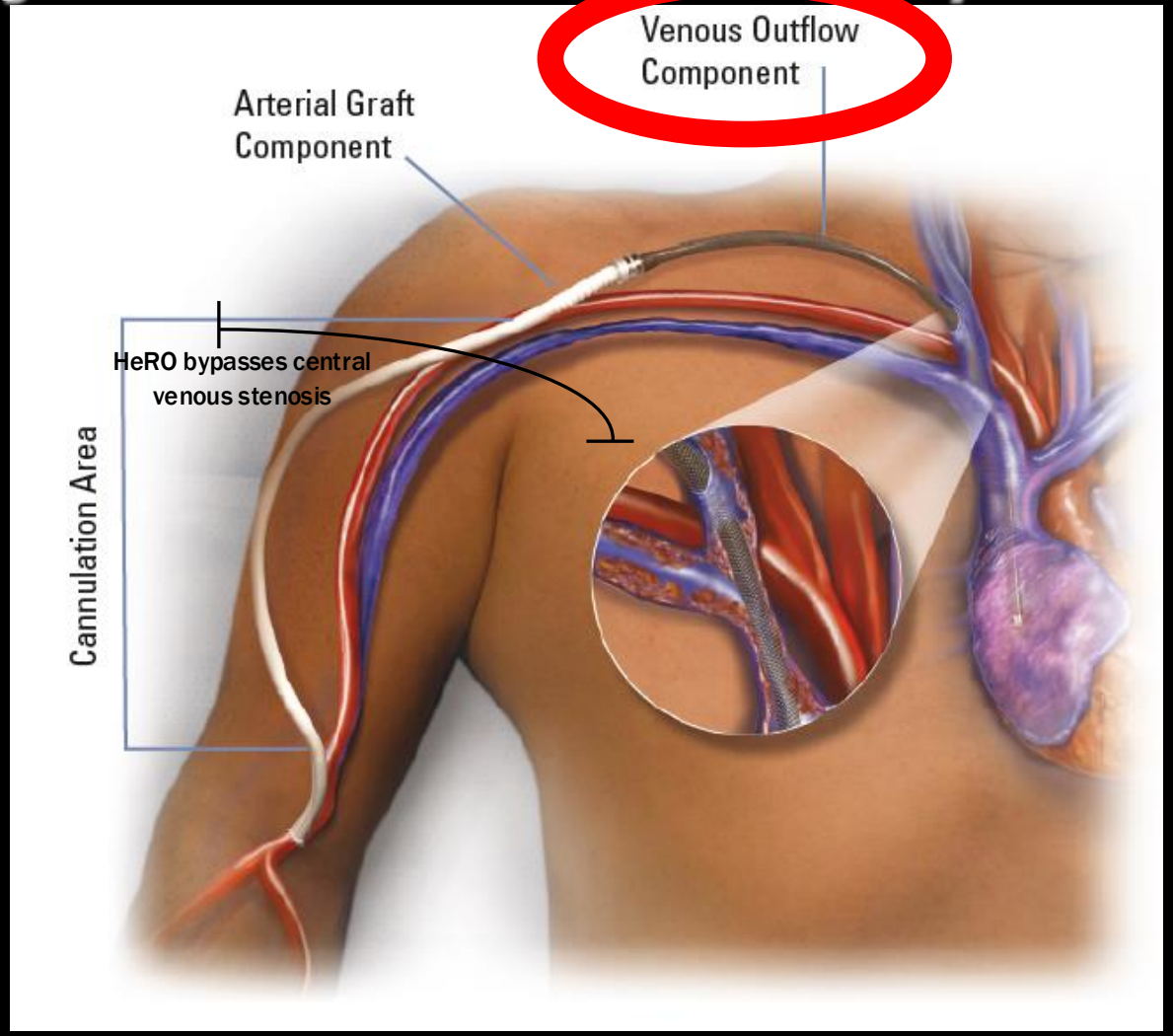
- **Cost Savings: $$$**
  A 23% average savings per year compared with catheters[3]



HeRO® GRAFT

1) Katzman et al., J Vasc Surg 2009; IFU: Comparisons to catheters and AVGs are from literature review on file. 2) Gage et al., EJVES 2012. 3) Dageforde et al., JSR 2012.

The HeRO Graft (Hemodialysis Reliable Outflow)



My Clinical Experience

- Easy to implant
- “Customizable, sizable, REMOVABLE stent”
- Very inexpensive “stent”
- Crush resistant “stent”
- Starts a conversation

Advantages

Very strong stent

Nothing else works well in the central venous system

Brand recognition

Customizable length

Removable

persnickety adjective

per·snick·e·ty pər-ˈsni-kə-tē

Synonyms of *persnickety* >

NEW Simple Definition

1 a : fussy about small details : **FASTIDIOUS**

a *persnickety* teacher

b : having the characteristics of a snob

2 : requiring great precision

a *persnickety* job

And What is a SuperHeRO?

Super HeRO®



GIVING YOU MORE GRAFT OPTIONS TO BYPASS CENTRAL VENOUS STENOSIS

The Super HeRO Adapter and Support Seal system expands upon the clinically proven HeRO Graft by allowing surgeons to utilize other standard wall and early cannulation vascular graft options.

HIDI
“How I do It”

HeRO
Placement

1. Examine patient
2. Cath Lab - Perform venography
3. OR - Gain access
4. Put wire into IVC
5. Place outflow component
6. Tunnel graft
7. Arterial anastomosis
8. Connect graft to outflow component
9. Close wounds
10. Post operative orders

Step 1: Examine the patient

- Look for signs of central venous stenosis (dilated chest veins, AICD/pacemaker, multiple previous catheter scar sites)
- Feel for pulses (NEED INFLOW, CONDUIT AND OUTFLOW)
- See where previous grafts have been placed
- Ask where the last functioning access was and how long it lasted





NEED TO: Examine the Patient

- Look
- Listen
- Feel

Step 2

Perform Venogram (RoadMap)

- Performed by surgeon or interventional colleague
- ***Access brachial or basilic veins (preferred over cephalic as you usually get better view)***
- US guided access
- Micropuncture
- Best done before planning HeRO

NEED TO: Do Ultrasounds Do Venograms

PS – Do an arteriogram if you feel you need to!



If patient coming from a distance or unreliable, considering posting venogram day before planned access placement.

Step 3:

Gain Access to Vein

- Proper room arrangement and supplies
- Supplies and equipment ready:
  - *Ultrasound guidance*
  - *C-arm*
  - *Micropuncture*
  - *6F sheath*
  - *Angled glide catheter*
  - *Bentson wire (atraumatic wire)*
  - *Amplatz wire (stiff wire)*
  - *8mmx4cm balloon*
  - *SuperHeRO kit*
- Access internal jugulars, external jugulars, subclavian or femoral veins




RELIANCE XK
2.1 mL
2.2 mL



Step 4: Put Wire Into IVC

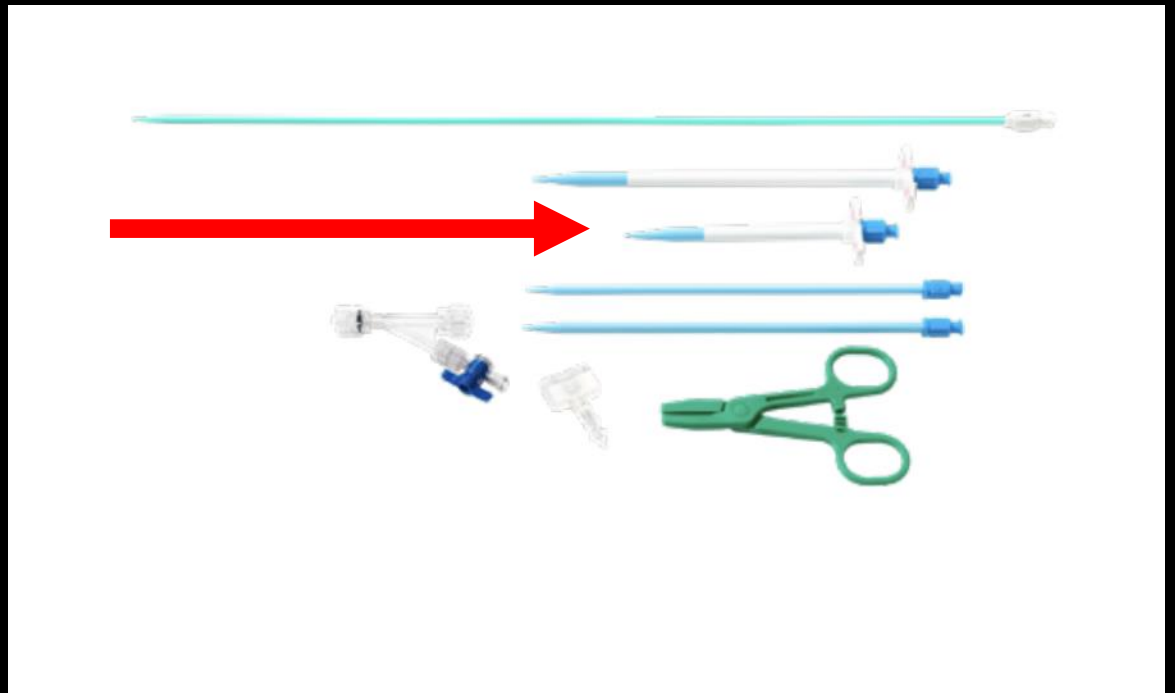
- Seemingly simple, but a KEY to success of a HeRo graft placement
- Hydrophillic catheter
- Bentson to get there and Amplatz to stay there
- What if IVC is occluded?



