

Patient Preparation

- Standard induction / monitoring for cardiac surgery
 - Invasive and non-invasive pressure monitoring
 - Central line or PA catheter
 - Foley catheter
 - Transesophageal Echo (TEE)
 - Capnography
 - Pulse oximetry
- Radiolucent defibrillation pads placed on all patients in bi-axillary position
- Patient intubated by anesthesia (if using TEE)
- Bilateral groins prepped and patient draped
 - Patient prepped from neck to knees

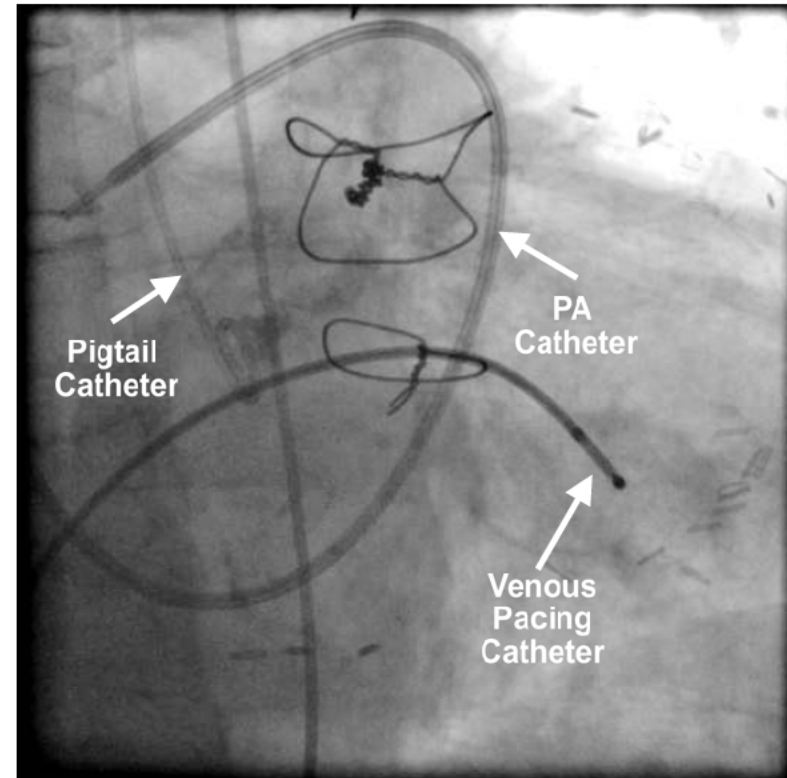


Patient Preparation

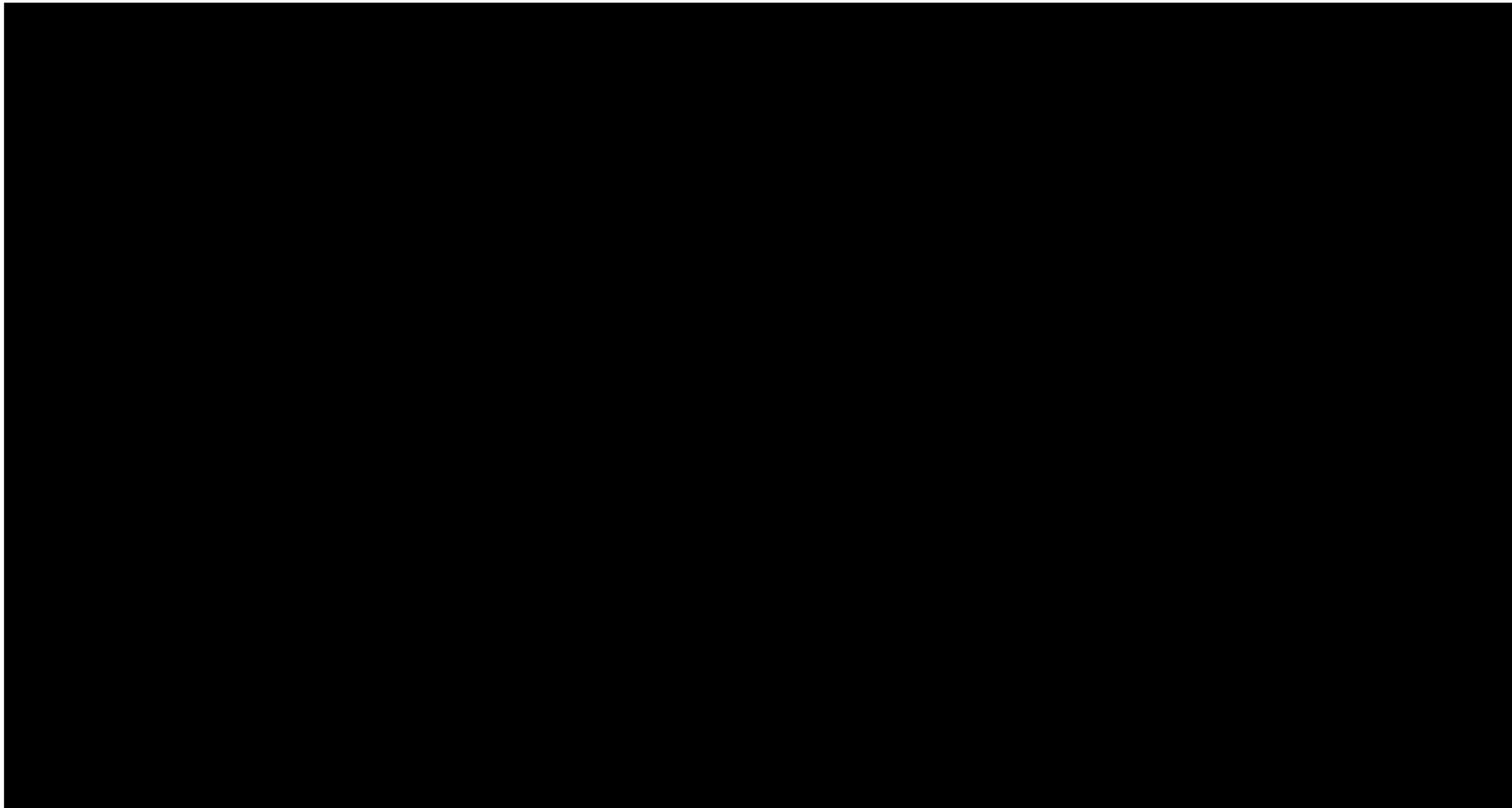
- Venous / arterial access obtained (suitable for venous / arterial cannulation for bypass)
- Diagnostic pigtail advanced from the femoral artery to the level of the aortic annulus for root aortography
- If using bipolar transvenous pacing catheter, track from femoral or internal jugular vein
- Check thresholds to ensure capture (unless using epicardial pacing leads)

NOTE:

