

# Kapsus – Procedural Steps & Project Update

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August 2013

Presented by Bavaria Medical Technology

# Agenda

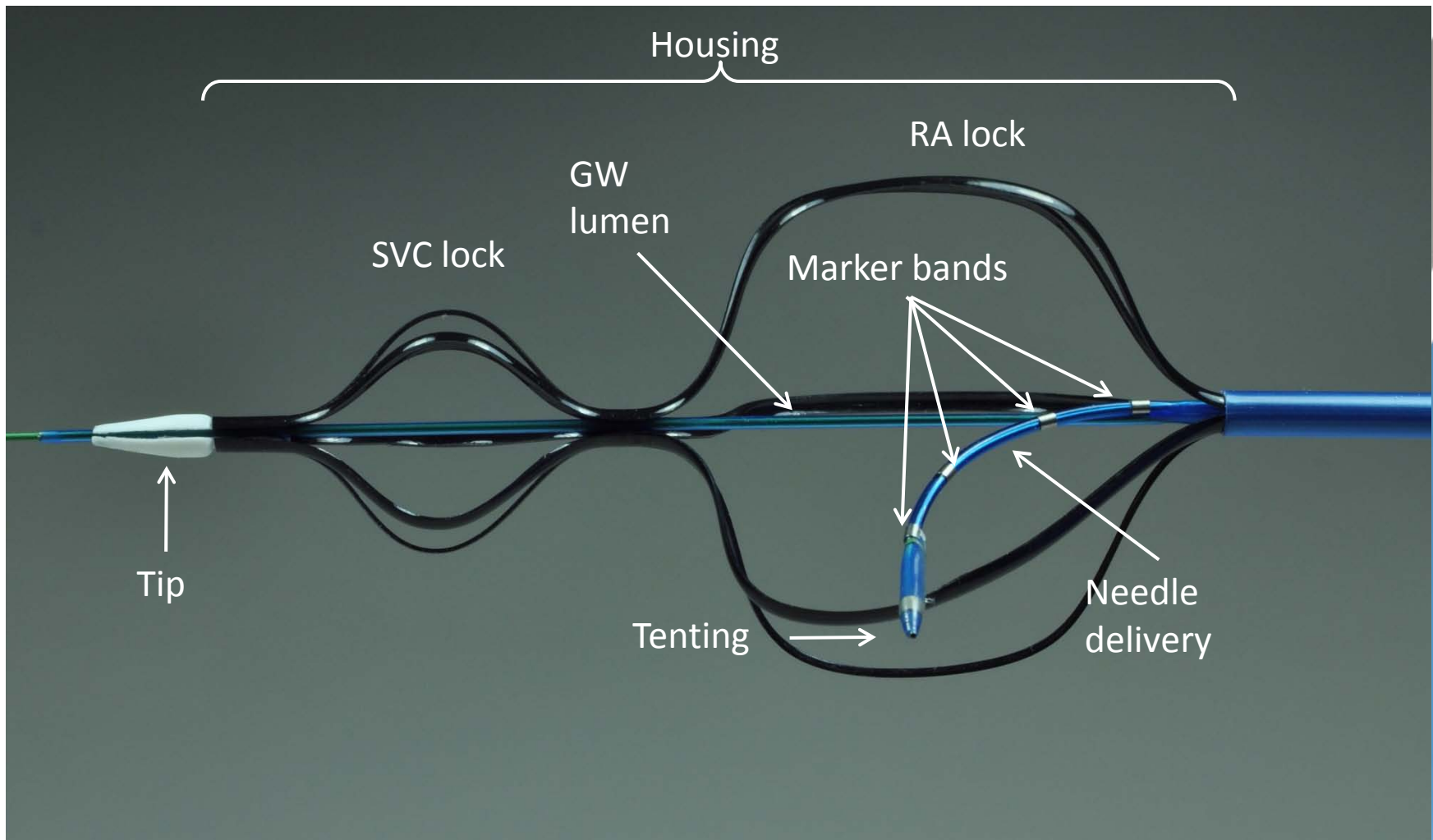
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- Device Overview
- Procedural Steps
- Engineering Progression
- Future Improvements
- Potential Development

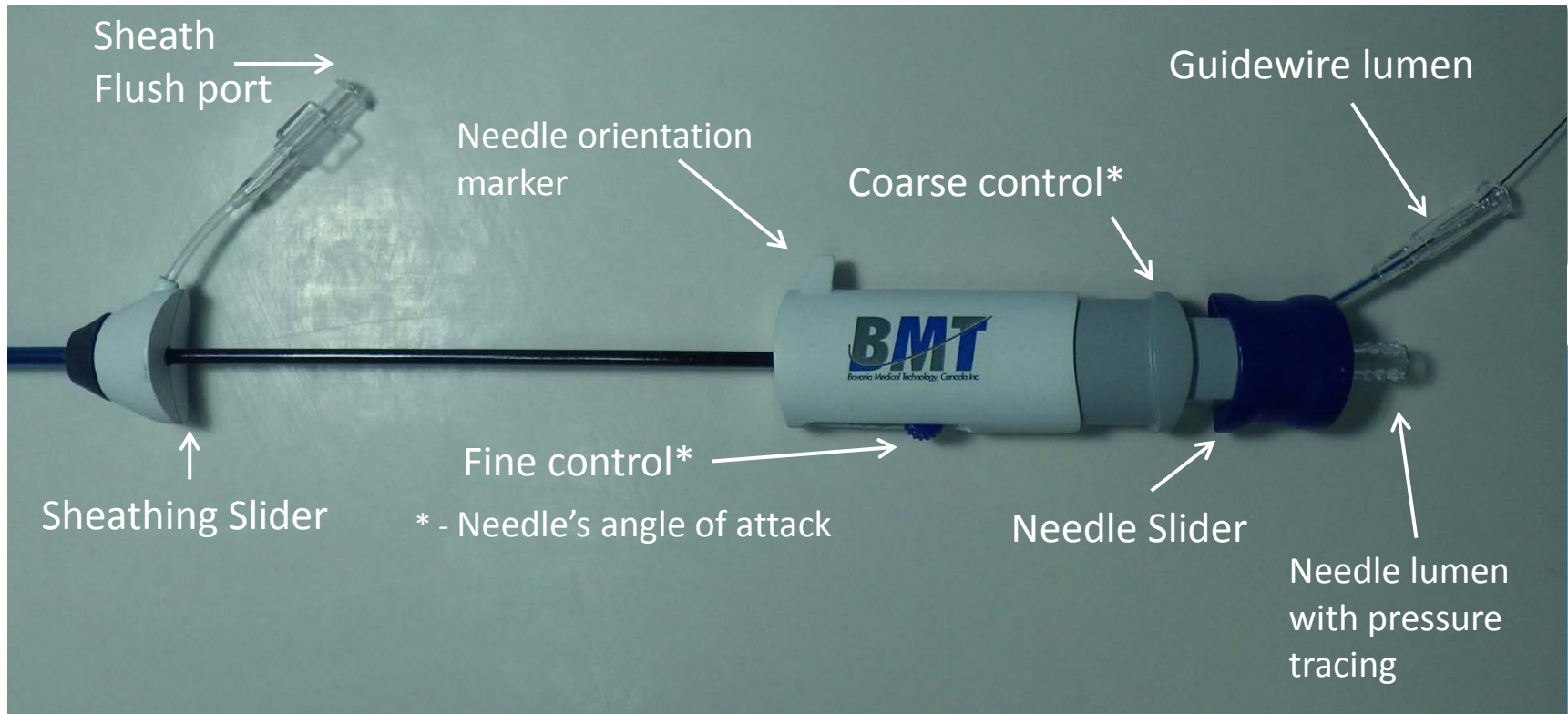
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# Device Overview

