The EsoSure Esophageal Retractor Training Sheet Reference

Welcome to the EsoSure family,

This PowerPoint reviews all the information we cover during face-to-face training. It is best used as an introduction before we arrive, as a review after training, and later as a reference to answer questions that will arise. Please be patient with yourself. Your fingers as well as your mind will need time to get the feel of handling the EsoSure and become proficient in its use.

In this PPT, the text in red and blue is the same text that is in the Training Sheet. The text in black, provides additional information. You are welcome to add notes, arrows, and highlights as you wish to assist with your own learning.

As a reminder, my email address and cell phone number are in the upper right-hand corner of the Training Sheet that is in each box. Please call any time you have questions, and we would love your feedback. If you are in a procedure and are not sure of something please call to Facetime, WhatsApp or Zoom so I can view the EsoSure use in order to provide input.

Thank you,

Steve Email: steve@epreward.com Cell: 561-779-1040

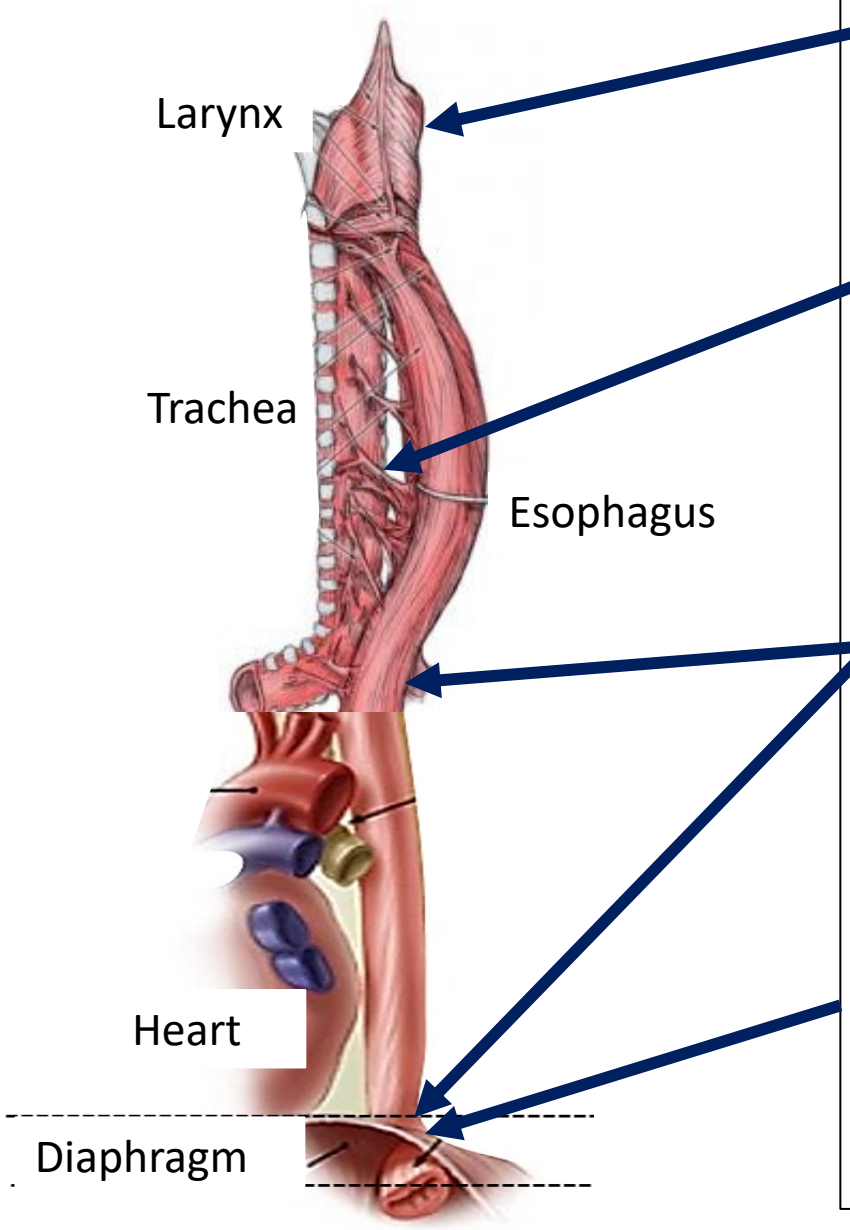
Index

Background page of Training Sheet

(Blue and Red text in the index and PowerPoint is from the EsoSure Training Sheet and black text is additional information.)

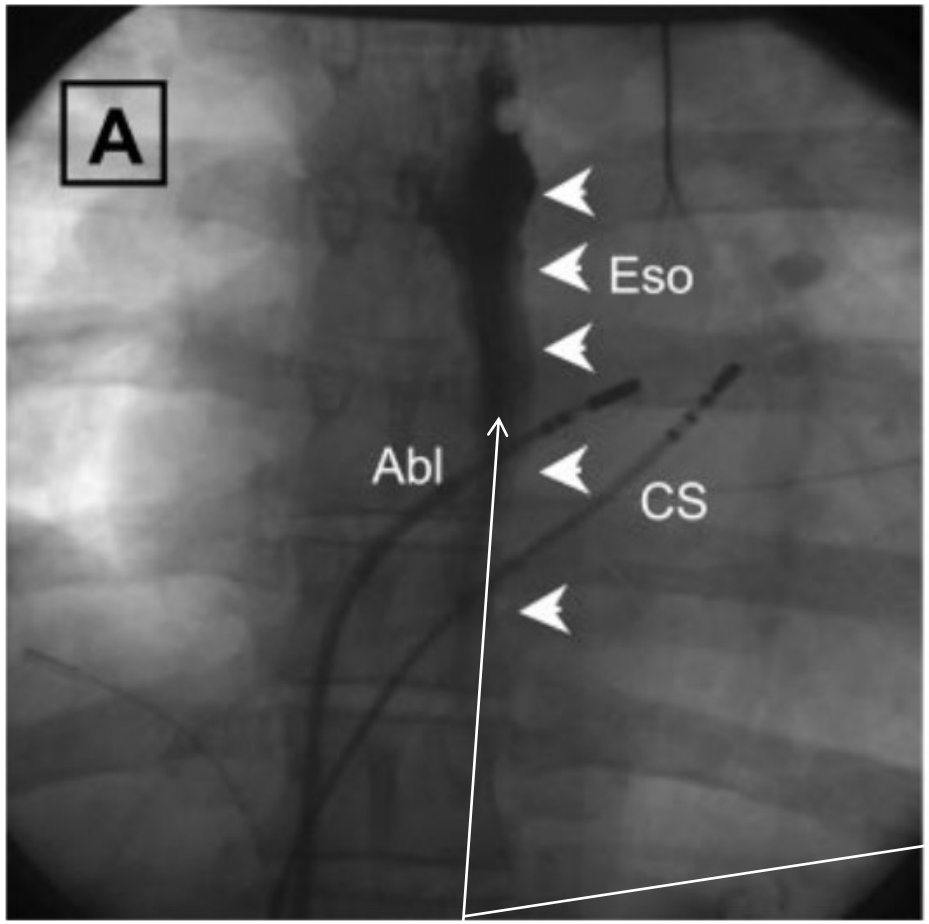
Procedure page of Training Sheet

First, some background anatomy.

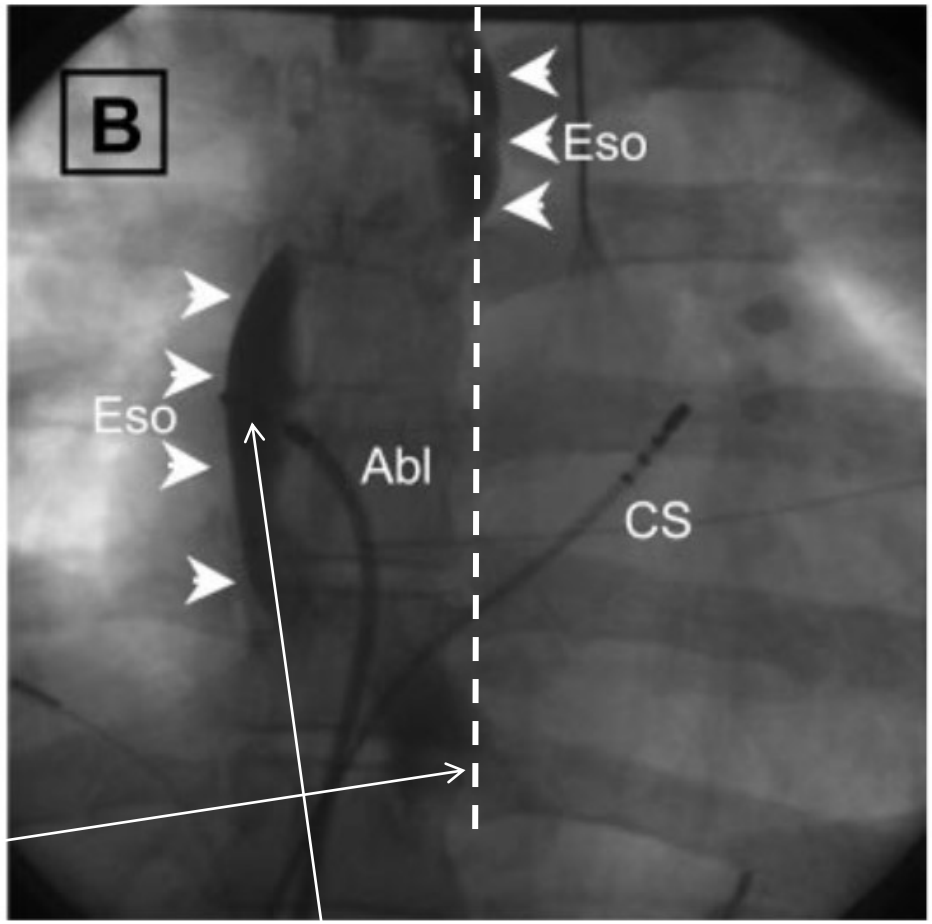


- The esophagus is fixed superiorly by muscles from the larynx.
- Fibroelastic membranes and thin muscle fibers loosely connect the esophagus and the trachea.
- Between the tracheal bifurcation and diaphragm there are no attachments to the esophagus.
- The esophagus is fixed inferiorly at the esophageal hiatus.

Between the trachea and diaphragm, behind the heart, the esophagus moves all by itself.



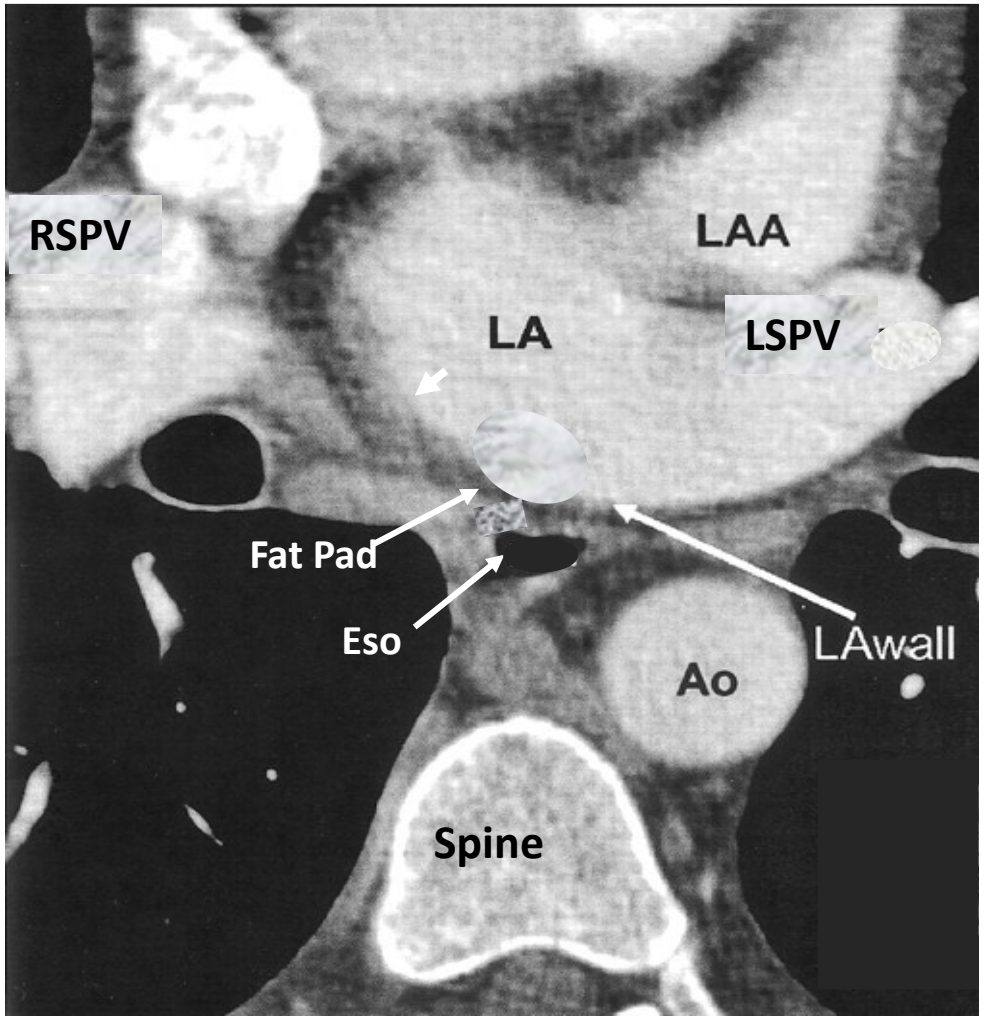
Baseline position



Migrated position 40 min. later, without mechanical influence.

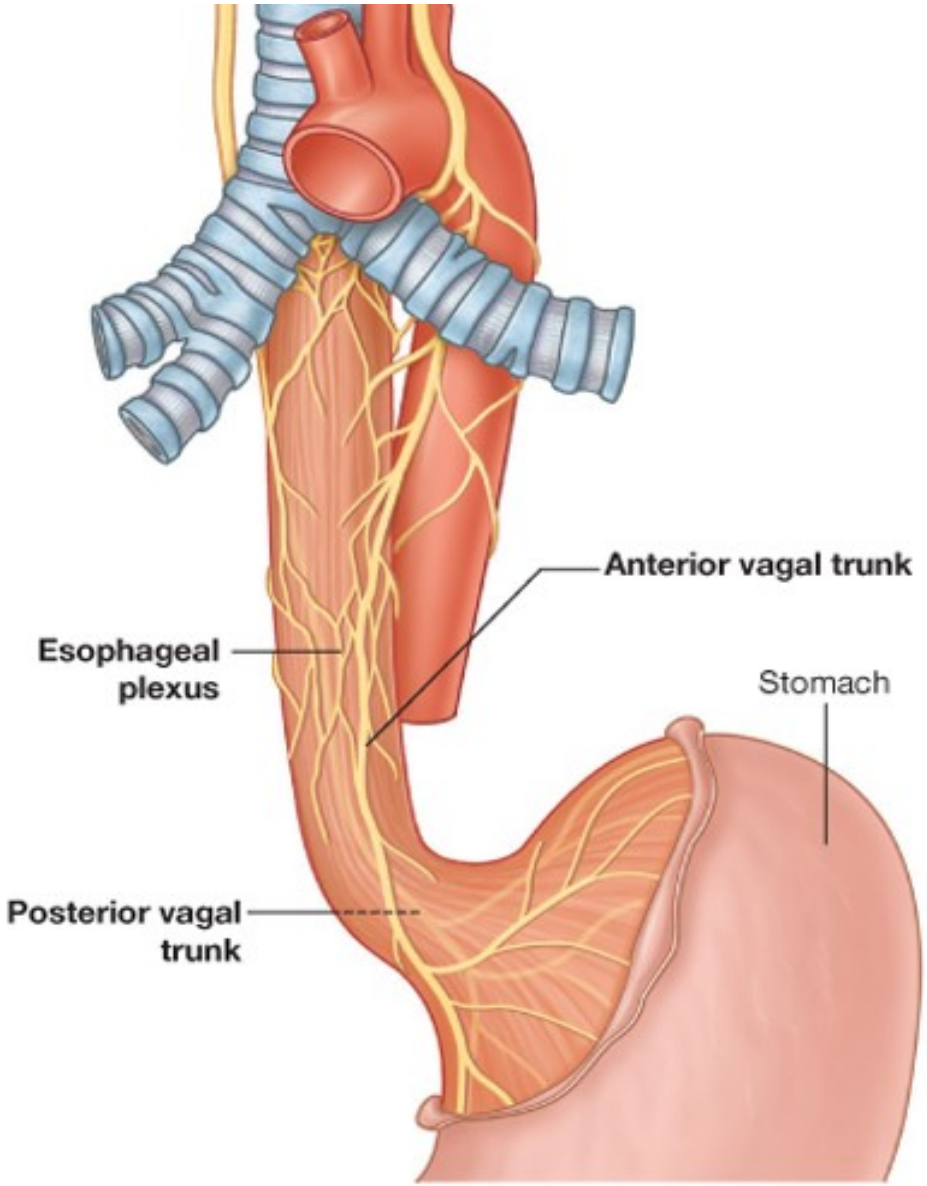
The esophagus can move laterally up to 2.5 cm through physiologic migration. (1) This has been noted more frequently with conscious sedation but is minimized with general anesthesia. The EsoSure is designed to create esophageal deflection in a shape that mimics physiologic migration.

The esophagus is frequently adjacent to the LA posterior wall.



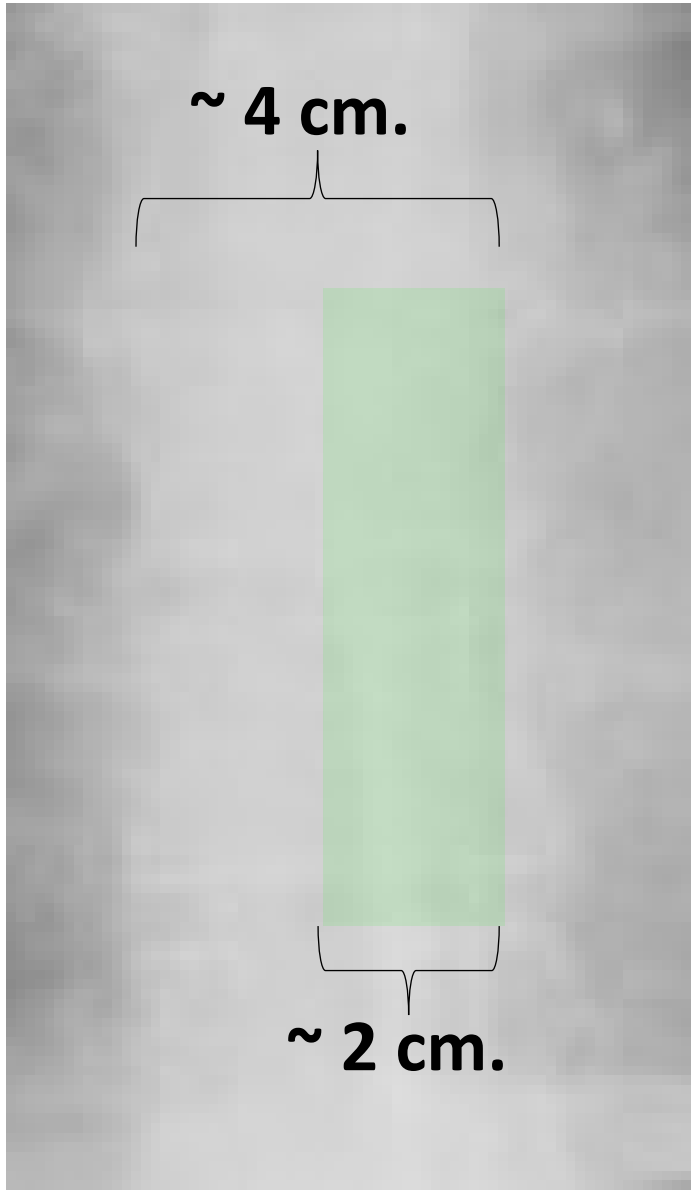
The total distance from the inside of the Left Atrium to the Esophageal lumen varies and may be as little as 3.2 mm. (2) It is estimated that an atrial esophageal fistula occurs in 0.2% to 0.4% of AF Ablations. (3-10) However, thermal injury to the esophagus occurs in 30% to 47% of these procedures. (11-13)

Vagal nerve injury is more common than esophageal injury.



RF and Cryo injury to the vagal nerve and esophageal/vagal nerve plexus (located on the anterior and lateral surfaces of the esophagus) is a frequent complication that goes unreported. This results in impairment of the upper GI system including dysmotility, delayed gastric emptying and other GI problems in ~18% of Cryo Ablations (14) and 40% of RF Ablations (15).

Better Understanding the Esophagus

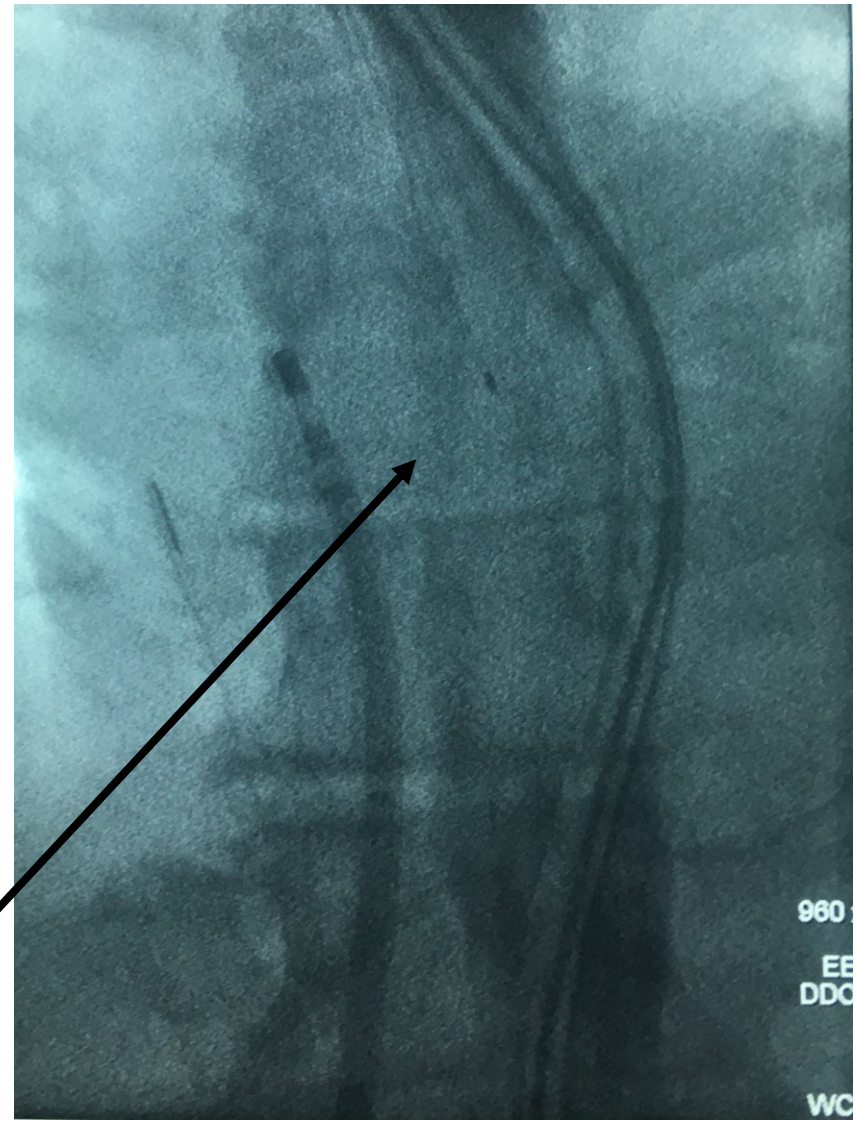


The typical spine, when viewed in AP is ~4 cm in diameter at its widest point.

