Hybrid AF™ Convergent Therapy

Epicardial Ablation & VATS LAAE via AtriClip®
for the Treatment of Long-Standing Persistent Atrial Fibrillation

Set-Up Guide

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Equipment and Supplies

- ❑ TEE Equipment
- ❑ Defibrillator
- ❑ Fluoroscopy C-Arm
- ❑ Bair Hugger
- ❑ SCD 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 (5 mm - 0 degree)
- ❑ Scope (5 mm - 30 degree)
- ❑ Camera
- ❑ Open Heart or Pericardial Window Instruments

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Equipment and Supplies

- ❑ Foley Catheter
- ❑ Gowns
- ❑ Towels
- ❑ 1010 Drapes
- ❑ Valve Drape
- ❑ Left VATS Drape
- ❑ 19F or 24F Blake Drain (hold) **x 2**
- ❑ Chest Drainage System or JP Bulb
- ❑ Defib Pads
- ❑ Esophageal Temperature Probe
- ❑ Bovie Pad
- ❑ Bovie & Extended Tip
- ❑ Endoscopic Defogger
- ❑ Surgical Gloves
- ❑ Suction Tubing **x 2**

- ❑ Endoscopic Trocars (5 mm) **x 3**
- ❑ Endoscopic Trocar (12 mm) **x 1**
- ❑ Insufflation Tubing
- ❑ Endoscopic Peanuts (Kitners)
- ❑ Endoscopic Retention Stitch (hold)
- ❑ Suction Irrigator (hold)

- ❑ EPi-Sense® / EPi-Sense ST™ Coagulation Device
- ❑ Cannula
- ❑ RF Cable CSK-2000
- ❑ Grounding Pad
- ❑ RF Generator (with power cord & foot pedal)
- ❑ AtriClip PRO2® and/or AtriClip PRO•V® (all sizes)

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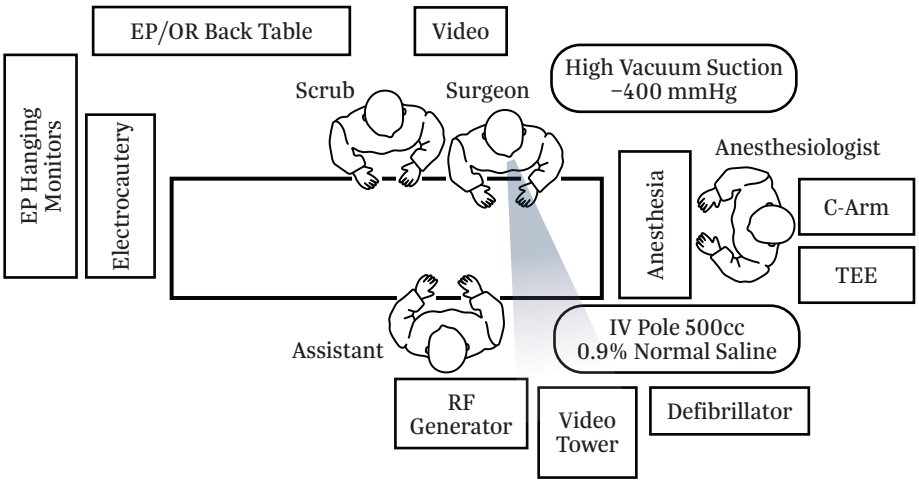
Hybrid AF Convergent Therapy Procedure: Room Setup



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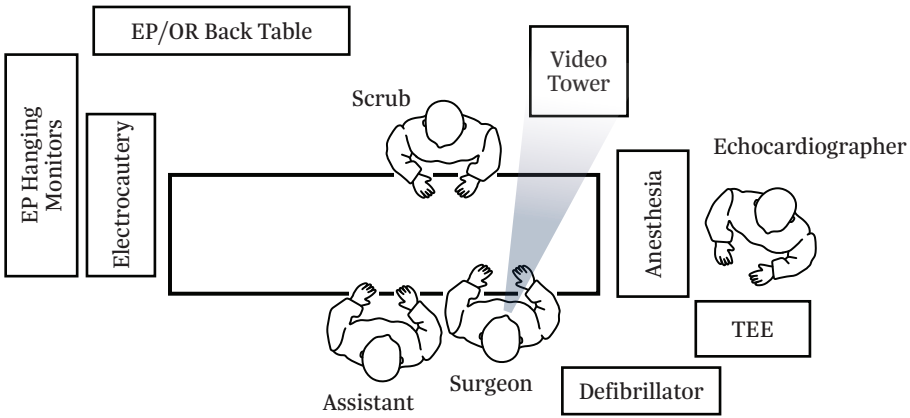
VATS LAAM via AtriClip: Room Setup