Step 5:

Place Outflow Component

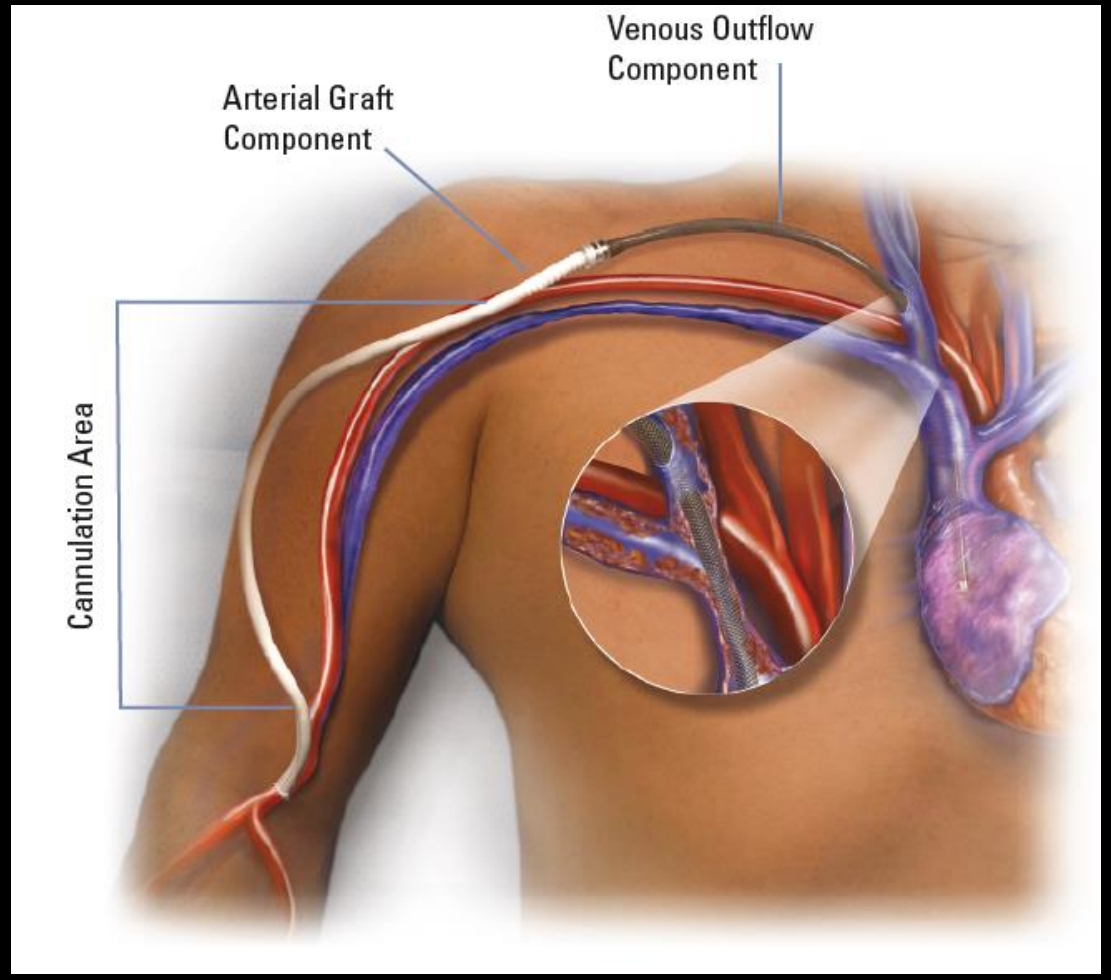
- Dilator (short rather than long)
- Always place over stiff wire
- Angioplasty ahead of time if needed (8mm)
- Location of tip of outflow component – VERY IMPORTANT – mid atrium – if unsure inject some contrast



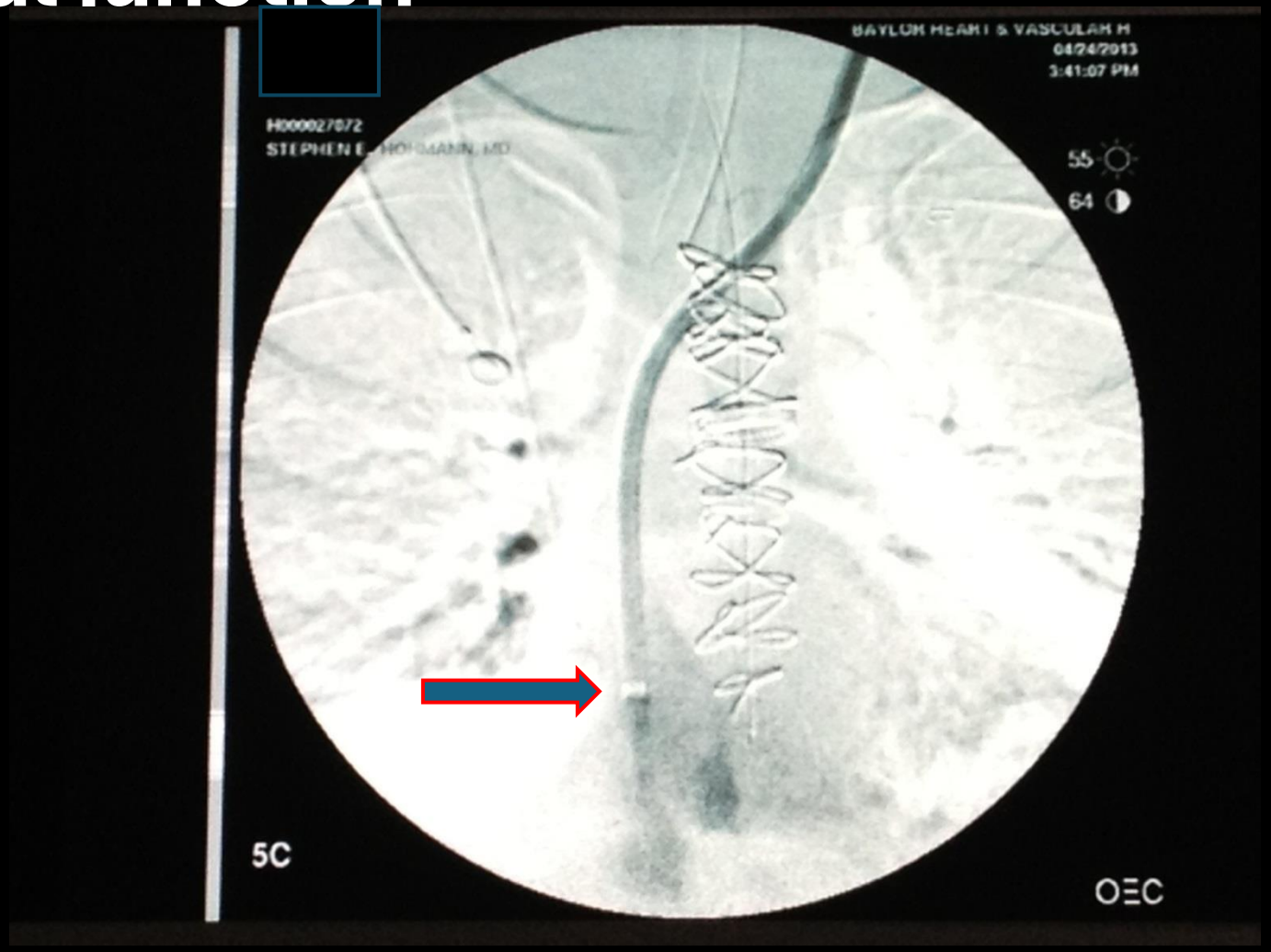
VENOUS OUTFLOW COMPONENT

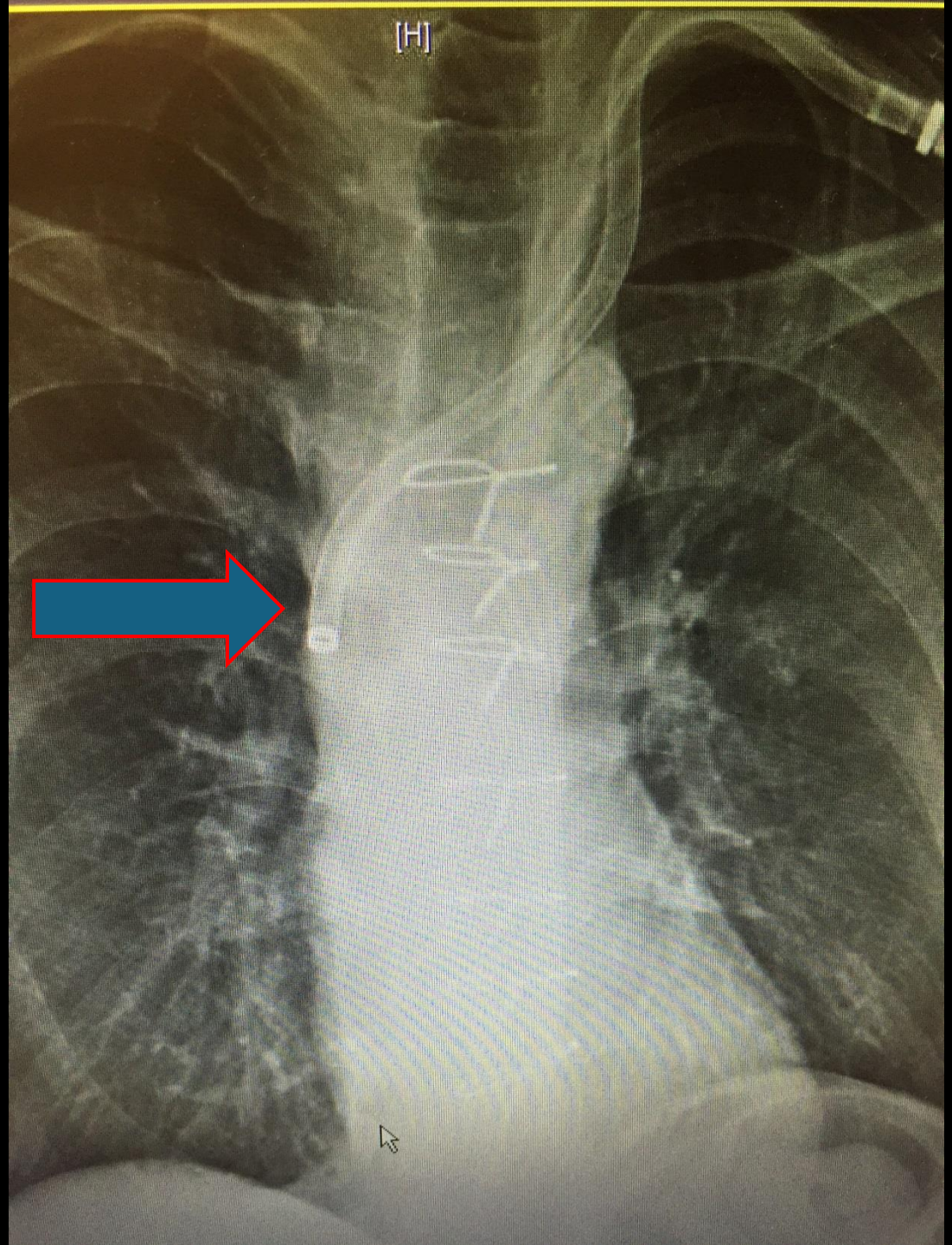
SPECIFICATIONS

- ✓ *5mm ID, 6.3mm OD*
- ✓ *Silicone with braided nitinol reinforcement (for kink and crush resistance)*
- ✓ *Radiopaque marker band at the distal tip*
- ✓ *40cm long*



NEED TO: Do Angiography to be sure at atriocaval junction




[H]

Step 6
Tunnel Graft

- I prefer to use high brachial/axillary artery for my arterial inflow because it is large and there is concern that low flows lead to clotting
- Standard tunneling techniques for whatever graft is chose