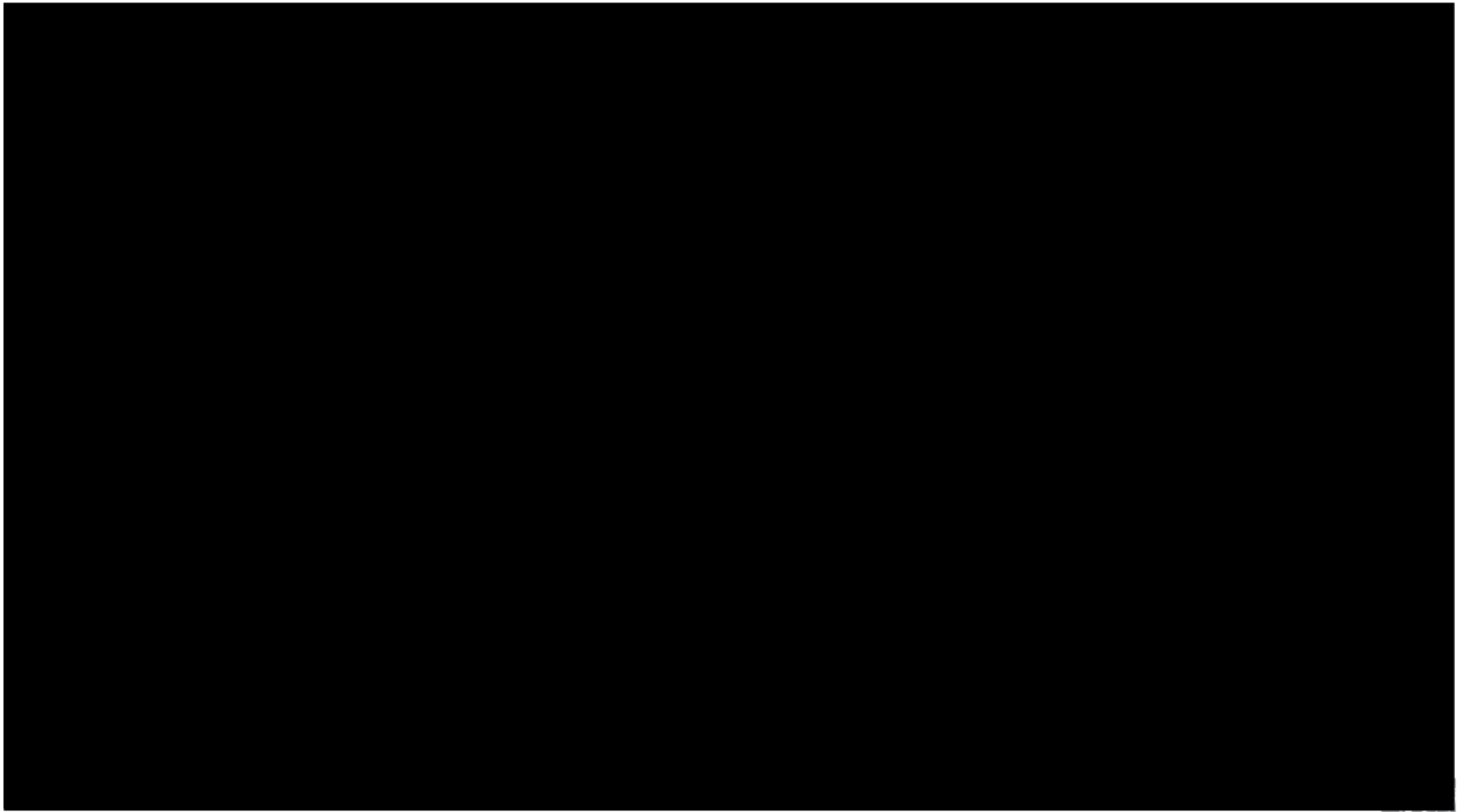
When using venous pacing, observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation