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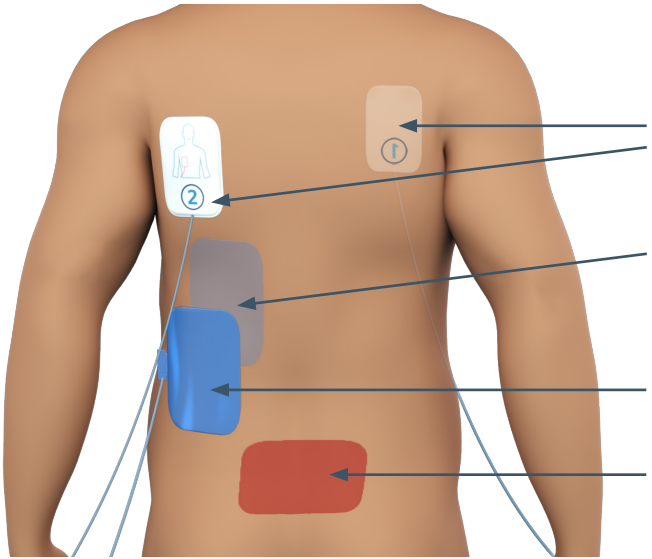
1 Amp Ground Pad & Defibrillator Pad Placement



- ❑ If defibrillator pads are not sterile, place Tegaderm™ 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

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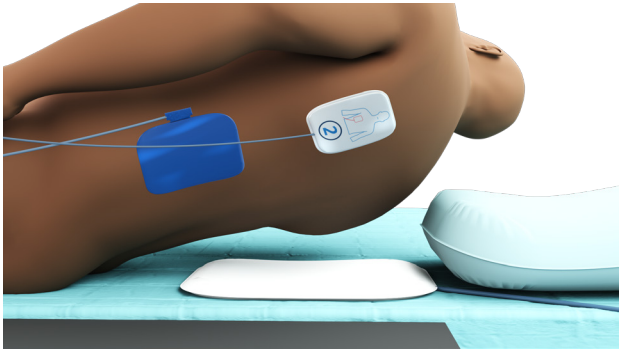
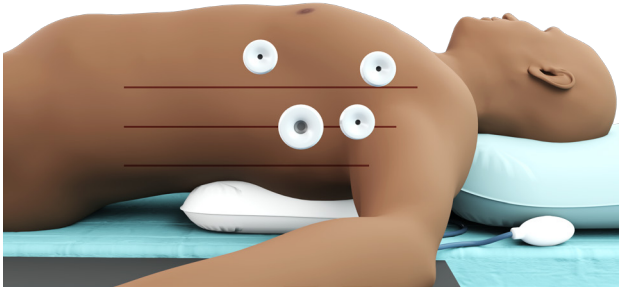
Patient Positioning with Inflatable Device





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

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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
- ❑ SCD (institution dependent)

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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 **(-250 mmHg)** with tubing to Cannula
- ❑ High vacuum suction **(-400 mmHg)** with tubing to EPi-Sense Device/ EPi-Sense ST 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

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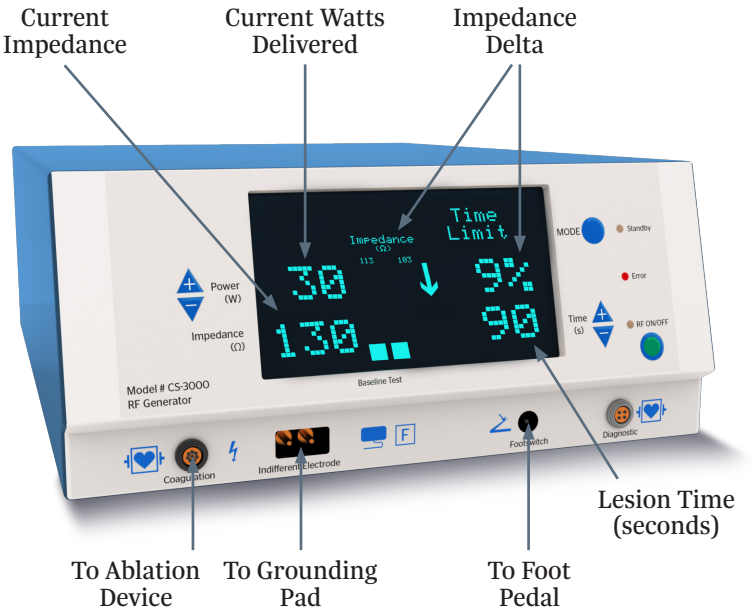
CSK-320/CS-3000 RF Generator



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.

