

**Hybrid AF™ Convergent Therapy
Epicardial Ablation & VATS LAAM
via AtriClip™**

AtriCure

Set-Up Guide

Equipment and Supplies

- TEE equipment
- Defibrillator
- Fluoroscopy C-Arm
- Sequential compression device machine (per standard of care)
- Electrocautery machine
- Electrothermal machine (Harmonic™, LigaSure™, ENSEAL®)
- Inflatable patient positioning device: placed under left scapula (Assess for optimal placement by inflating and deflating prior to prepping)
- Laparoscopic Graspers
- Long Instruments (hold)
- Sternal saw (hold)
- Video monitor tower & 2nd monitor
- Insufflator
- Light source & light cord
- Scope (5mm - 0 degree)
- Scope (5mm - 30 degree)
- Camera
- Open Heart or Pericardial Window instruments

Equipment and Supplies

- Foley catheter
- Gowns
- Towels
- Surgical sterile drapes
- Valve drape
- Left video assisted thoracoscopic drape
- Chest drainage system (chest tube or flexible drain)
- Defibrillator pads
- Esophageal Temperature Probe
- Electrocautery grounding Pad
- Electrocautery pencil with extended tip
- Endoscopic defogger
- Surgical gloves
- Suction tubing x 2
- Warming blanket (per standard of care)
- Endoscopic trocars (5mm) **x 3**
- Endoscopic trocar (12mm) **x 1**
- Insufflation tubing
- Endoscopic peanuts (Kitners)
- Endoscopic retention stitch (hold)
- Suction irrigator (hold)
- EPI-Sense[®] Coagulation Device
- Cannula
- RF Cable CSK-2000
- 1-amp Grounding pad
- RF Generator (with power cord & foot pedal)
- AtriClip PRO2[®] device +/- AtriClip PRO-V[™] device (all sizes)

Patient flow and preparation

Patient Positioning: Patient will be in supine position, arms tucked with no shoulder roll. If arm retainers must be used, try to avoid use on the right side as it may interfere with surgeon

Trans-Esophageal Echo: TEE performed to rule out thrombus in LAA-consider performing TEE before further invasive lines are placed

Arterial Line / Foley Catheter / Central Line: central line typically employed only when performing concomitant VATS LAAM (and usually placed after TEE)

Grounding Pad Placement:

- Standard grounding pad for electrocautery—usually placed on thigh or buttock
- Grounding pad (1 Amp) for RF generator — placed on left or right flank
- Defibrillator pads placed and connected to AED

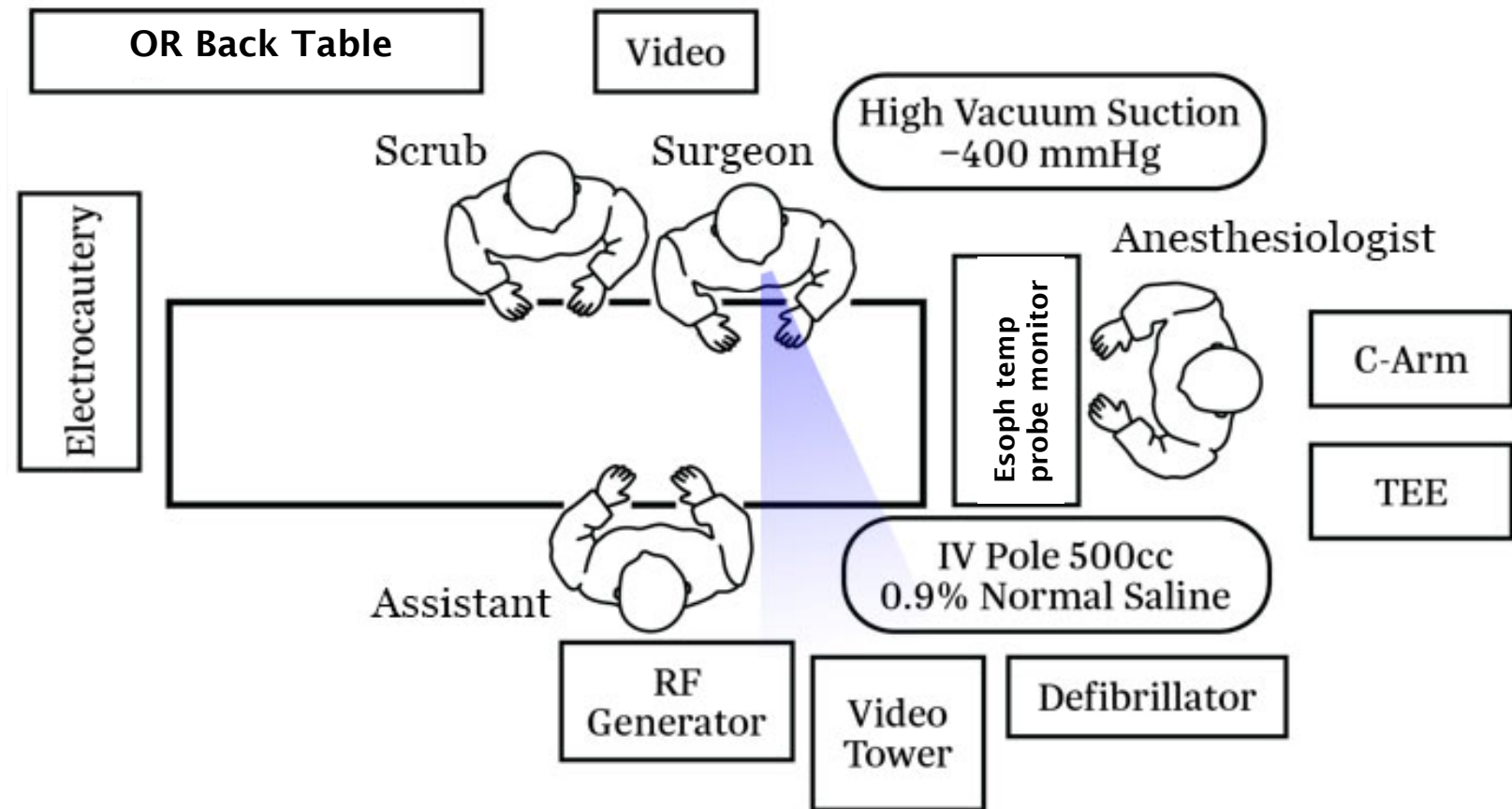
Temperature Probe Placement & Verification: Esophageal temperature probe placed by Anesthesia and verified under fluoroscopy (C-Arm needed if done in cardiac OR)

