EsoSURE® Esophageal Retractor — Training Sheet v77 Background

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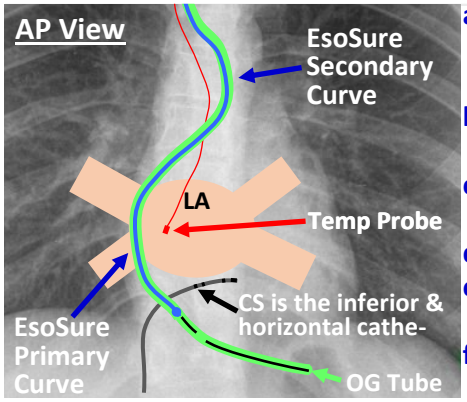
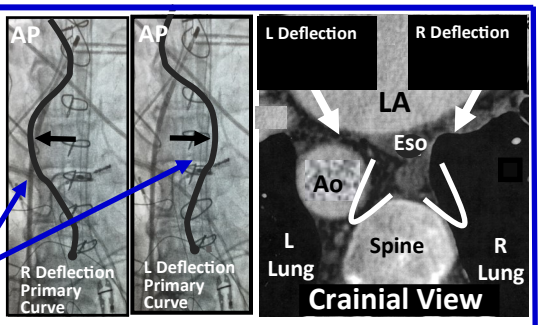
R Deflection Primary Curve



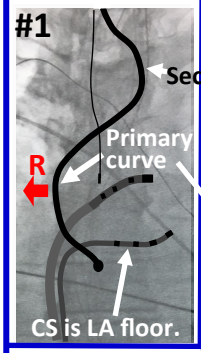
1) Anatomy

a. The R & L spinal borders, viewed with Fluoro in AP, often correlate with the LA and R & L Pulmonary Vein Ostea.
b. The Coronary Sinus (CS) identifies the floor of the Left Atrium (LA).
c. Normal EsoSure deflection is from the R to the L spinal border in AP.
d. View insertion & rotation in AP.
e. Envision the EsoSure position on Fluoro in 3D. Deflection is usually posterior-lateral between the lung & spine on the R or the aorta, lung & spine on the L.
f. After deflection, view the EsoSure, esophagus, and therapeutic device from a perpendicular view: RAO for R Deflection & LAO for L Deflection.

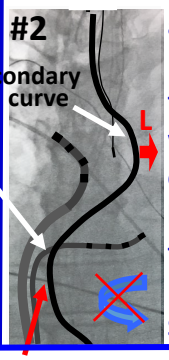


2) EsoSure positions. Primary curve to the Right or Left, Secondary curve only to the Left, or the Tip to R or L.

#1 R Deflection Primary curve:



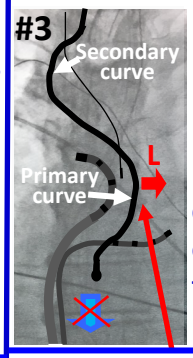
#2 L Deflection with Secondary curve for L sided Esophagus



a. Advance OGT/ EsoSure together for L deflection with secondary curve.
b. Then reposition the Temp Probe inside the Secondary curve.

* When the Primary curve is to the right, below the CS, do not rotate or advance the EsoSure.

#3 L Deflection with larger Primary curve for Midline or R sided esophagus

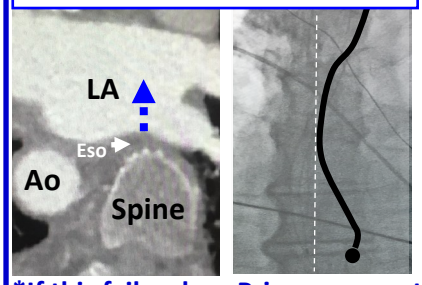


a. With the EsoSure tip near the CS, above the diaphragm,
b. Rotate handle 2-3 x, so curve apex rotates posteriorly
c. Then slowly retract stylet ~6" out of OGT while watching with Fluoro. Rotation usually occurs above the heart. If it spins or doesn't rotate, rotate in the opposite direction.
d. After rotation to the correct side, release the torque &
e. Advance the EsoSure curve to the desired position.
f. Then reposition the TP inside the stylet's curve.
* If curve doesn't advance for R or L deflection, use the tip.