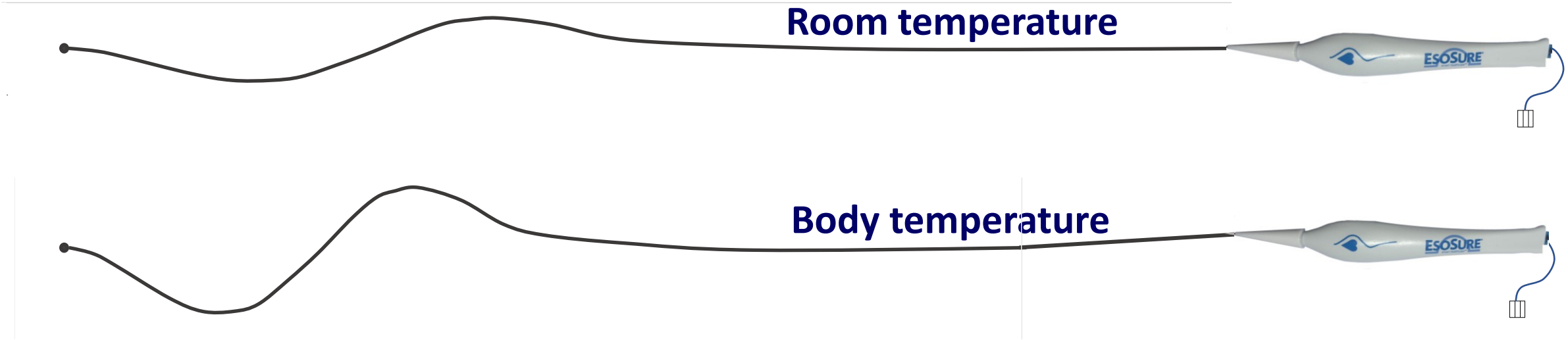
The average esophagus is ~2 cm in diameter, or half the width of the spine.

Esophagi have been observed up to 6 cm in diameter at baseline.

Identifying the width of the esophagus with contrast or ICE is very helpful.



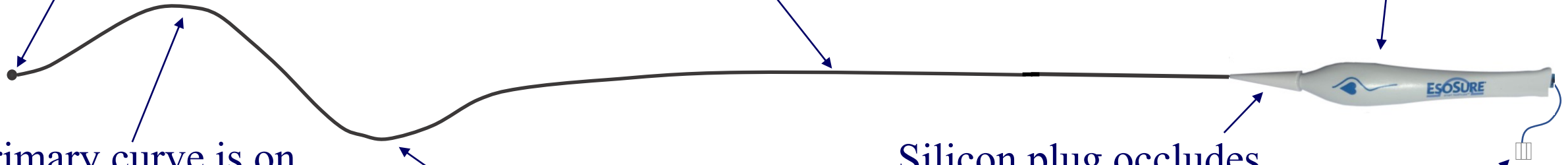
Intro to the EsoSure Esophageal Retractor



The EsoSure has a temperature-programmed Nitinol stylet which slides into the lumen of an 18 Fr Salem Sump OG Tube (OGT) that has been placed into the stomach.

The stylet is malleable at room temperature and assumes a firm S-shaped curve at body temperature to deflect the esophagus.

EsoSure Anatomy



Even with the use of the sensitive Circa S Cath, "Esophageal injury during High Power Short Duration Pulmonary Vein Isolation does not correlate to esophageal temperature changes during ablation. However, esophageal injury does correlate to a shorter proximity of the esophagus to the Left Atrium." (16) Therefore, move the esophagus.

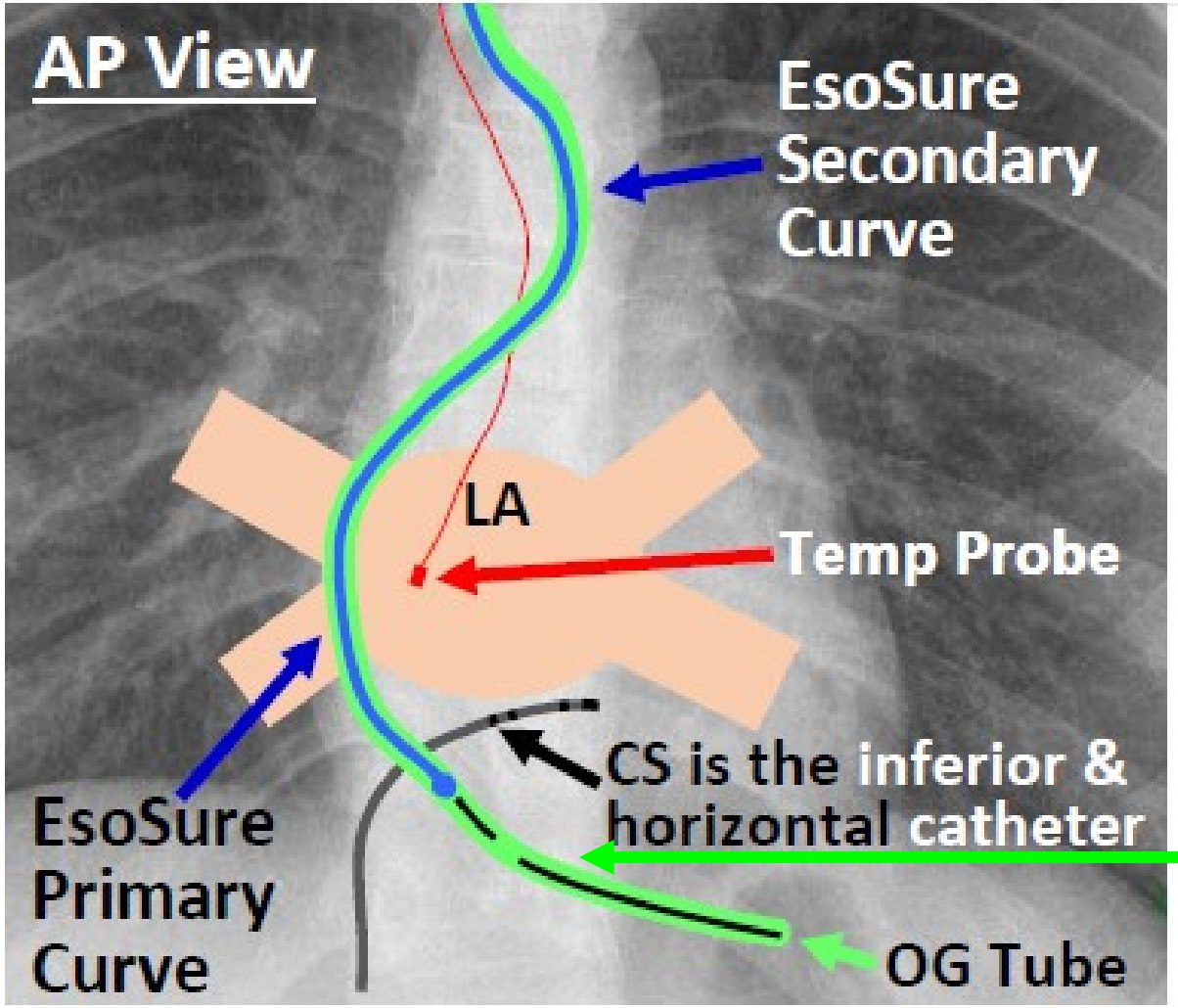
Benefits of esophageal deflection with the EsoSure during A Fib ablation- The DEFLECT GUT study (17).

Efficacy Endpoint	EsoSure (n=180)	Non-EsoSure (n=180)	p value
Esophageal Displacement Mean (cm)	2.45 ± 0.9	-	-
Mean Change in Esophageal Temp (°C)	0.34 ± 0.59	1.66 ± 0.54	< 0.001
Esophageal Temp Rise > 1.0°C (cases)	6 (3%)	143 (79.4%)	< 0.001
Total Procedure Time (minutes)	180 ± 36	206 ± 32	< 0.001
AF Recurrence at 12 months	42 (23.3%)	60 (33.3%)	0.05

* The EsoSure, like most things in medicine, does not work every time. Its success rate is about 80%. In those patients where it is not successful, anatomy in the mediastinum either impedes deflection or prevents insertion of the EsoSure into position.

The spine and CS catheter outline the LA.

Example: Initial R Deflection



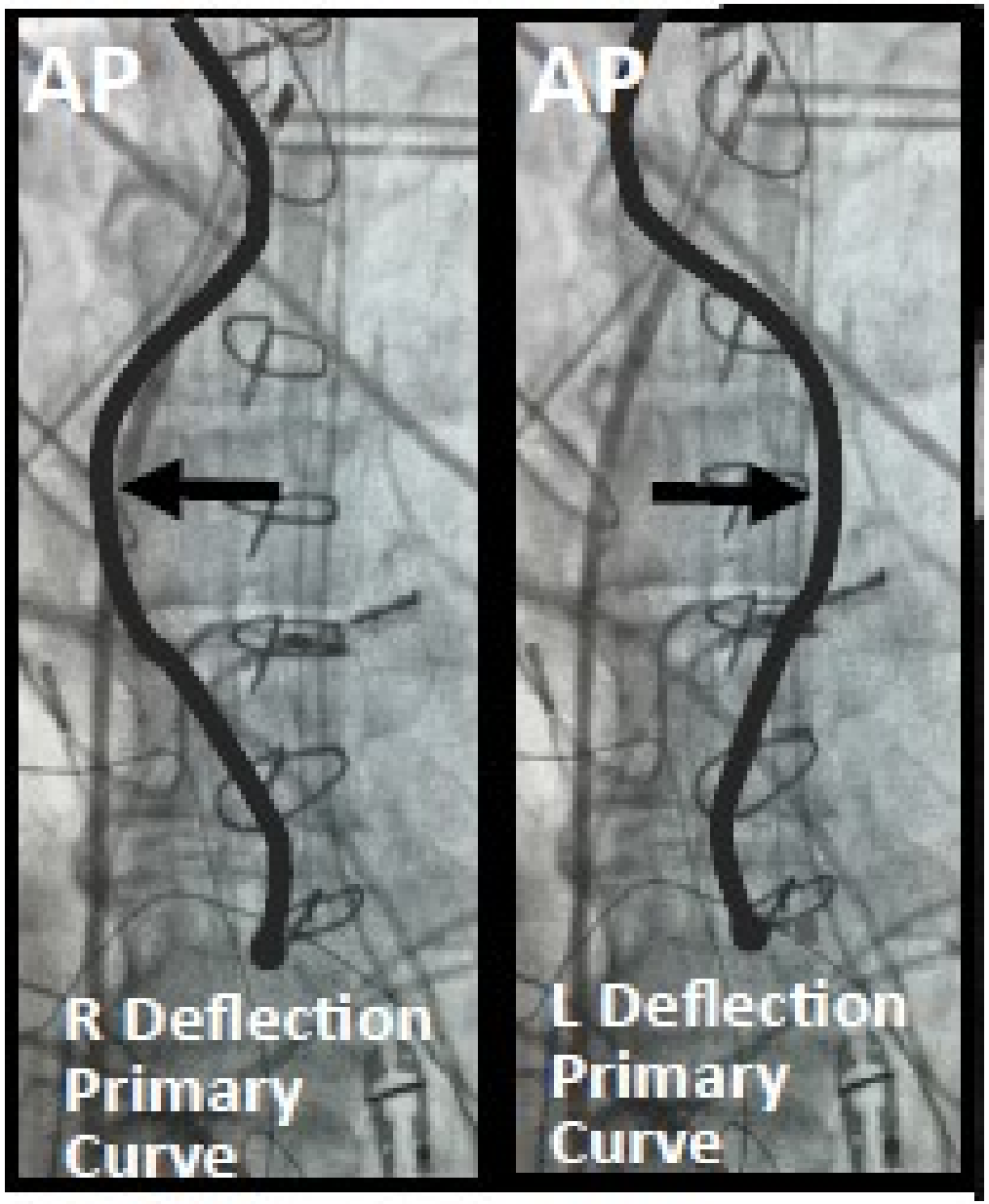
1) Anatomy

a. Use the right and left borders of the spine as an AP Fluoro reference for the right and left sides of the left atrium (LA).

b. The Coronary Sinus (CS) identifies the floor of the LA.

- The spine is usually behind the Left Atrium (LA) in an AP view. Occasionally the heart it will be rotated leftward, rarely is it to the right.
- The tip of the EsoSure gets support from the diaphragm which is 2-3 cm below the CS catheter.
- There is a gap in the radiopaque stripe on the OGT that indicates the proximal hole. The tip of the EsoSure will stop 1-2 cm above this hole.

R to L side of spine is usually R to L side of LA in AP.



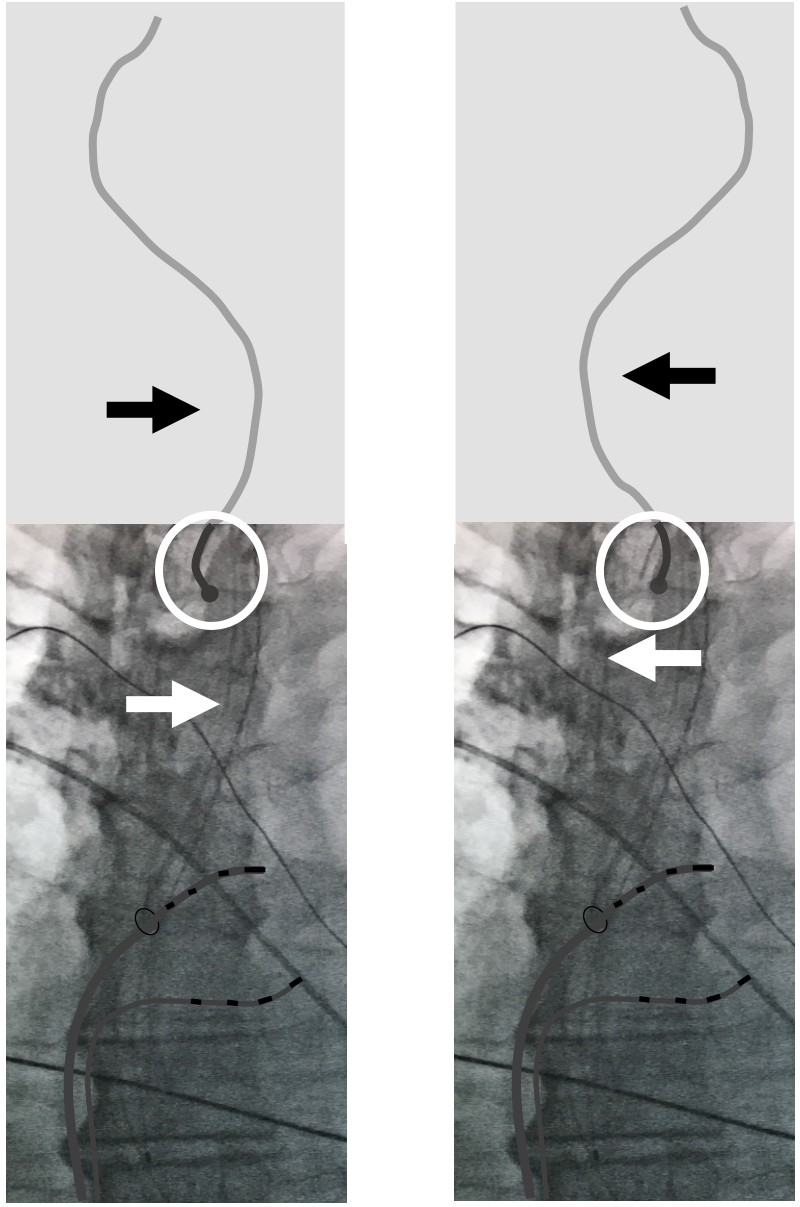
1) Anatomy

c. Normal EsoSure deflection is from the R to the L spinal border in AP.

d. View insertion & rotation in AP.

- These images show the EsoSure's Primary curve positioned over the right and left spinal borders. This is normal deflection.
- The right and left pulmonary vein antrum usually equates to the right and left spinal borders.
- If the EsoSure does not reach the left or right spinal border, then deflection is being limited by the patient's anatomy.

The tip points to the curve.



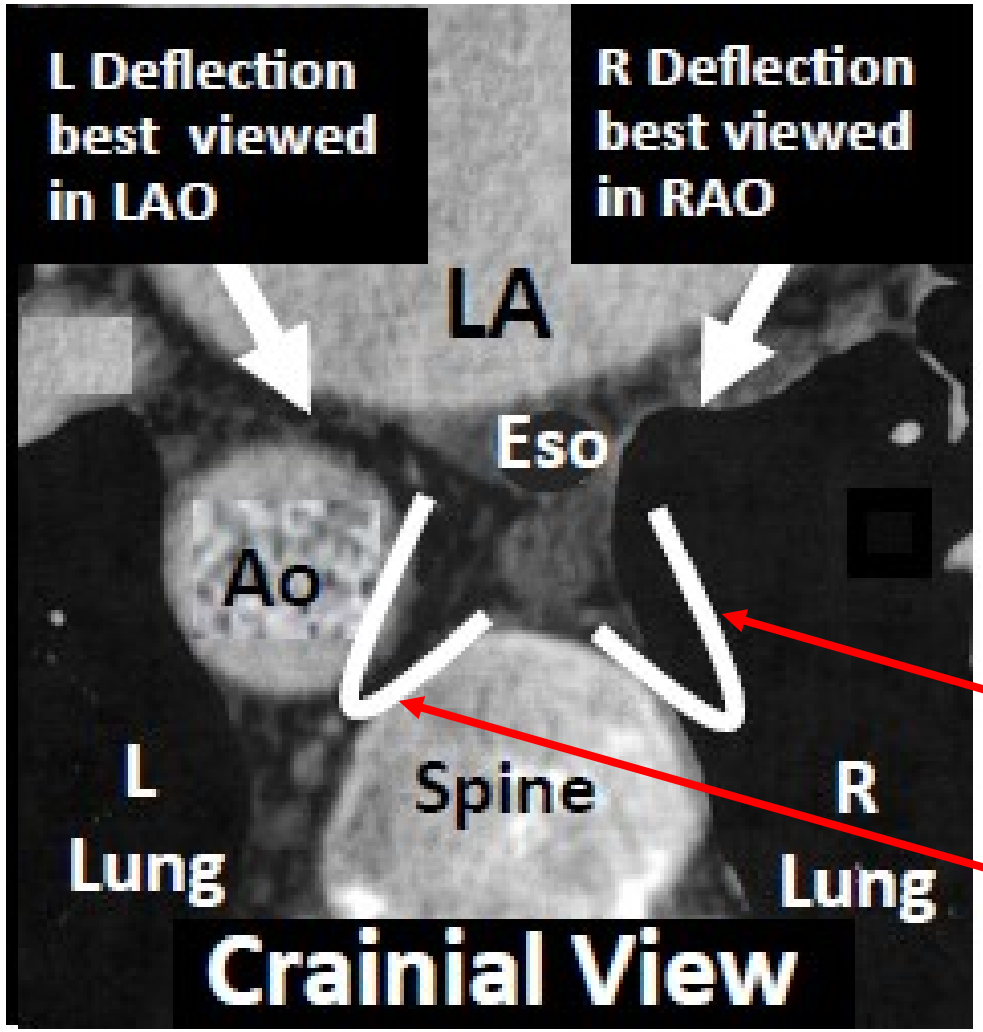
During insertion and rotation, when most of the stylet is above the Fluoro field of view, note which side the tip is pointed towards as it comes into view.

The tip will point to the same side that the primary curve is on.

View Insertion and rotation in AP. This allows you to immediately see if the curve is going to the right or left.