- Option One: Fluoroscopy prior to incision
- Option Two: Fluoroscopy after cannula and EPI-Sense device insertion

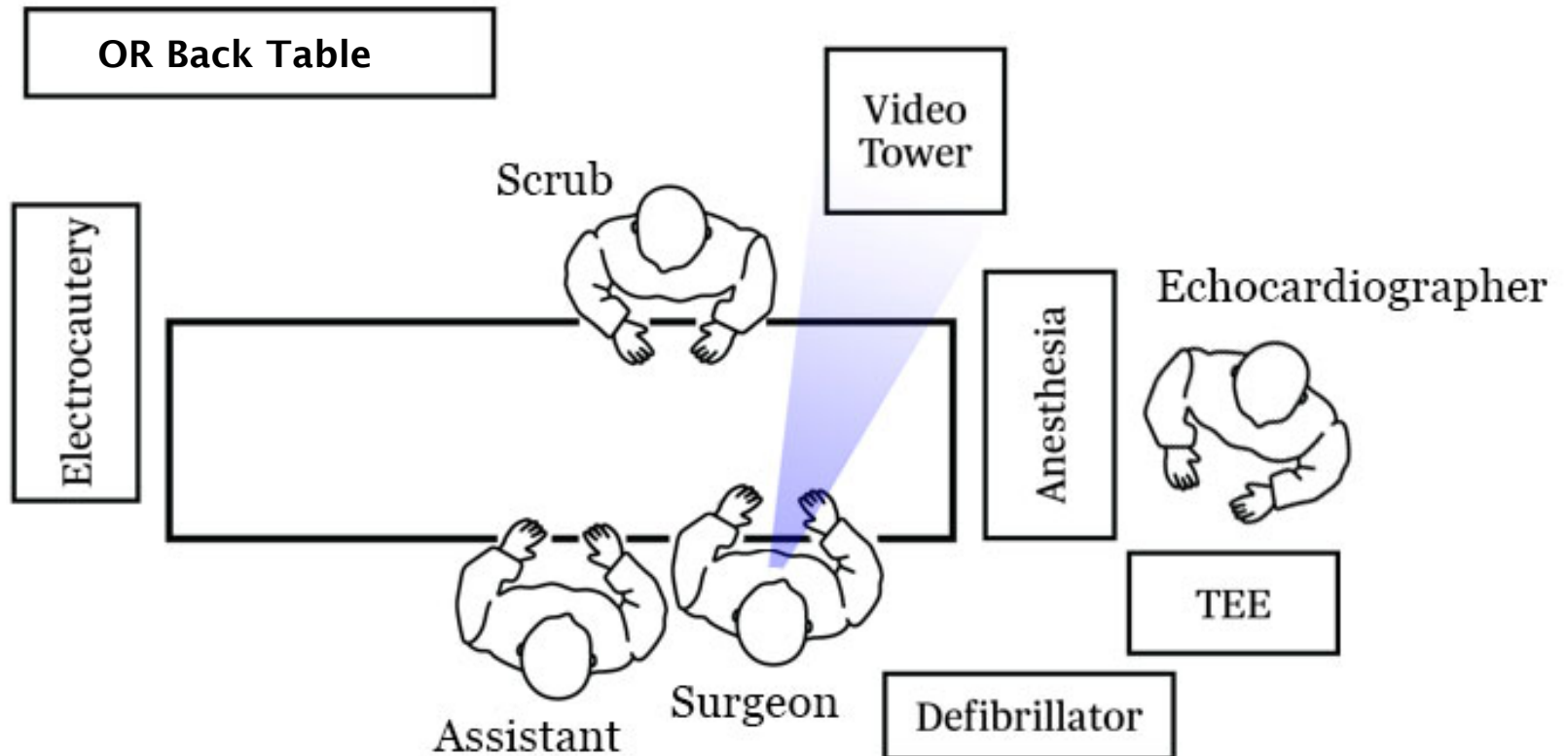
Sterile Prep: chin to mid-thigh

Perfusion: equipment and perfusionist immediately available on standby

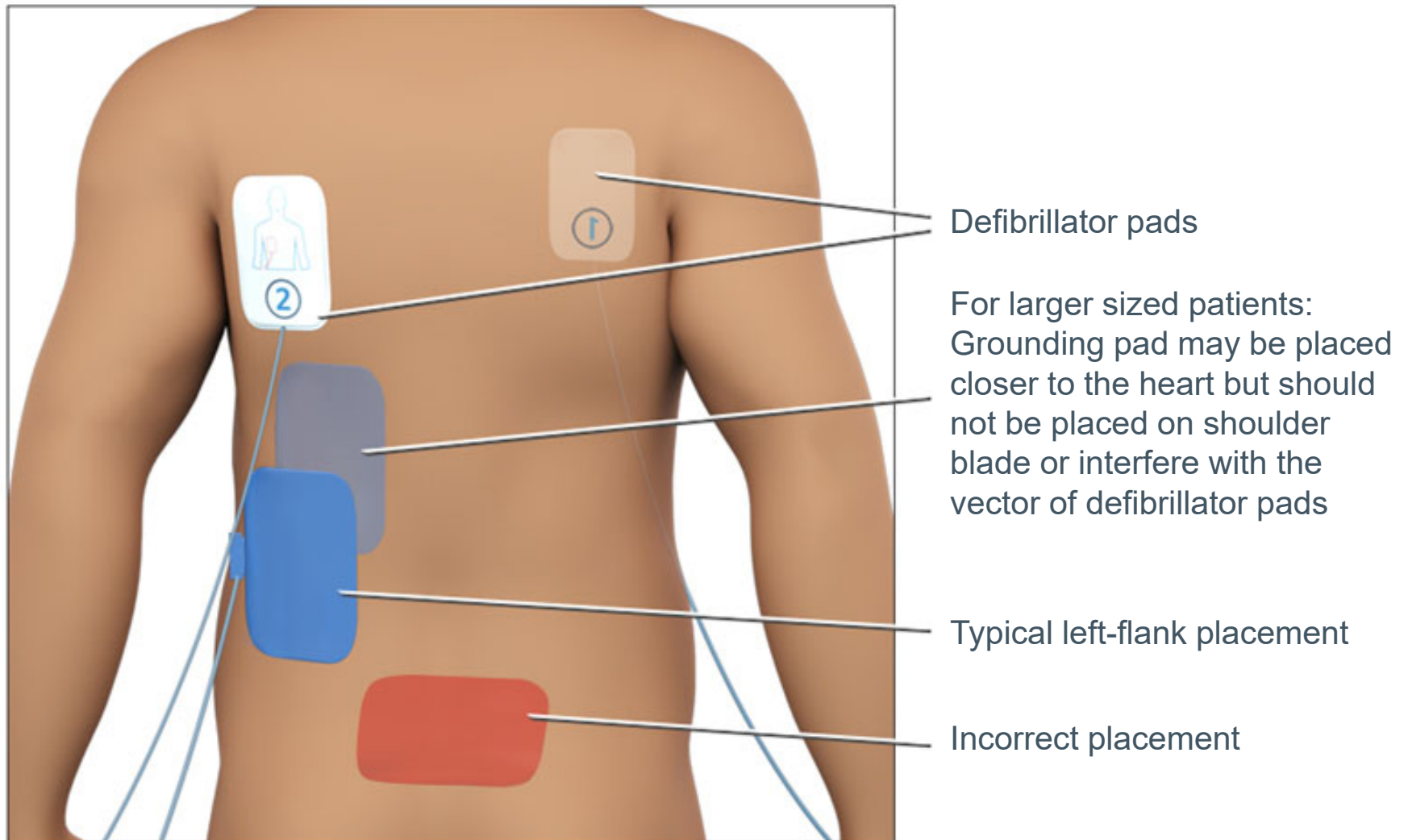
Hybrid AF Convergent Therapy: Procedure Room Setup