* When the Primary curve is to the left, do not advance the EsoSure tip below the diaphragm, only rotate the stylet for R Deflection with the primary curve.

3) Use the ventilator to change the anatomy if deflection is unsuccessful or poor.

A narrow LA to spine distance may block deflection. Fluoro shows the EsoSure curve stops at mid-spine.

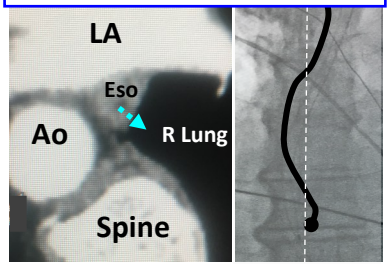


If deflection stops at mid-spine, use a Valsalva or PEEP. (If no CT, anticipate this is the situation.)

a. Rotate Primary curve to the desired side, above the heart;
b. Have anesthesia give & hold a deep inspiration to expand chest & lift the heart off the spine;
c. Slowly advance primary curve behind the LA. ~75% success.

*If this fails, place Primary curve to desired side above heart, give one clockwise rotation, Valsalva, and advance the EsoSure slowly.

The lung may reduce deflection. Fluoro shows the EsoSure curve crosses mid spine, but doesn't reach the spinal border.

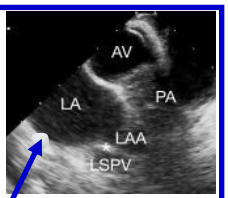


If deflection is not optimal, use Apnea.
a. Disconnect ET Tube for ~15 sec. to deflate the lungs;
b. Gently slide the stylet ~6" in and out of the OG Tube ~4x with one posterior rotation of the handle;
c. Position the primary curve behind the LA.

4) Contraindications: same as TEE or OGT. Esophageal abnormalities or Hx of: Surgery, strictures, varices, hematomas, UGI bleeding, severe GERD; Frail female + <5' tall + <50kg + >80 yo. If Hx stomach surgery, keep EsoSure above diaphragm.

5) Safety Tips

a. Avoid ablating over the deflected esophagus.
b. If resistance is felt while advancing the EsoSure, do not force it. Assess the cause and decide how to proceed.
c. After deflection, visualize the trailing edge of the esophagus using Fluoro with contrast or an ICE image on the 3D map.
d. After deflection, view LA posterior wall with ICE for a bump possibly caused by anatomy displaced by the esophageal trailing edge. Avoid Rx over this area.



ESOSURE® Esophageal Retractor — Training Sheet v77 Procedure & Checklist

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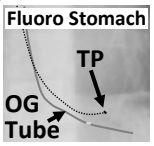
Equip

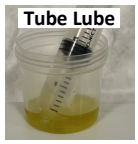
- ☐ 18 Fr 48" Salem Sump OG Tube (OGT). Don't use silicone models.
- ☐ Medicine/Specimen cup to pour Tube Lube & draw into syringe.
- ☐ 20 cc syringe to inject Tube Lube & IV fluid into OGT for cooling... and lubrication.
- ☐ EsoSure
- ☐ Tube Lube is included for lubricating OGT lumen (Or olive/veg oil).
- ☐ Esophageal Temp Probe (TP). Use a smooth shaft 9-12 Fr model. Avoid Acoustascope probes with a balloon over the thermistor/tip.
- ☐ Peds 4-5 mm ET tube or nasal trumpet airway placed orally as an introducer for 9 Fr TPs.

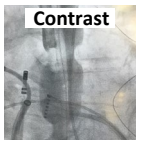
Prep

- ☐ Ask patient about esophagus & stomach Hx while attaching electrodes.
- ☐ Check CT/MRI, if done, for a narrow LA-spine, lungs, Ao and esophagus size.
- ☐ Lubricate TP & OGT shaft with lots of Surgilube and insert to stomach before heparin. Insert OGT to ~60 cm/3rd black mark. Use a Peds 4-5 mm ET or nasal trumpet (oral) as an introducer for 9 Fr TPs. Remove OGT if EsoSure not used.
- ☐ Fluoro TP & OGT in AP for baseline esophagus, angle to stomach & work flow.
- ☐ Prep Tube Lube: 1) Draw 12cc of IV fluid into 20 cc syringe; 2) When EsoSure is requested Pour Tube Lube into cup & aspirate into syringe with IV fluid.