# DISTAL SECTION OF THE KAPSUS DEVICE



# PROXIMAL SECTION OF THE KAPSUS DEVICE



# Kapsus Product

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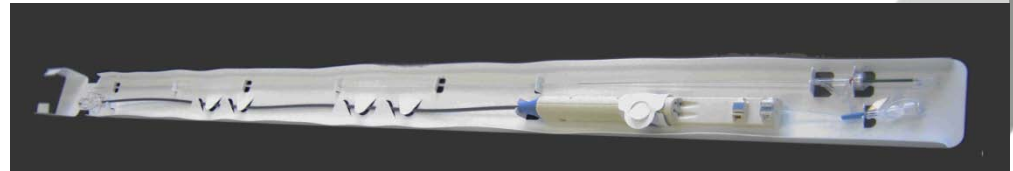
- Guidewire lumen: 0.025" (OTW)
- Profile: 12Fr compatible
- Workable Length: [75 – 85cm]
- Overall Length: Workable length+10cm
- Needle size: 0.018" → 0.025" future dev.
- Single needle
- Radiopaque PEEK
- Echogenic delivery needle.

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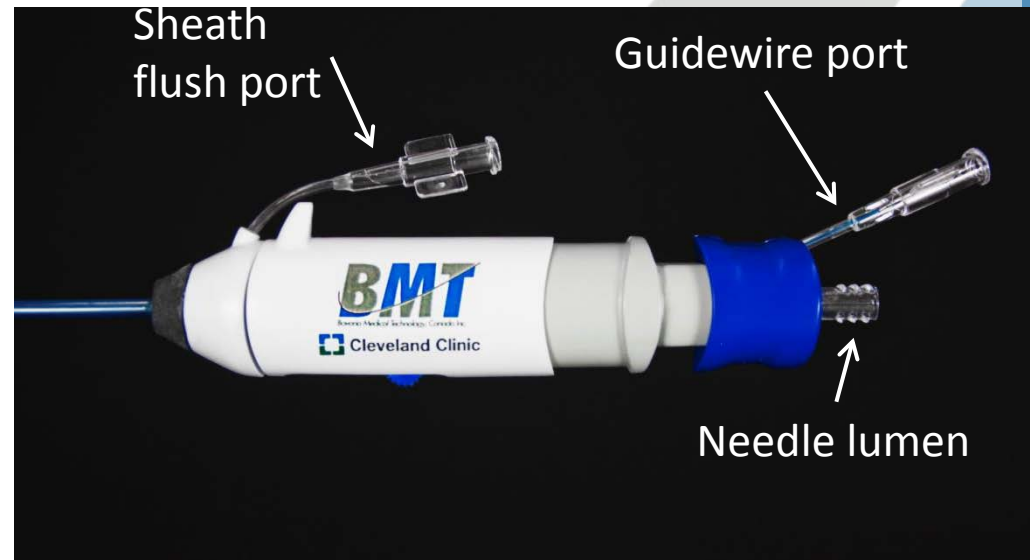
# Procedural Steps

# PREPARE AND ASSEMBLE EQUIPMENT

- Unpack the Kapsus catheter from its packaging and sheath the housing.



- Flush the Sheath, the Guidewire lumen and the Needle lumen with sterile heparinized saline.

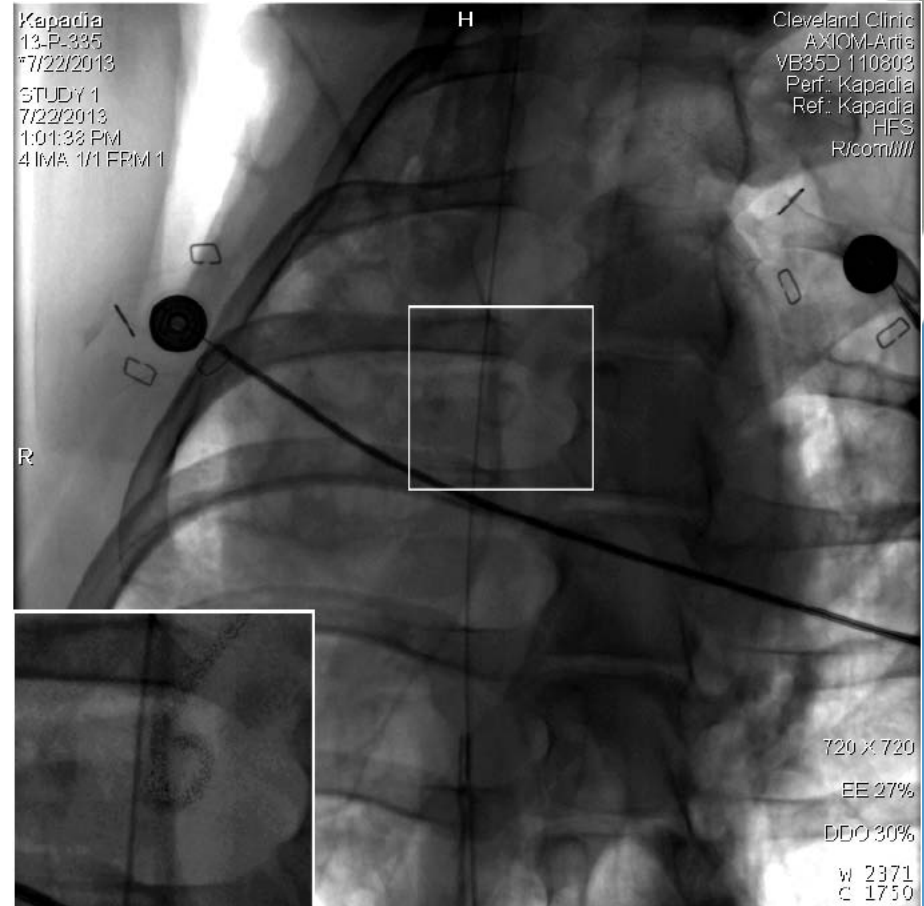




# PRE-PROCEDURAL IMAGING

## ARTERIAL SIDE

- Insert Pigtail catheter to locate the aortic root
- Locate the anatomical landmarks:
  - Non-coronary sinus leaflet
  - RA, LA, SVC, RV, LV through contrast injection
- Optionally, confirm location of septum with ICE or TEE.