Deflection is posterior-lateral

1) Anatomy

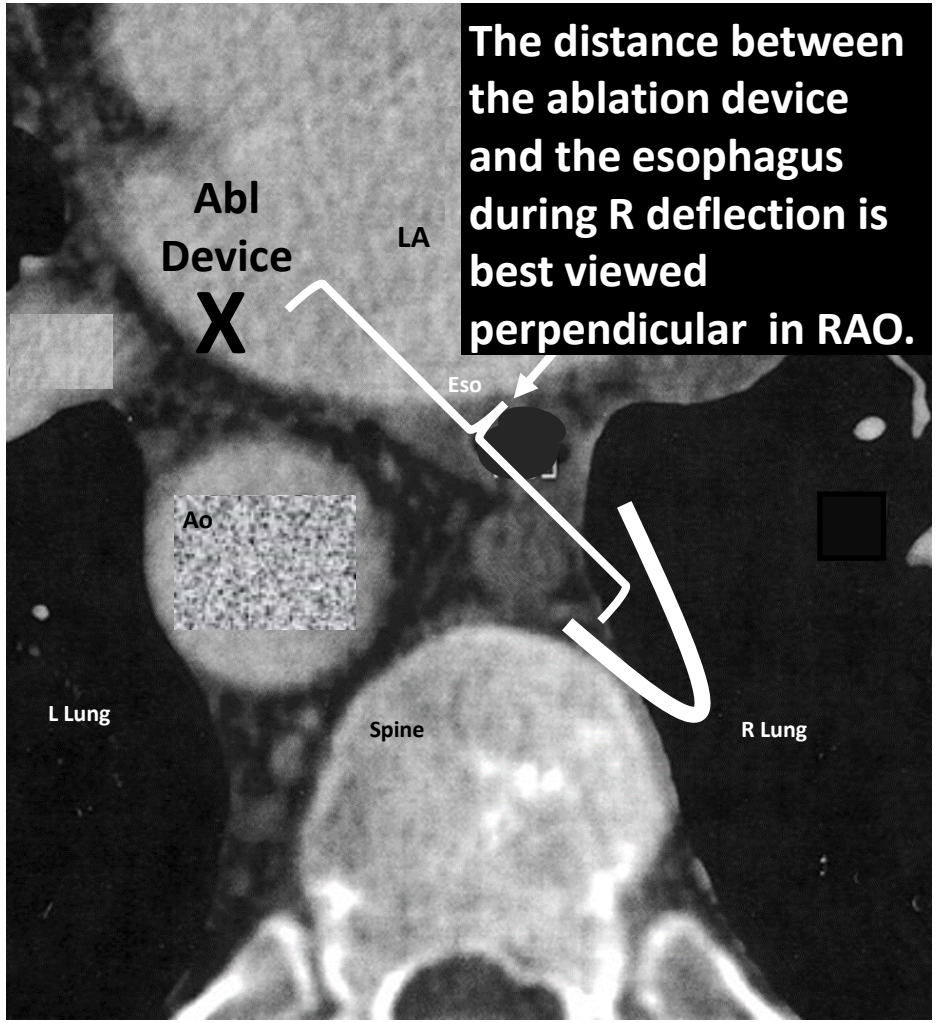


e. Watching Fluoro, visualize the position of the EsoSure in 3D. Deflection occurs posterior-laterally between the lung and the spine or between the aorta-lung and the spine.

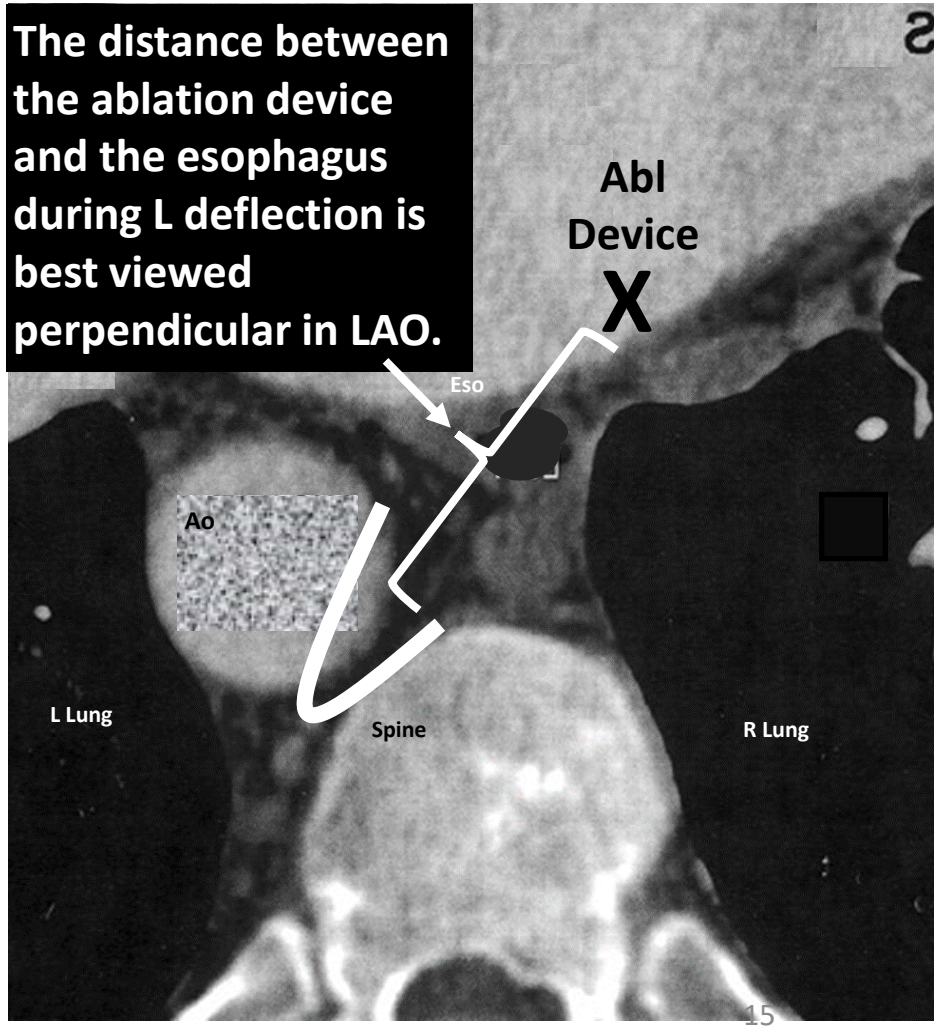
(White arc represents EsoSure curve.)

A perpendicular view is best.

1) Anatomy



Before or after EsoSure placement, position the ablation catheter on the LA posterior wall near the targeted PV or the Cryo balloon in the PV. After deflection, evaluate the distance from the ablation device to the esophagus. RAO for Right deflection and LAO for L deflection.



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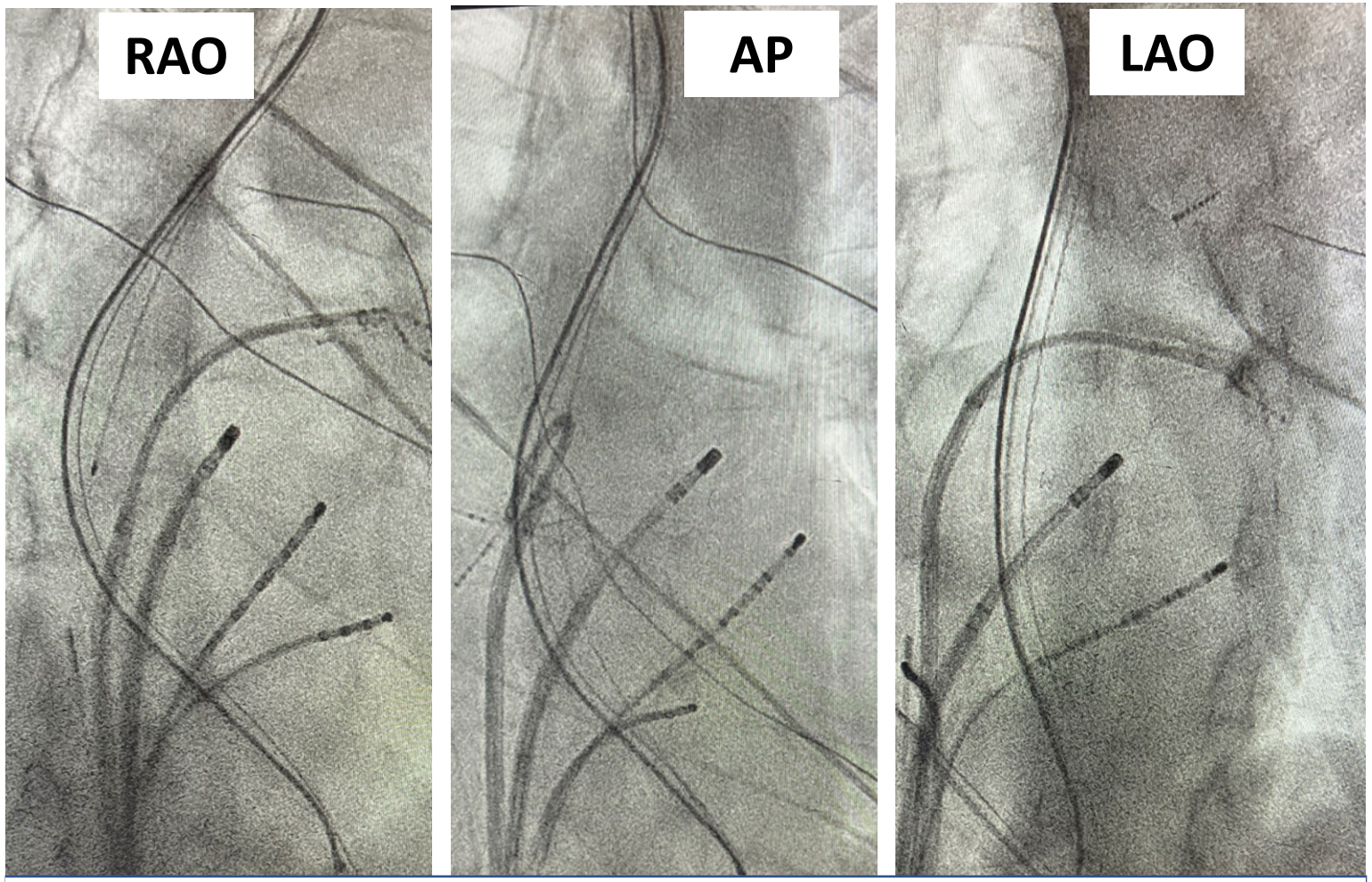
A perpendicular view is best

1) Anatomy

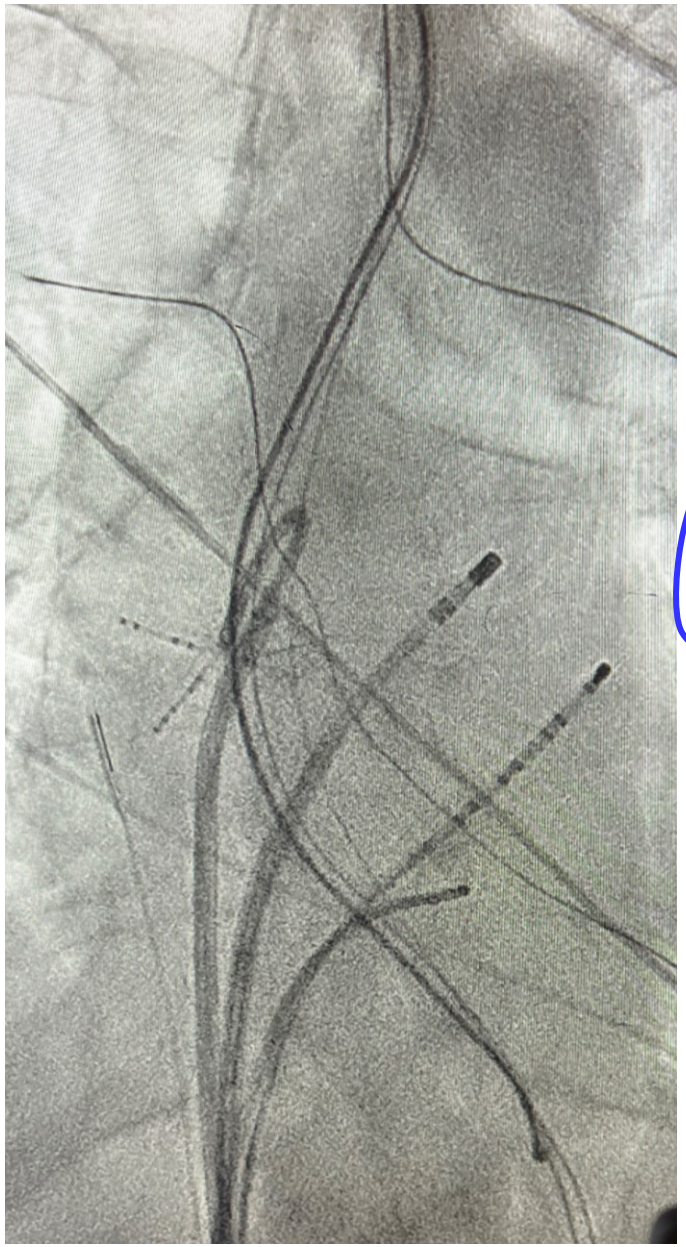


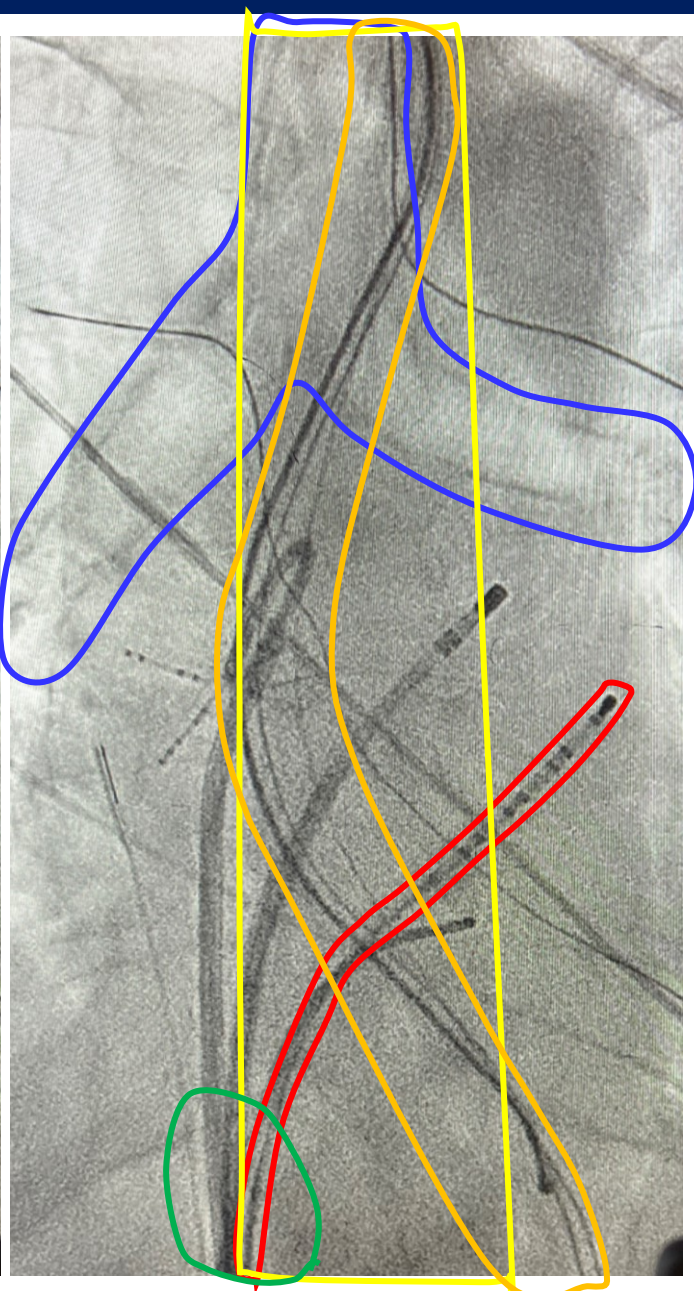
Right deflection

f. After deflection, evaluate esophageal position and the LA anatomy from a perpendicular view: RAO for R deflection and LAO for L deflection.

The EsoSure pulls the esophagus in a posterior lateral direction. A RAO view of R deflection is more perpendicular to the plane of the curve and better shows the curve vs. LAO that is more parallel to the plane of the curve.

Intro to Fluoro Images: Anatomy





The green line outlines the catheters and sheaths coming up the inferior vena cava along the right border of the spine in an AP view, The inferior vena cava generally enters the chest anterior to the right side of the spine. If there is a1-2 cm space between the catheters and sheaths and the right border of the spine the view is LAO and if the catheters and sheaths are towards the middle of the spine the view is RAO.

The yellow line outlines the spine. Depending on the resolution of the Fluoro settings and the mass of the patient, the spine may be dark and blurry, as in this image, or the vertebrae may be clear and distinct.

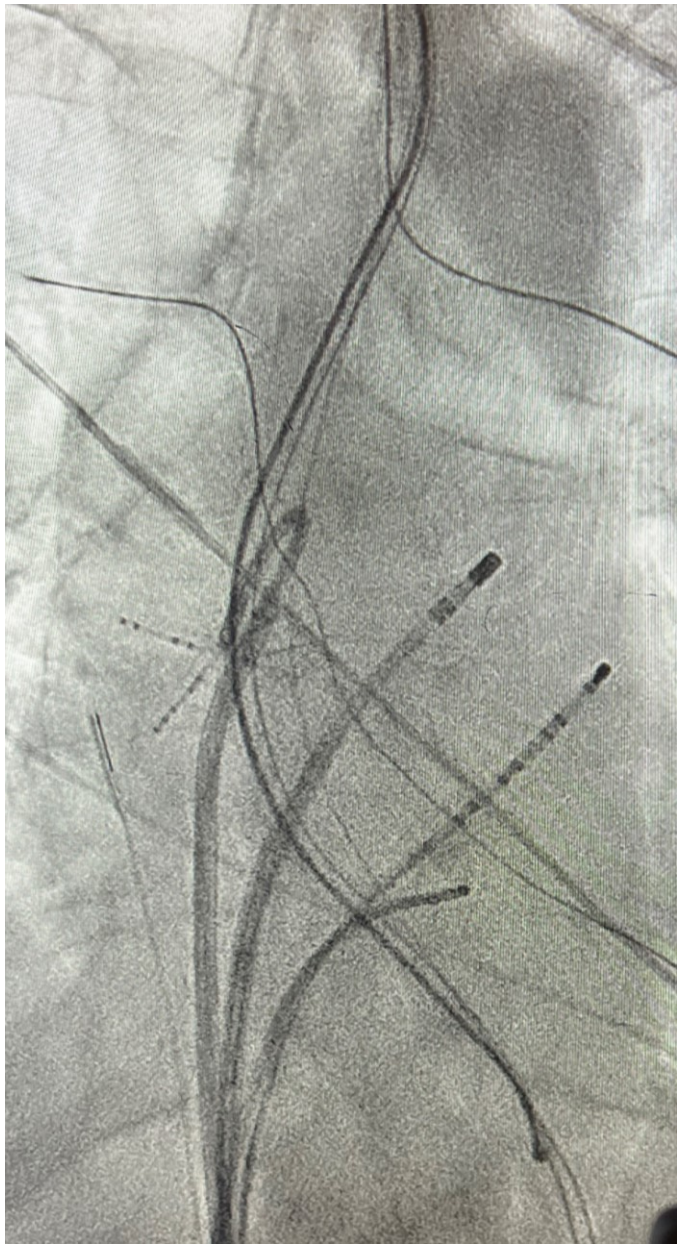
The blue line outlines an upside-down Y light area that is the trachea and the right and left branches of the mainstem bronchus. The heart is below the bifurcation of the trachea.

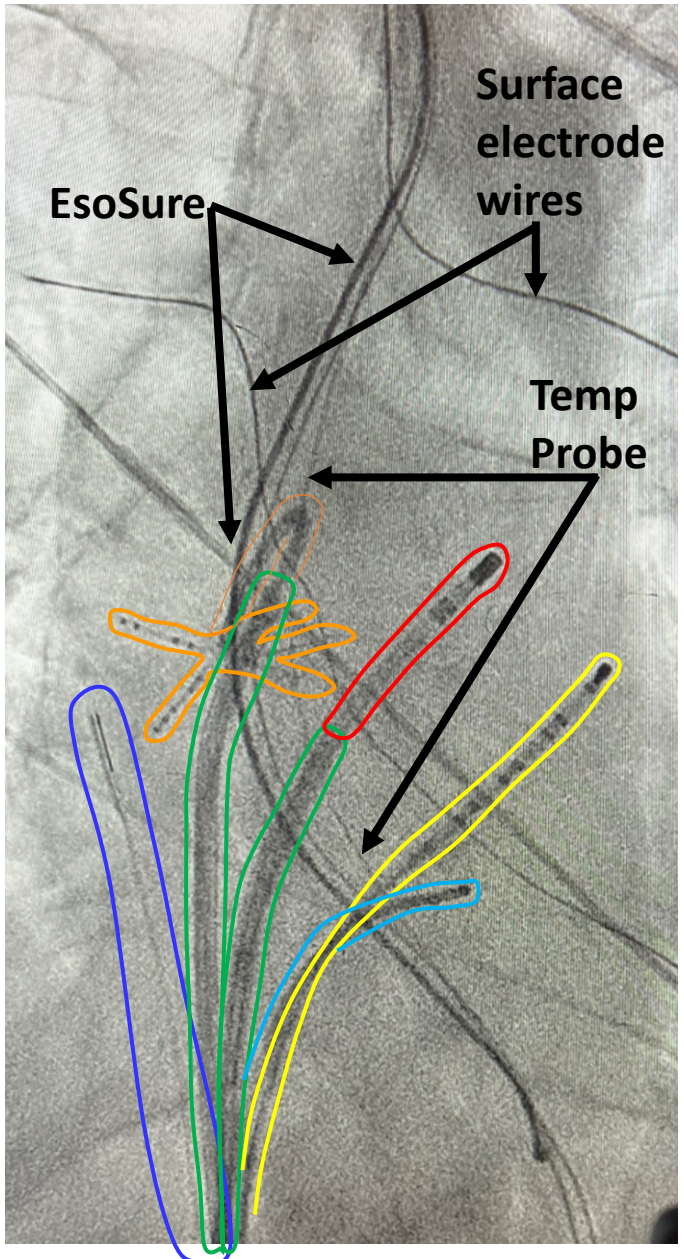
The right and left sides of the left atrium are usually anterior to the right and left borders of the spine in an AP view. The floor of the left atrium is identified by the Coronary Sinus (CS) catheter.

The red line outlines the coronary sinus identified by the CS catheter which is usually has 10 dark spots (electrodes) and is one of the lower and more horizontal catheters.

The orange line outlines the esophagus during right deflection with the EsoSure. The esophagus is behind the trachea and in front of the heart.

Intro to Fluoro Images: Catheters & EsoSure





This image of an RF ablation is nice and simple. In most Fluoro images the catheters are not separated in this manner and may cross each other. This procedure has two transeptal sheaths. Some EPs only use one transeptal sheath and have either the mapping or the ablation catheter in it.

The dark blue outline is the around the Intra Cardiac Ultrasound (ICE) Catheter. Other models may have a darker catheter and are distinguished by the dark ~ 1cm line near the tip.

The green outlines are for two transeptal sheaths. They are usually of a larger diameter and darker and support the mapping and/or ablation catheter from the right atrium to the left atrium through the atrial septum. Some EPs use a single transeptal sheath and for either the mapping catheter or the ablation catheter.