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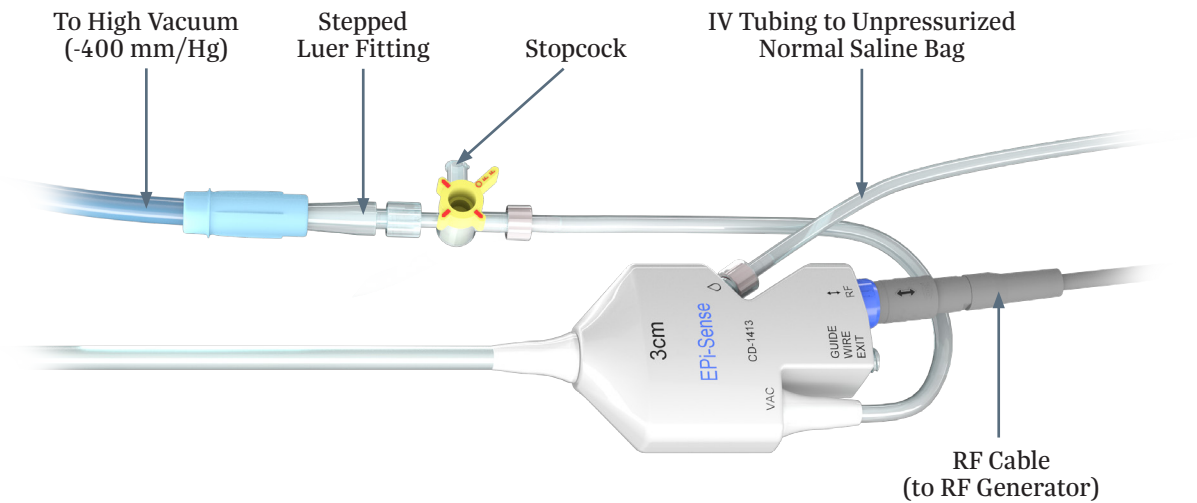
EPi-Sense Device Set-Up



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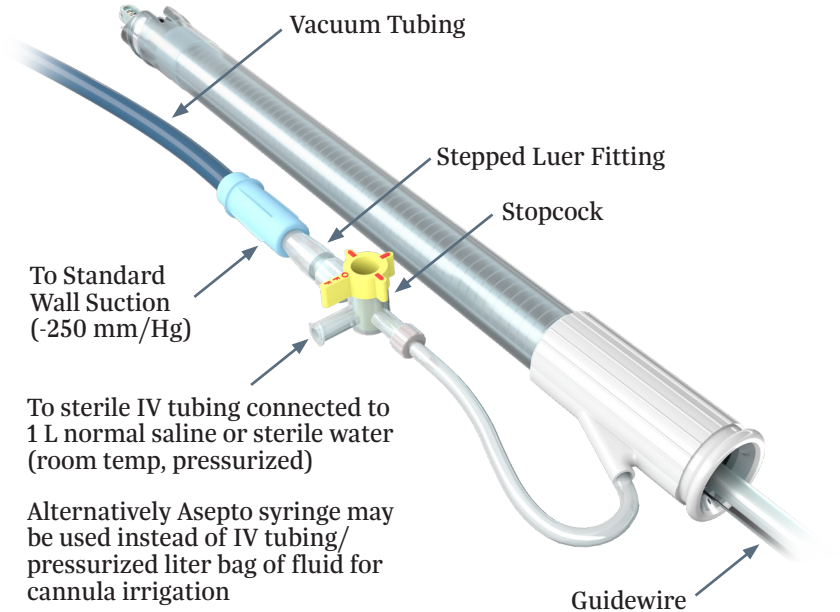
Cannula Set-Up