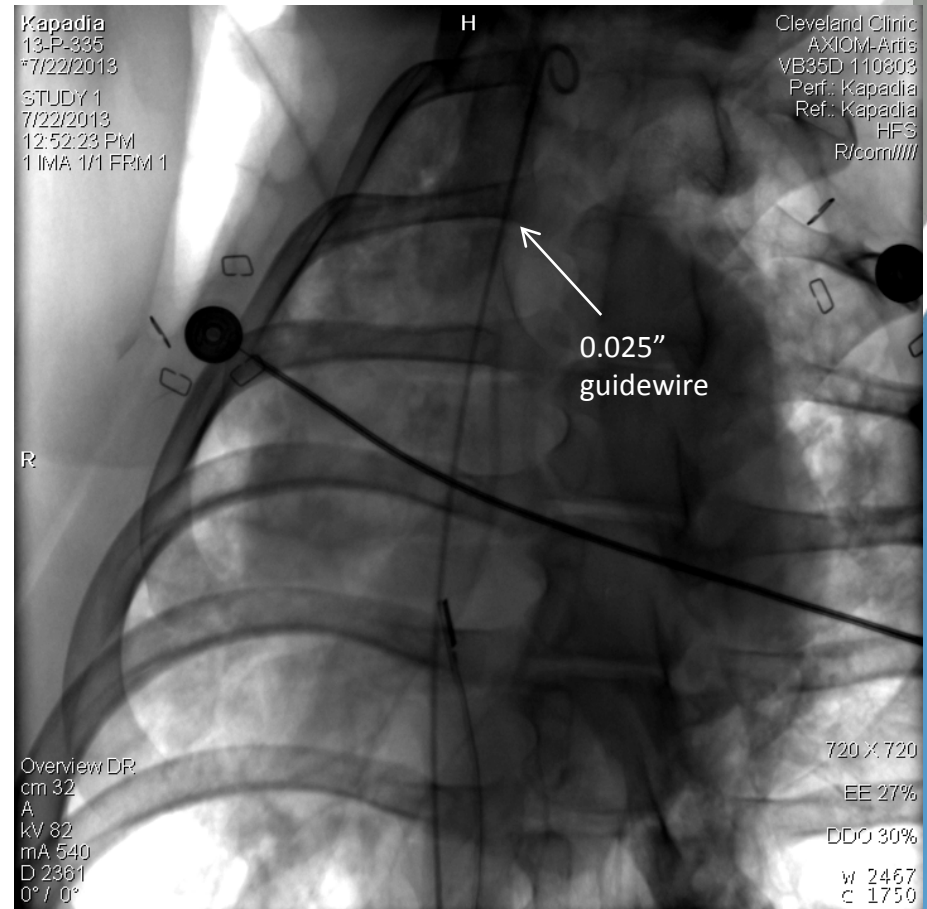


# ADVANCE GW INTO SVC

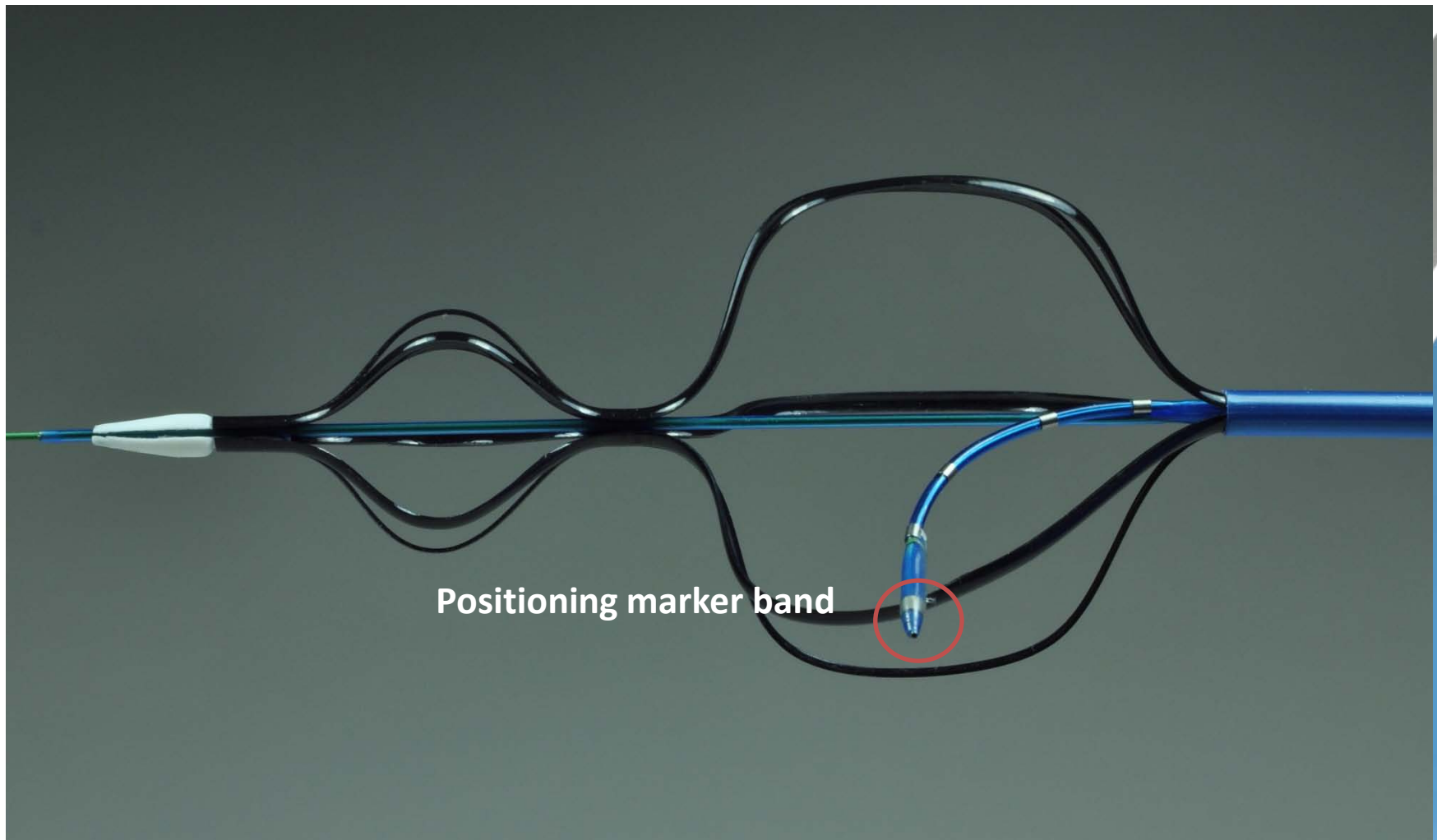
## VENOUS SIDE

- Obtain femoral venous access with the 12FR introducer
- Position an 0.025" extra-stiff guidewire\* into the superior vena cava