Step 7

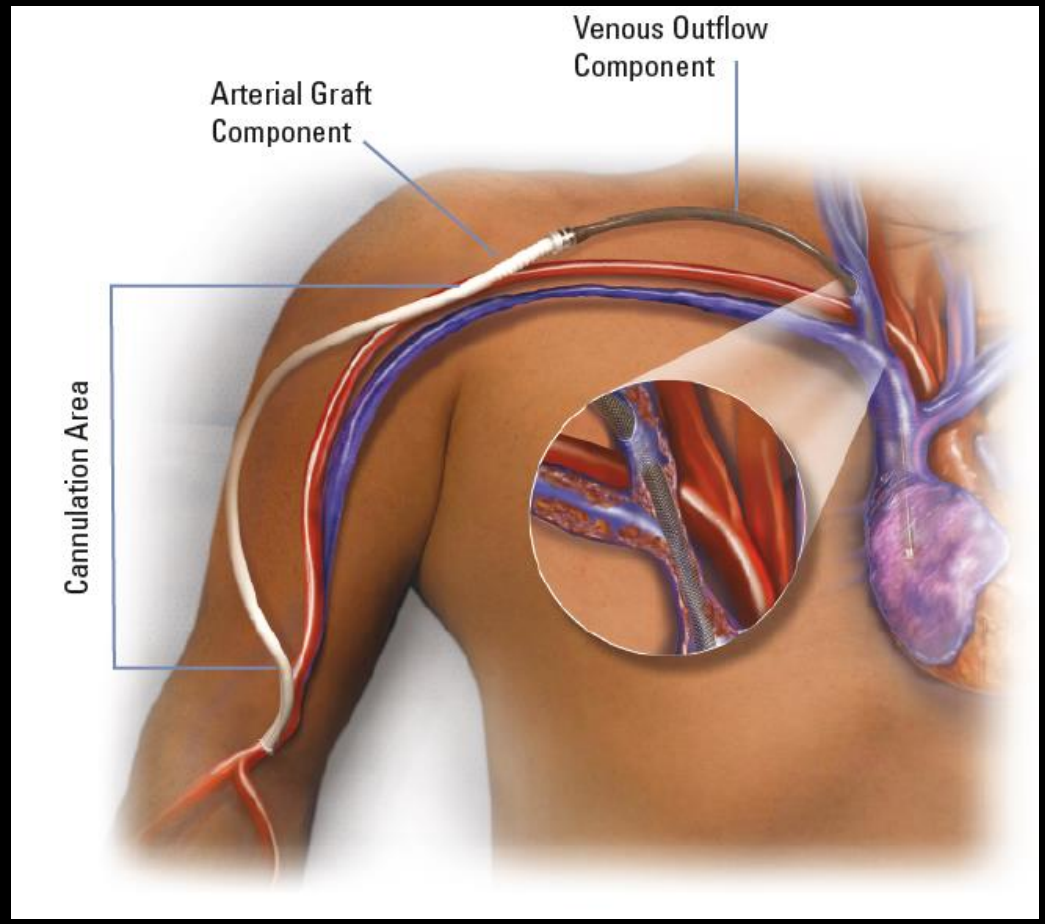
Arterial Anastomosis

- For some people this is number 8
- I do think it best to always put in outflow component first because otherwise you cannot do the case
- Some people like to connect the outflow component to the graft prior to the arterial anastomosis, but I prefer to do anastomosis first
- What about steal?

SPECIFICATION S Arterial

A proprietary ePTFE Arterial Graft Component

- **6mm ID and 7.4mm OD**
- **53cm long, inclusive of the connector.**
- **PTFE hemodialysis graft with PTFE beading to provide kink resistance near the proprietary titanium connector**
- **Titanium connector attaches the Arterial Graft Component to the Venous Outflow Component.**
- ***<u>SuperHeRO – can use your GRAFT OF CHOICE</u>***



Step 8

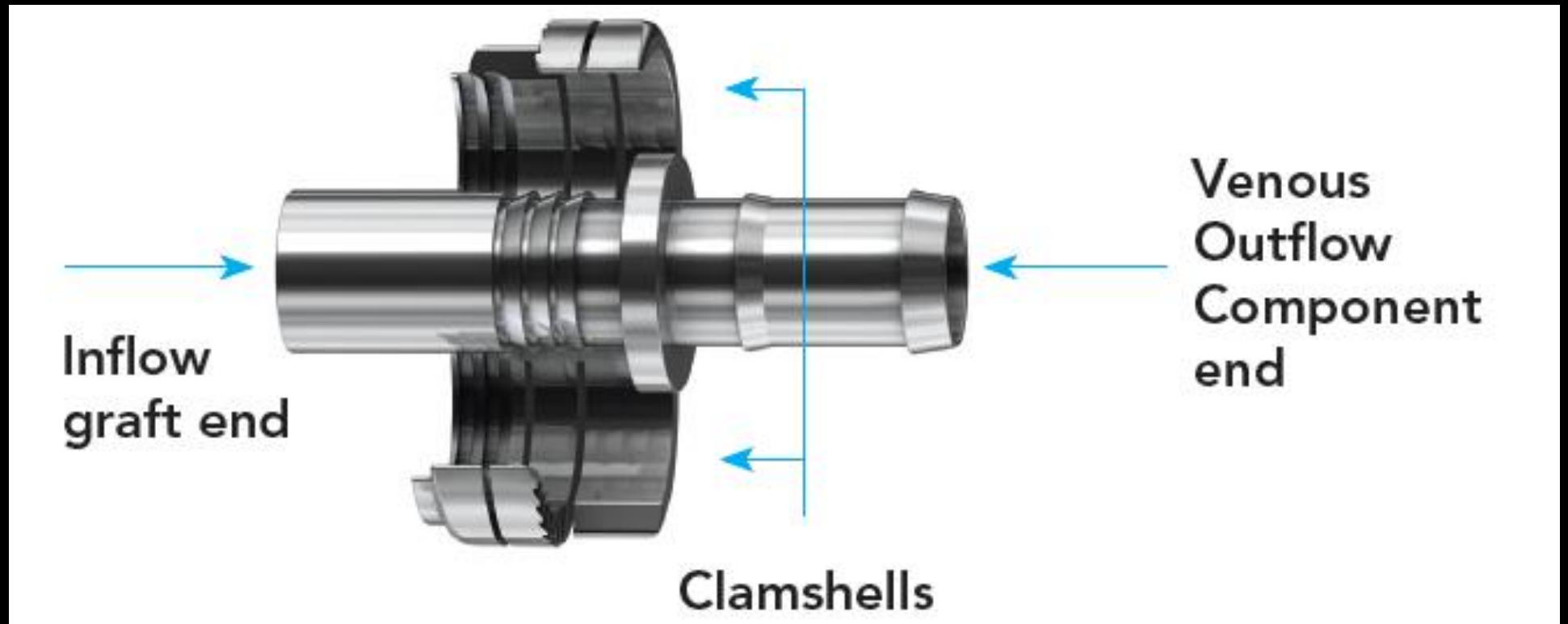
Connect Graft to Outflow Component

- Must cut outflow component with Mayo scissors (straight) or Bandage scissors
- Universal connector – be sure to dilate with dilator a few time prior to connection
- Ideally done at the deltopectoral groove (coracoid process)

Adapter Assembly

Ensure clamshells are open and centered around the Adapter base.

ATTENTION: The clamshells CANNOT be opened once closed. Do NOT close prematurely.



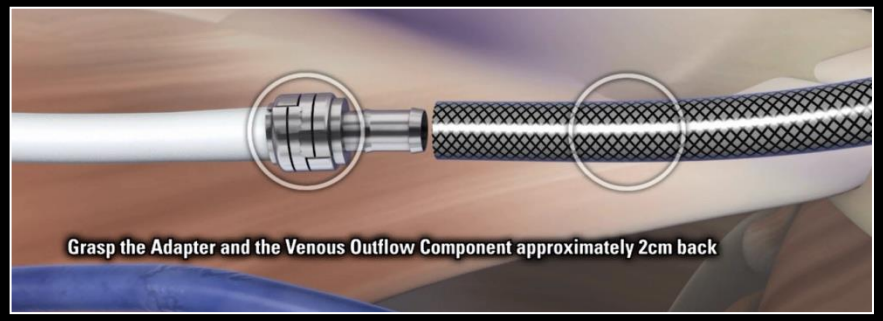
1) HeRO Graft IFU.

Adapter Assembly

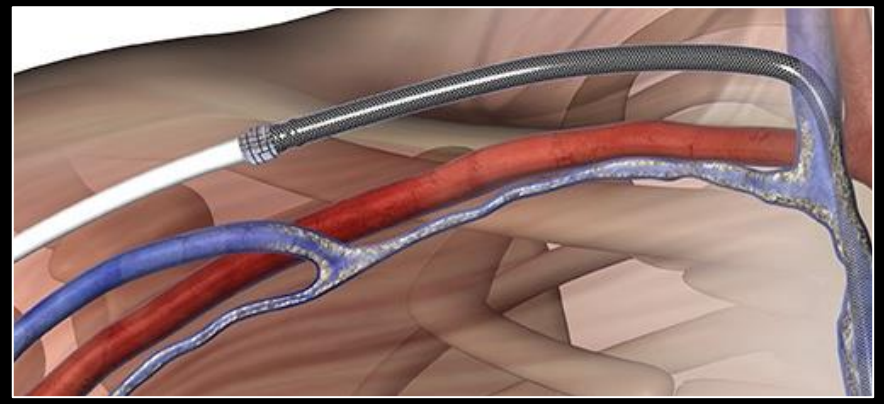
Ready for implant. See Instructions for Use (IFU) for full instructions.