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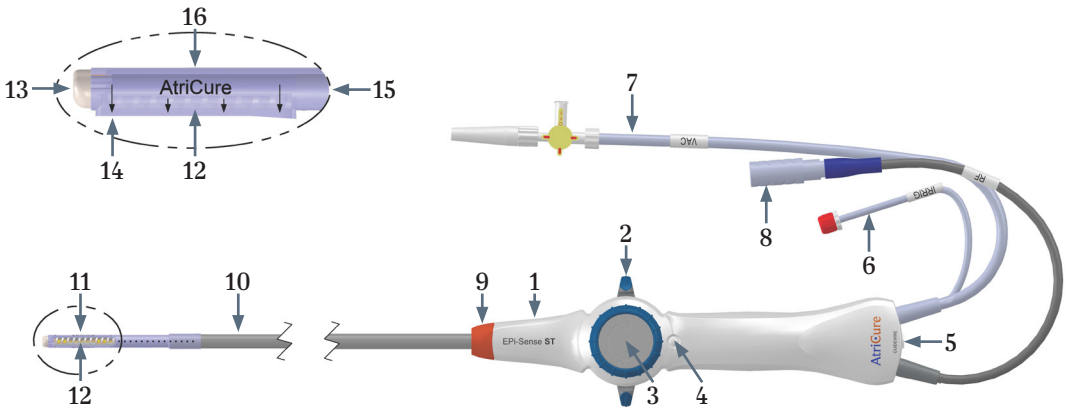
EPi-Sense ST Product Description



1. Handle
2. Steering Lever
3. Tension Control Knob
4. LED Indicator Light
5. Guidewire Port
6. Perfusion Tubing with Luer Connection [“IRRIG”]
7. Vacuum Tube Connector [“VAC”]
8. CSK-2060 RF Cable Connector
9. Nose Cone
10. Main Body
11. Distal Shell
12. Ablation and Sensing Electrodes
13. Guide Tube Opening
14. Locator Arrows (1cm spacing)
15. Vacuum Lumen
16. Insulative Covering

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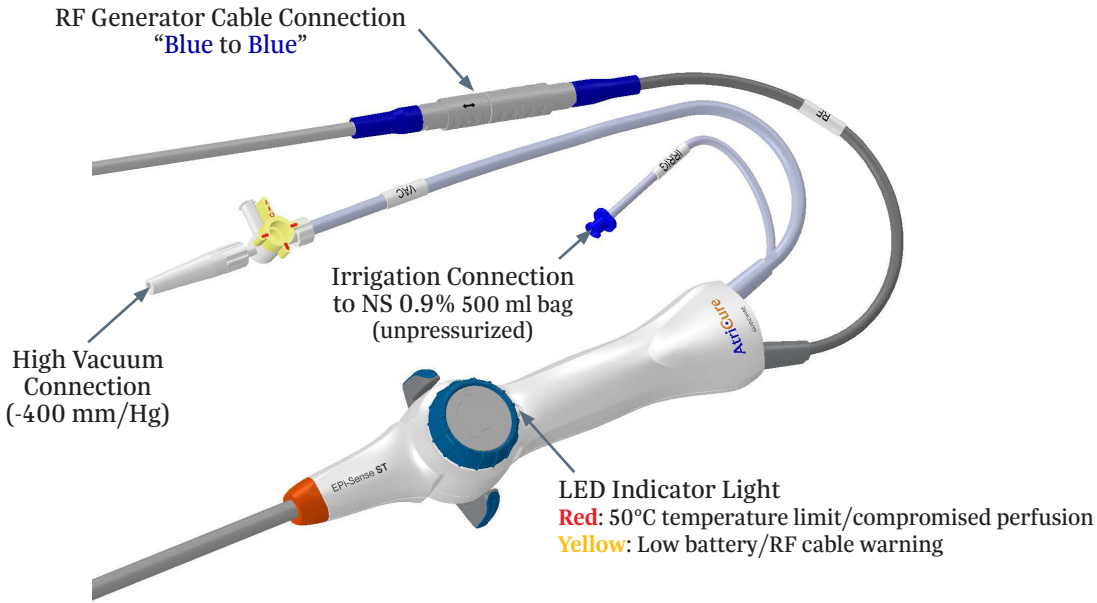
EPi-Sense ST Device Set-Up