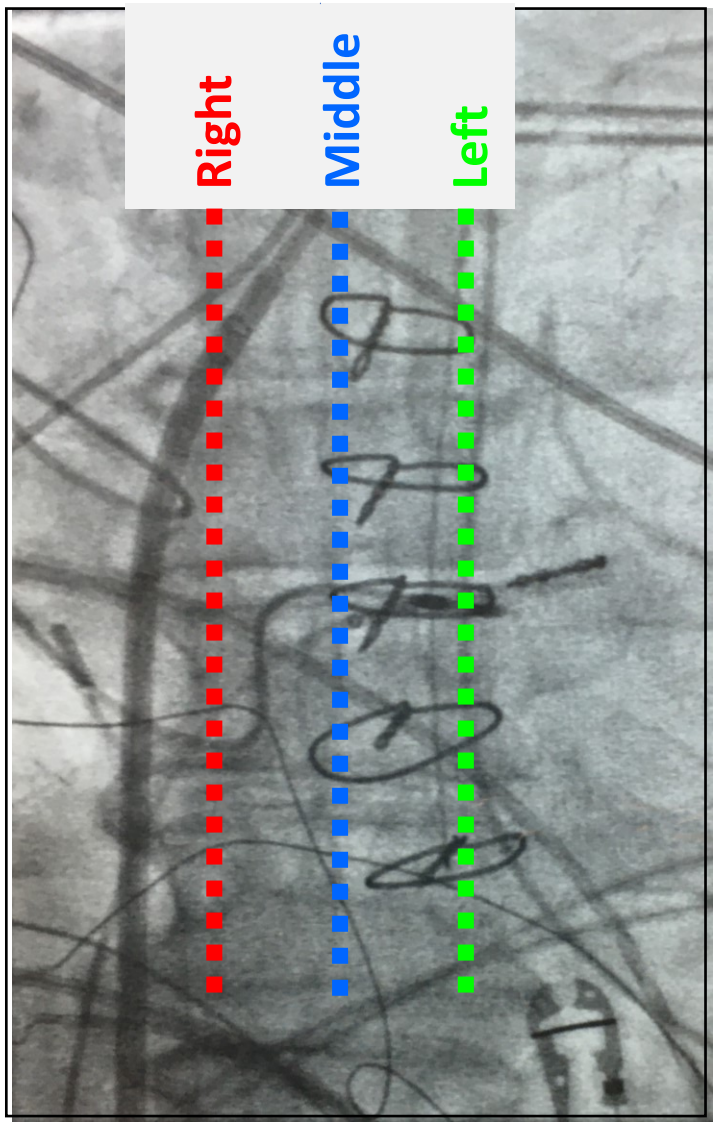
The orange area outlines a Pentaray mapping catheter as it exits one of the sheaths.

The red line is around the ablation catheter which is wider than the other catheters, has a couple of visible electrodes and the largest and darkest tip.

The yellow line identifies a decapolar (dark tip and nine bands) catheter which is frequently placed in the Coronary Sinus. This identifies the floor of the Left Atrium.

The light blue line is around a quadrapolar catheter which is sometimes placed in the right atrium.

EP Preference + Baseline Esophagus = Workflow



The <u>baseline</u> esophagus is usually in 1 of 3 locations, and this effects how and when the EsoSure is used:

- ~50% of patients have it along the L side of the spine.
- ~25% of patients have it in the middle of the spine.
- ~25% of patients have it on the R side of the spine.
- Sometimes it is oriented diagonally.

* Using contrast or ICE + 3D Map to see the lateral borders of the esophagus is very helpful and recommended.

EP Preference + Baseline Esophagus = 3 Workflow Scenarios

1) Most EPs want to begin isolating the LUPV in all first time AF Ablations.

- **If the baseline esophagus is left sided, and contrast is not used to visualize the esophagus,** right deflection may be done before the EP enters the room or gains vascular access. That way EsoSure insertion and positioning will not interrupt work later on. Also, after resting in its deflected position for 5-10 minutes the EsoSure curve frequently gains additional deflection. However, if contrast is used, it should be injected after the transeptal as contrast may obscure visualization of the anatomy with Fluoro.
- **If the baseline esophagus is midline**, it usually needs to be moved to the right and the left. Don't be mislead by a midline OGT/Temp Probe (TP) which may be along one side of the esophagus, with the rest of the esophagus extending laterally behind the R or L pulmonary veins. Contrast or an ICE image on a 3D map should be used to evaluate the trailing edge of the esophagus closest to the area of ablation.
- **If the baseline esophagus is right sided,** then the left pulmonary veins may be isolated without deflection, and the esophagus will only need to be moved once, from right to left, when it is time to isolate the RPVs.

EP Preference + Baseline Esophagus = 3 Workflow Scenarios

2) Some EPs will ablate the RPVs first when the baseline esophagus is on the left.

- **With a left sided esophagus**, RPV isolation may be done first, and the esophagus may only need to be moved once, from L to R when it is time to ablate the LPVs.
- **If the esophagus is midline**, the EsoSure can be inserted and ablation begun on the PVs opposite deflection as the EsoSure primary curve may go to the R or L during insertion.
- **With a right sided esophagus**, isolate the left PVs first, then deflect the esophagus to the left in order to ablate the right PVs.

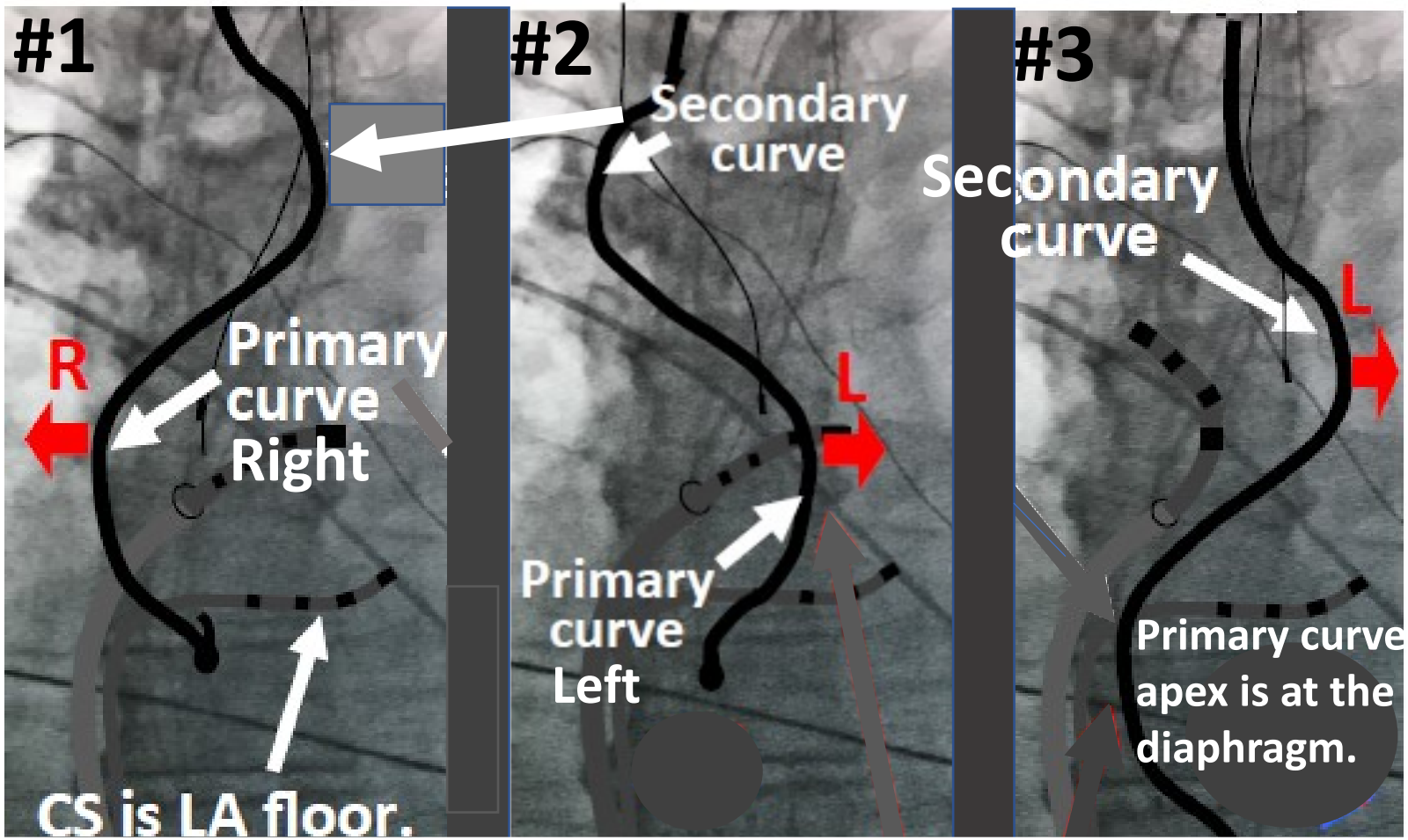
EP Preference + Baseline Esophagus = 3 Workflow Scenarios

In a repeat procedure, begin on the side of the posterior wall opposite initial deflection

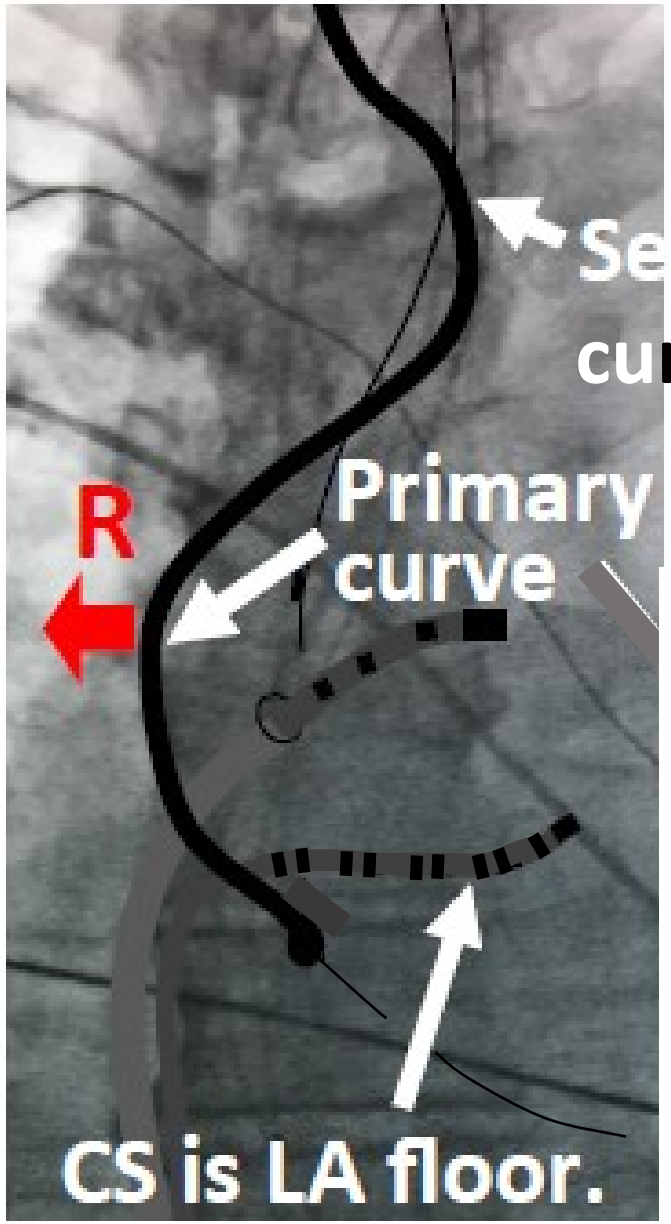
- **In a repeat procedure**, when the posterior wall is not isolated, ablation may not need to be done near the esophagus. Wait until after mapping to determine the need for deflection.
- **In a repeat procedure,** when the posterior wall is isolated, insert the EsoSure and work on the half of the posterior opposite deflection, then rotate the curve and work on the other side. Or, if the esophagus is on one side begin on the opposite side then deflect.

EsoSure Positions

2) There are 3 EsoSure positions.
Primary curve to the R or L & Secondary curve only to the L.



EsoSure Positions



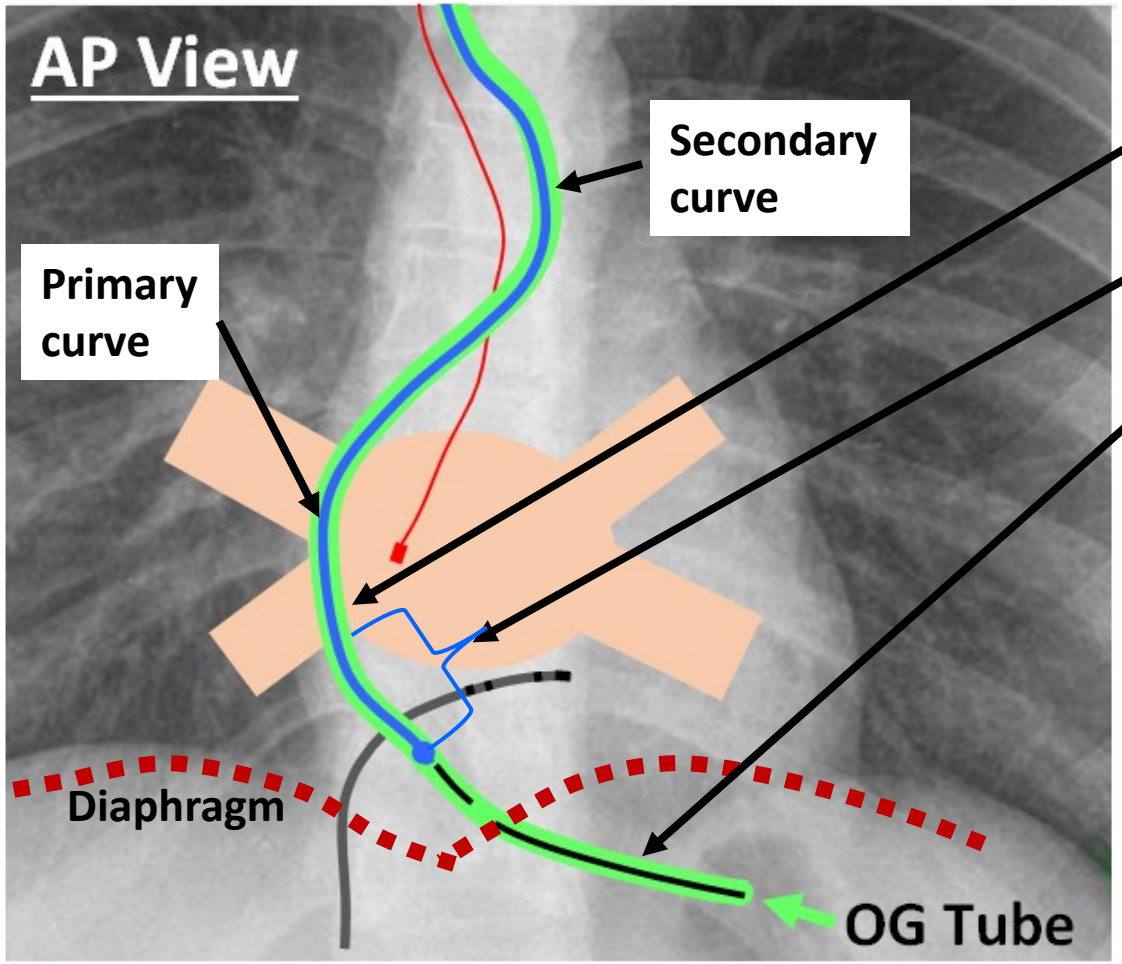
#1 Right Deflection with the Primary Curve

This is the typical starting position for EPs who want to isolate the Left Upper Pulmonary Vein first.

Frequently, the secondary curve will be out of view, above the Fluoro image.

The tip of the EsoSure gets support where the esophagus passes through the diaphragm's hiatus.

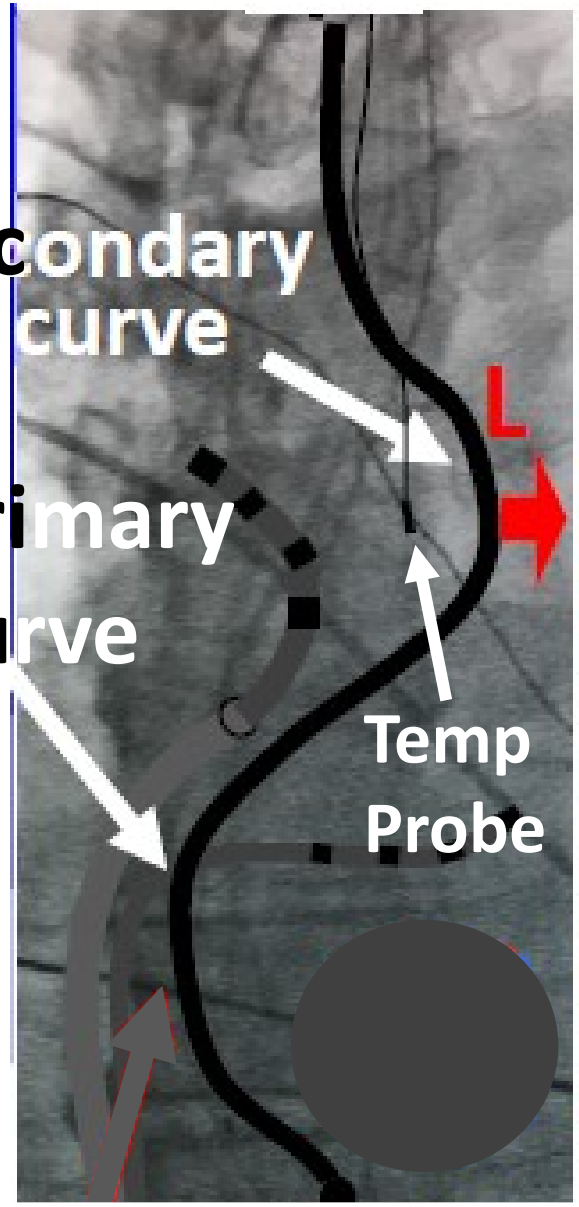
EsoSure Positions



When the EsoSure's (blue line) primary curve is to the right, the distal section of the EsoSure is angled leftward in the same direction the esophagus travels leftward towards the stomach below the diaphragm.

Slowly advancing the EsoSure and OG Tube below the diaphragm, brings the primary curve apex to the diaphragm and the secondary curve down behind the left atrium.

EsoSure Positions

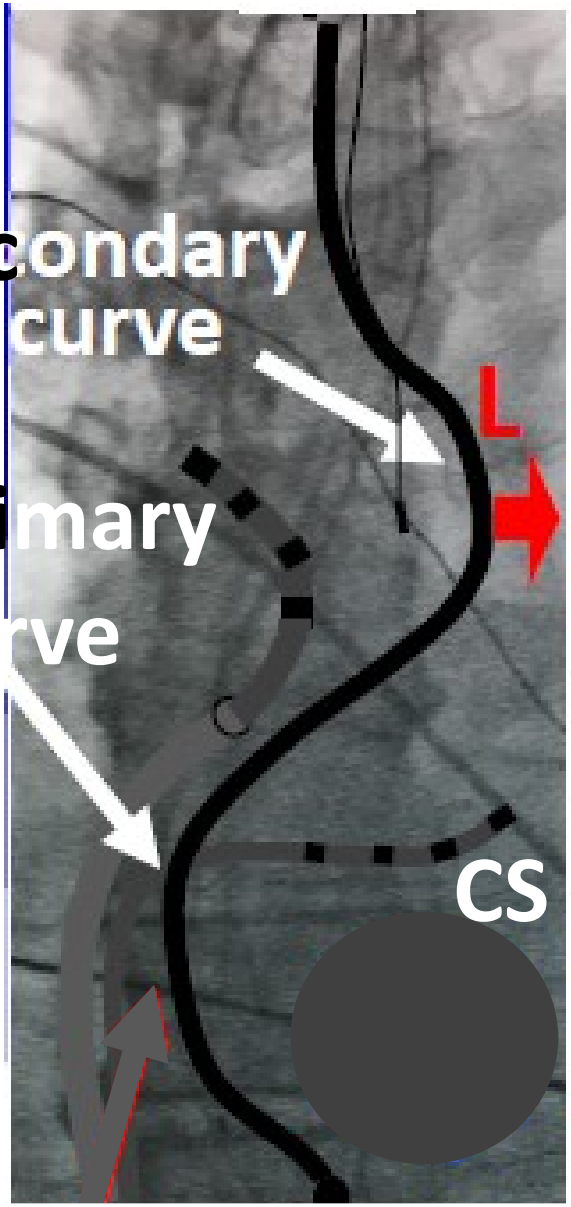


#2 L deflection with the Secondary curve for a L sided esophagus

a. Advance the OGT & EsoSure together for L deflection with Secondary curve.

b. Then reposition the Temp Probe inside the Secondary curve.

EsoSure Positions

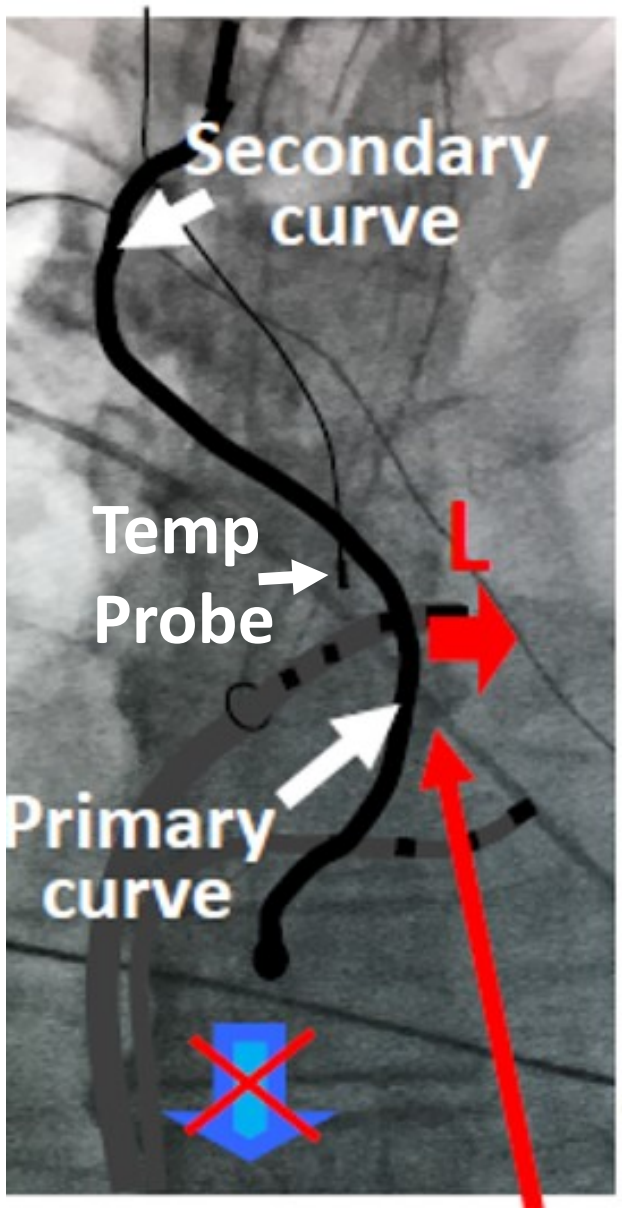


Going from right deflection to left deflection.