Connect the VOC to the Adapter

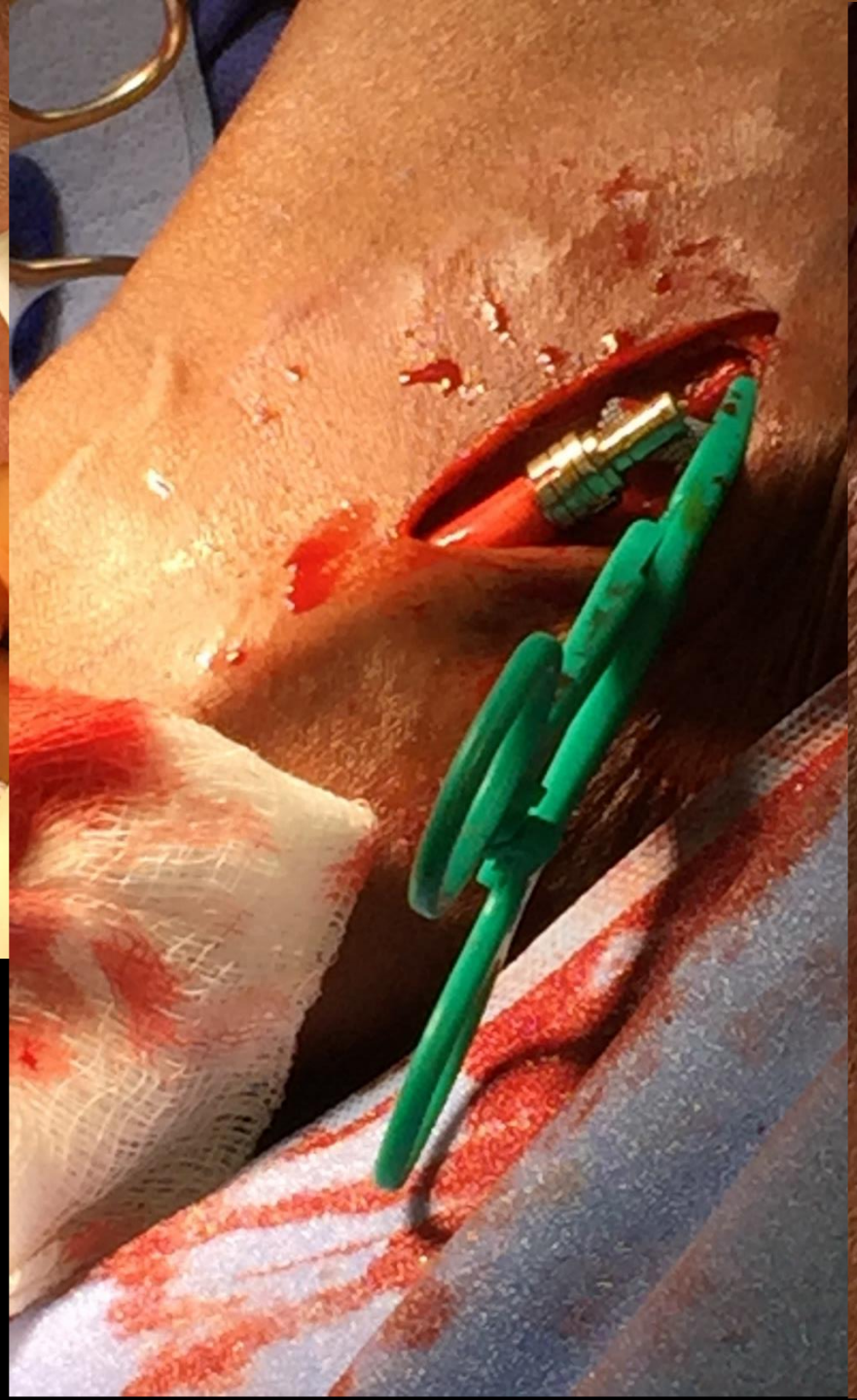


- At the deltopectoral groove, the **Adapter** is joined to the **Venous Outflow Component**.



- Remove the clamp, check the device patency and verify there is no leakage at the **Venous Outflow Component** connection site and graft connection site with the **Adapter** using angiography.







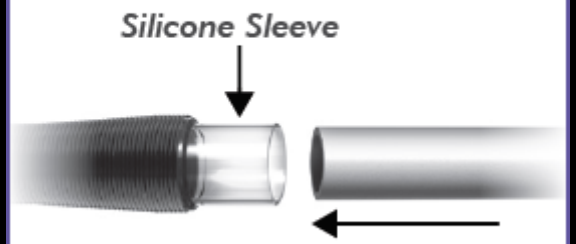
What is the Support Seal

- The Support Seal is a nitinol “slinky” with a silicone sleeve that is glued to the proximal end of the device
- The nitinol slinky allows for kink resistance
- The silicone sleeve helps to create an airtight seal between the Adapter and ePTFE Graft once the Adapter is clamped
- The Support Seal is an accessory product to the Adapter
- Allows for the option of Gore and Bard standard wall grafts

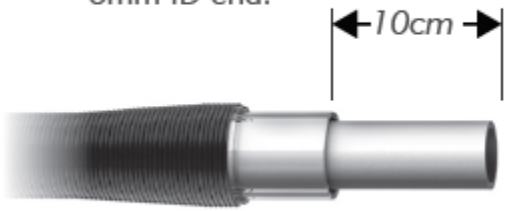


Support Seal Placed Before Connector

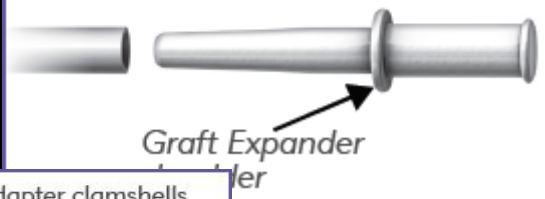
2 Insert graft into silicone sleeve of Support Seal.



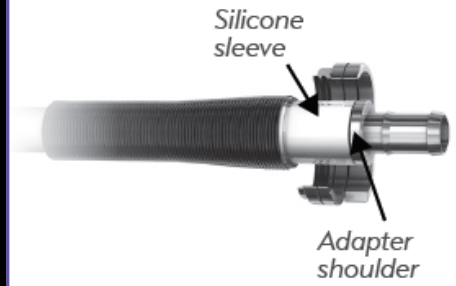
3 Advance Support Seal down the graft and stop approximately 10cm from 6mm ID end.



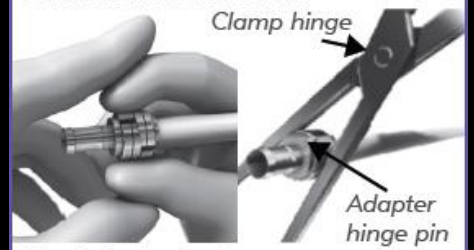
4 Insert Graft Expander into 6mm ID end of graft. Advance graft as much as possible up to shoulder and leave in place.



7 If using Support Seal, advance to the Adapter shoulder. Ensure the end of the silicone sleeve is flush with the graft and shoulder.