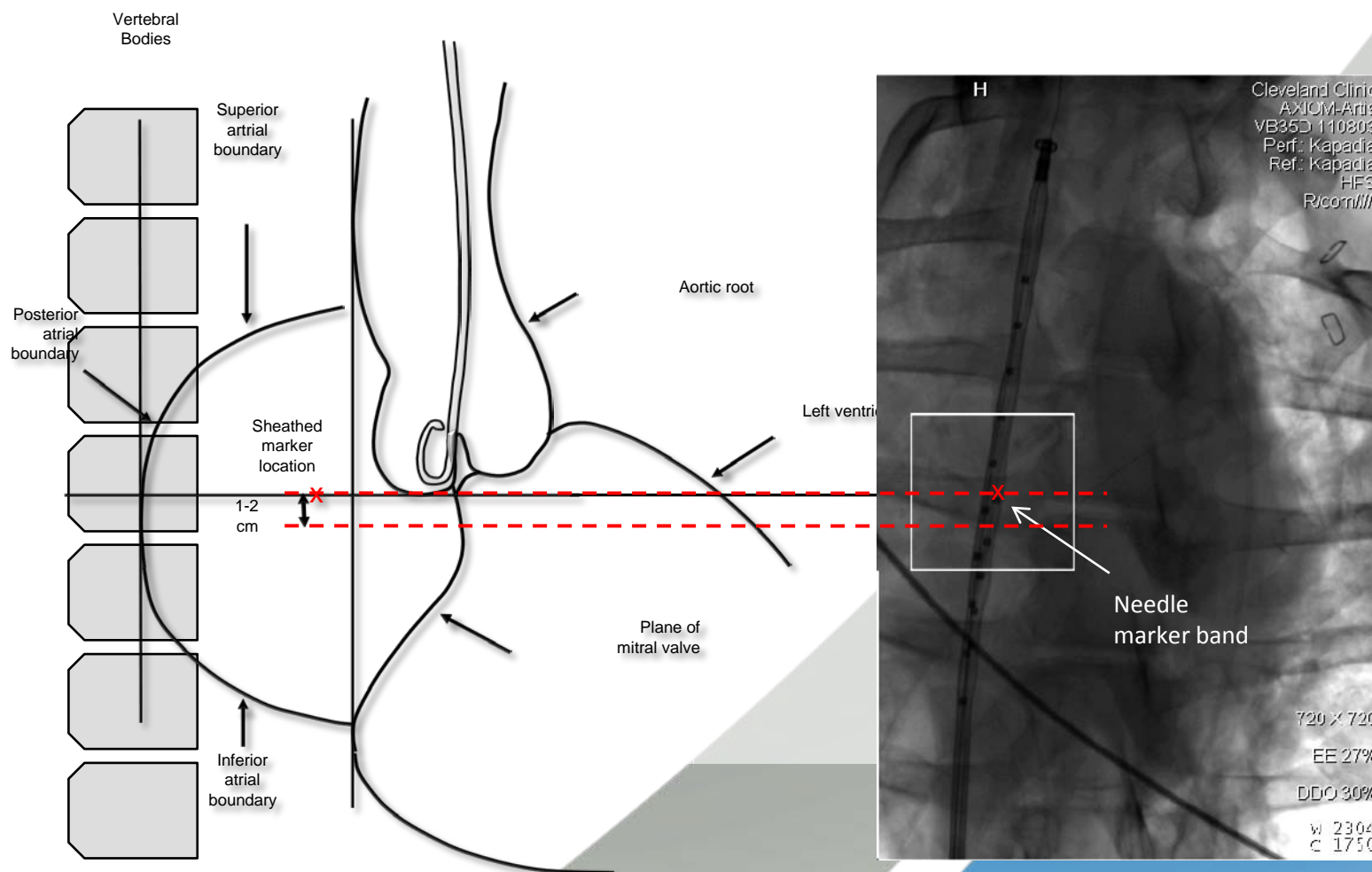
\* - Could be provided as accessory with device