- If the baseline esophagus was on the left side of the spine, the EsoSure and OG Tube can be advanced to use the EsoSure's smaller, secondary curve to pull the esophagus back to its baseline position.

- If the baseline esophagus was in the middle or right side of the spine, then the smaller secondary curve will not have enough force to pull the esophagus to the left and the primary curve should be rotated from right to left.

EsoSure Positions

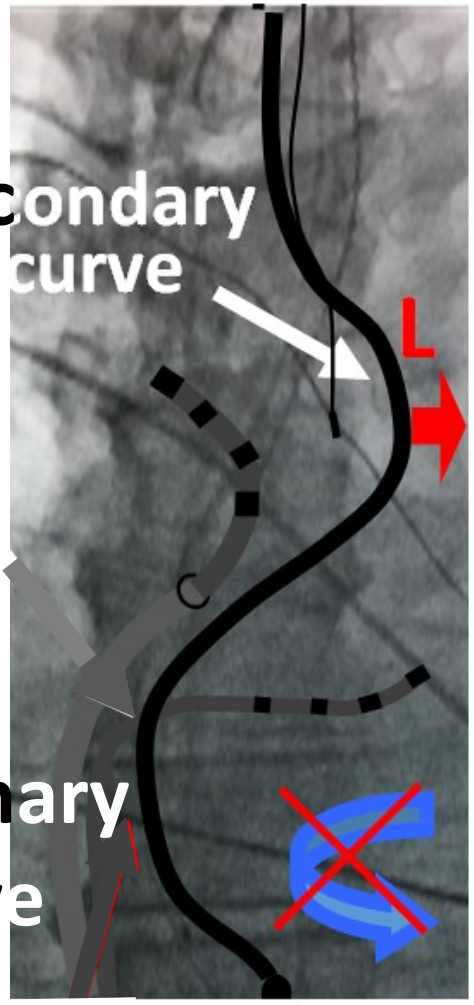


#3 L deflection with the larger Primary curve for a midline or R sided esophagus

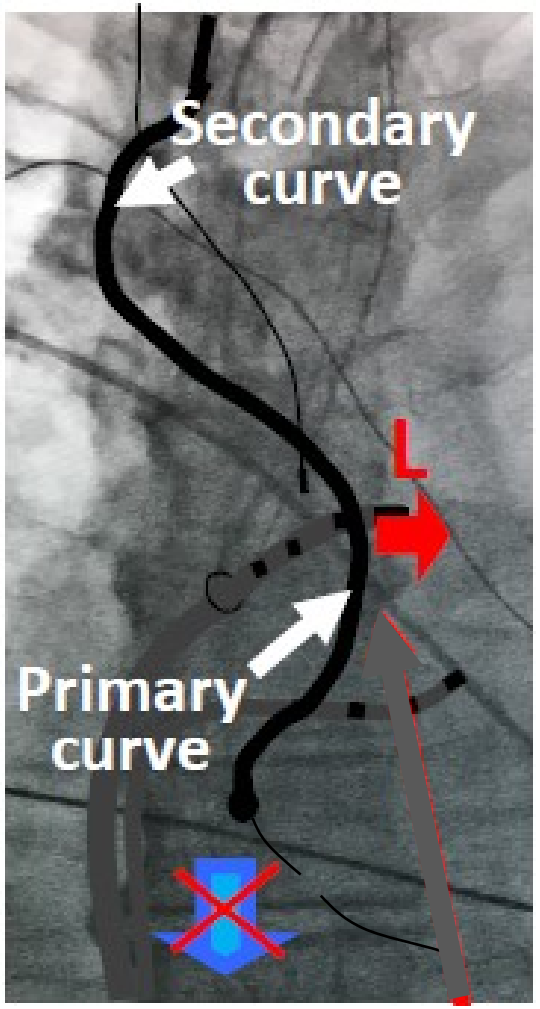
a. With the EsoSure tip near the CS, above the diaphragm
b. Rotate handle 2-3 times,
c. Then slowly retract stylet ~4" out of the OGT while watching with Fluoro. Rotation usually occurs above the heart. If it spins or doesn't rotate, rotate in the opposite direction.
d. After rotation to the correct side, release the torque &
e. Advance the Primary curve to the desired level,
f. Then reposition the TP inside the stylet's curve.

Movements to avoid

Avoid movements that put rightward pressure on the esophagus below the diaphragm, as the esophagus angles leftward from the diaphragm's hiatus towards the stomach.



When the Secondary curve is to the left and the Primary curve is at the diaphragm, do not rotate or advance the EsoSure.

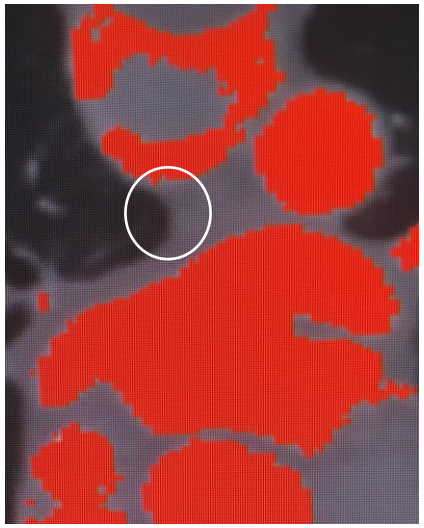


When the Primary curve is to the left, do not advance the EsoSure tip past the diaphragm, only rotate the stylet for R Deflection.

Poor deflection – Change the anatomy.

3) If deflection is unsuccessful or poor, use the ventilator to change the anatomy.

- If a CT or MRI of the heart is available, have your mapping person evaluate the distance from posterior left atrial wall to the spine. It does not need to be measured as an approximation is fine. If the distance is less than 0.5 cm the EsoSure/OG Tube curve may have difficulty crossing the midline of the spine and you may need to use a Valsalva. A CT is not required for EsoSure use, however, it is helpful if available.
- Also, have them note if the lungs impinge upon the mediastinal space where Apnea may be helpful.

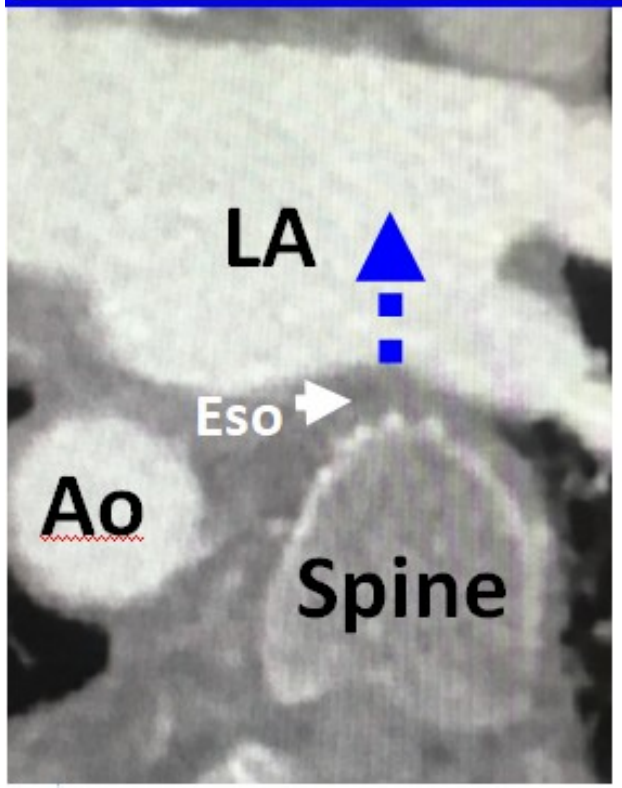


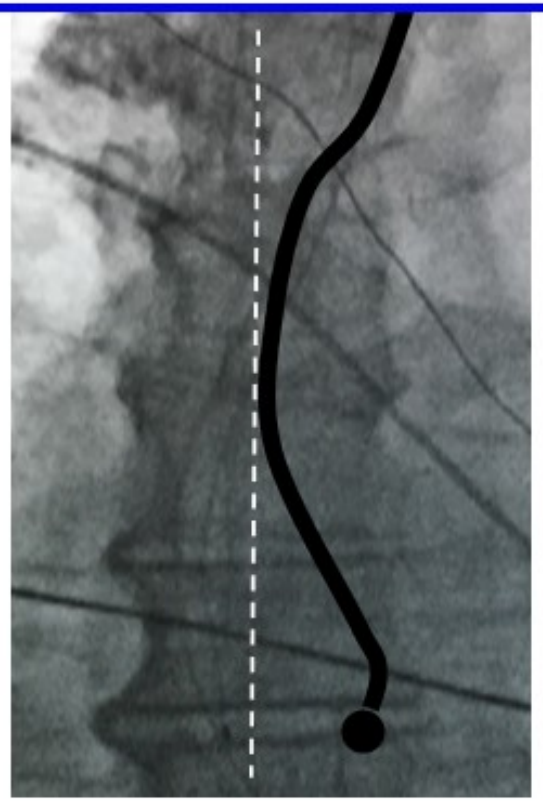
Tight space
(A Valsalva enabled us to move this esophagus from L to R. Before the procedure, I told the EP that deflection would most likely not be successful.

Normal Space
(Typical LA to spine distance. However, the lung extends to the middle of the spine. Apnea decreases lung volume allowing the OGT to slide between the lung and spine.

Poor deflection – Change the anatomy.

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





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

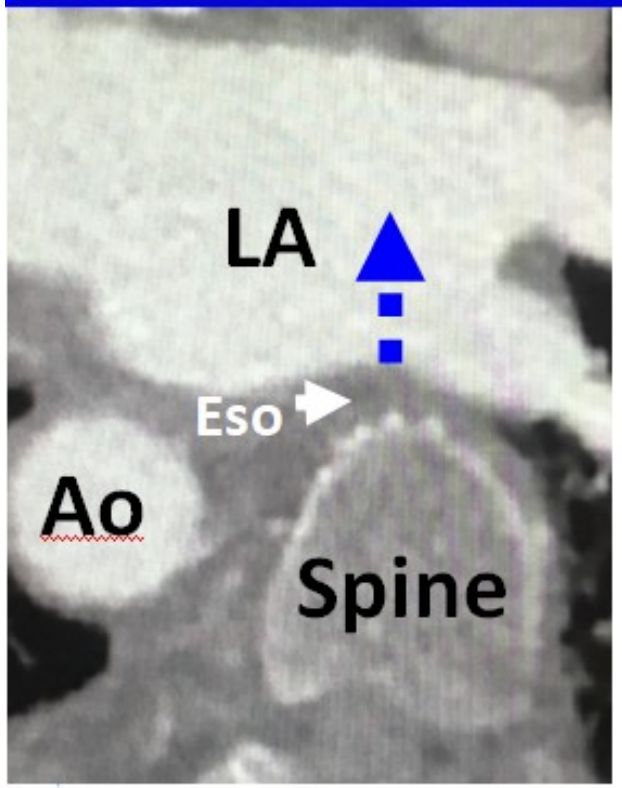
a. Rotate Primary curve to the desired side behind the trachea;

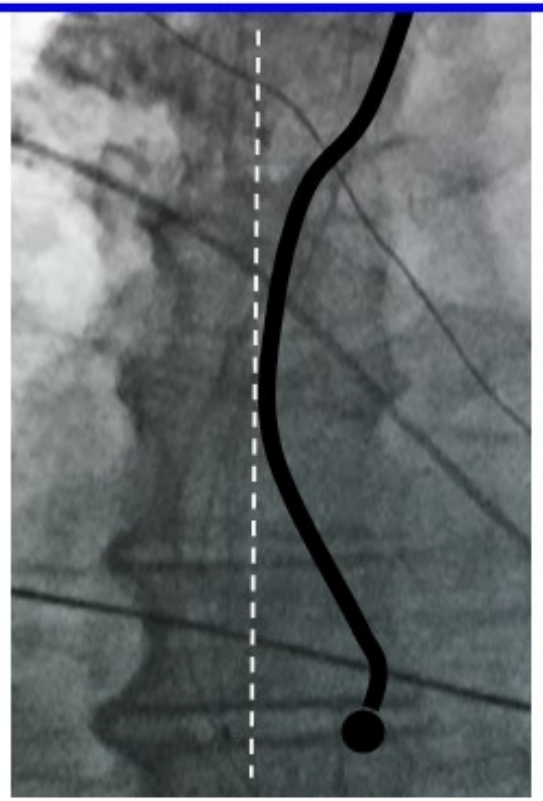
b. Have anesthesia give & hold a deep inspiration to expand chest & lift the heart off of the spine;

c. Slowly advance the primary curve behind the LA.

Poor deflection – Change the anatomy.

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



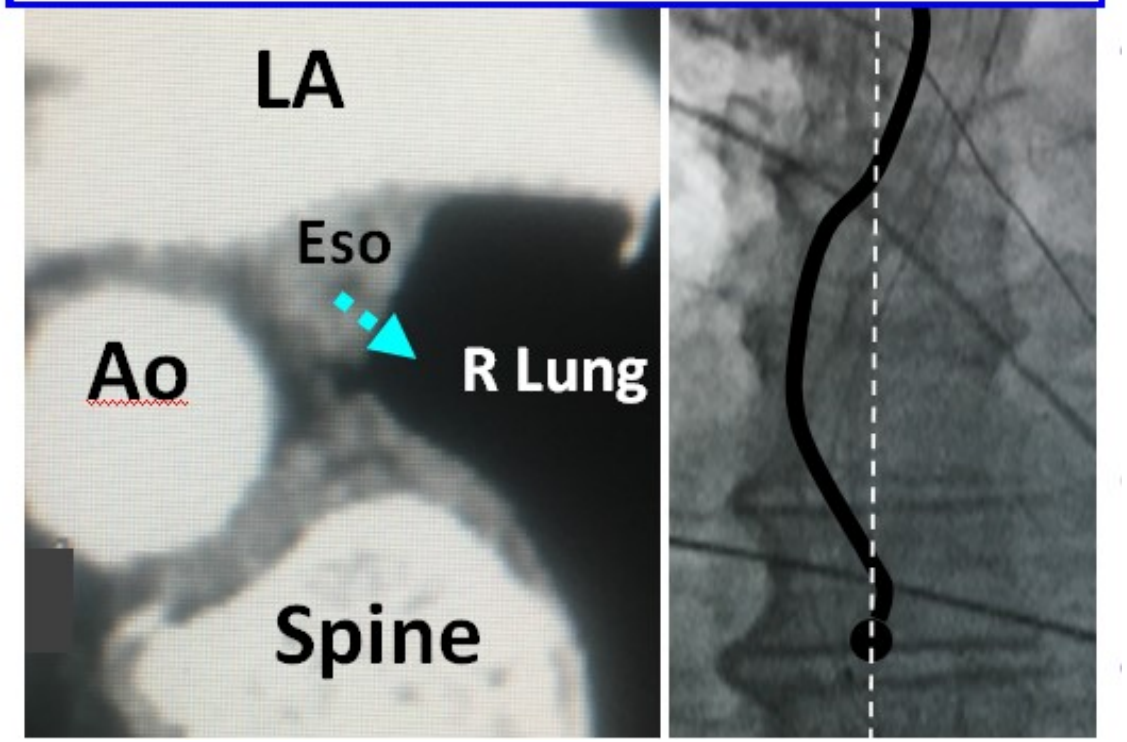


***If a Valsalva fails, put Primary curve to desired side behind the trachea & advance ~1 cm q ~3 sec.**

If a Valsalva alone does not work, then incremental advancement of the EsoSure frequently allows pressure from the stylet's curve to gradually slide the OG Tube between the heart and the spine to obtain deflection.

Poor deflection – Change the anatomy.

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



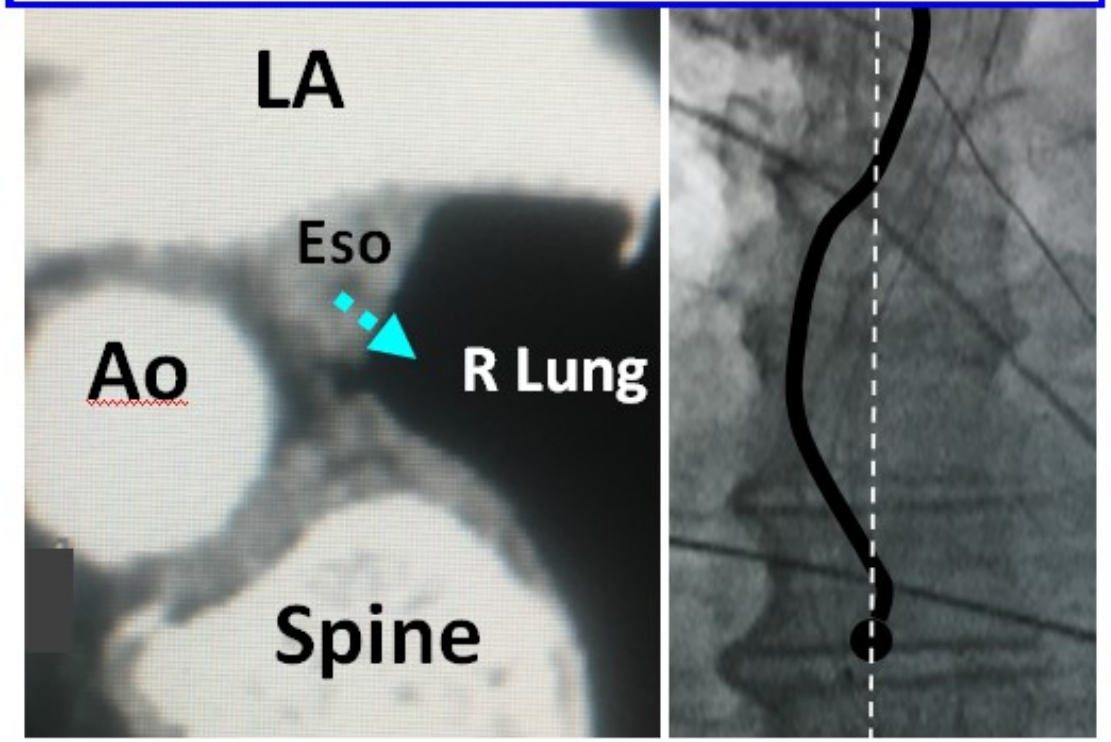
The lung, which is a big balloon, may put pressure against the mediastinum and spine to block successful deflection.

By deflating the lungs, there is less resistance to slide the esophagus between the lung and spine for more deflection.

Sliding the EsoSure in and out about 6" at 2-3 second intervals, is atraumatic and very safe, and helps to wiggle the esophagus between the lung and spine.

Poor deflection – Change the anatomy.

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. Go Apneic for ~15 seconds to deflate the lungs;

b. Gently slide the stylet 4-6" in and out of the OG Tube 4-5 x to work Primary curve between the spine & lung;

c. Position the primary curve behind the LA

Abnormal Upper GI Contraindications

4) Contraindications are the same as for a TEE or OGT.

Upper GI or esophageal disease/abnormalities, including Hx:

Surgery

Stricture

Varices

Tumors

Hematomas

Female >80 yo., <5' tall & <50 kg

Lg hiatal hernia

UGI bleeding

Severe GERD

An excellent time to ask your patient about contraindications, is when the patient is on the table, and you are attaching the patches.

Abnormal Upper GI contraindications

4) Contraindications

Gastric bypass surgery is a frequent concern: In these patients, the EsoSure has been successfully used, but was kept above the diaphragm at all times, using only the primary curve to the right and left. The secondary curve should not be used.

Hiatal Hernias are fairly common: They may be identified by the tip of the OG Tube not being able to find the hiatus and proceed into the stomach. Also, the tip of the EsoSure may extend several cm lateral to the L spinal border. If these occur, anticipate that the esophagus is enlarged and covers a large portion of the LA posterior wall. The EsoSure will not be able to be positioned with the tip in the diaphragm. The tip itself may provide some deflection.

5) Safety Tips

a. DO NOT ablate over the EsoSure or the side of deflection.

As the EsoSure pushes the esophagus toward one side or the other, an ablation should not be done over the side of deflection as the distance between the posterior wall of the Left Atrium and the esophagus would be reduced rather than increased.

5) Safety Tips

b. If resistance is felt while advancing the EsoSure, do not force it. Assess the cause and decide how to proceed.