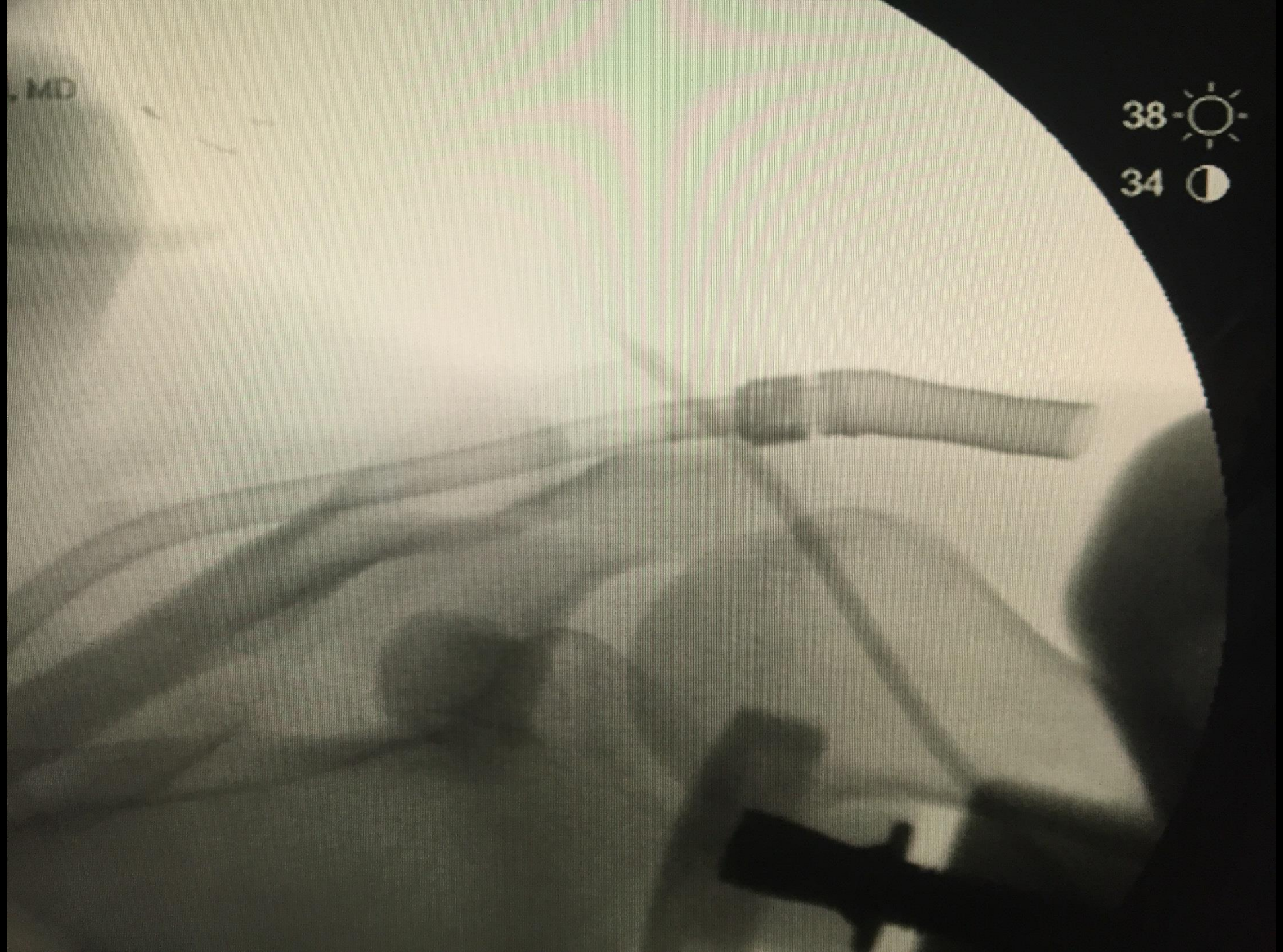


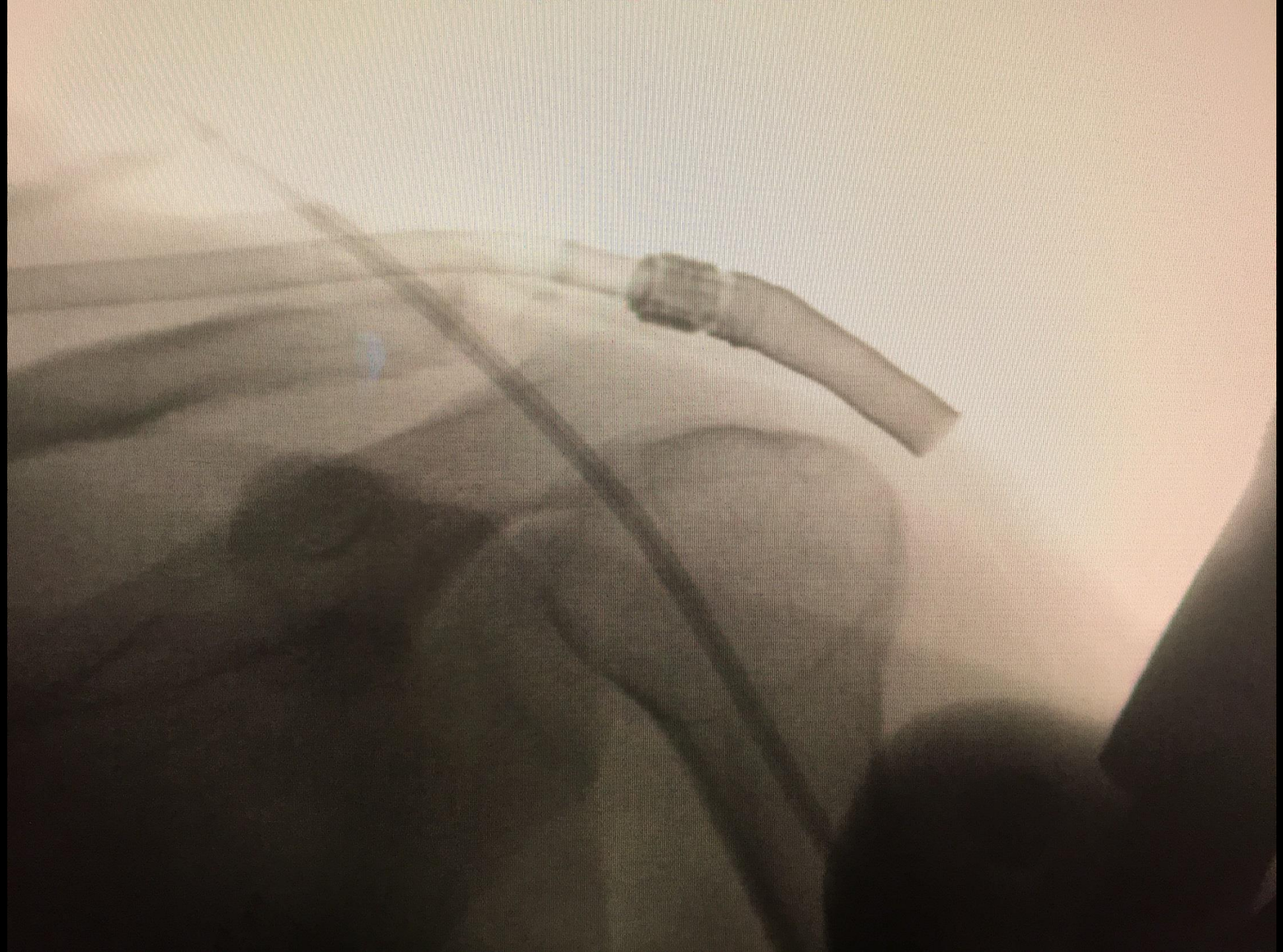
8 Pinch the Adapter clamshells tightly between thumb and index fingers. Ensure full closure of clamshells using a serrated vascular clamp (e.g. Kocher) per orientation shown below.



Ready for implant.
See IFU for full instructions.




MD
38
34







Step 9
Close wounds

- Standard closure
- I tend to use staples or Nylon for swelling and to avoid wound breakdown
- Mark graft – especially if it is an early stick graft to be sure staff knows what direction the flow is and where they can reliably access it

Step 10

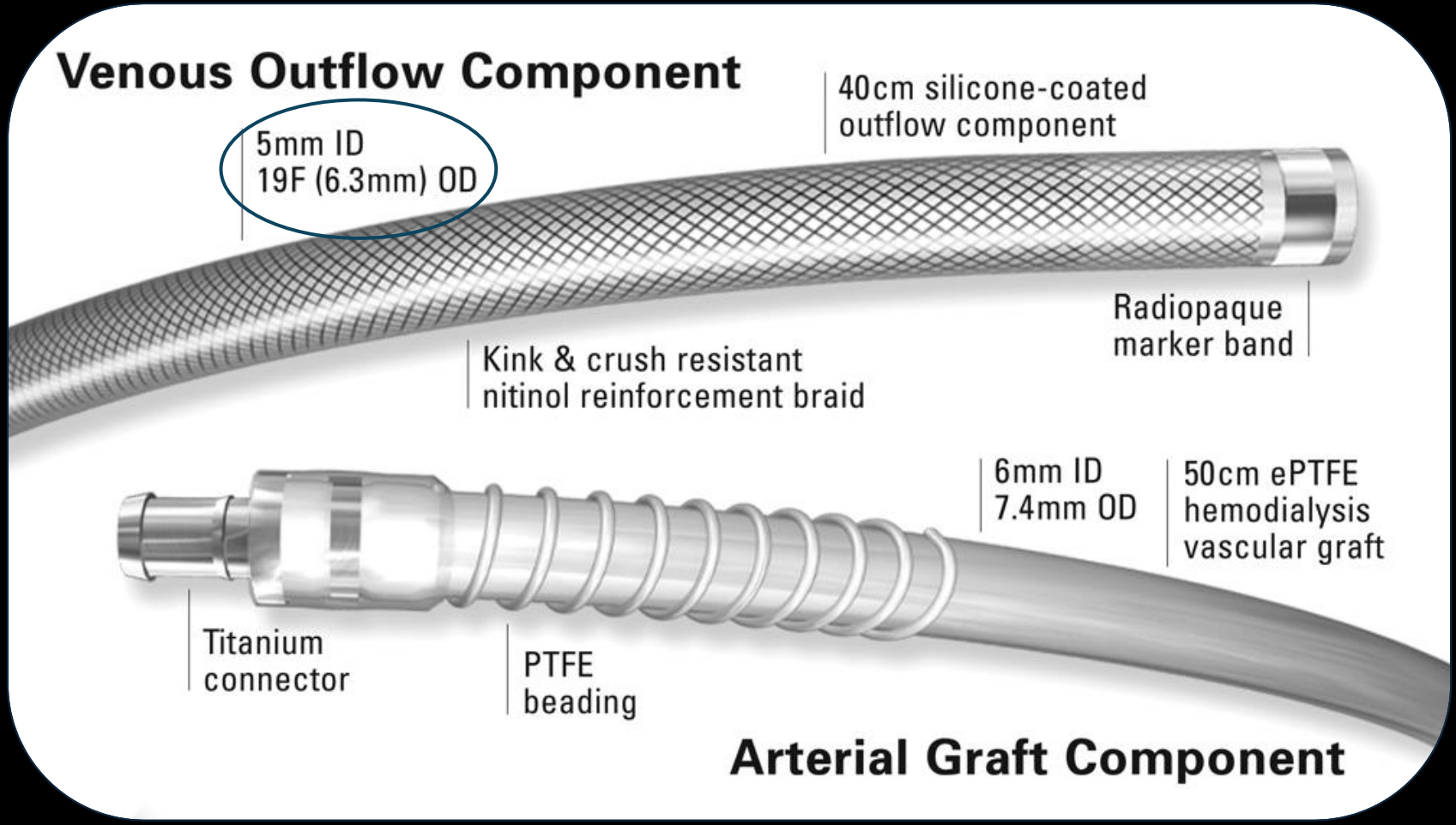
Post-operative orders

- Review blood pressure medications – if patient is chronically hypotensive, then may consider stopping
- Plavix if not on anti-platelet therapy and consider Eliquis for hypercoagulability or recurrent thrombosis
- Call center or nephrologist – especially early in experience





NEED TO: Know your product

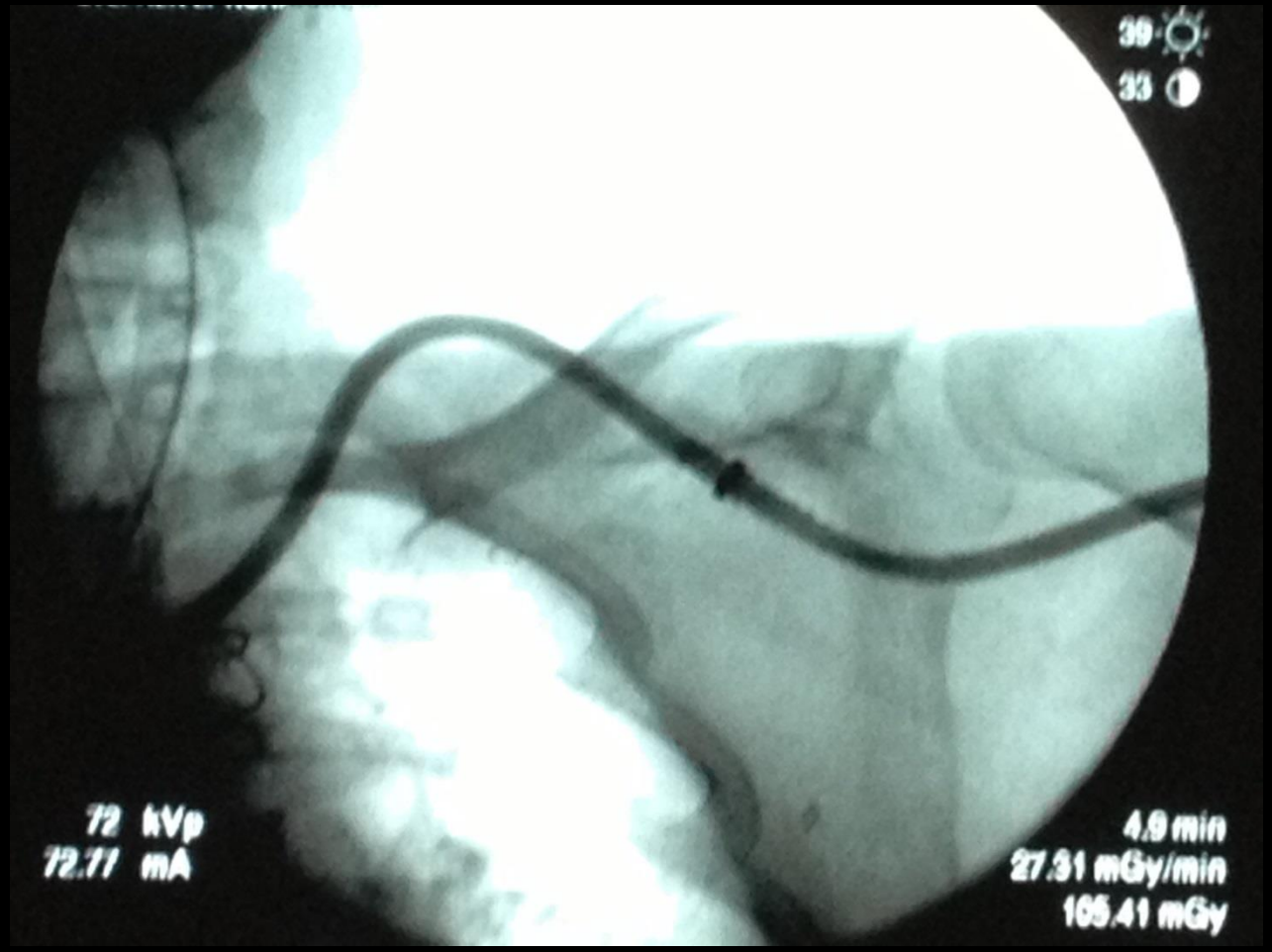


NEED TO: Get wire into IVC - new access if possible, but don't be afraid to overwire