# DISTAL SECTION OF THE KAPSUS DEVICE



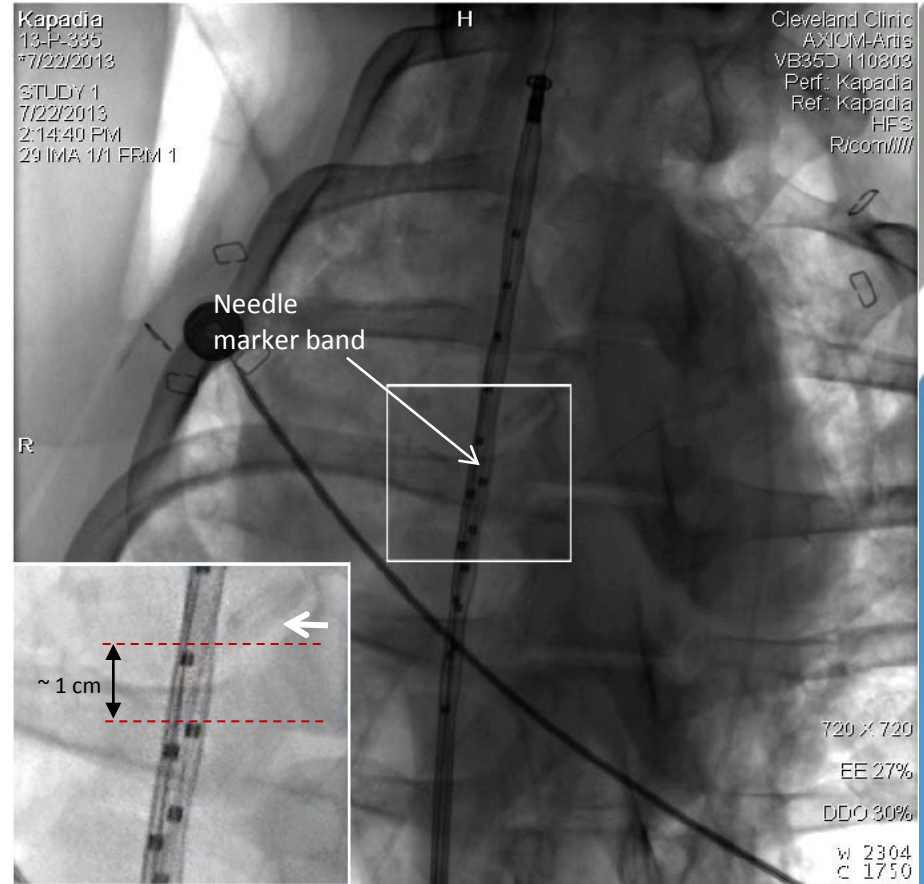
# "THE PLAN" STEP 1



# ADVANCE KAPSUS INTO SVC

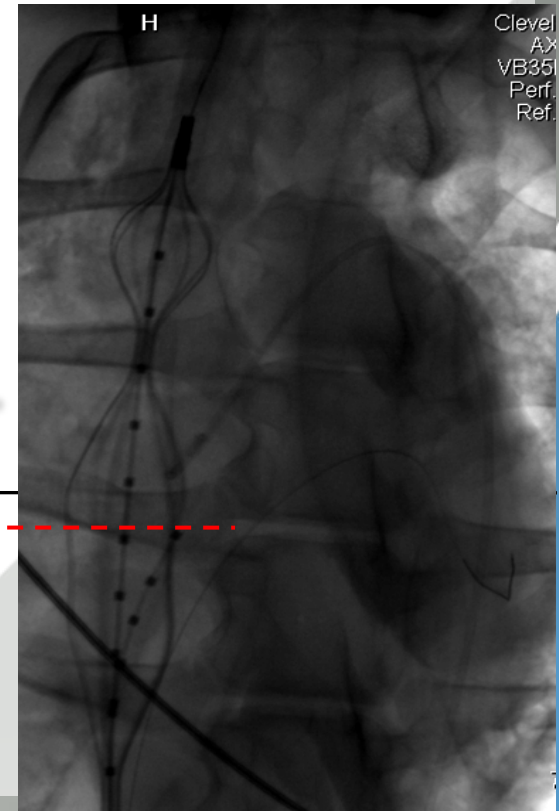
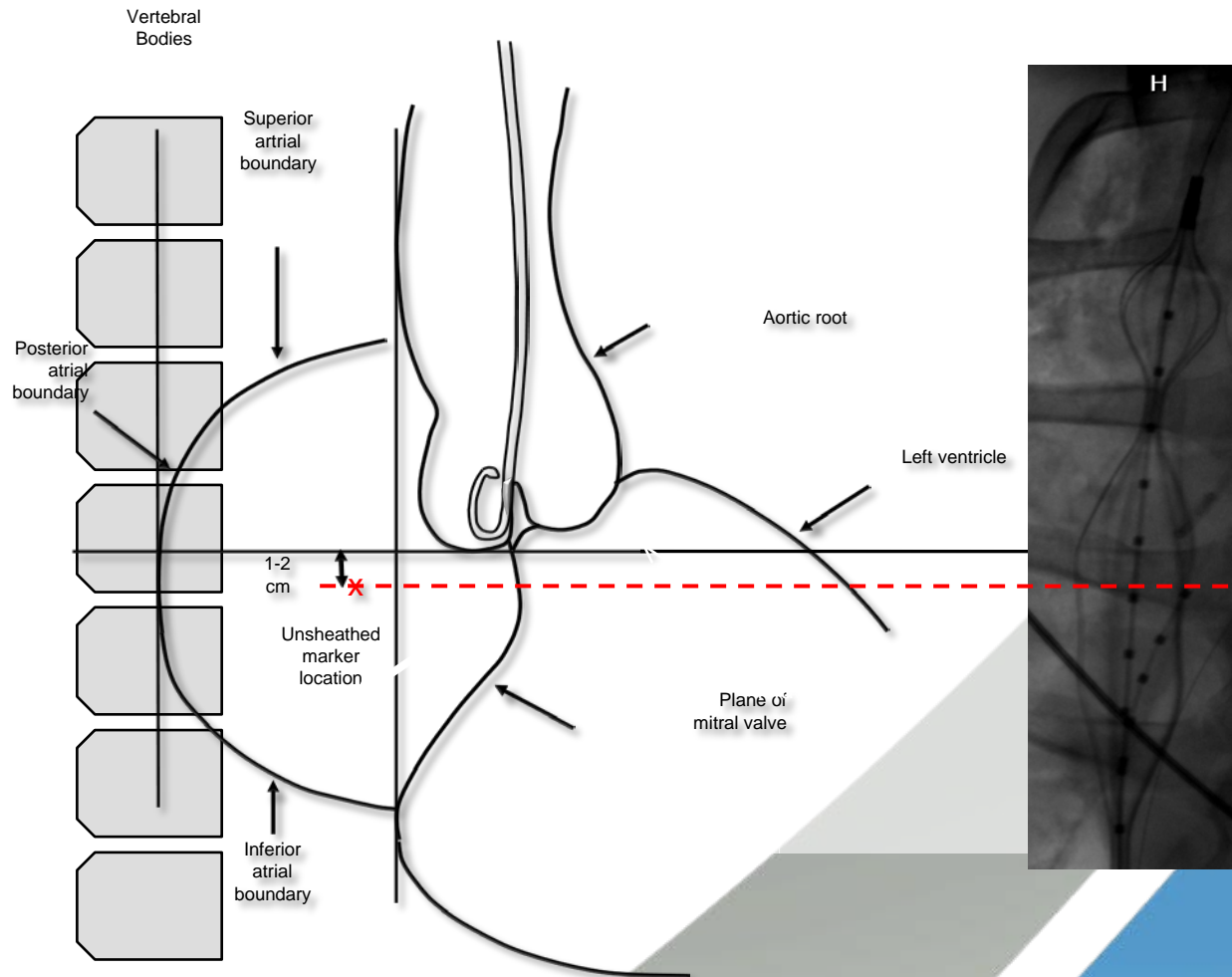
- Advance the Kapsus until the markerband on the needle delivery catheter is aligned with the aortic root.
- Ensure the device points towards a “5’o clock” orientation\*

\*use arrow on handle



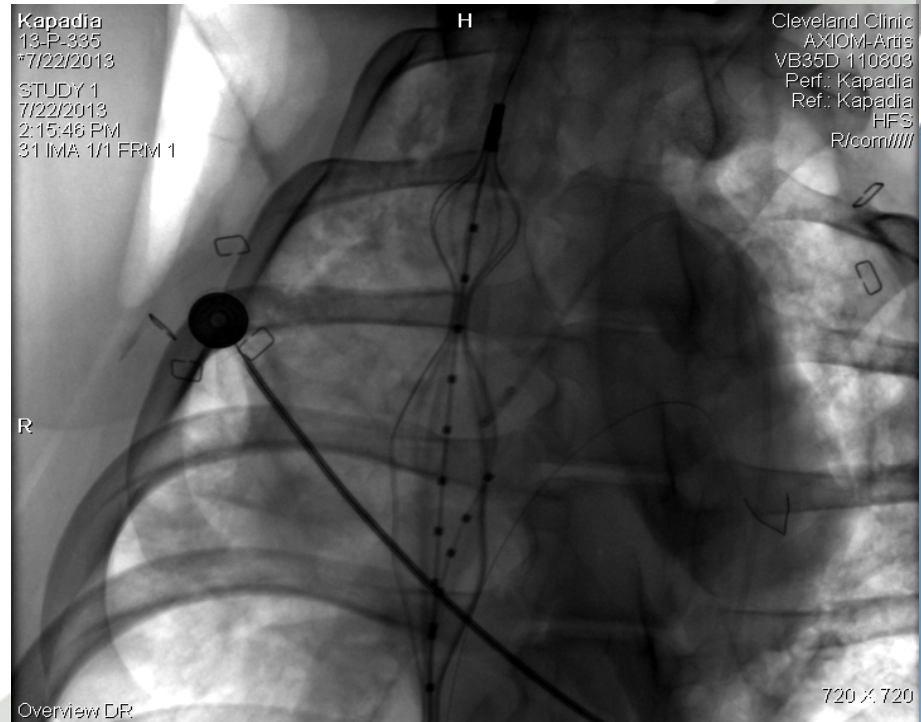
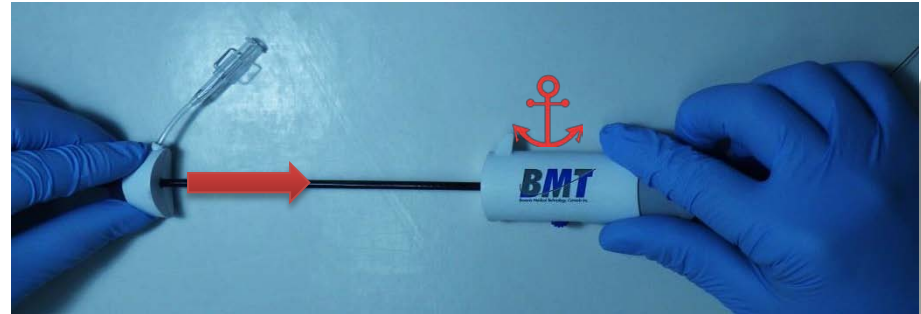


# “THE PLAN” STEP 2 – UNSHEATHE



# DEVICE DEPLOYMENT

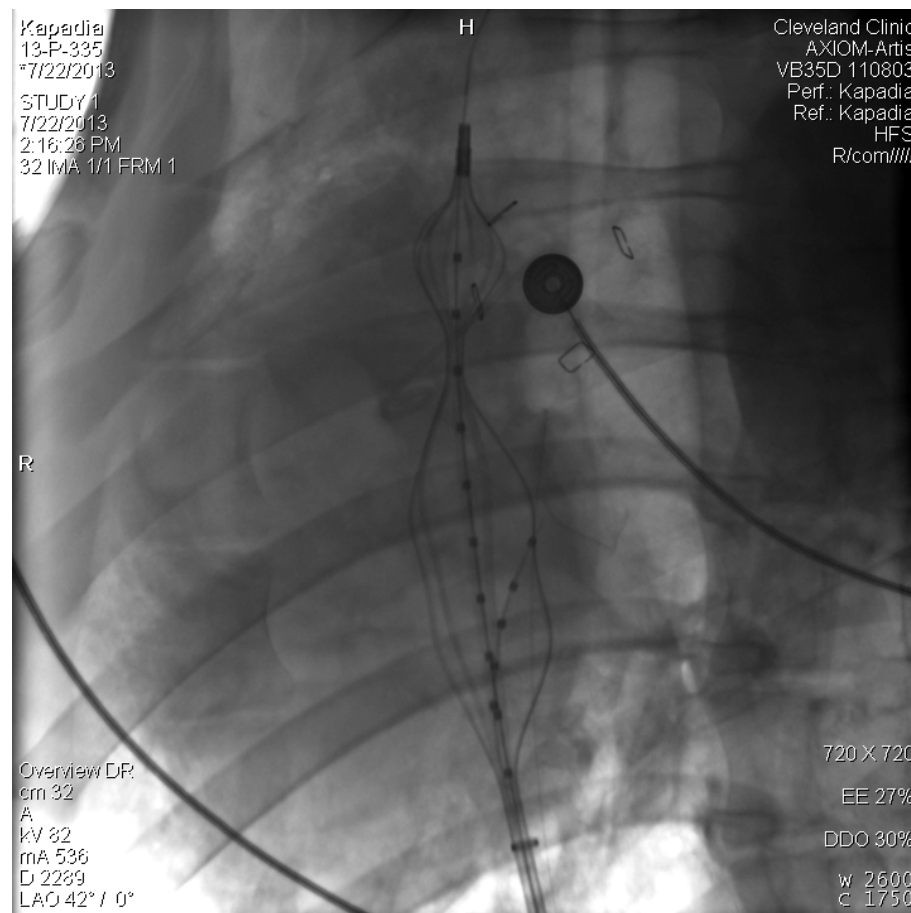
- Unsheath the device
  - Keep the proximal side of the handle fixed
  - Using left hand, slide sheath slider towards the main handle body