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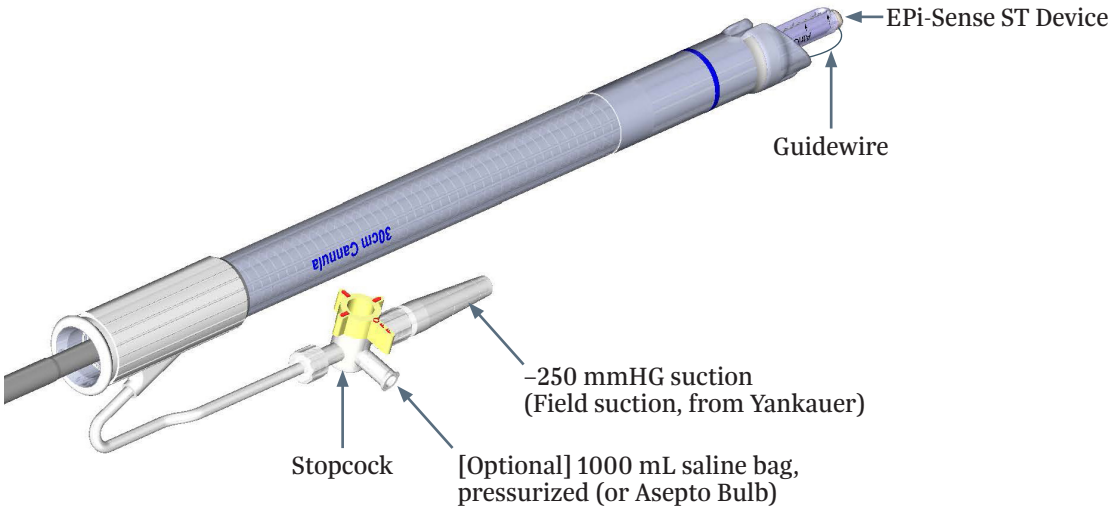
Cannula Set-Up



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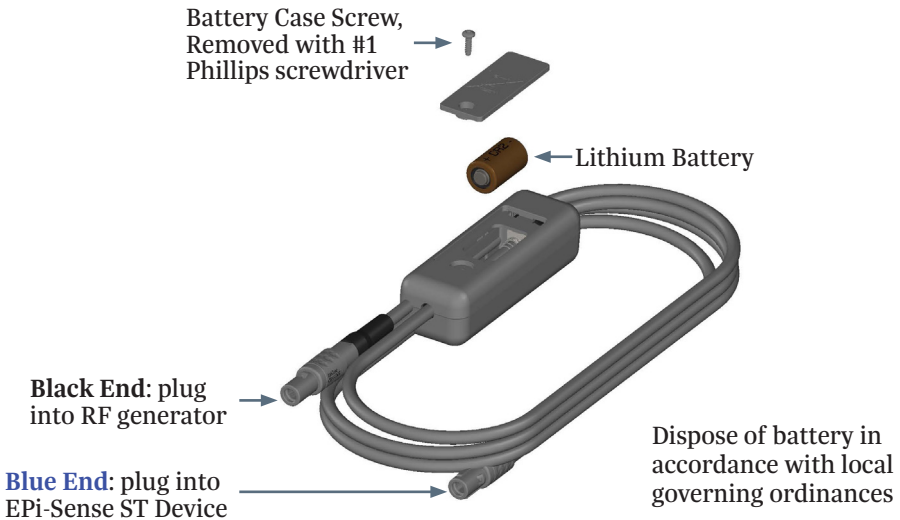
CSK–2060 RF Cable



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Hybrid AF Convergent Therapy Procedure: Device Set-Up *continued*

- ❑ Ensure adequate anticoagulation prior to ablation
- ❑ 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. Make sure the device is primed by observing perfusion at distal end of coagulation device before starting operation of device. Ensure IV line is fully open.
- ❑ Insert device into cannula and advance to target tissue
- ❑ Confirm arrows point toward target tissue and apply vacuum
- ❑ Irrigate field (1 L normal saline pressurized bag connected to cannula)

EPi-Sense Irrigation Set-Up

- ❑ Prepare the Vacuum
  - ❑ 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 **–400 mmHg**
- ❑ Prepare the 0.9% Normal Saline Bag
  - ❑ Place *unpressurized* saline IV bag at patient height or above.
  - ❑ Connect perfusion tubing to the female Luer connection as indicated on device handle by the perfusion droplet symbol. **Verify IV line is fully open.**