VATS LAAM via AtriClip Room Setup

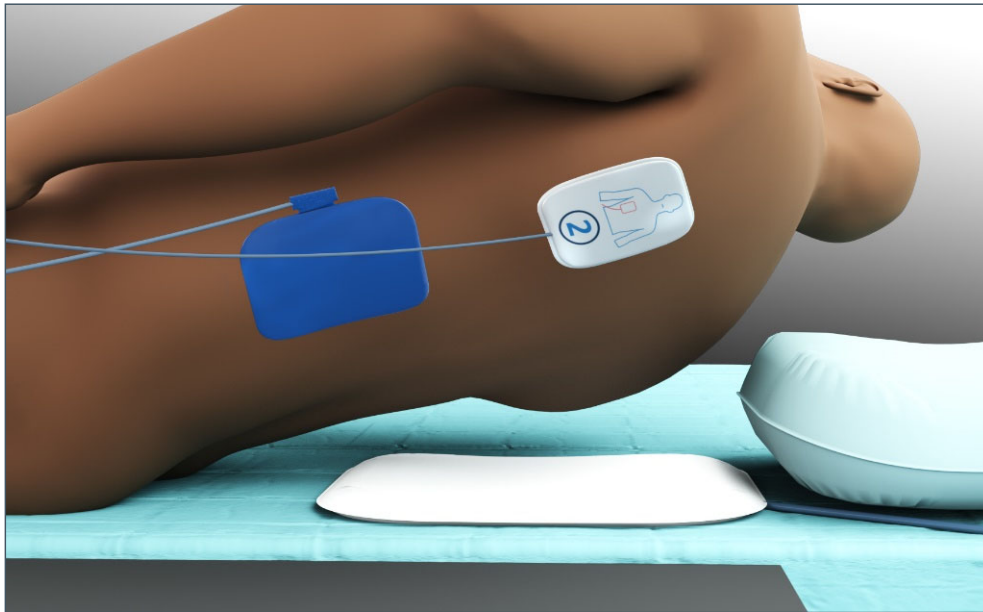


1 Amp Ground Pad & Defibrillator Pad Placement



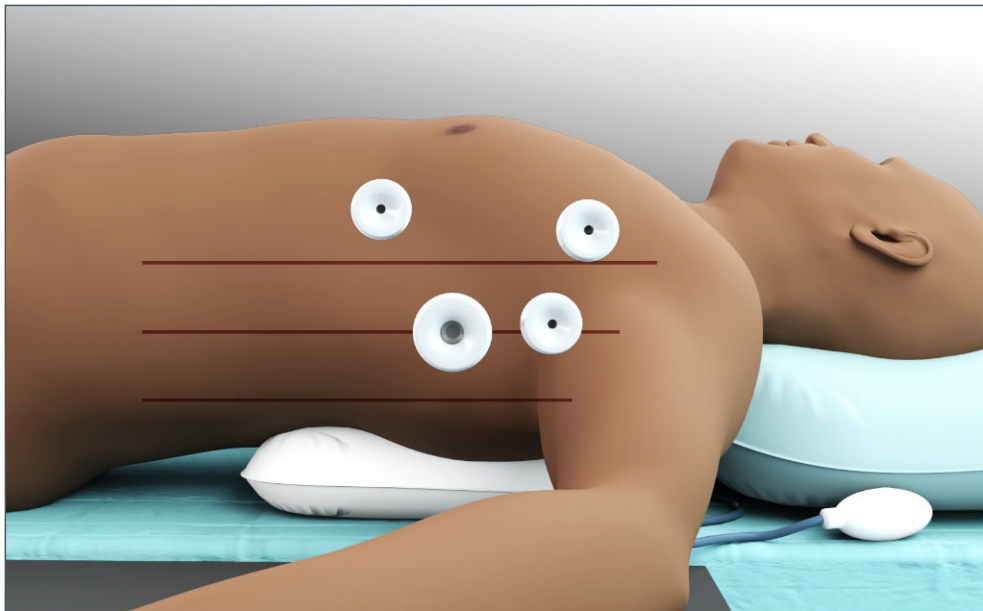
- ❑ If defibrillator pads are not sterile, place clear adhesive tape over pads then prep with skin—making sure pads do not interfere with 2nd intercostal port placement
- ❑ Anterior defibrillation pad: right-side, lateral to sternum
- ❑ Posterior defibrillation pad: mid-thoracic, left of spine

Patient Positioning with Inflatable Device



Place IV pressure bag or inflatable patient positioning device below left scapula. Make sure the pressure bag is not under shoulder/arm as they will otherwise lift with chest once the bag is inflated. The goal is to have the arm tucked and resting on the OR table even after the chest rises from pressure bag being inflated. This technique provides optimal exposure to medial and posterior axillary lines.

- Leave bag inflated during prep and drape
- Deflate bag for Convergent Approach portion of procedure
- Inflate for Left sided VATS LAAM