**Note:** Animal's RA, see gross anatomy pictures

# DEVICE DEPLOYMENT

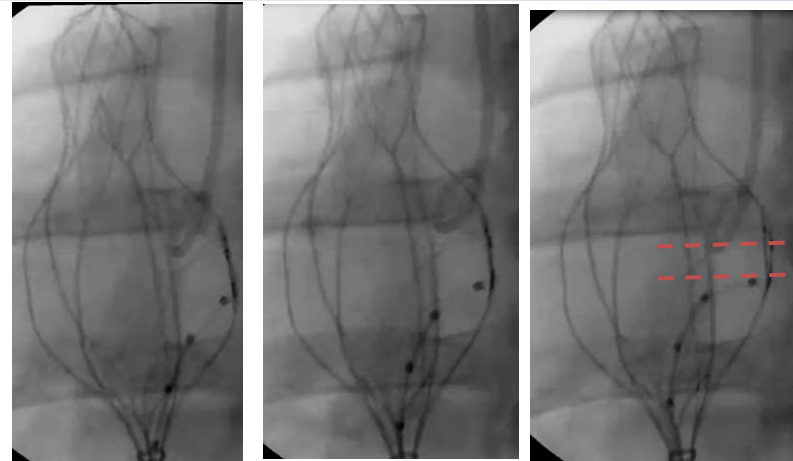
- Use RAO/LAO(30°-40°) imaging to confirm needle location with respect to the FO.





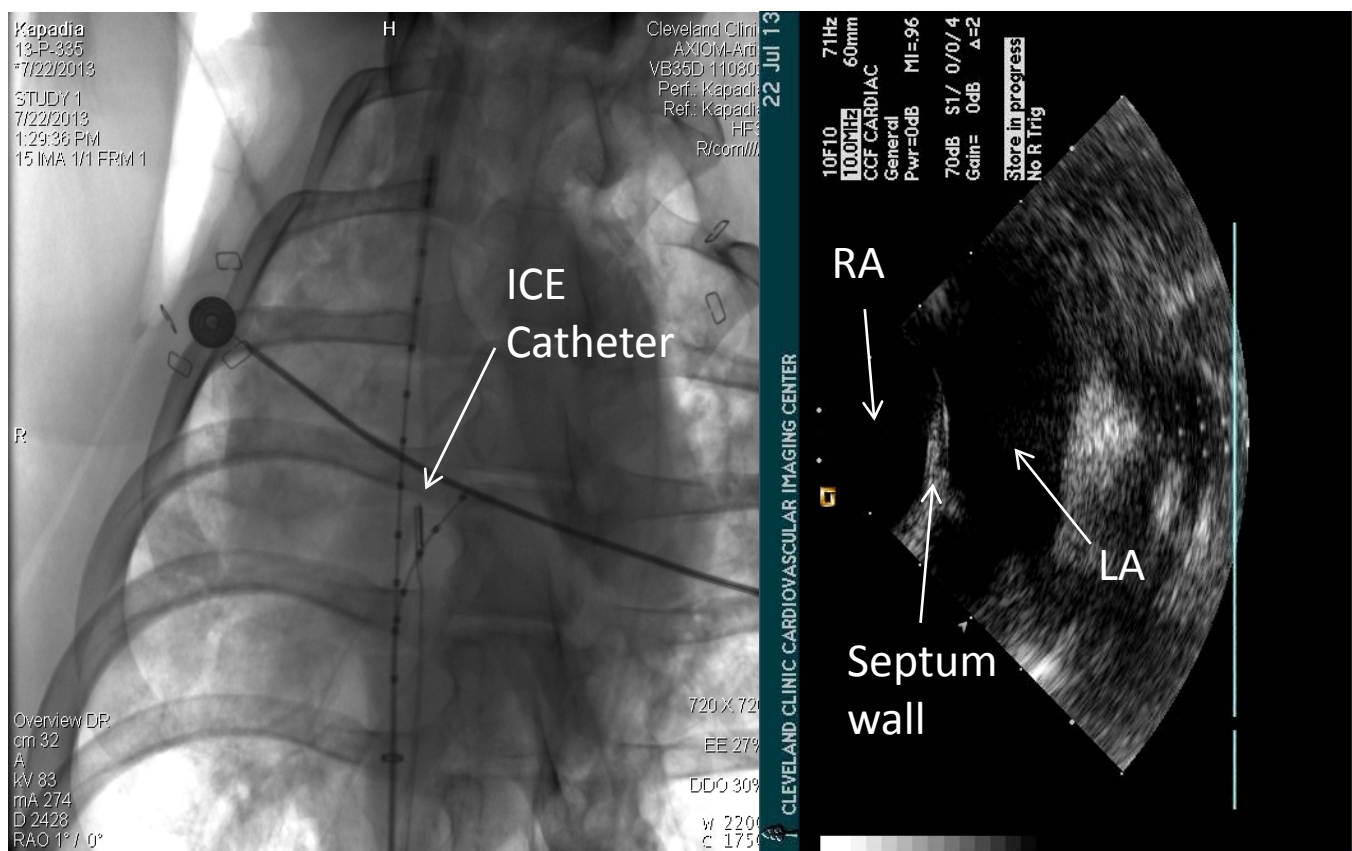
# DEVICE DEPLOYMENT

- Using the thumbwheel on the handle, adjust the priming angle of the delivery catheter until the desired angle of puncture is reached