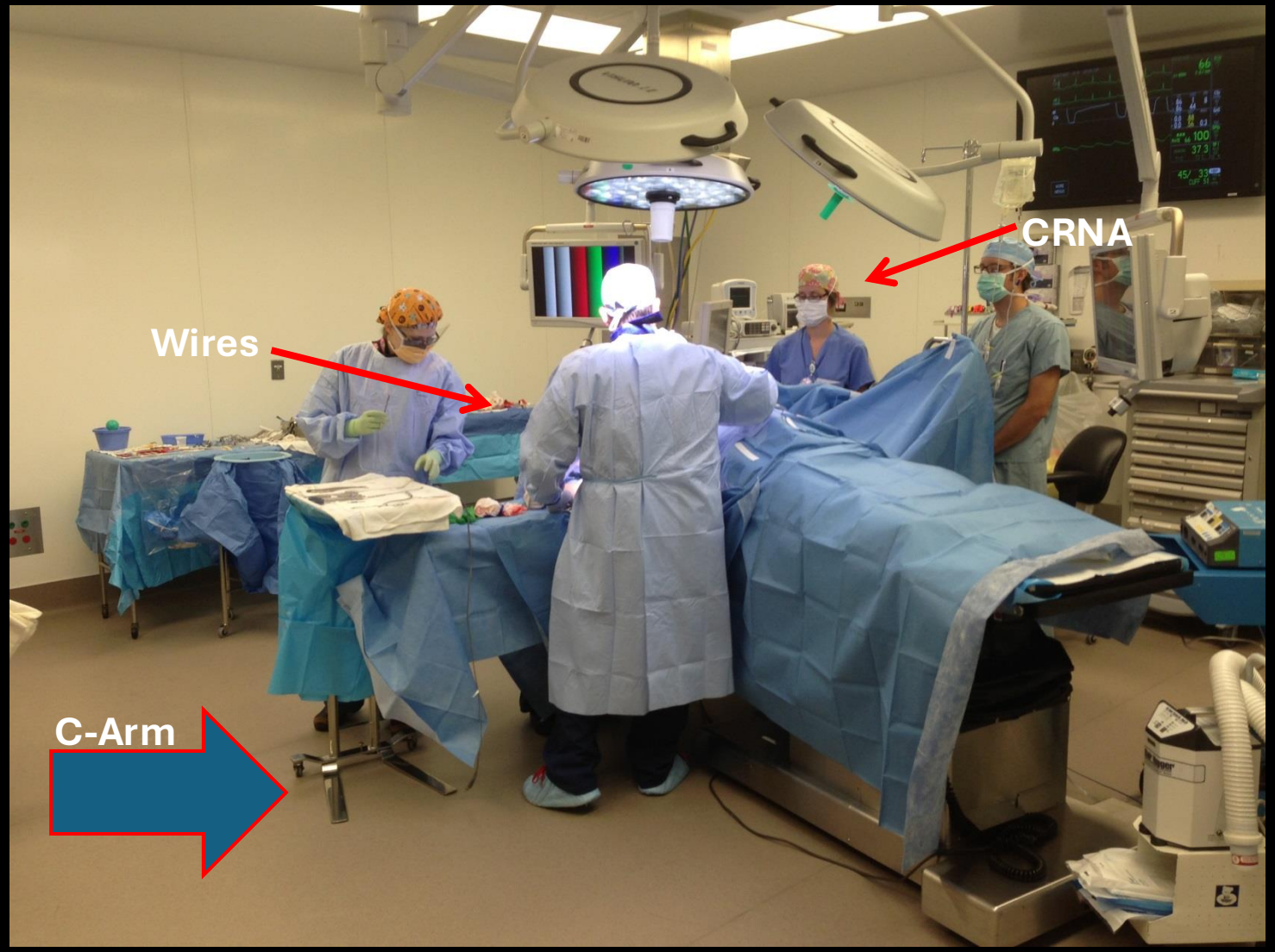


Consider Vancomycin (MRSA, recent hospitalizations, etc)