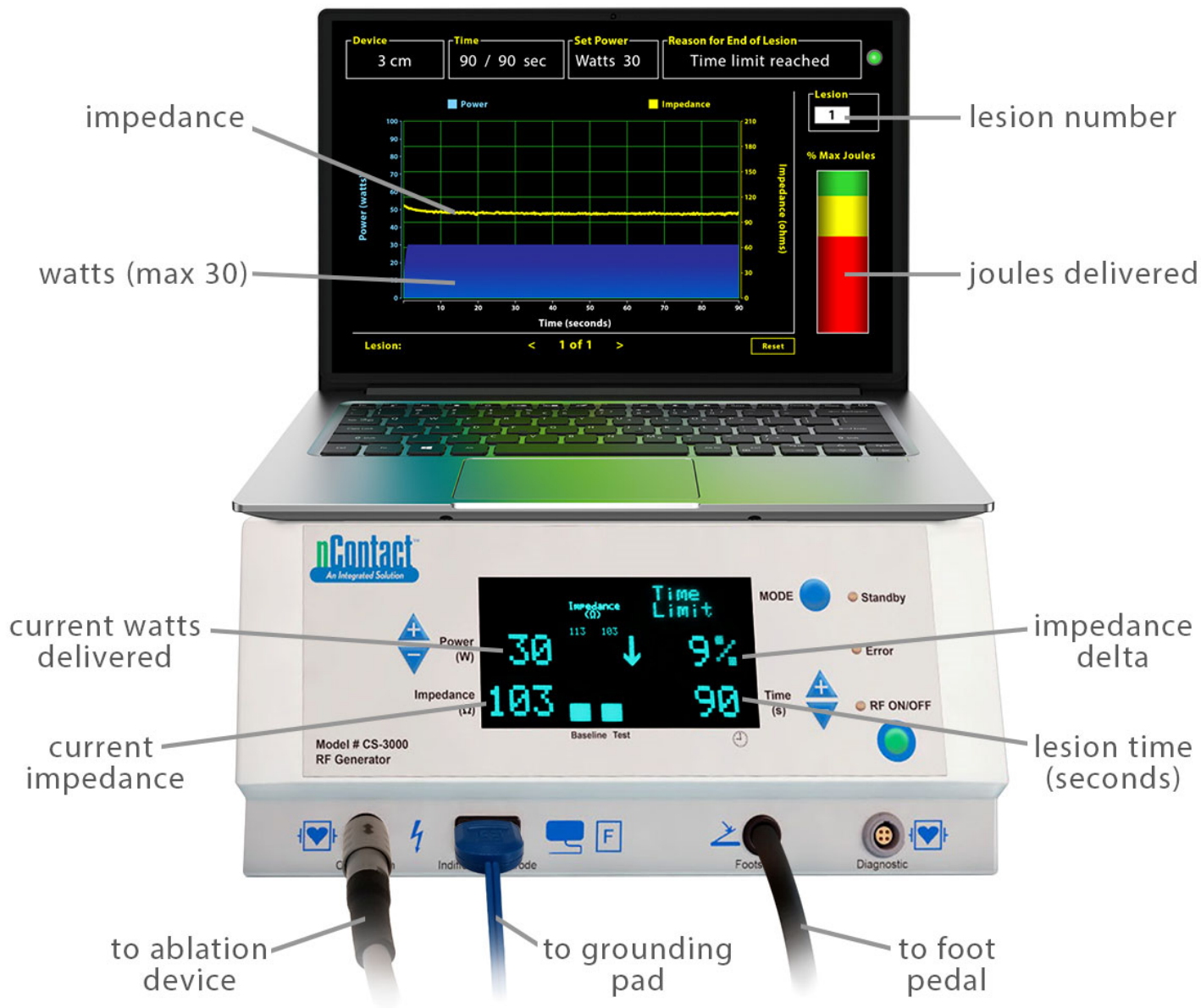
Patient Positioning and Prep

- Patient placed in supine position
- Right arm tucked
- Left-sided inflatable shoulder roll (positioning device with left arm secured and in a hammock position)
- General anesthesia with dual-lumen endotracheal tube for single-lung ventilation (during VATS LAAM component)
- Standard grounding pad for Bovie (usually placed on thigh or buttock)
- 1 Amp grounding pad for CS-3000 RF Generator (placed on left flank: see image)
- Defibrillator pads placed and connected to external defibrillator (see image)
- TEE to rule out LAA thrombus (partially retract probe to 20cm after TEE imaging is complete—or remove completely)
- Central line placed (usually done after TEE cleared)
- Arterial line placed
- Foley catheter placed
- Warming blanket
- Sequential compression device machine (per standard of care)

Equipment and Supplies

- Esophageal temperature probe placed by anesthesia and verified under fluoroscopy (C-Arm needed if done in cardiac OR)
- Sterile prep: chin to mid-thigh (ensure positioning device under left shoulder is inflated)
- Standard wall suction (-250mmHg) with tubing to Cannula
- High vacuum suction (-400mmHg) with tubing to EPI-Sense Device
- RF Generator default settings are 30 Watts over 90 seconds – *these settings should not be changed unless requested by the surgeon*
- Insufflation available for LAAM