Saline should drip at **one drip per second** when vacuum is engaged

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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 at the posterior wall behind heart within pericardial window
- ❑ Introduce 0-degree 5 mm scope through cannula
- ❑ Through scope, identify landmarks on posterior left atrium
- ❑ Insert EPi-Sense/ST device prior to ablation
- ❑ Ready to ablate
- ❑ After posterior wall is ablated – Blake drain may be placed in the pericardial space

Hybrid AF Convergent Therapy: Procedural Steps

- ❑ Anesthesia inflates the positioning device for LVATS LAAM & deflates Left lung
- ❑ Surgeon places ports (5 mm in the 2nd ICS, 5 mm in the 4th ICS, 12 mm in 6th ICS, mid-axillary line, posterior-axillary line)
- ❑ Insufflates (flow & pressure)
- ❑ Surgeon performs pericardiotomy
- ❑ Appendage is exposed, measured and clipped
- ❑ Echo confirms occlusion
- ❑ Blake drain may be placed in pericardial space and attached to chest drainage system

VATS LAAM via AtriClip: Procedural Steps

First Port

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

Second Port

- With scope in the 4th intercostal port, look cranially towards the 2nd intercostal space
- 5 mm port 2nd intercostal space no more medial than mid-clavicular

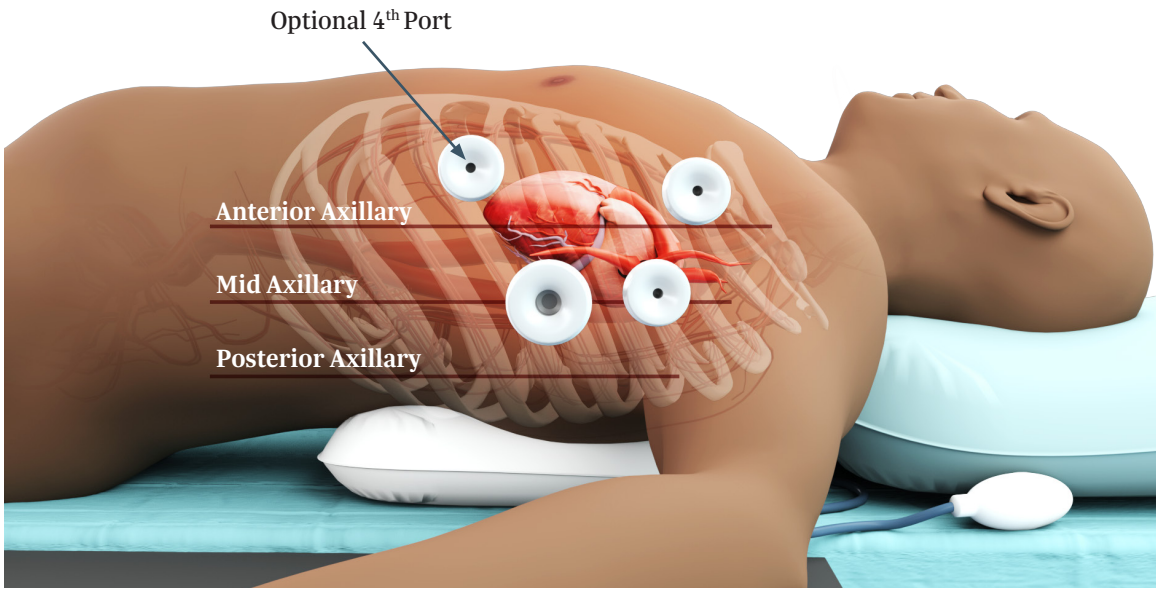
Third Port

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

Fourth Port

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

VATS LAAM via AtriClip: Procedural Steps



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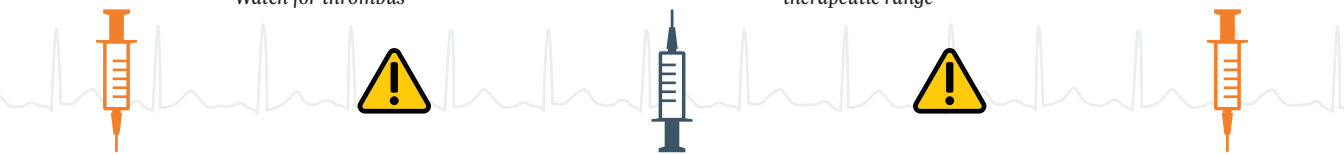
Hybrid AF Convergent Therapy* Recommended Anticoagulation Regimen: Epicardial Pre, Intra and Post Procedure Treatment