NEED TO: Consider Plavix post op, if clots early, consider Coumadin



NEED TO: Be there for prepping

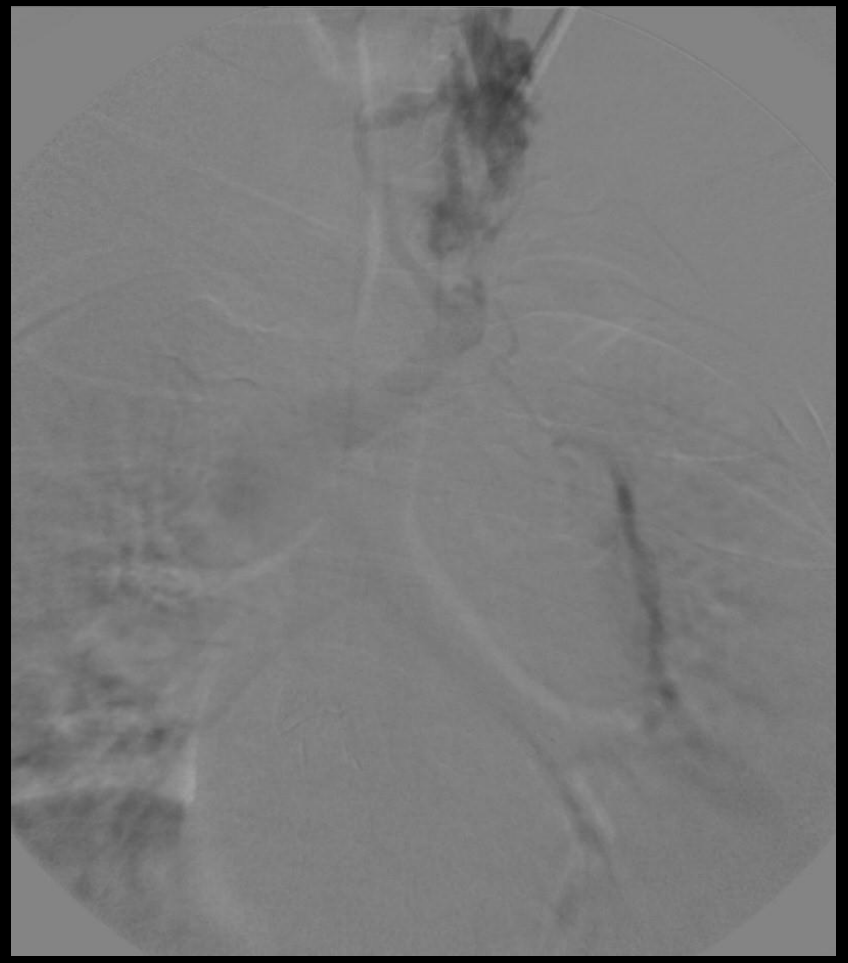


NEED TO: Peel Sheath Outside Body



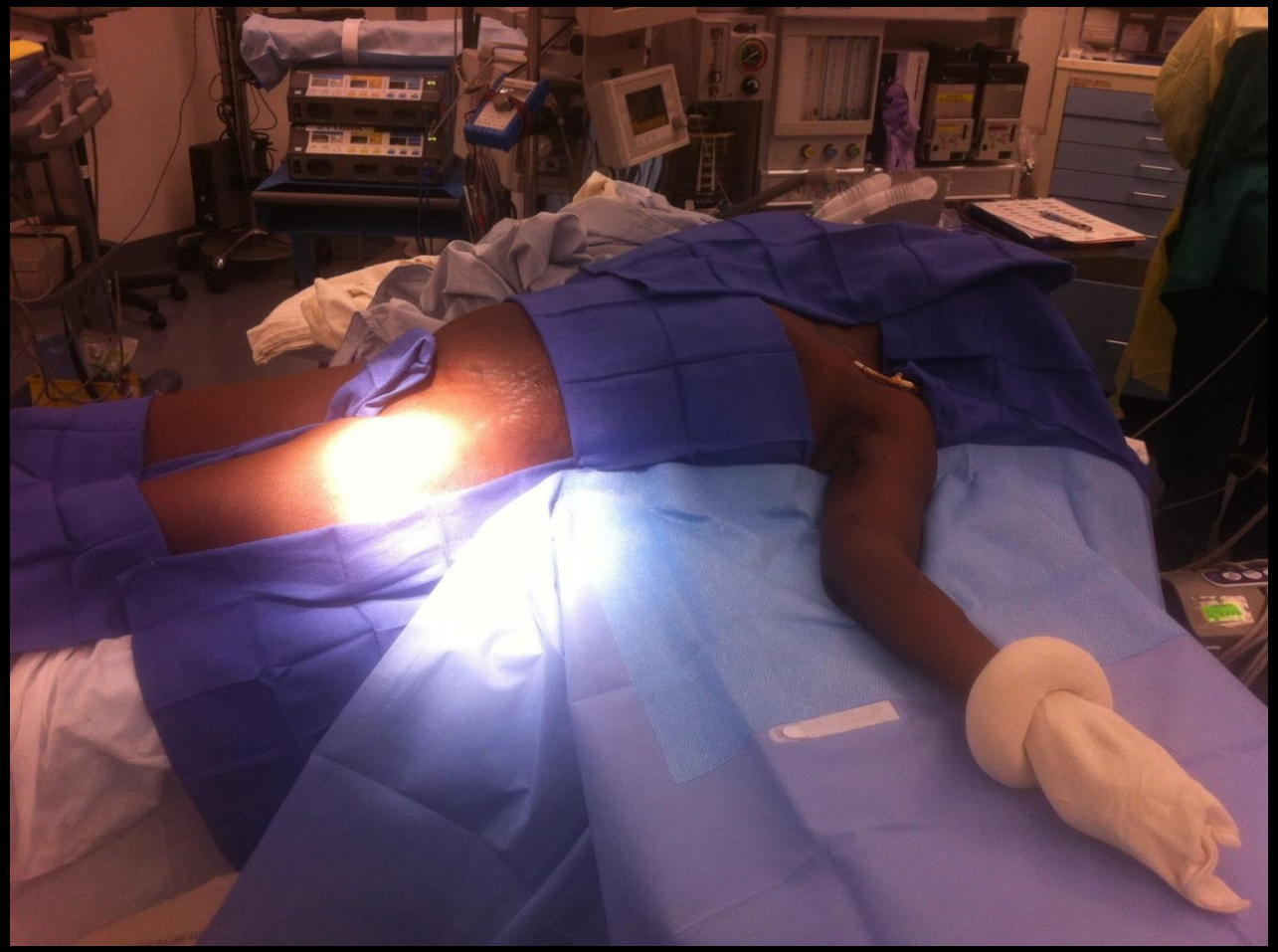
Don’t #1: Overcommit

- **Location, location, location**



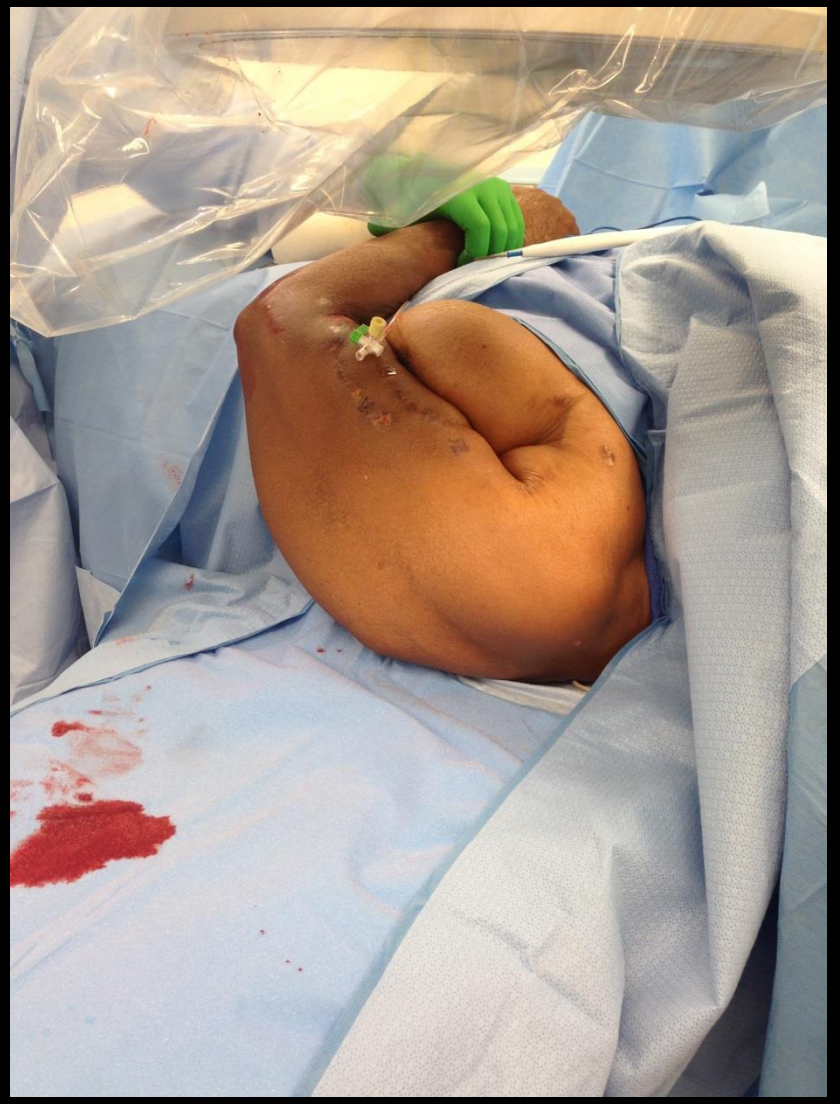


Don’t #2: Don’t ever place HeRO without stiff wire in IVC



Don’t #3: Put connection on arm





Don’t #4: Use Long Sheath if you don’t need it



Don’t #5: Don’t Force It – Outflow component will not track

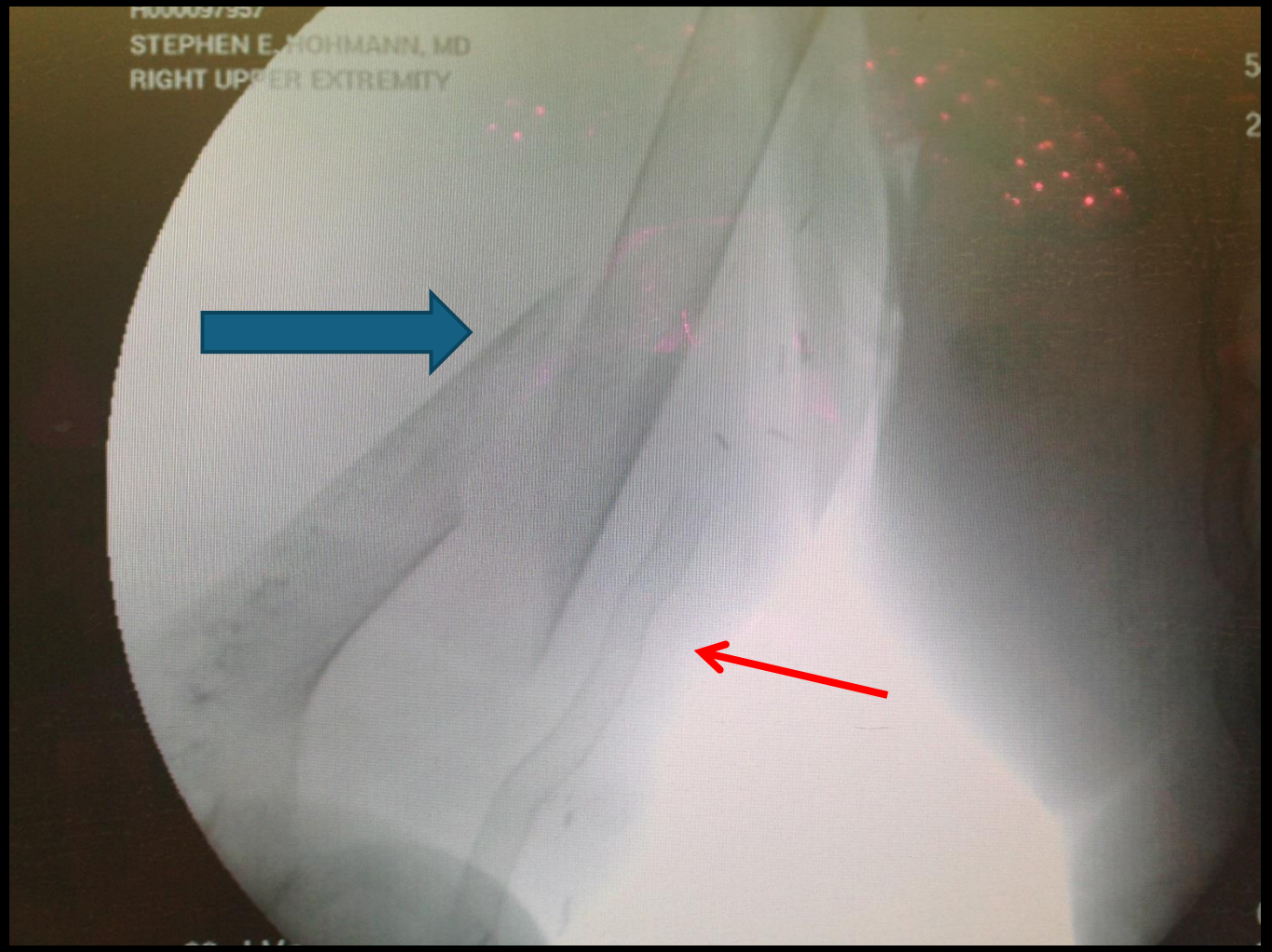
- Maintain wire access and do not peal sheath
- Put plug back in
- Put 6-8F sheath over wire
- Get 8mm by 4-6cm balloon and PTA
- Then try to place outflow again
- Pull peal away sheath back before pealing

Don’t #6: Don’t declot without fluoroscopy

- Standard declotting technique
- Check outflow component placement before declotting
- If open declot, put small amount of contrast in Fogarty balloon to ensure outflow component is not pulled back
- If percutaneous, standard technique, avoid over ballooning outflow component

Don’t #7-10:

Don’t overmanipulate an arm with a contracture



Bonus – Clotted HeRO

Early (<6 months)	Mid (6months– 2 yrs)	Late (> 2years)
• Position of VOC (check CXR) • Technical Error • Hypotension • Hypercoagulability	• Usually the graft itself versus migration	• Graft stenosis • Stenosis at connector site

SUMMARY

- Central venous tool which is removable
- Not as easy to put in as you would think
- Early failure, check CXR (mid atrium location? And think hypercoagulable/hypotension)
- Just because someone else said it could not be done – does not mean it is true
- MILLION DOLLAR QUESTION – What about stents?

Thank you!

Stephen E. Hohmann, MD FACS
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Table 6 Secondary patency of the access circuit

	AVF peripheral % (n/N)	AVG anastomosis % (n/N)	AVG periph % (n/N)	AVF/AVG central % (n/N)	patients n/N)
30 Days	100% (16/16)	100% (8/8)	100% (10/10	100% (11/11)	% (45/45)
3 months	100% (16/16)	100% (8/8)	100% (10/10	90.9% (10/11)	8% (44/45)
6 months	100% (16/16)	100% (8/8)	100% (10/10	81.8% (9/11)	6% (43/45)
12 months	93.3% (14/15)	87.5% (7/8)	90.0% (9/10	81.8% (9/11)	6% (39/44)

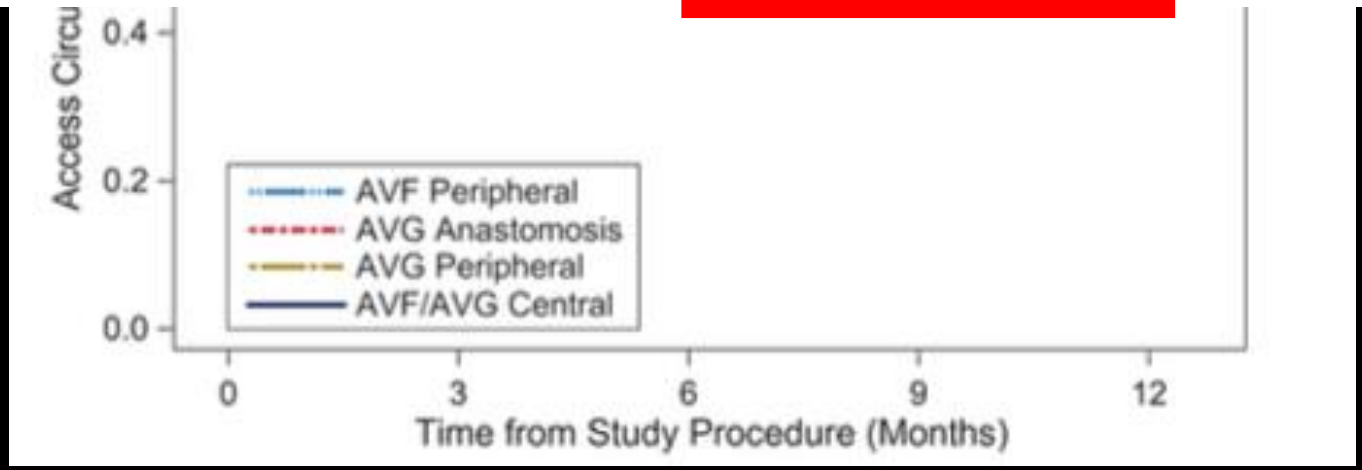


Table 6 Secondary patency of the access circuit

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30 Days	100% (16/16)	100% (8/8)	100% (10/10)	100% (11/11)	100% (45/45)
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6 months	100% (16/16)	100% (8/8)	100% (10/10)	81.8% (9/11)	95.6% (43/45)
12 months	93.3% (14/15)	87.5% (7/8)	90.0% (9/10)	81.8% (9/11)	88.6% (39/44)