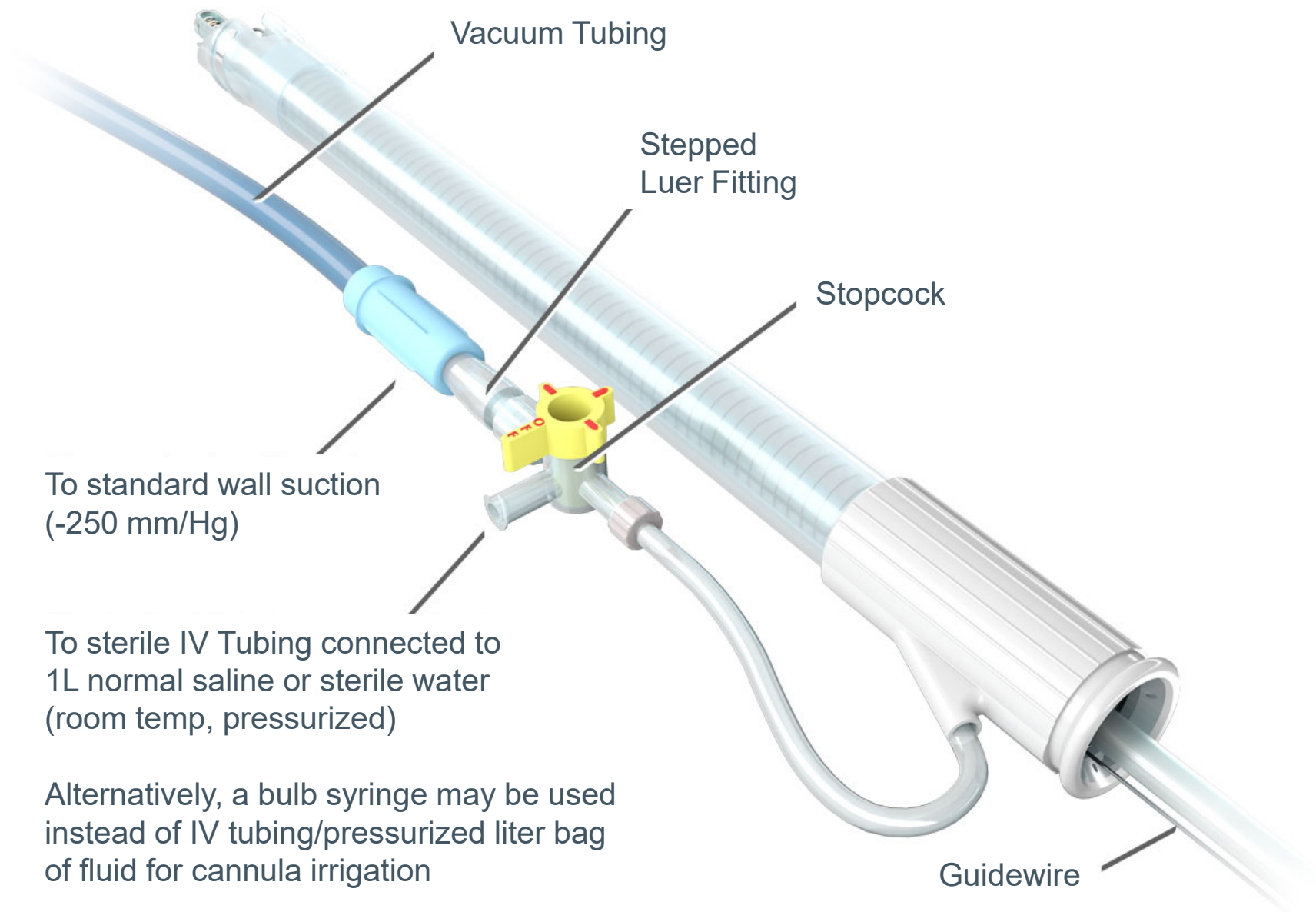
Generator & Laptop Display



Note: When no device is connected to generator a power of 4 Watts (W) and time of 0 seconds will display on RF Generator.

The Error LED will remain lit until a connected device is in contact with tissue.

Cannula Set-Up



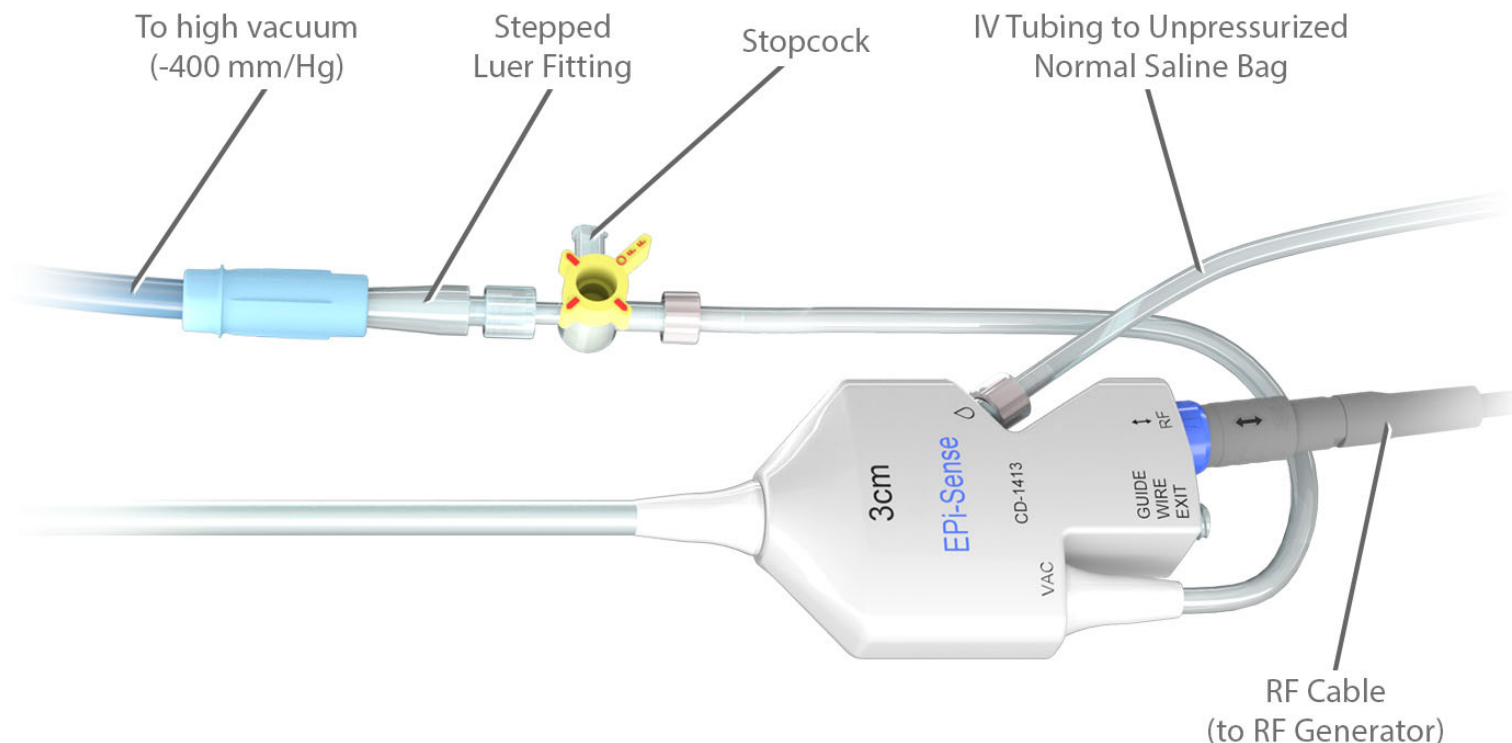
To standard wall suction
(-250 mm/Hg)

To sterile IV Tubing connected to
1L normal saline or sterile water
(room temp, pressurized)

Alternatively, a bulb syringe may be used
instead of IV tubing/pressurized liter bag
of fluid for cannula irrigation

Guidewire

EPI-Sense Device Set-Up



Attach one end of the sterile vacuum tubing to the graduated fitting as indicated on device handle by the vacuum symbol (VAC) and the other to the vacuum trap. Use the stopcock to apply and release the vacuum to the distal assembly.