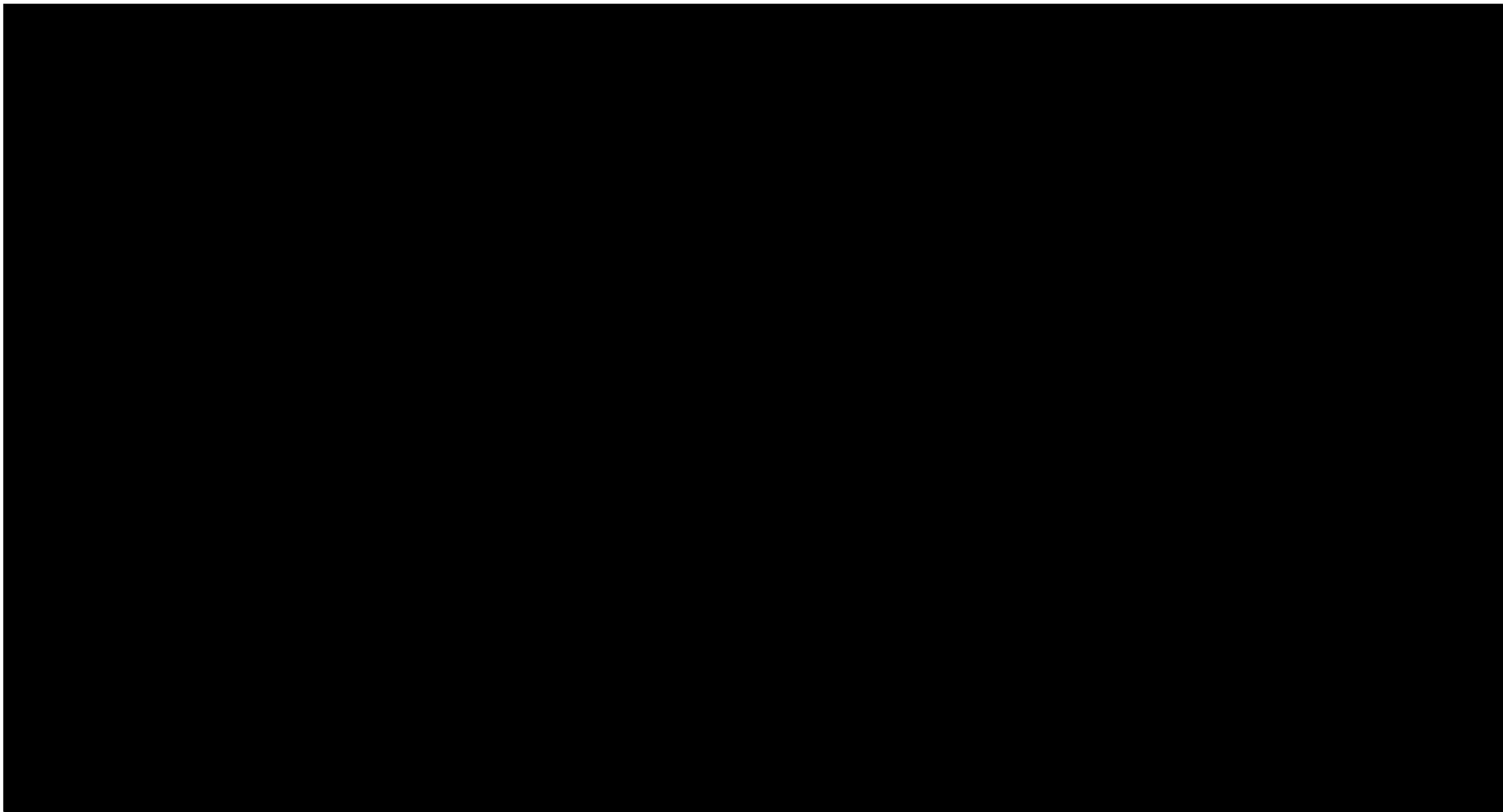
Rapid Ventricular Pacing: Test Run



Rapid Ventricular Pacing: Test Run

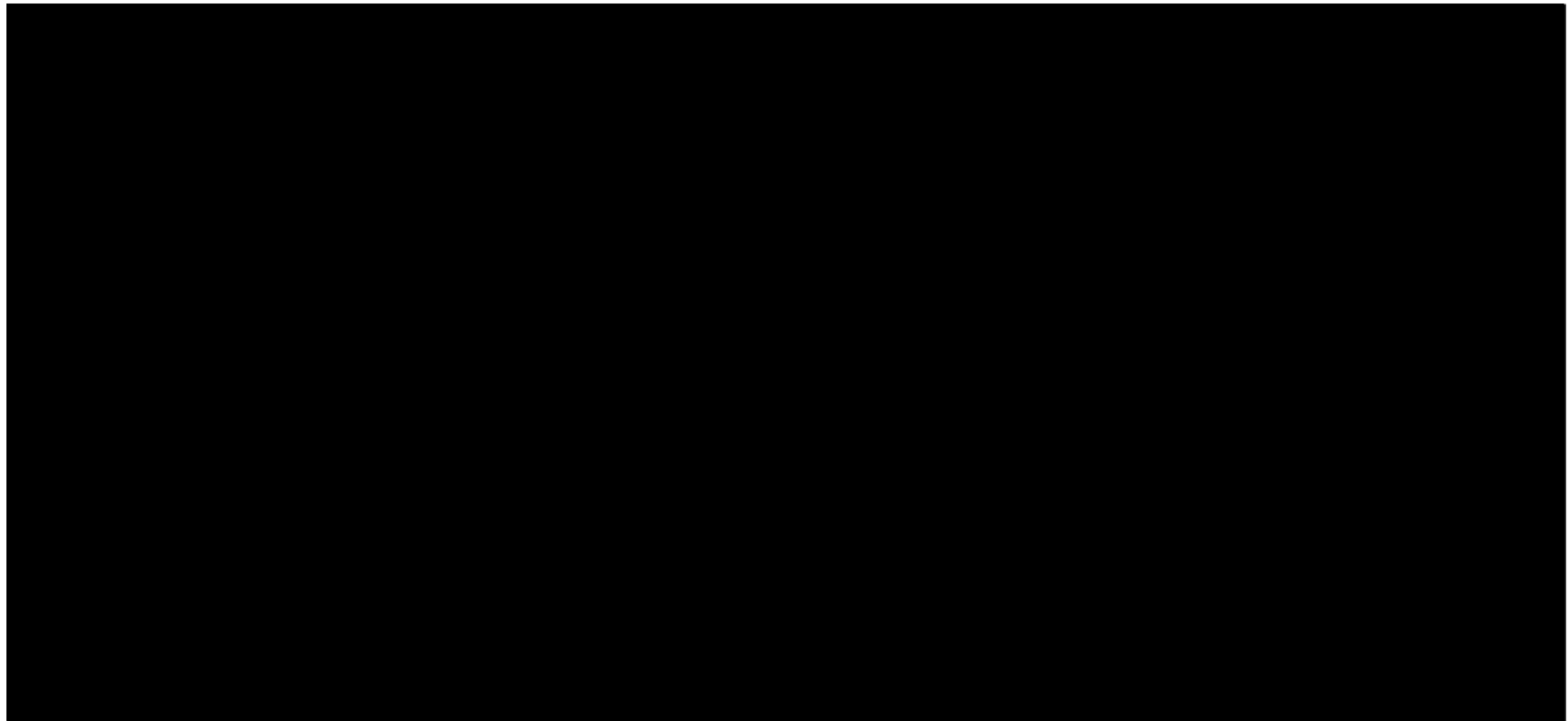


Rapid Ventricular Pacing: Test Run



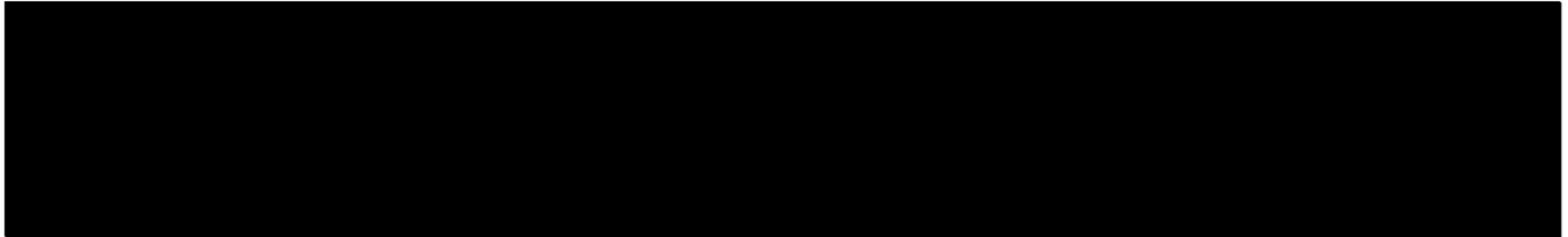
Rapid Ventricular Pacing: Anesthesia Considerations

- Prevent myocardial ischemia during BAV and THV deployment

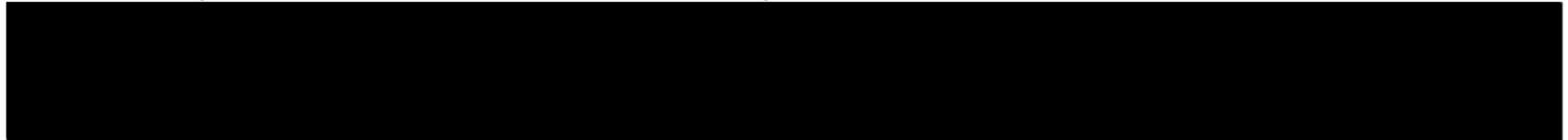


Rapid Ventricular Pacing: Anesthesia Considerations

- Patients with implanted cardiac devices will require pre-procedural evaluation/reprogramming