Cardiovasc Intervent Radiol
https://doi.org/10.1007/s00270-024-03790-1

CIRSE

CLINICAL INVESTIGATION VENOUS INTERVENTIONS

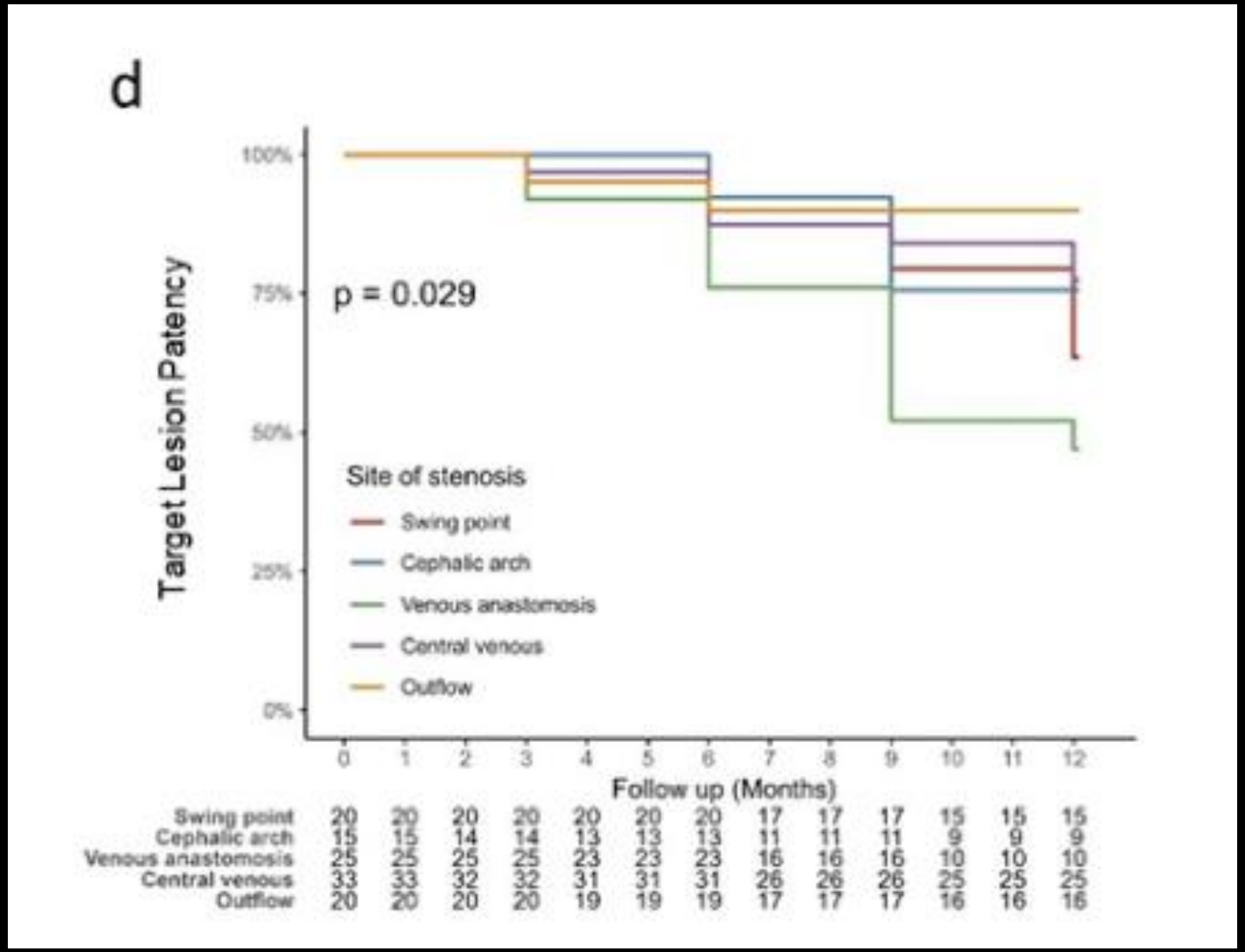
Safety and Performance of a Cell-Impermeable Endoprosthesis for Hemodialysis Vascular Access Outflow Stenosis: A Brazilian Multicenter Retrospective Study

Leonardo de Oliveira Harduin[1] · Thiago Almeida Barroso[2] · Julia Bandeira Guerra[3] · Márcio Gomes Filippo[4] · Leonardo Cortizo de Almeida[5] · Brunno Ribeiro Vieira[6] · Renata Silveira Mello[7] · Adriano Martins Galhardo[2] · Jorge Paulo Strogoff-de-Matos[8]

site.

TLPP rates of 92.3% at 6 months and 75.0% at 12 months for the basilic swing point in the present study aligns with prior evidence showing primary patency rates of 57% and 40% at 6 and 12 months, respectively [15]. In central veins, TLPP rates of 87.5% at 6 months and 76.7% at 12 months were observed. These rates are higher than those reported in other studies that included treatment of central venous stenosis [24–30]. A primary limitation when addressing central venous stenosis with covered stents is their size availability [31]. While other covered stents have been used to treat dysfunctional vascular access [31], the device used in this study is currently the only one available in sizes up to 16 mm and the only one evaluated in patients with central venous stenosis [7]. The high patency rates observed in central veins in our cohort, along with enhanced primary patency rates in patients treated with devices with diameters of 10, 12, 14, and 16 mm, suggest that the device can effectively manage difficult cases.

a


Target Lesion Patency
100%
75%
50%
25%
0%
p = 0.029
Site of stenosis
Swing point
Cephalic arch
Venous anastomosis
Central venous
Outflow
0 1 2 3 4 5 6 7 8 9 10 11 12
Follow up (Months)
Swing point 20 20 20 20 20 20 20 17 17 17 15 15 15
Cephalic arch 15 15 14 14 13 13 13 11 11 11 9 9 9
Venous anastomosis 25 25 25 25 23 23 23 16 16 16 10 10 10
Central venous 33 33 32 32 31 31 31 26 26 26 25 25 25
Outflow 20 20 20 20 19 19 19 17 17 17 16 16 16

Initial six-month clinical outcomes of patients from the thoracic central venous cohort of the WRAP Global registry

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WRAP Registry Design Overview

- **Prospective**, multicenter registry (41 international centers)
  - Real-world observational study*
  - Includes 496 hemodialysis patients (AVF & AVG) with venous outflow stenosis or obstruction, including central veins
    - Inclusion / exclusion criteria aligned with commercial Instructions for Use
- Follow-up data being collected at 6, 12, 24 months following device placement

*Rajan & Kitrou, 2023. *Cardiovasc Intervent Radiol*.

Effectiveness Endpoints

6-month target lesion primary patency (TLPP)‡	TLPP: freedom from clinically-driven target lesion revascularization (CD-TLR) or target lesion thrombosis measured through 6 months post-procedure, which is the time interval of uninterrupted patency after study procedure to the next intervention performed on the target lesion or uncorrectable target lesion occlusion ‡ Target lesion restenosis included the adjacent 5 mm on either side of the treated vessel segment, as adjudicated by core laboratory[a,b]
Access circuit primary patency (ACPP)	Time to loss of primary patency of the entire access circuit, specifically, the time from the index procedure to any venous outflow circuit re-intervention, access thrombosis, or access abandonment

[a] Garcia-Garcia, et al. 2018. *Circulation*.
[b] Dolmatch et al., 2023. *Kidney Int*.

Rajan & Kitrou, 2023. *Cardiovasc Intervent Radiol*.

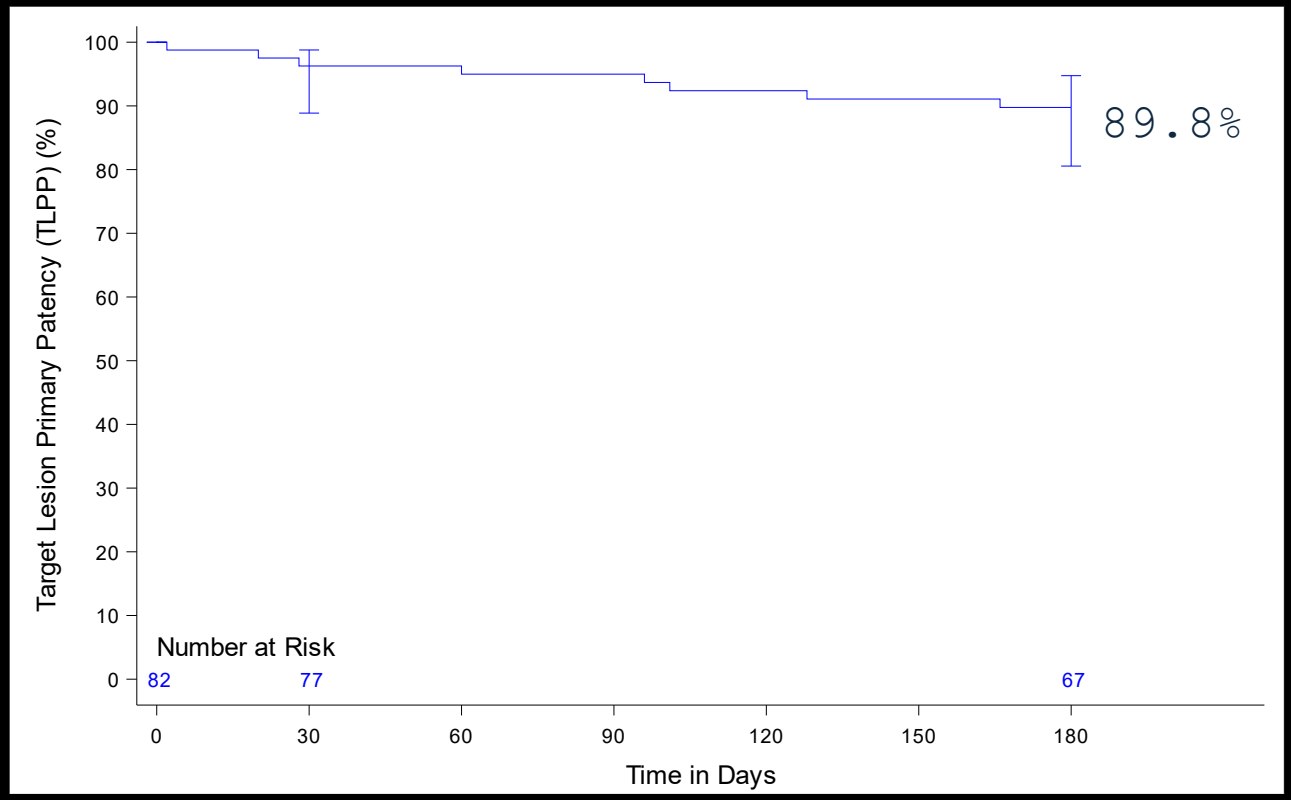
Population

- 143 patients had devices placed centrally
  - Of this group 82 assessable at 6 months for safety
  - At 6 months patency available in 75 patients
    - Loss to follow-up, access abandonment and death

30-Day Safety Endpoint

	Patients (N=82)
Freedom from localized or systemic safety events (Intention to Treat Population), n/N (%)	79 / 81 (97.5)
Freedom from localized or systemic safety events (Per Protocol Population), n/N (%)	77 / 78 (98.7%)

Target Lesion Primary Patency



Access Circuit Primary Patency