- *Minimize time between discontinuation of DOACs and first incision*
- *Patient thrombogenicity increases*
- *Watch for thrombus*

- *Recognize window of minimal protection between loss of heparin effectiveness and DOAC effective therapeutic range*



Pre-Procedural (24-48 hours)

Antiarrhythmic regimen | Anticoagulants

- Continue antiarrhythmic regiment (e.g. Tikosyn vs Amiodarone)
- Consider rate control medications (e.g. Diltizem vs Metoprolol)
- Discontinue Pre-surgical DOAC 24 hrs prior to first incision
- If discontinuing Pre-surgical DOAC > 24 hrs prior to first incision, consider bridging with Lovenox, Heparin if patient:
  - Is at increased risk of LA thrombus/ history of LAA thrombus
  - Has an elevated CHADSVASC > 4
  - History of TIA/CVA

Intra-Procedural

- Heparinization during epicardial ablation w/EPi-Sense and EPi-Sense ST™ ACT > 300 prior to ablating
- During endocardial catheter ablation -per anticoagulation protocol consistent with HRS guidelines[1]

Post-Procedural

Post-Op anticoagulation management

- Develop strategy with EP and combine with Post-surgery anticoagulation therapy
- Follow 2017 HRS Expert Consensus for anticoagulation management post ablation[1]
- Immediately following transfer to unit activate anticoagulation and before ACT reaches normal (100-125) when patient is at highest risk of thrombi
- Consider resuming DOACs (every DOAC has a different therapeutic time) within 4-6 hours post-procedure if there is no bleeding

*When using EPi-Sense/EPi-Sense ST

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EPi-Sense® ST Guided Coagulation System

The EPi-Sense Coagulation System/EPi-Sense ST™ Coagulation Device is intended for the treatment of symptomatic long-standing persistent atrial fibrillation (continuous atrial fibrillation greater than 12 months duration) when augmented in a hybrid procedure with an endocardial catheter listed in the instructions for use, in patients (1) who are refractory or intolerant to at least one Class I and/or III antiarrhythmic drug (AAD); and (2) in whom the expected benefit from rhythm control outweighs the potential known risks associated with a hybrid procedure such as delayed post-procedure inflammatory pericardial effusions. 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. Adverse Events: Reported adverse events associated with epicardial ablation procedure may include, but are not limited to, the following: pericardial effusion/cardiac tamponade, pericarditis, excessive bleeding, phrenic nerve injury, stroke/TIA/neurologic complication. Warnings: Physicians should consider post-operative anti-inflammatory medication to decrease the potential for post-operative pericarditis. and/or delayed post-procedure inflammatory pericardial effusions. Physicians should consider post-procedural imaging (i.e. 1-3 weeks post-procedure) for detection of post-procedure inflammatory pericardial effusions. Precautions: Precautionary measures should be taken prior to considering treatment of patients: (1) Deemed to be high risk and who may not tolerate a potential delayed post-procedure inflammatory pericardial effusion. (2) Who may not be compliant with needed follow-ups to identify potential safety risks. To ensure patients undergoing treatment with the EPi-Sense device are well informed, the benefits, potential risks and procedural outcomes associated with the EPi-Sense Hybrid Convergent procedure should be discussed with the patient. Physicians should document accordingly in the medical record. Qualified operators are physicians authorized by their institution to perform surgical sub-xyphoid pericardial access. The coagulation devices should be used by physicians trained in the techniques of minimally invasive endoscopic surgical procedures and in the specific approach to be used. Operators should undergo training on the use of EPi-Sense device before performing the procedure. Safety and effectiveness of concomitant left atrial appendage closure was not evaluated in the CONVERGE study. Follow-up should be conducted at approximately 30 days post procedure to monitor for signs of delayed onset pericarditis or pericardial effusion.

Rx Only.

AtriClip LAA Exclusion System

U.S. Indications: *The AtriClip LAA Exclusion System is indicated for the exclusion of the heart's left atrial appendage, under direct visualization and in conjunction with other cardiac surgical procedures. Direct visualization, in this context, requires that the surgeon is able to see the heart directly, with or without assistance from a camera, endoscope, etc., or any other viewing technology.* ***Warnings:*** *The safety and effectiveness of this device is atrial rhythm control management, either alone or in combination with ablative treatment, has not been established.*

Rx Only.

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