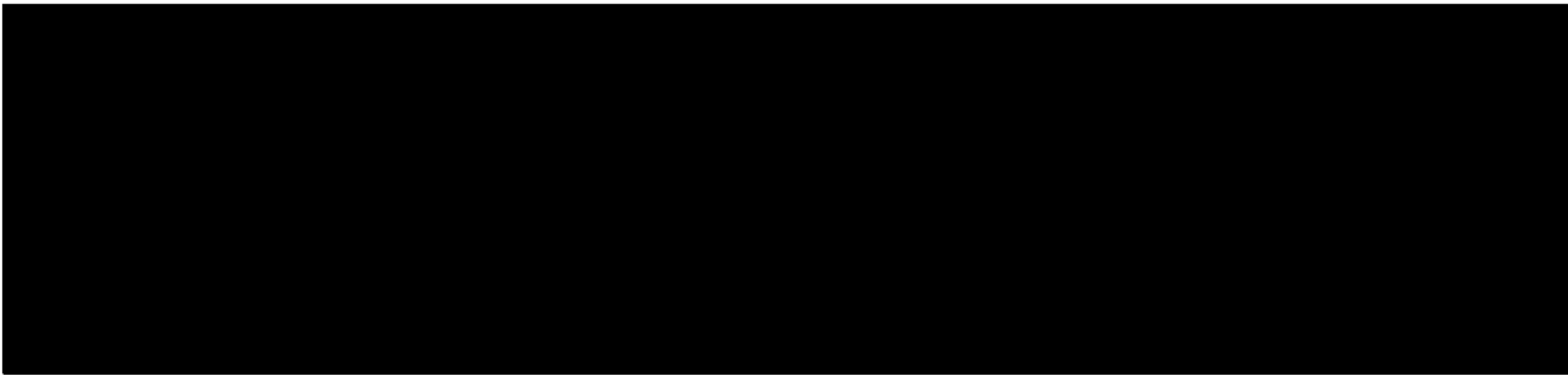


- Failure of blood pressure to recover promptly after an episode of rapid burst pacing suggests persistent myocardial ischemia or severe LV dysfunction



Preparing for Emergency CPB

- Perfusionist and fully primed CPB circuit should be immediately available
- Based on preoperative contrast or CT angiography, identify which femoral artery will be used in case of emergency CPB



- Smaller cannula can be used due to full bypass flow not generally needed and the duration of bypass is brief (< 20 min)
 - Arterial (14-18F)
 - Venous (20-24F)
- If peripheral access cannot be achieved, central cannulation should be performed via emergency sternotomy



Transfemoral Procedure Overview



Edwards

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IPR2017-00060 U.S. Patent 8,992,608
Exhibit 2034 - Part 3
PROTECTIVE ORDER MATERIAL

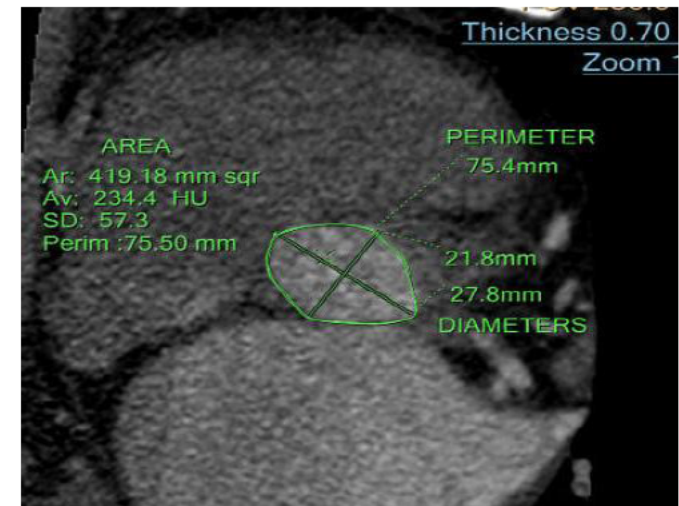
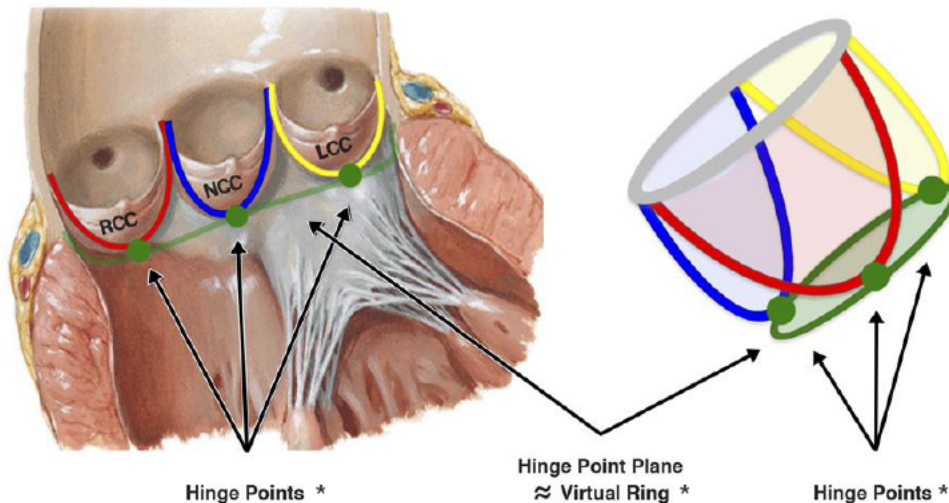
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Valve Sizing