☐ Inject contrast after transseptal:
a) Verify OGT is in stomach c̄ Fluoro.
b) Retract OGT gap ~1" above CS.
c) Inject 10-20 cc contrast slowly.
d) Adjust OGT up or down as needed.
e) Re-advance OGT into stomach.
f) Flush barium contrast into stomach.







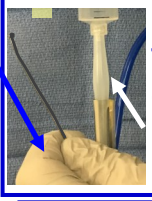
Procedure

Insert

☐ **1 Bolus Propofol or a sedative** to relax the airway & avoid a gag reflex & moving. Tap on ET tube if unsure. Use paralytics if EP OKs.

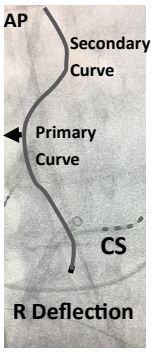
☐ **2 Open & align airway.** Hold tip of EsoSure & OGT. Have other staff lift the chin with thumb behind the front teeth & fingers under the jaw.

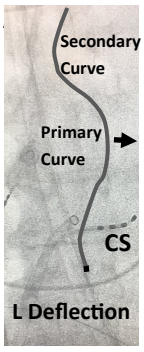
☐ **3 Lubricate & Cool OGT lumen** by injecting 12 cc of IV fluid & Tube Lube through the OGT connector over 5-10 sec. Keep connector in the OGT & insert EsoSure through it.



Position

☐ **4 Immediately after injecting** cooling/lubricating fluid advance EsoSure 2-3" at a time, with OGT straight & up >45°. If tip of stylet stops above CS, advance OGT & EsoSure together. Stop when stylet tip is ~1" below CS or primary curve is at upper heart.





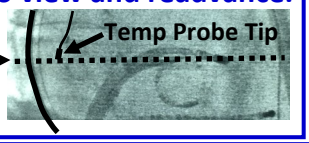
☐ **5 Rotate primary curve to desired side.** With primary curve behind the heart, rotate handle 2x, then slowly retract ~6" out of OGT. Rotation usually occurs above heart. Rotate third time if needed. If it spins or doesn't rotate, release torque, advance tip to CS, rotate 2x opposite way and retract 6".

☐ If stylet stops advancing in throat, it is most likely a loop in the OGT. To resolve, fix OGT, retract stylet ~2", then fix stylet and retract OGT over stylet 2" 3X, then re-advance the stylet. If it won't advance, reassess with Fluoro or remove.

☐ Use the tip of the stylet for deflection if you are unable to optimally position the primary or secondary curve.

☐ **6 If the primary curve does not cross mid-spine use a Valsalva:** After rotating primary curve to the desired side behind trachea, Valsalva & slowly advance the curve behind the heart. **If primary curve crosses mid-spine but not spine's side border:** Go apneic for 15 sec, & slide EsoSure in & out of OGT ~6" 4x.

☐ **7 Position Temp Probe** inside EsoSure curve. If TP is lateral to OGT, retract ~6" out of Fluoro view and readvance.



Assess

☐ **8 Assess the esophageal trailing edge** with Fluoro & contrast, or with US while sliding EsoSure in & out ~2" to wiggle esophagus. Lastly, use US to check LA posterior wall for possible indentation.

EsoSure Removal:

☐ Starting with the stylet tip above the diaphragm, fix the end of the OGT and hold the stylet at the end of the OGT. Smoothly pull the EsoSure out ~6" and push it back in 2X to slide the esophagus to the R & L behind the LA, then remove the stylet. It is hypothesized that side to side esophageal movement by the tip and curve may break esophageal-fat pad thermal adhesions & reduce the potential for AEF formation.

☐ Lastly, suction the stomach, and if contrast was used suction the esophagus during OG Tube removal.