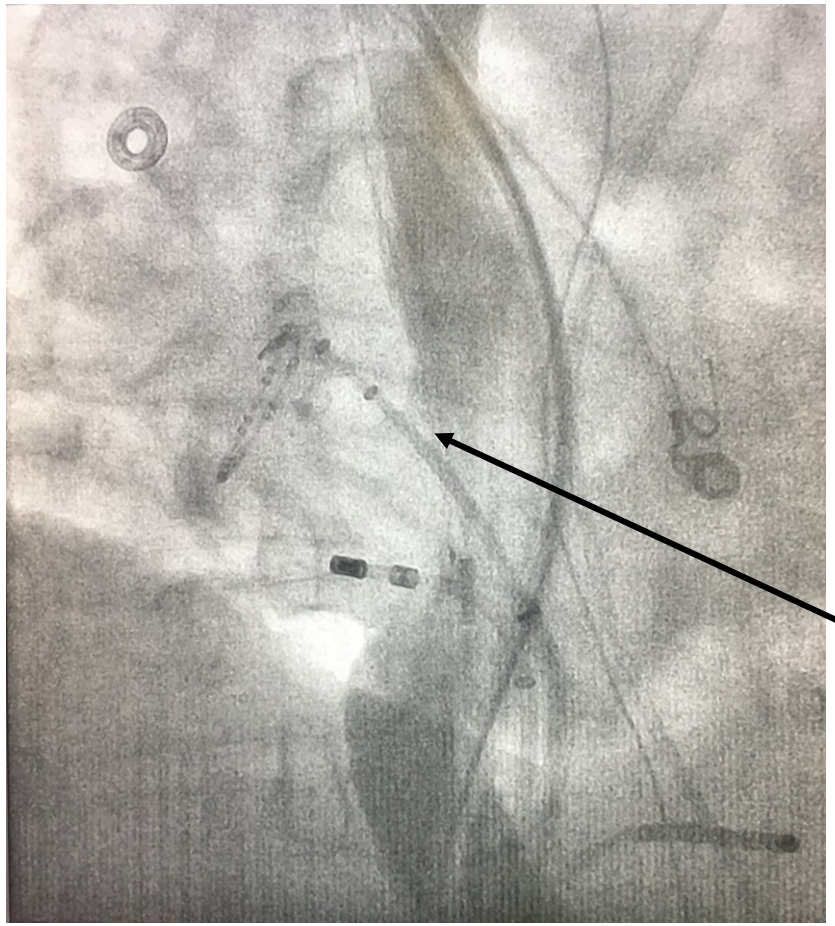
There is often a little resistance as the EsoSure passes through the bend in the oropharynx. The most common impediment to EsoSure insertion is a loop in the OG Tube. The method for removing a loop is on the Procedure page. (Pg. 66 of the PPT)

The second most common cause is a tight airway, forecast by a difficult intubation or TEE insertion. If the EsoSure won't advance past the throat, do not force it. Remove it.

The third most common cause is when the esophagus makes a sharp bend, rather than a gradual curve, below the diaphragm. If resistance is felt, while advancing the EsoSure from right deflection with the primary curve to left deflection with the secondary curve, do not advance it below the diaphragm. Rotate the primary curve for R or L deflection.

5) Safety Tips

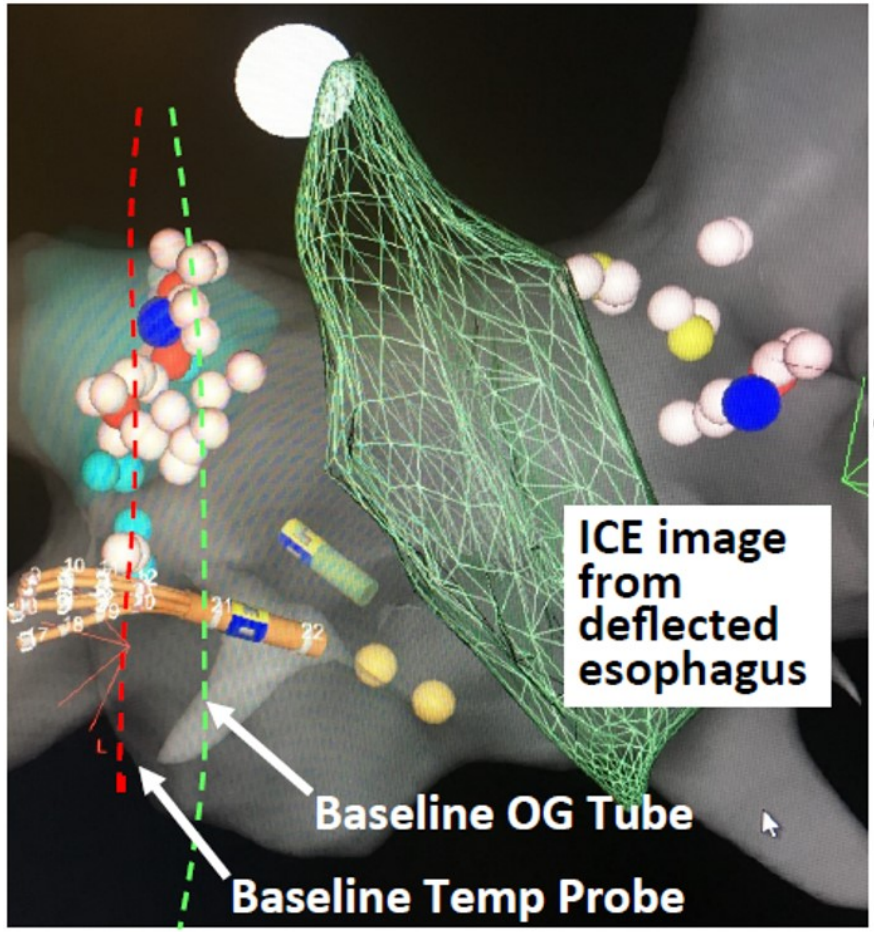
c. After deflection, visualize the trailing edge of the esophagus using Fluoro with contrast or ICE.



10-20 cc's of contrast injected into the esophagus allows visualization of the esophageal diameter as well as identification of the trailing edge of the esophagus during deflection. The contrast is suctioned out at the end of the procedure.

5) Safety Tips

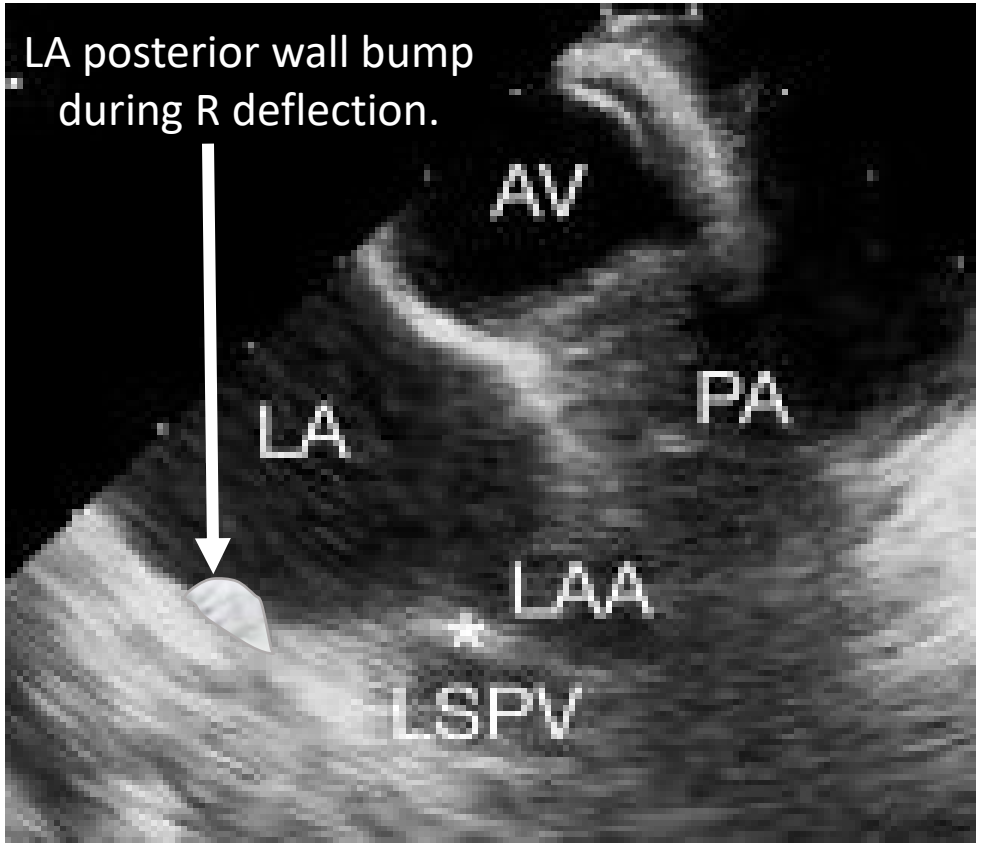
c. After deflection, visualize the trailing edge of the esophagus using Fluoro with contrast or ICE.



With the Biosense Webster mapping system, an ICE image of the esophagus, or its medial border, can be drawn on the 3D map. This provides an awareness of the trailing edge of the esophagus relative to the Ablation catheter or Cryo balloon.

5) Safety Tips

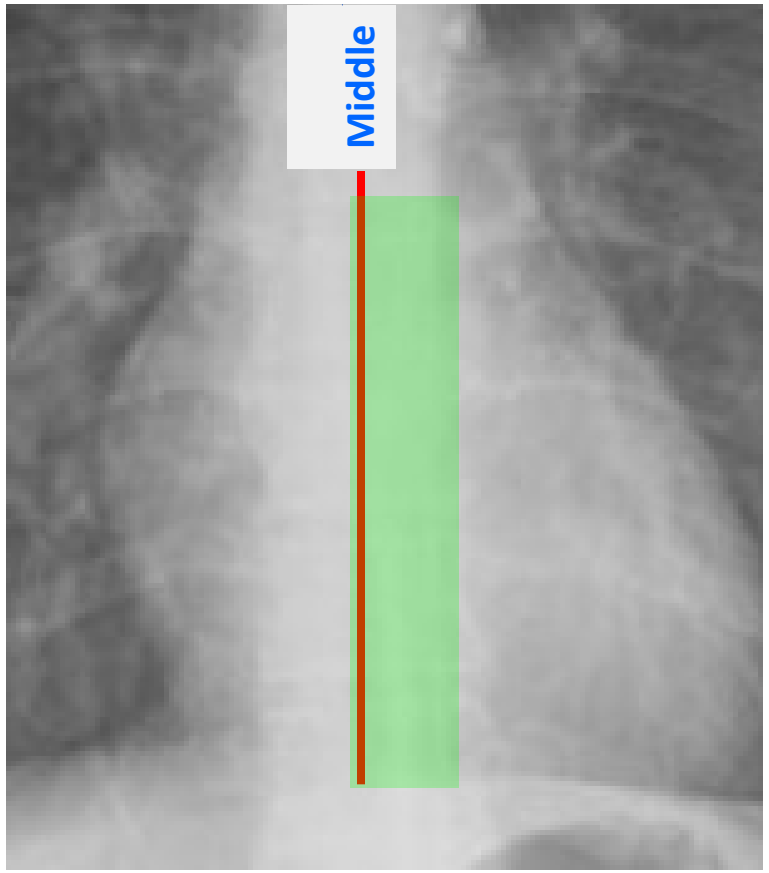
d. After deflection, scan the LA posterior wall with ICE for a bump possibly caused by anatomy displaced by the esophageal trailing edge. Avoid Ablating over this area.

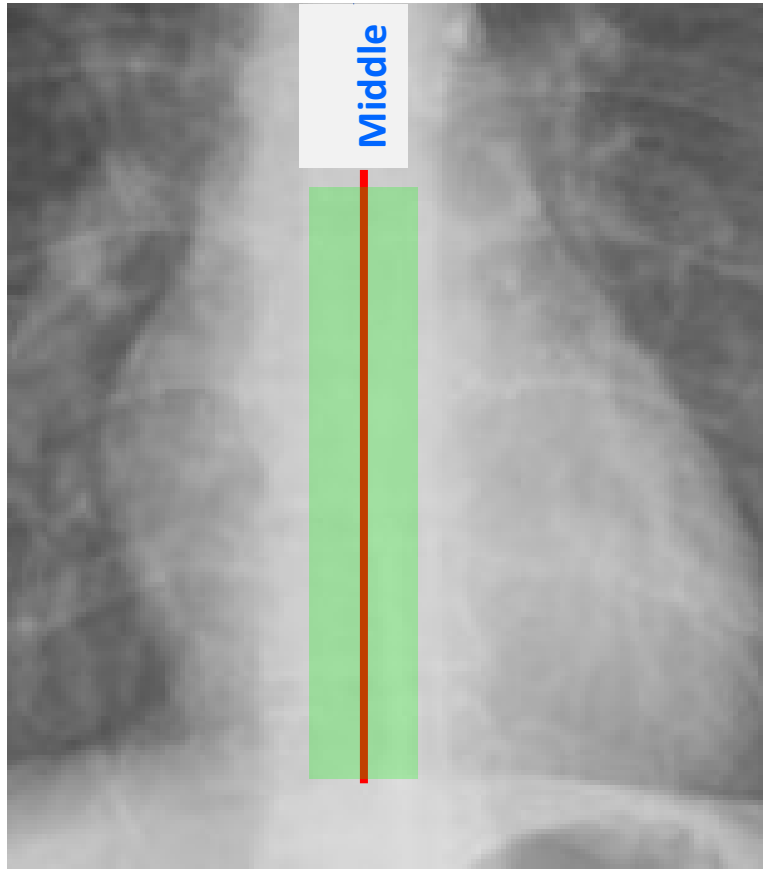


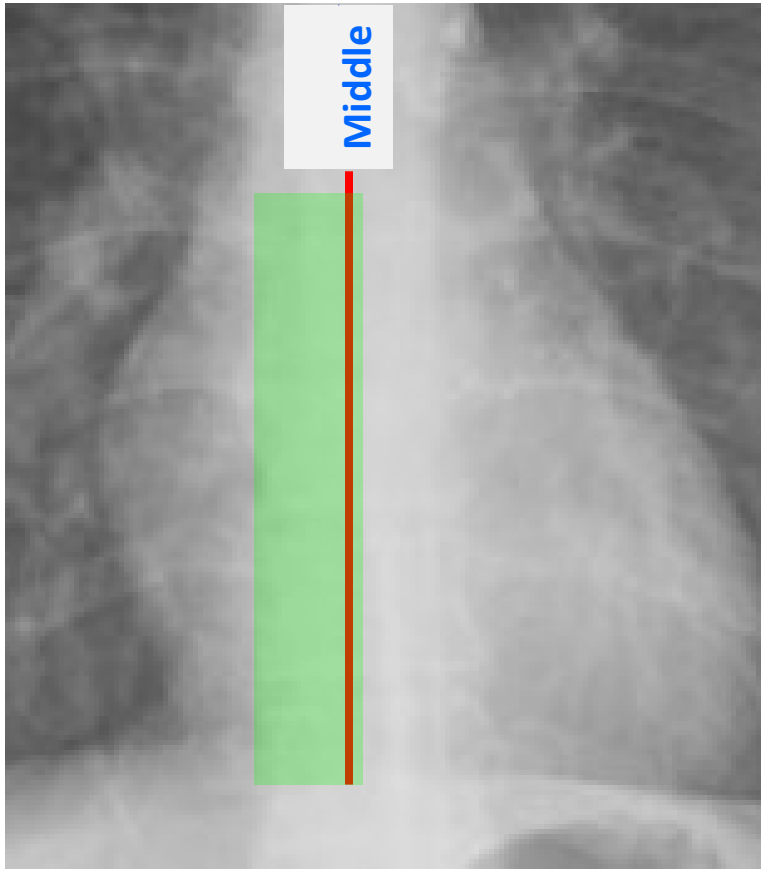
This phenomenon is rarely seen, but is worth evaluating. It has been hypothesized that during deflection, the trailing edge of the esophagus may displace mediastinal anatomy which presses against the posterior wall of the left atrium.

Ablation over this area should be avoided as pressure against the left atrial wall could potentially predispose it to thermal injury.

Identifying the Position of the Esophagus Relative to the OGT/TP

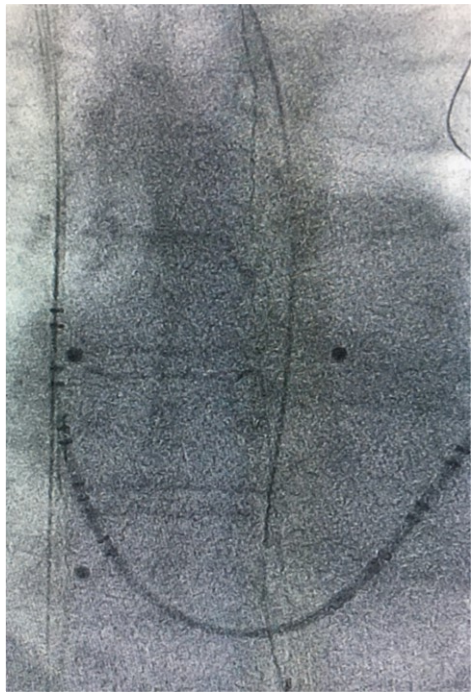






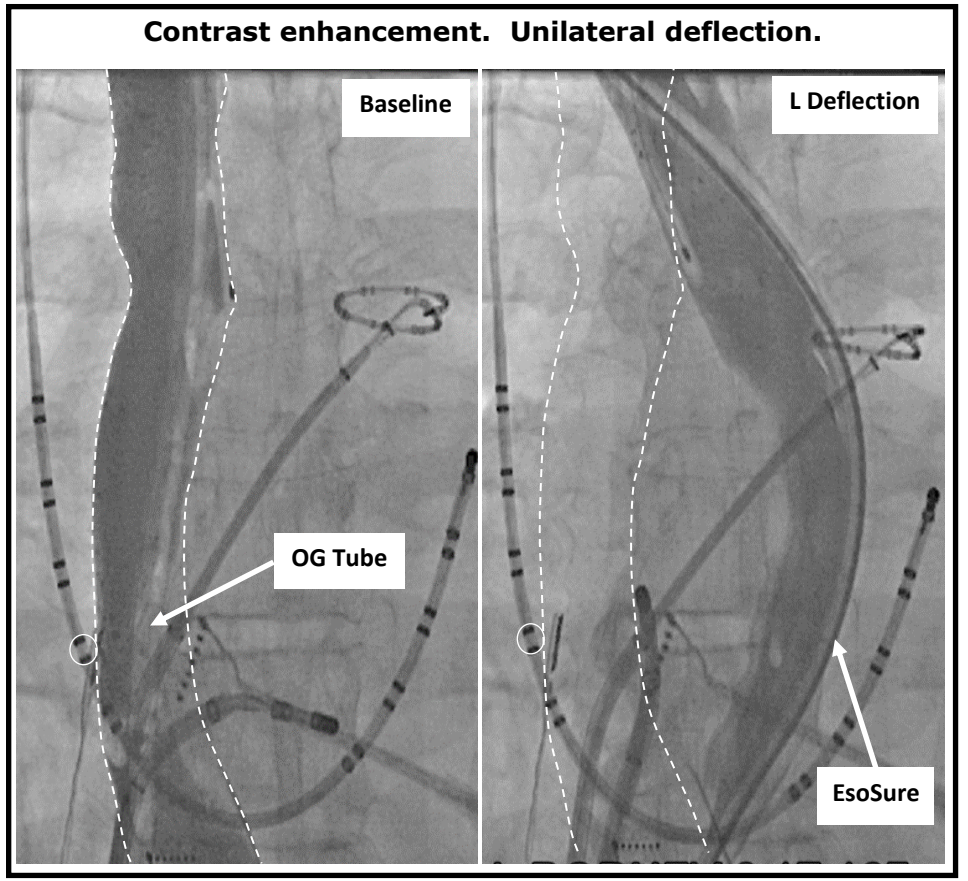
An esophagus (green area) identified only by an OG Tube/Temp Probe (red line) may be in one of 3 positions depending upon where the OG Tube/Temp Probe lies within the esophagus. Injecting contrast into the esophagus or placing an US image of the esophagus on the 3D map helps to identify the edge of the esophagus closest to the treatment area. The widest part of the spine is ~4 cm and the average width of an esophagus is ~2 cm. However, an esophagus 3 cm or larger is frequently seen and covers a larger area.

Contrast allows for better visualization of the esophagus.



"another example of how a linear temperature probe can be misleading if used by itself to delineate the course of the esophagus. ICE or contrast should always be used to see the esophagus..."

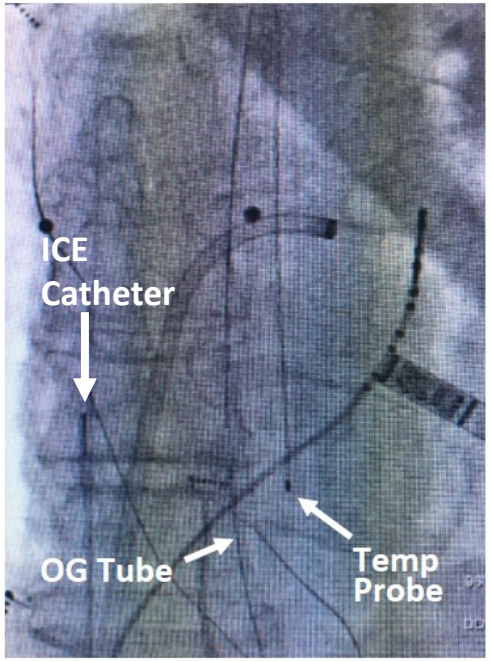
Dr. Andrea Natale, MD, FACC, FHRS. St. David's Medical Center By permission- Twitter April, 2018.



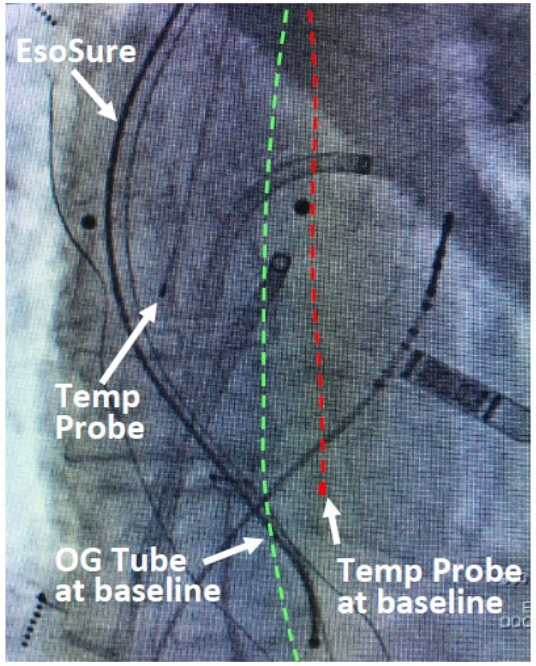
10-20 cc of contrast injected through an OG Tube into the esophagus allows for assessment of the esophageal diameter and the trailing edge of the esophagus after deflection.

Use ICE and EsoSure movement to better identify the esophagus.