- 3D imaging is fast becoming an important component in the THV procedure for:
 - Case planning
 - Assessing annular complex size and location of calcium (LVOT, supra-annular, leaflets, etc...)
 - Selecting appropriate THV size



* Hinge Points = Base of Cusps for THV positioning

Source: Kasel, A.M. et al; Standardized Imaging for Aortic Annular Sizing

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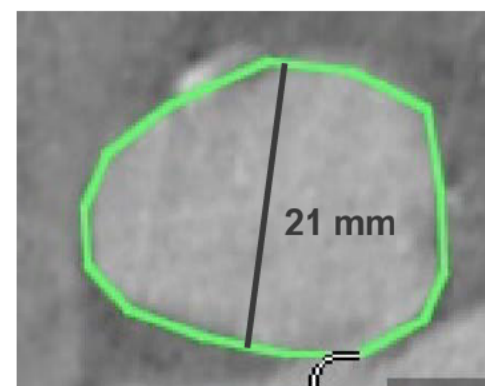
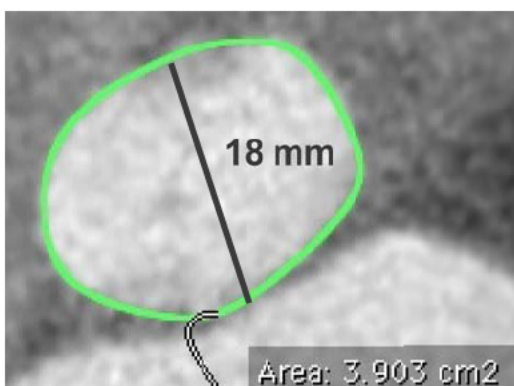
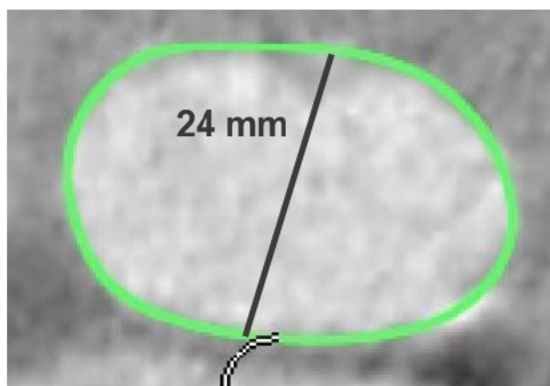
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Valve Sizing