Ensure the vacuum unit pressure is set to **negative 400 - 550 mmHg**

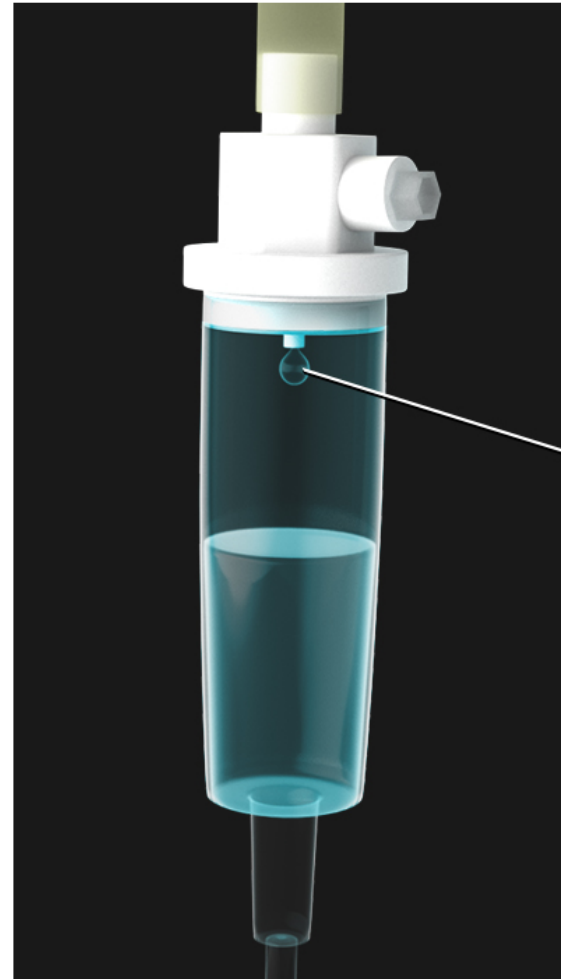
Connect perfusion tubing to the female luer connection as indicated on device handle by the perfusion *droplet* symbol. **Verify IV line is fully open**

Insert the grey RF cable (blue to blue and arrows facing same direction) onto the handle of the device. The opposite end with the black ring will be handed off to the nurse to connect to the generator

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EPI-Sense Priming

- ❑ Vacuum is set to **negative 400 - 550 mmHg**
- ❑ Prepare the 0.9% Normal Saline Bag
 - Place *unpressurized* saline IV bag at patient height or above
 - Insert IV tubing set into 0.9% normal saline bag.
 - Turn on vacuum pressure and prime device by engaging the suction with a sterile surface (gloved hand).
 - Ensure perfusion flow is functioning by observing drops in IV tubing drip chamber.
 - The device is primed by observing perfusion at distal end of coagulation device before starting operation of device.



Saline should drip at one drip per second when vacume is engaged

Hybrid AF Convergent Therapy

Procedural Steps

- Surgeon makes small (2-3 cm) incision over xiphoid process – surgeon may elect to remove some (or all) of xiphoid process
- Surgeon establishes sub-xiphoid (Sub-X) pericardial window
- AtriCure cannula placed behind heart within pericardial window
- Introduce 0-degree 5 mm scope through cannula
- Through scope, identify landmarks on posterior left atrium
- Ready to ablate
- After posterior wall is ablated - drain may be placed in the pericardial space

If LAAM is included in the procedure

- Anesthesia inflates the positioning device for LVATS LAAM & deflates LT lung
- Surgeon places ports (5mm in the 2nd ICS, 5mm in the 4th ICS, 12mm in 6th ICS)
- Insufflates (flow of 8 & pressure of 12)
- Surgeon performs pericardiotomy
- Appendage is exposed, measured and clipped
- Echo confirms occlusion
- No ECG changes noted
- Drain may be placed and attached to chest drainage system

VATS LAAM via AtriClip Procedural Steps

First Port

- 5mm port 4th intercostal space axillary lines
- Attach CO2 and turn on to a pressure of 8 flow 20mmHg

Second Port

- With scope in the 4th intercostal port, look cranially towards the 2nd intercostal space
- 5mm port 2nd intercostal space not more than mid-clavicular

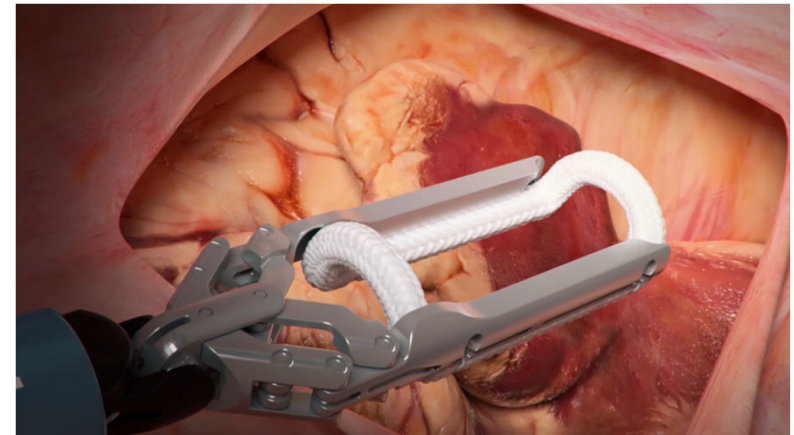
Third Port

- Third port trajectory oriented towards hylum or pulmonary veins
- With scope in the 2nd intercostal port, look caudally down the rib-cage towards the diaphragm
- 12mm port 6th intercostal space mid-to-posterior-axillary lines