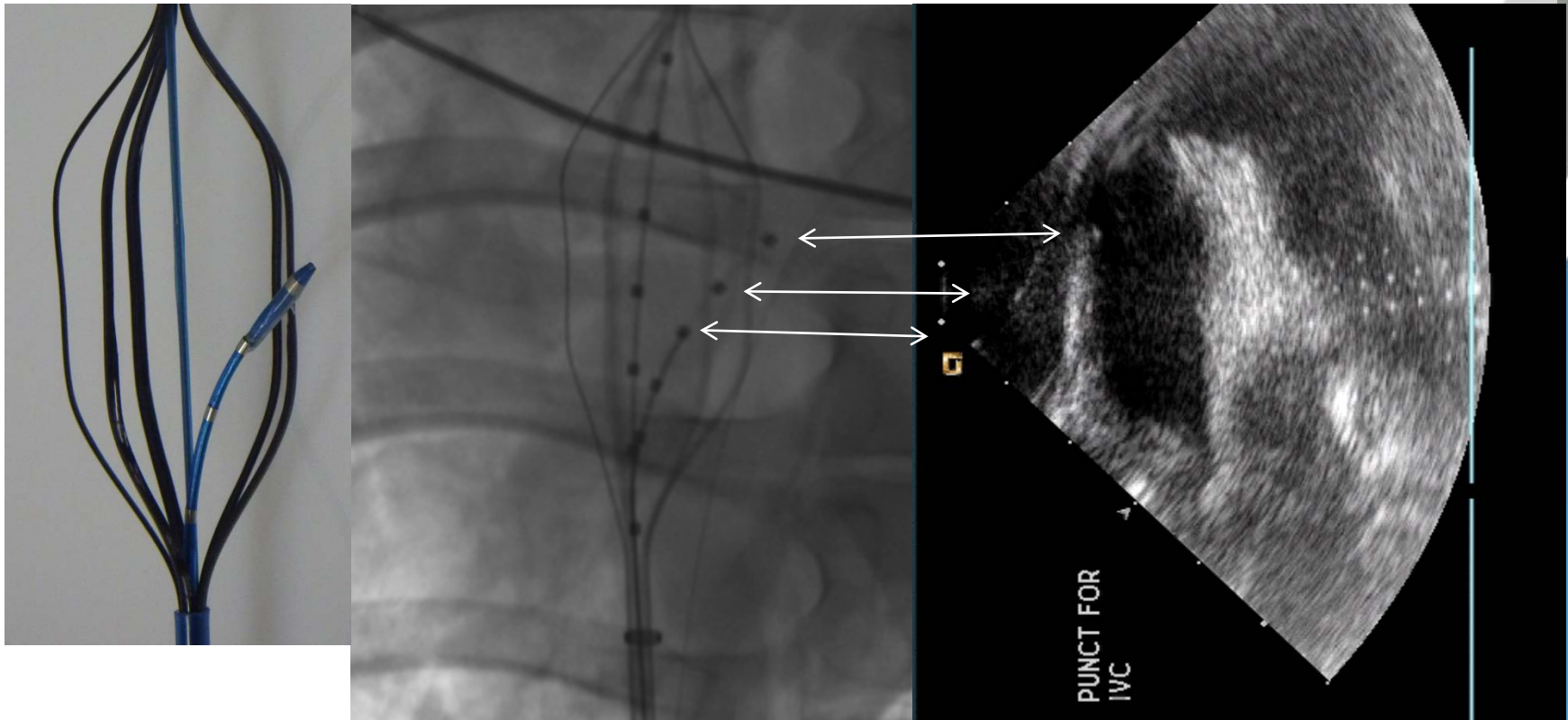
# CONFIRM POSITION OF THE FO

- Position ICE Catheter within RA to verify position of the FO.



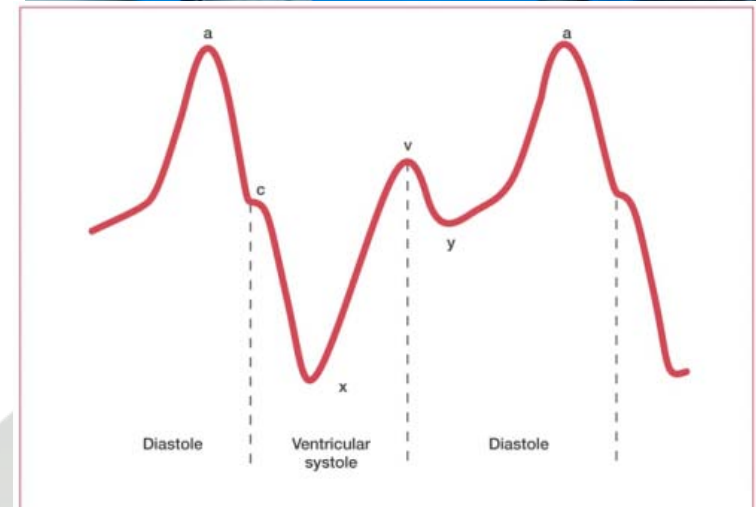
# CONFIRM POSITION OF THE FO

- Confirm needle of the Kapsus is against the FO using ICE
- See video



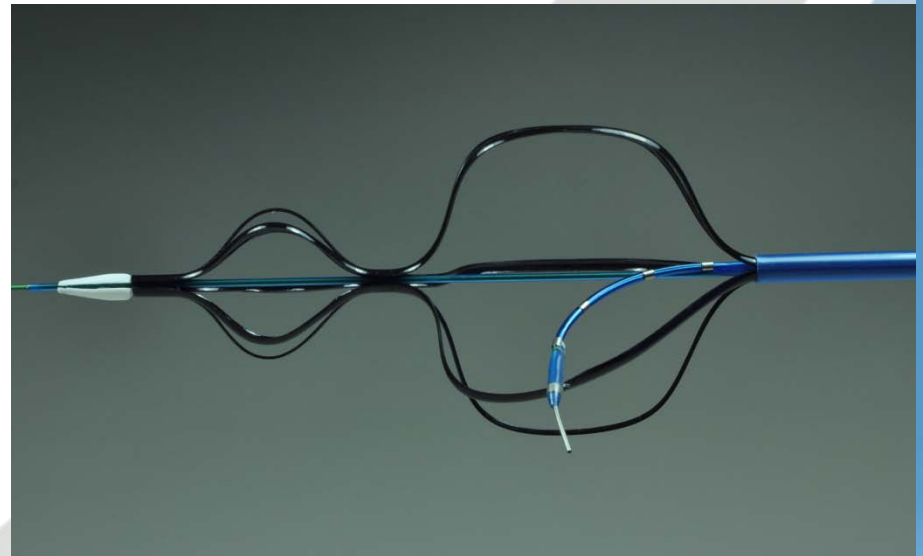
# PRE-PUNCTURE PRESSURE TRACE

- Connect the pressure transducer to the needle luer
- Confirm that the pressure waveform corresponds to the RA



# PUNCTURE THE FOSSA OVALIS WITH THE KAPSUS

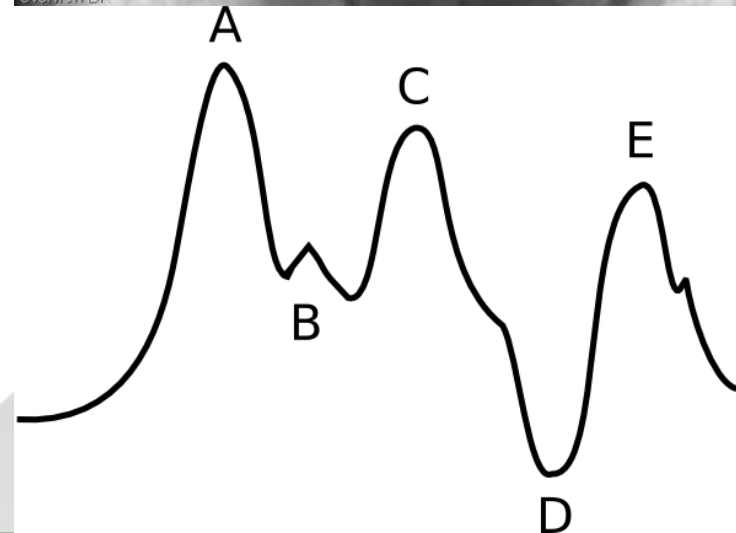
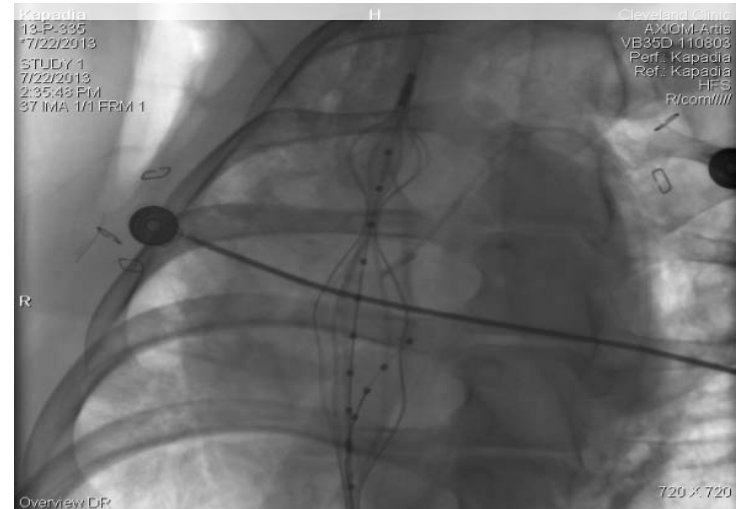
- Once the correct location / pressure trace is confirmed, fully advance the needle across the inter-atrial septum by pushing on the needle slider on the handle