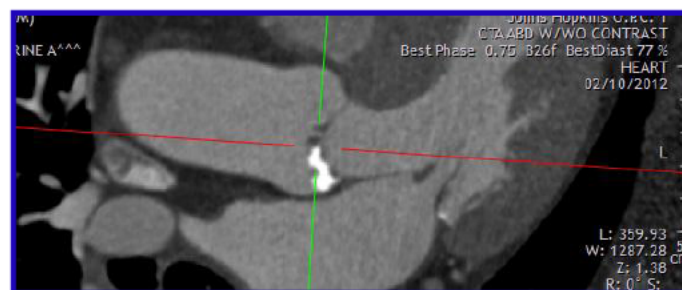
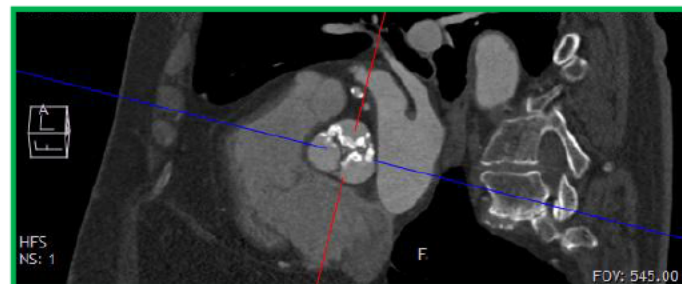
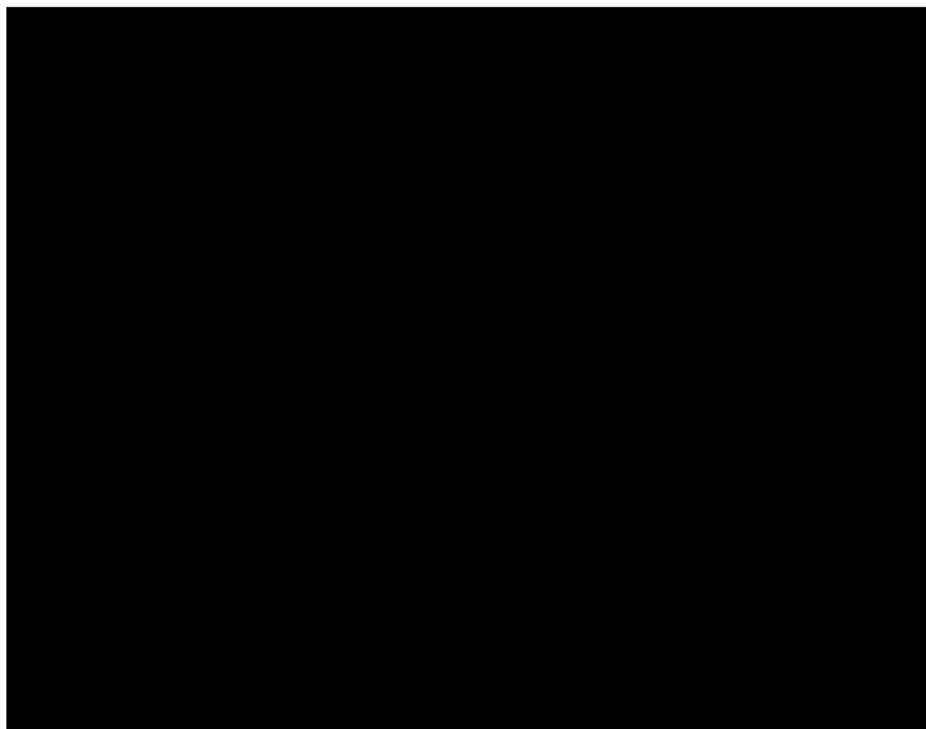
Non-Circular Annuli: Why we need 3D

Any single diameter cannot completely characterize the annulus "size" due to its non-circular shape



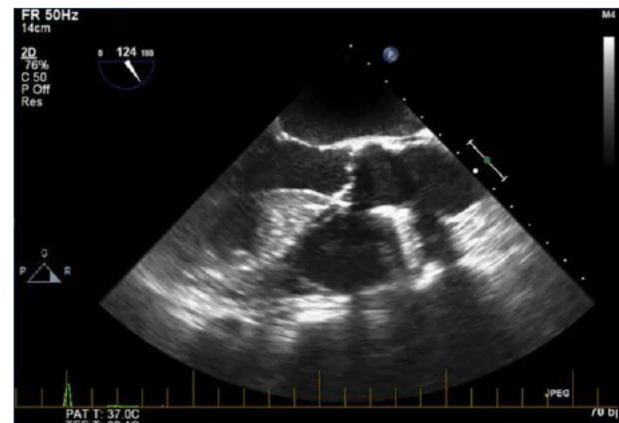
Valve Sizing: CT

- It is crucial that good 3D CT images are obtained
- It is recommended:



Valve Sizing: Multimodality Imaging

- Multimodality imaging is an additional important key to accurate sizing
- Size Variations:
 - It has been established that there is difference in annulus size depending on imaging modality and where the measurement was obtained
 - MDCT and 3D derived diameter measurements tend to be larger than 2D TTE/TEE diameter measurements
 - TEE measurements tend to be larger than TTE
- Multiple imaging studies are critical in borderline cases



Valve Sizing: Annulus Measurements

- Annulus is a dynamic structure it changes shape during the cardiac cycle
- The annular area also changes during the cardiac cycle:
 - Largest during systole when the valve leaflets are open
 - Smaller and more ovoid in shape during diastole
- It is critical that accurate measurements are obtained
- It is recommended that measurements are obtained during systole

Source



SAPIEN 3 Valve Sizing: Confirm THV Size

- Confirm native annulus diameter and/or area
- Assess anatomy and calcification
- Select THV size

NOTE:

THV size recommendations are based on native valve annulus size, as measured by TEE or CT. Multiple imaging modalities should be considered during THV size selection.