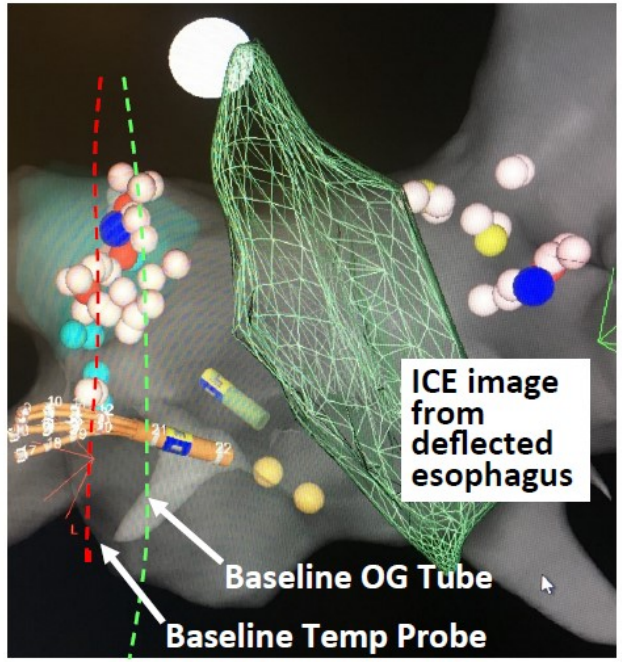
Baseline ~AP



R Deflection ~AP



Esophagus Position with Movement



The esophageal "wiggle" helps to visualize the trailing edge.

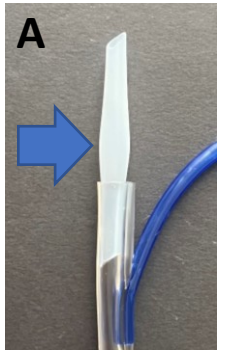
1) During ICE visualization of the border of the esophagus closest to the ablation catheter;
2) Rhythmically slide the EsoSure stylet 1-2" in and out of the OG tube at ~2 sec. intervals while the esophageal trailing edge is being evaluated by ICE (This is done after deflection.);
3) This will help ICE distinguish the moving esophageal tissue from the still surrounding tissue;
4) In the same manner, slide the temperature probe in and out ~1", or spin the Temp Probe, to create movement and better identify the position of the temperature probe within the esophageal image.

Equipment

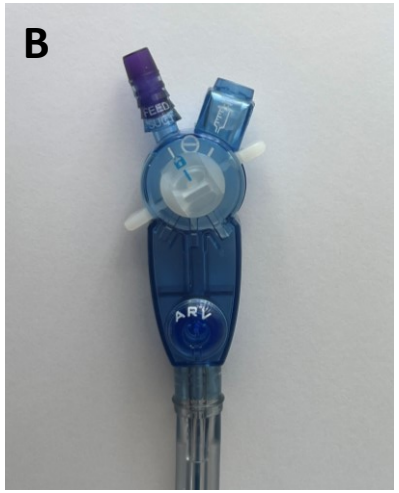
- 18 Fr 48” Sump OG Tube. Not Silicone.
- 1- 20 cc syringe & medicine/specimen cup, for injecting Tube Lube and/or water/IV Fluid to lubricate & cool the OG Tube.
- EsoSure
- Tube Lube is included for lubricating the OG Tube lumen (Or olive oil.)
- Esophageal Temp Probe (TP). Use a smooth shaft 9-12 Fr model. Avoid Acoustascope probes with a balloon over the thermistor/tip. (Pg 45-46)
- Peds 4-5 mm ET Tube or nasal trumpet airway placed orally as an introducer for 9 Fr TPs to minimize coiling and improve placement.

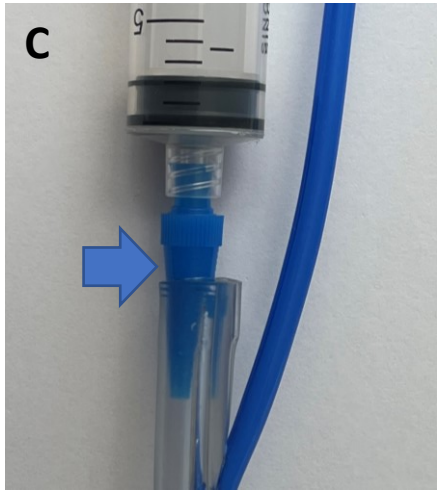
Equipment

- **18 Fr 48” Sump OG Tube.**



- Some manufacturers have reduced the length of their 48” OG Tubes to 46”. Insert the EsoSure and check your OG Tube to see if the EsoSure tip is near the proximal hole. If it is, then leave the connector on the end of the OG Tube to increase it’s length.
- Also, some 16 Fr OG Tubes have recently been manufactured with a smaller lumen that does not allow for EsoSure insertion. Therefore, an 18 Fr is recommended.
- One model of OG Tube has a Multi-Port connector (B). It needs to be removed as you cannot inject fluid or insert the stylet through it. A slip tip syringe adaptor (C) can be requested with each EsoSure to use with these OG Tubes.





Equipment

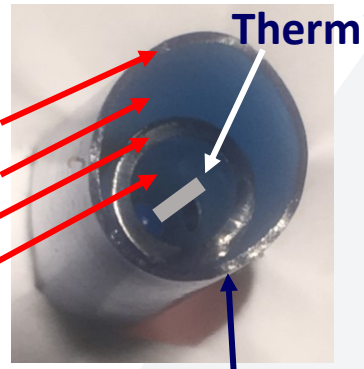
- **1- 20 cc syringe & medicine/specimen cup.** (There is often an unused cup on the sterile tray that can be used to pour the Tube Lube into, and then drawn into the syringe for injection into the OG Tube before insertion of the EsoSure. This is easier and less messy than drawing the olive oil through the Tube Lube package with a needle.)
- **EsoSure**
- **Tube Lube** **(**Some labs pre lubricate every OG tube by obtaining a container of olive oil and dipping the OG Tube into it with suction on before placement in the patient.)

Equipment

- **Esophageal Temp Probe (TP).** The most commonly used Acoustascope Temp Probe is the one Anesthesia has in stock and is poorly suited for EP procedures. A smaller diameter temperature probe without a balloon has a faster thermal response rate and does not dilate the esophagus.
- **Peds 4-5 mm ET Tube or nasal trumpet airway** inserted orally. The thinner diameter temperature probes may coil in the throat as they warm and soften. Using an introducer greatly improves repositioning.

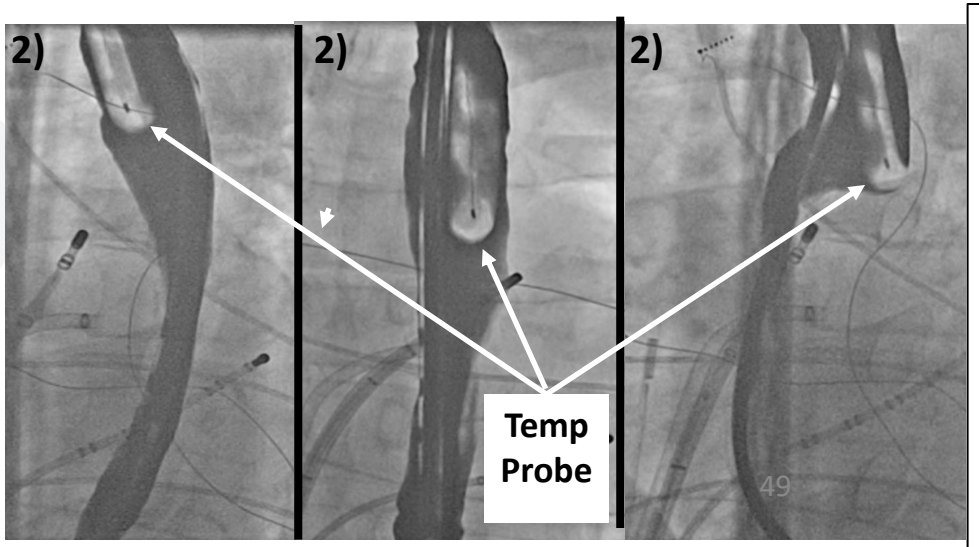
Do NOT use an 18 Fr Acoustascope Temp Probe (18)

1)

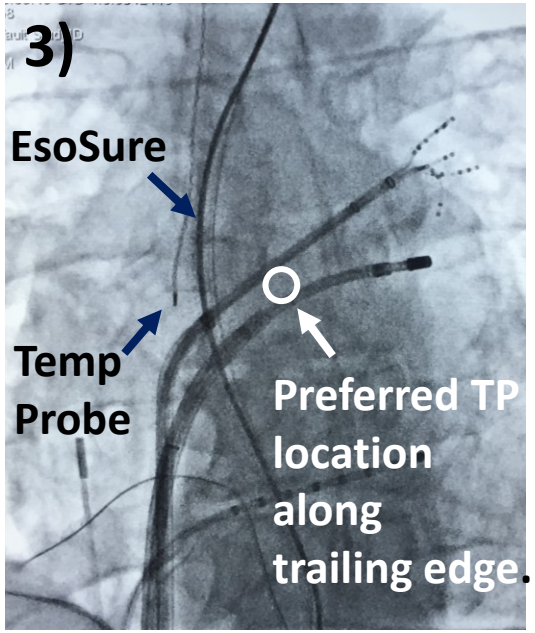


18 Fr Acoustascope

2 layers of plastic and air around the thermistor insulate the thermistor and make responses to temperature changes 3-4 x slower than the 9 Fr solid shaft models.



2) Air in the18 Fr balloon expands at body temp to 27 Fr, dilates the esophagus and may press it against the LA.



3) When the 18 Fr Acoustascope Temp Probe is used with the EsoSure, the large balloon often prevents the Temp Probe from being slid under the OGT and repositioned on the medial side of the esophagus for optimal temperature sensing.

Use better Esophageal Temp Probes that cost $4.

DeRoyal Industries, Inc.

Ref # 81-020409 for 9 Fr model

*Best temp probe with a combination of 9 Fr diameter, 4 x faster thermal response, firm shaft and smooth surface.

Novamed, Inc.

Ref # 10-1620-001 for 12 Fr model.

Good thermal response and stiffness. * A 5 Fr EP catheter can be placed inside the sheath for location on a 3D map. If the EP catheter is steerable, it may be guided to the R or L side of the esophagus and positioned closer to the trailing edge.

The smaller diameter 9 Fr TPs are more prone to coiling in the throat. To prevent this, a 4-5 mm peds ET tube (uncuffed is better) or nasal trumpet airway should be placed orally to serve as an introducer to facilitate insertion past the tongue and assist with repositioning.

Prep- Hx & CT

- **Ask patient about esophageal/upper GI Hx while attaching electrodes.** (Esophageal history may be missed by Cardiology and Anesthesia staff.)

- **Evaluate CT/MRI for a large esophagus & heart and a narrow LA-spine space.** (A CT is not necessary, but if done will give you a forewarning of potential challenges to deflection. Ask your mapping person to notify you if the LA to spine distance is tight. < ~.5 cm)

Prep- Slippery TP and OGT

- **Lubricate TP and OGT shaft with Surgilube and insert to stomach before Heparin. Insert OGT to 55-60 cm or the 3rd black mark.**

The Temp Probe and OG Tube will stick to each other and be difficult to position without a good coating of lubricant.

Inserting the OG Tube to the optimal position during initial insertion is helpful. If it is not inserted deep enough and is advanced later, the OG Tube inside the body will be warm and soft and the OG Tube outside the body will be cool and stiff. As the stiff OG Tube pushes against the warm soft tube in the oropharynx, it may create a loop in the throat.

Prep – Temp Probe Introducer

Use a Peds 4-5 mm Endotracheal Tube or Nasal Trumpet airway (placed orally) as an introducer for the smaller 9 Fr Temp Probes.

Remove the OG Tube if the EsoSure is not used.

The OG Tube may press against the LA and predispose it to injury.

Evaluate the TP and OGT with Fluoro in AP for the baseline esophagus position & workflow.

Refer to Pgs. 16-18

Prep – ID the Baseline Esophagus

- **If EsoSure use is known, suction Tube Lube through the OG Tube before insertion.**

This is less messy than injecting the combination of IV fluid and Tube lube before EsoSure insertion.

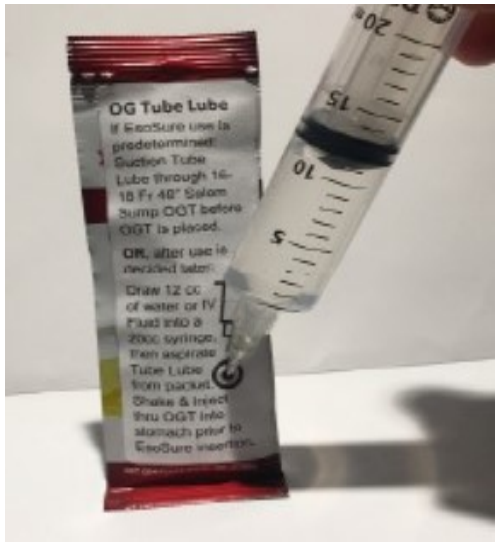
If EsoSure use is uncertain, hold off on using the Tube Lube.

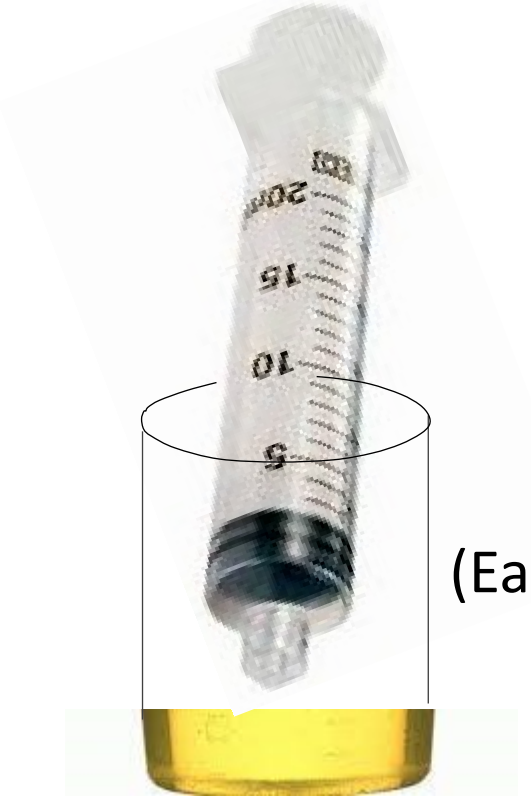
If the EsoSure is not used, you will have used the lubricant and will need a replacement for when you do use that EsoSure.

Prep – Lubricant & Cooling Fluid

Prep lubricant and & cooling fluid when EsoSure is requested:

- **1) Draw ~12 cc of IV fluid into a 20 cc syringe;**
- **2) Pour Tube Lube into a medicine cup or insert 18 ga needle into the Tube Lube packet and aspirate;**
- **3) Inject prior to EsoSure insertion.**





(Easier)

Prep - Contrast

- **Inject Contrast after the transseptal** (as contrast may obscure a Fluoro view of anatomical references for the transseptal.)

a) Verify the OG Tube is in the stomach with Fluoro.

b) Retract the OG Tube gap ~1” above the CS.

c) Inject 10-20 cc of contrast slowly.

Prep - Contrast

d) **Adjust the OG Tube up and down as needed** (to opacify the esophagus above the CS and behind the left atrium.)

e) **Readvance the OG Tube into the stomach.**

f) **Flush barium contrast into the stomach** (Inject air or IV fluid so it does not harden in the OG Tube and prevent EsoSure insertion.)

Procedure - Insertion

1 Bolus Propofol or a sedative to relax the airway and avoid a gag reflex & coughing. Tap on the ET Tube if unsure.

If it has been more than a half hour since intubation, the patient may need additional sedatives to prevent the EsoSure from eliciting a gag reflex, coughing, and bucking which may move the patient and change the 3D map.

Give sedation immediately after the EP requests deflection, as it will need ~30 sec. to take effect while you prep the syringe. The sedative will also relax the airway making insertion easier. Paralytics are OK if the phrenic nerve will not be tested.

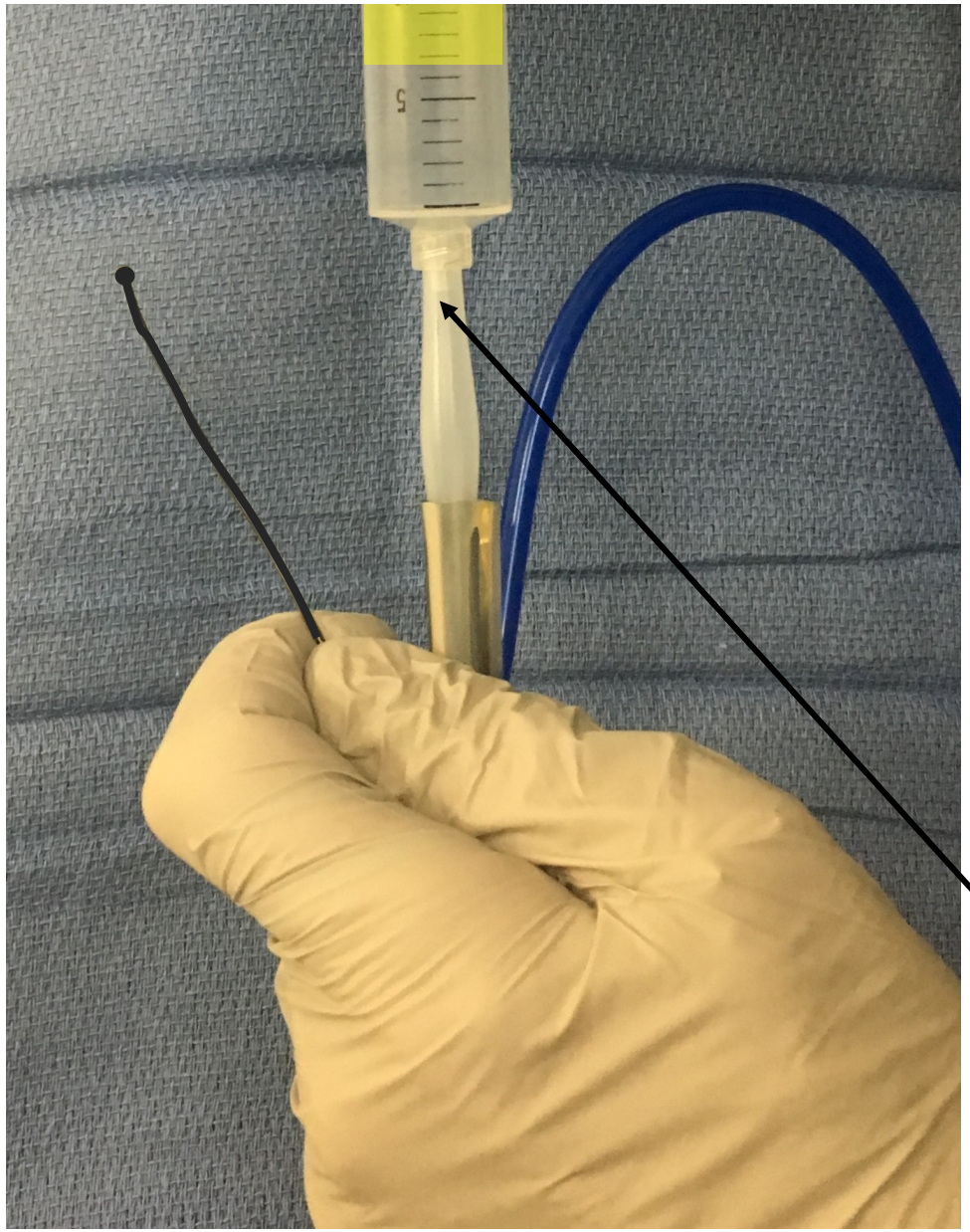
Procedure - Insertion

2 Open and align the airway. Have a 2nd staff lift jaw with their thumb behind the front teeth & fingers under the jaw. Hold tip of EsoSure and OGT in hand.

A two-handed head tilt-jaw thrust, or one-handed chin lift, often pull the teeth together and bite down on the OGT making passage of the EsoSure more difficult.

A “Fish Hook” jaw lift, with the thumb behind the front teeth, is better at pulling the tongue and jaw up and opens the airway for easier insertion of the EsoSure.

Procedure - Insertion



Take the EsoSure out of the circular holder and hold the end of the EsoSure and the OG Tube in one hand, while injecting fluid from the syringe with the other hand.

This way the EsoSure is ready for insertion immediately after the OGT is cooled by the injection of fluid.

The tip of the luer lock syringe fits nicely into the end of most OGT connectors. If your connector leaks, let us know and we will provide you with slip tips for your syringes.

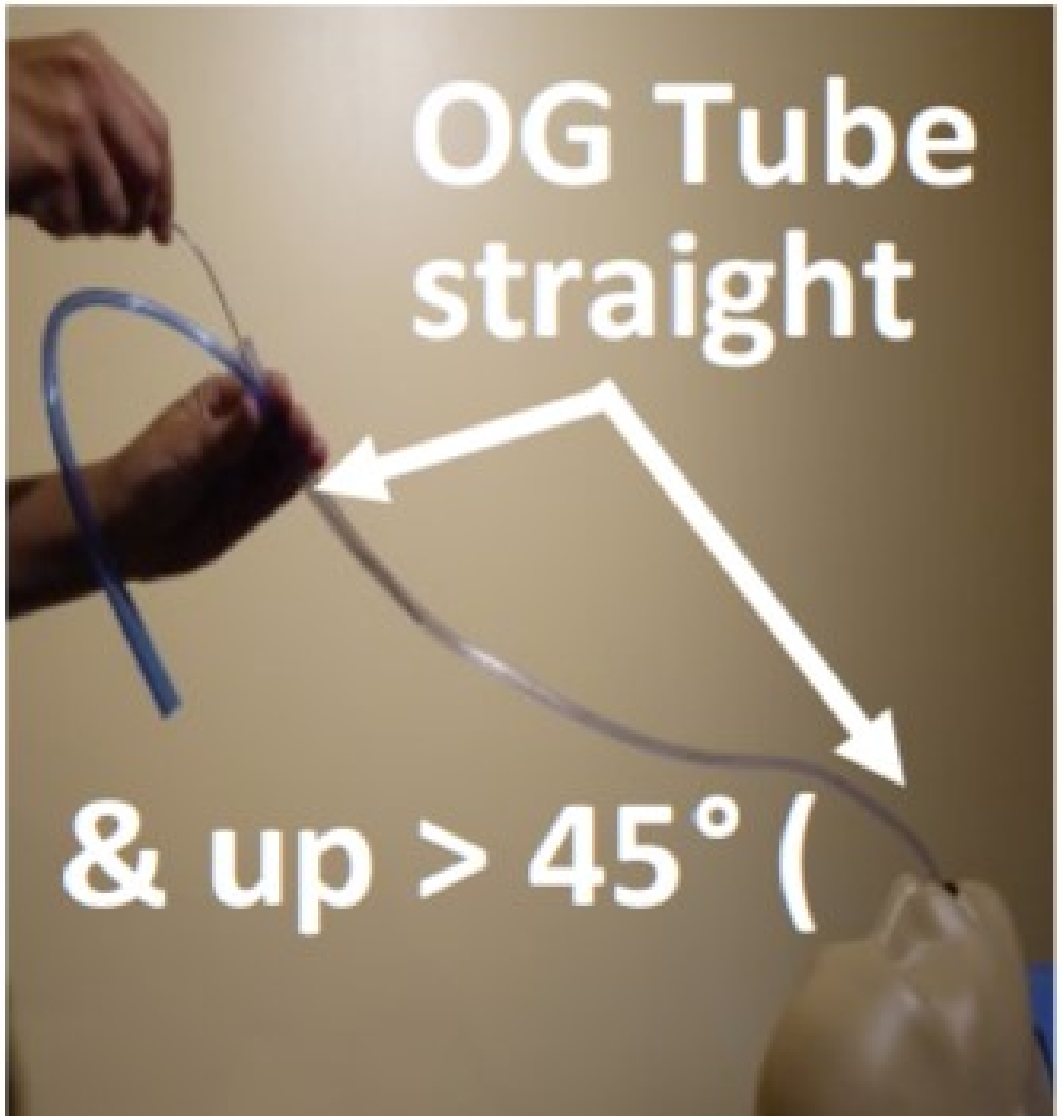
Procedure - Insertion

3 Cool and lubricate the OG Tube lumen by injecting 12 cc IV fluid/water & Tube Lube through the OG Tube connector over 10 sec. If OGT pre lubricated, inject 20 cc IV fluid/water over 10 sec.