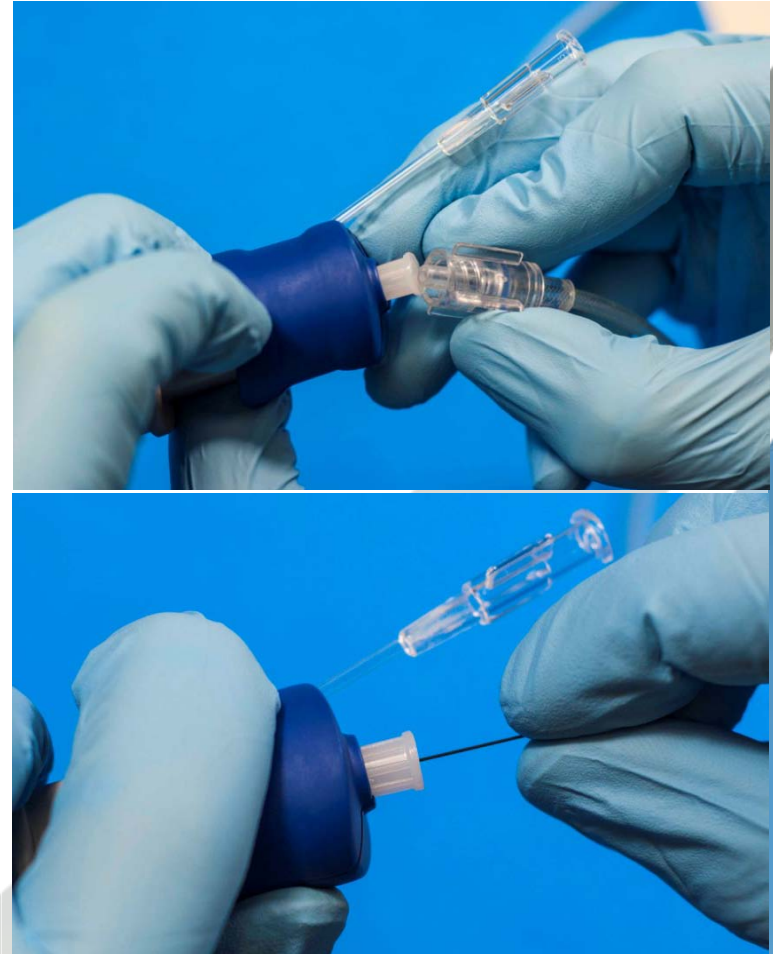
# PUNCTURE THE FOSSA OVALIS WITH THE KAPSUS

- Continuously monitor pressure trace through the Kapsus needle. LA trace should be read upon full puncture.



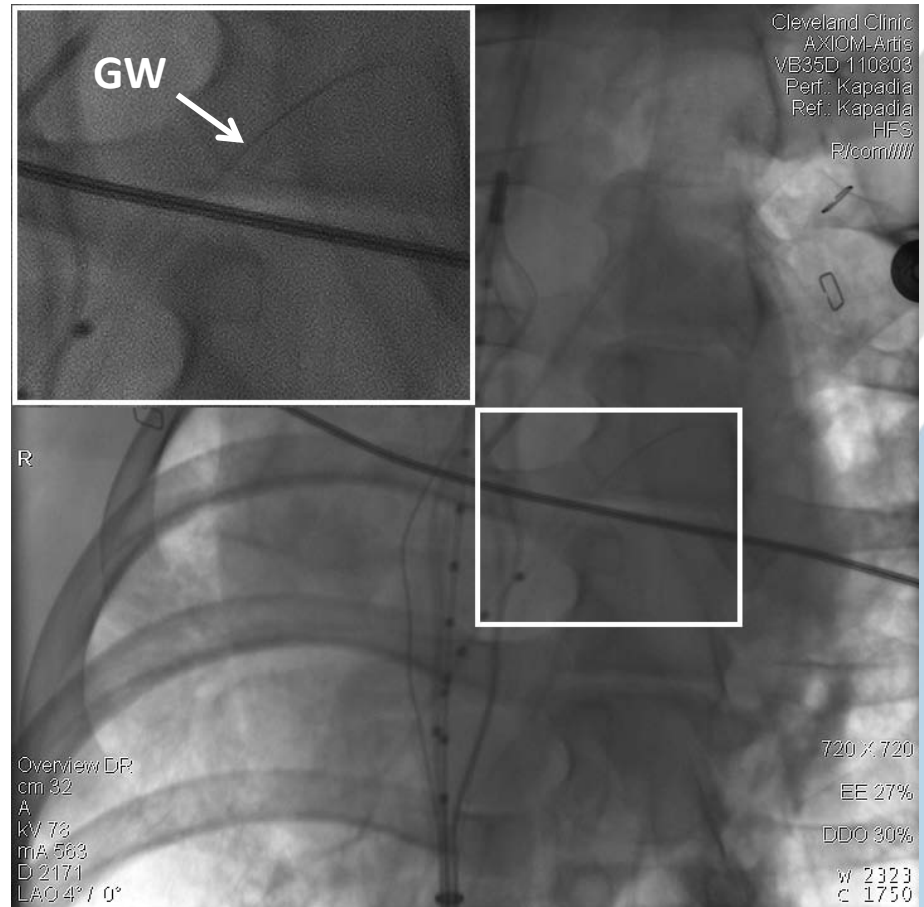
# DELIVERY OF THE GUIDEWIRE & RETRACTION

- Once pressure trace has been confirmed, disconnect the pressure transducer from the needle luer.
- Feed the 0.018" guidewire through the proximal end of the needle into the left atrium keeping the handle steady.



# DELIVERY OF THE GUIDEWIRE & RETRACTION

- Advance the guidewire until it reaches the LA





# DELIVERY OF THE GUIDEWIRE & RETRACTION

- Pull on the blue knob to un-prime and retract the needle
- Resheath the Kapsus catheter by keeping the sheath fixed relative to the body, and pulling proximally on the handle.
- Ensure the 0.018" GW remains within the LA



# DEVICE RETRACTION

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- Withdraw the Kapsus while feeding the 0.018" guidewire from the handle.
- *Optional: Retract 0.025" extra-stiff guidewire along with Kapsus.*
- ***Procedure Complete***