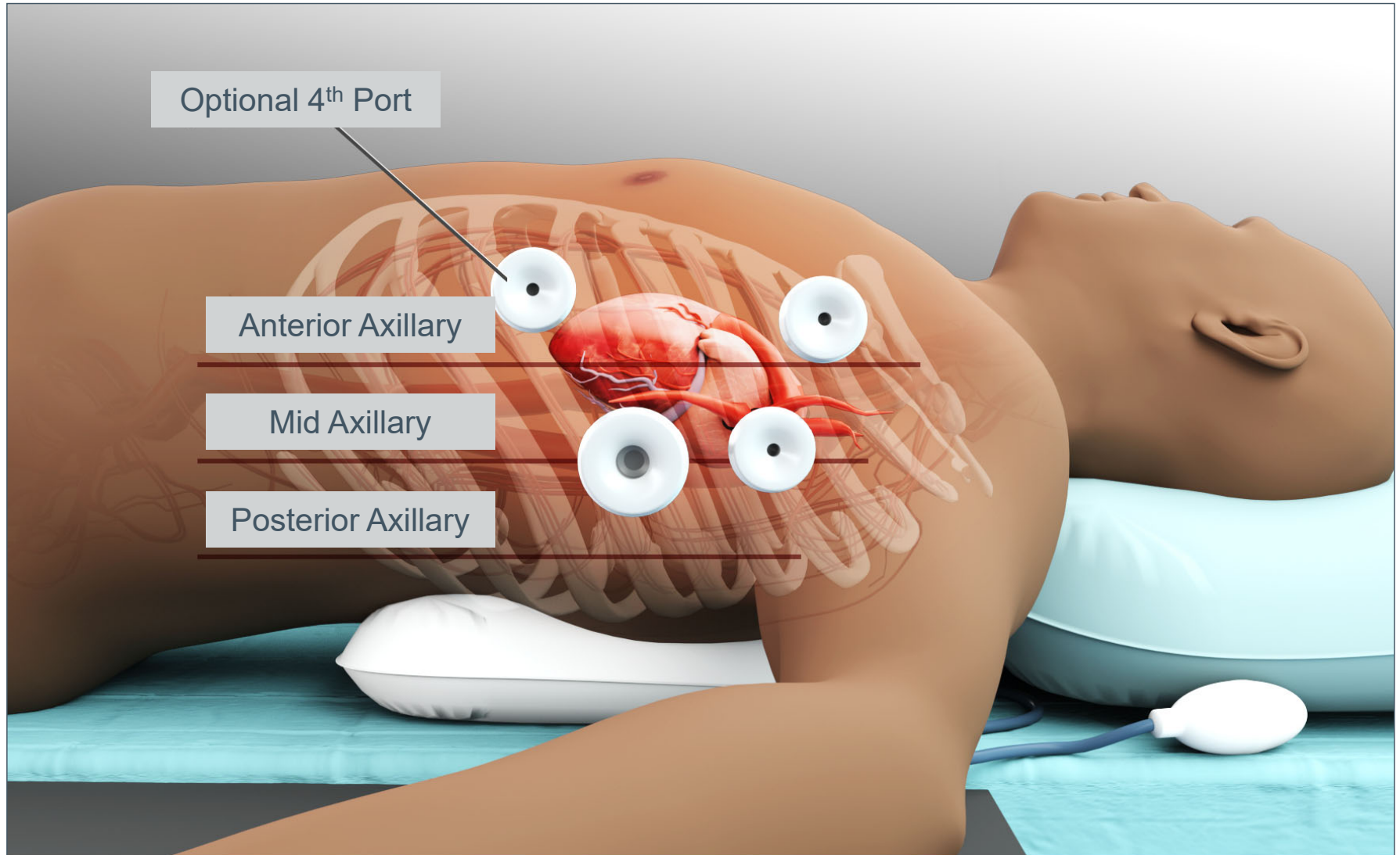
Fourth Port (if needed)

- Option One: 5mm port 6th intercostal space mid-clavicular line
- Option Two: 5mm port 3rd intercostal space (between 2nd & 4th ports)

Camera Port typically is the 4th intercostal port



VATS LAAM via AtriClip Procedural Steps



Epi-Sense® Guided Coagulation System

EU Indications: Epi-Sense: The Epi-Sense® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AFIB) or Atrial Flutter (AFL).

Contraindications include patients with Barrett's Esophagitis, left atrial thrombus, a systemic infection, active endocarditis, or a localized infection at the surgical site at the time of surgery.

Reported adverse events associated with epicardial ablation procedure may include, but are not limited to, the following: pericardial effusion, excessive bleeding, Pericarditis, phrenic nerve injury, stroke/TIA/neurologic complication.

Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events located at the following AtriCure web address: <https://www.atricure.com/instructions-for-use/international>

The Cannula with Guide is indicated for use in laparoscopic or general surgery to provide access for operative and diagnostic instrumentation in body cavity spaces.

The nContact Model CS-3000 RF Generator Unit is an electrosurgical generator that transmits RF current at a frequency of 480 kHz. The generator transmits up to 100 watts (W) of Power (+/- 20%). While the RF Energy is delivered, power, impedance, and time are continually measured and updated on the generator display.

Rx Only

AtriClip LAA Exclusion System

EU Indications:EU Indications (Flex•V, PRO, PRO2, PROV)

The AtriClip LAA Exclusion System is indicated for the occlusion of the heart's left atrial appendage.

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