The 20 cc of IV fluid/water/Tube Lube injected over 10 seconds cools the OGT lumen and keeps the EsoSure cool and soft for 10 seconds which makes for easier and quicker insertion. Inject the fluid after the other person is performing the jaw lift. If you inject, then ask for the jaw lift, the OG Tube will have warmed up.

Procedure - Insertion

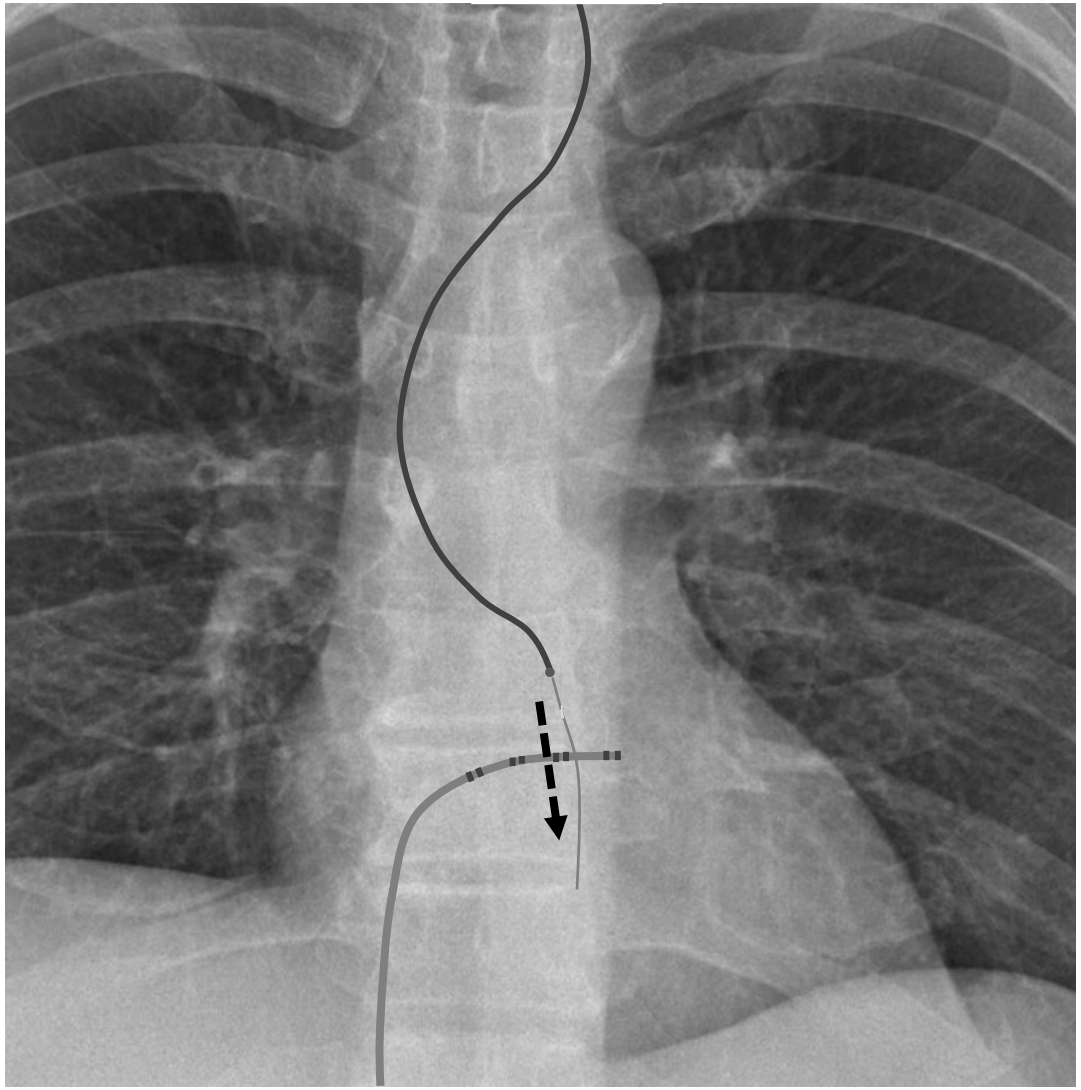
4 Advance the EsoSure 2-3” at a time, while OGT is straight & up >45° immediately after injecting cooling/lubricating fluid.



A slack or curved OG tube will create more resistance on the EsoSure as it is advanced.

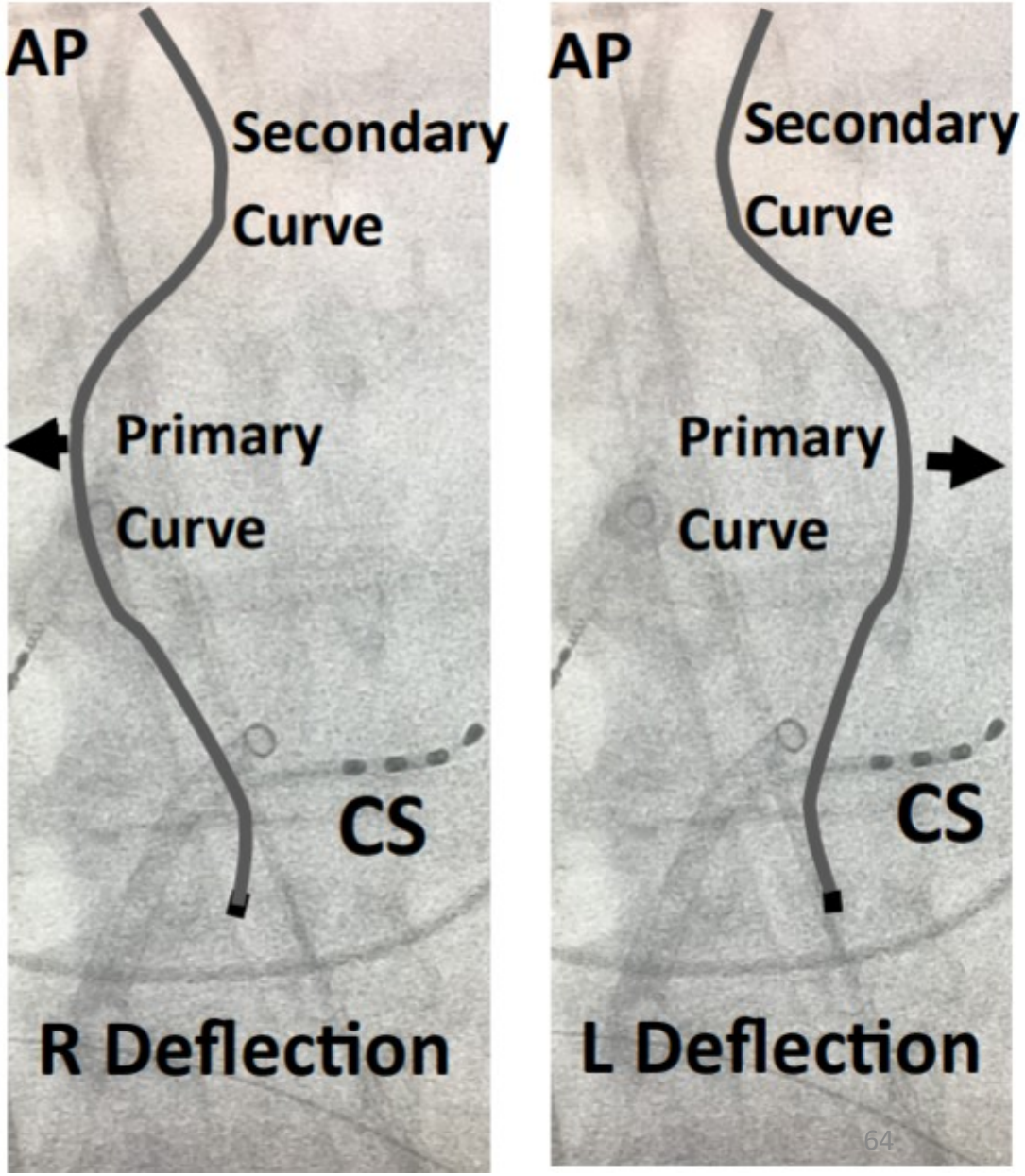
Procedure - Insertion

4 If the tip of the stylet stops above the CS, advance the OG Tube & EsoSure together.



Procedure - Insertion

4 Stop when the stylet is ~1” below the CS or the primary curve is at the upper heart if there is no CS catheter.



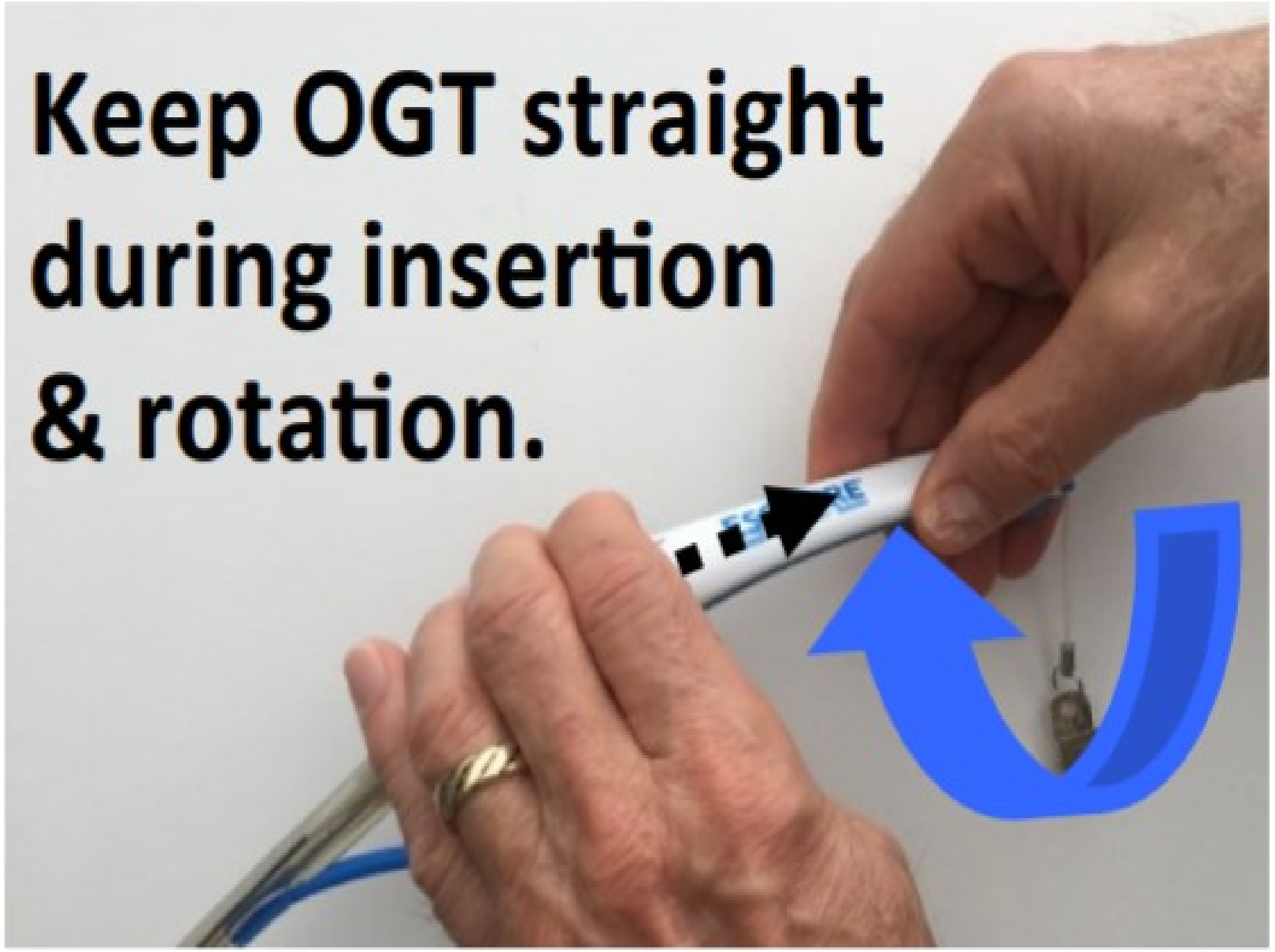
Procedure - Position

5 Rotate the primary curve to the desired side.

With the primary curve behind the heart, rotate the handle 2x then slowly retract the ~4" out of OGT. Rotation usually occurs above the heart.

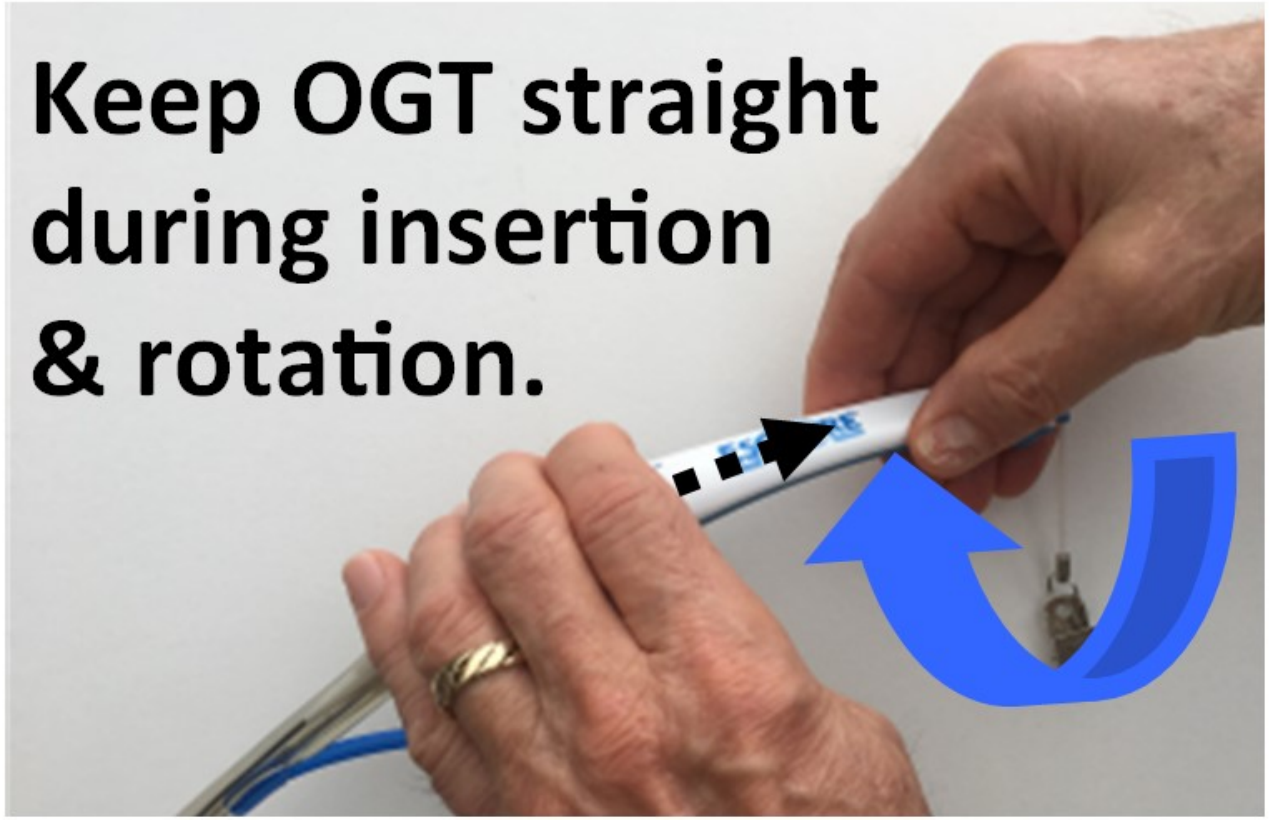
Watch Fluoro in AP during retraction, do not watch your hands or the patient's mouth.

It takes practice and experience to get the feel of insertion and rotation.



Procedure - Position

5 If it spins or doesn't rotate, rotate OGT with stylet, or rotate in other direction.



A straight OG Tube and stylet is necessary to transfer torque. If the OGT/stylet is curved, it will try to form a loop outside the body, and not transfer torque for rotation to the primary curve.

Procedure – Removing a Loop in the OGT

- **If the stylet stops advancing, the most common cause is a loop in the OG Tube in the throat. To resolve,**
- **Fix the OGT,**
- **Retract the stylet ~2”,**
- **Fix the stylet position,**
- **Retract the OGT over the stylet 2”, 3x,**
- **Then re-advance the stylet.**

If you are a new user, practice these steps three times so your hands know what to do when the time comes. This is guaranteed to happen.

Procedure - Removing a Loop in the OGT

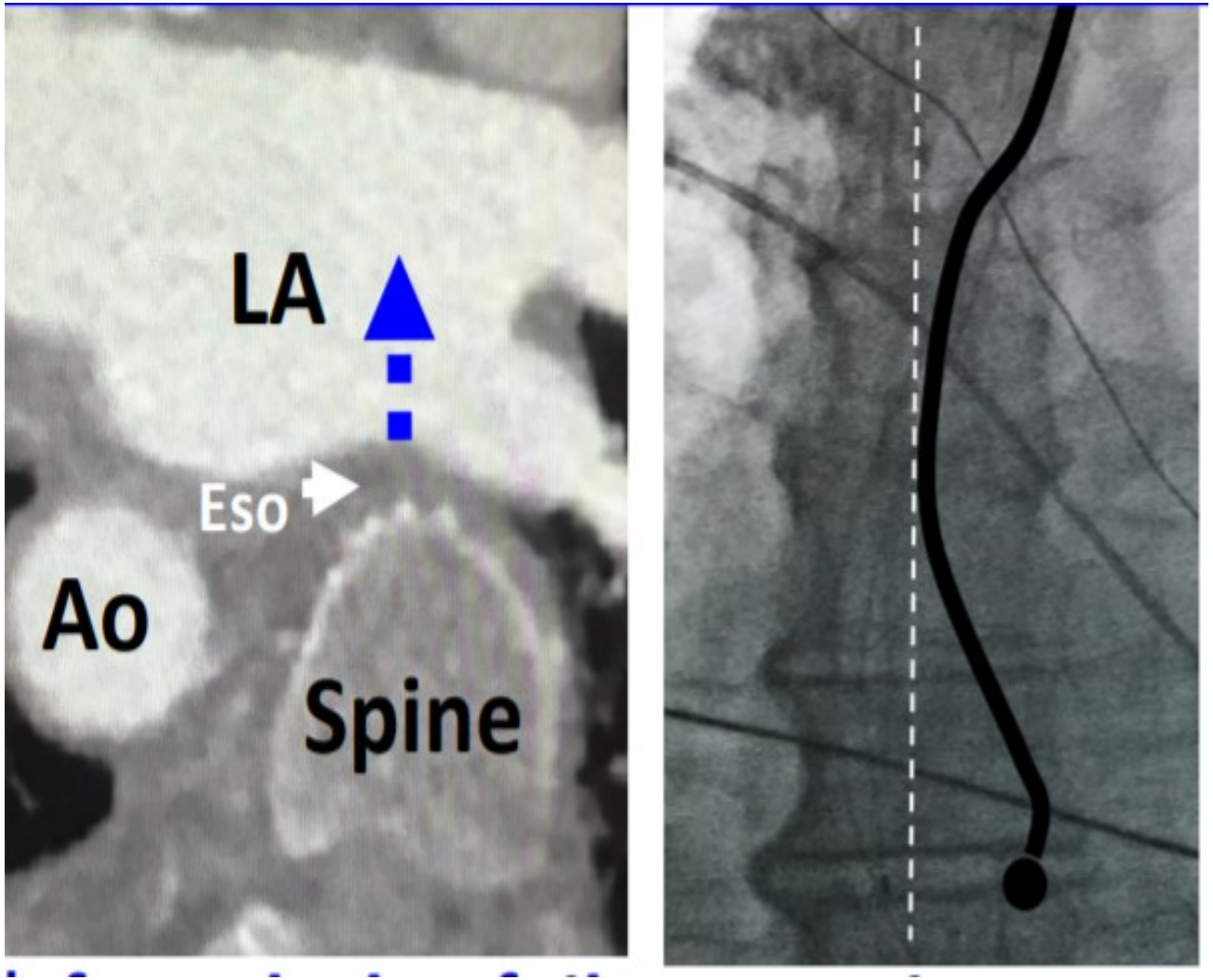
- **If it won't advance then look with Fluoro to see if there is another loop.**

If you do not see the problem, it may be a stricture in the esophagus, or other anatomy blocking advancement. Do not force it, and remove the EsoSure & OGT to avoid the potential for causing a hematoma or bleeding.

Procedure - Position

6 If the primary curve does not cross mid-spine use a valsalva:

Rotate the primary curve to the desired side behind the trachea, then during the Valsalva slowly advance curve behind the heart.



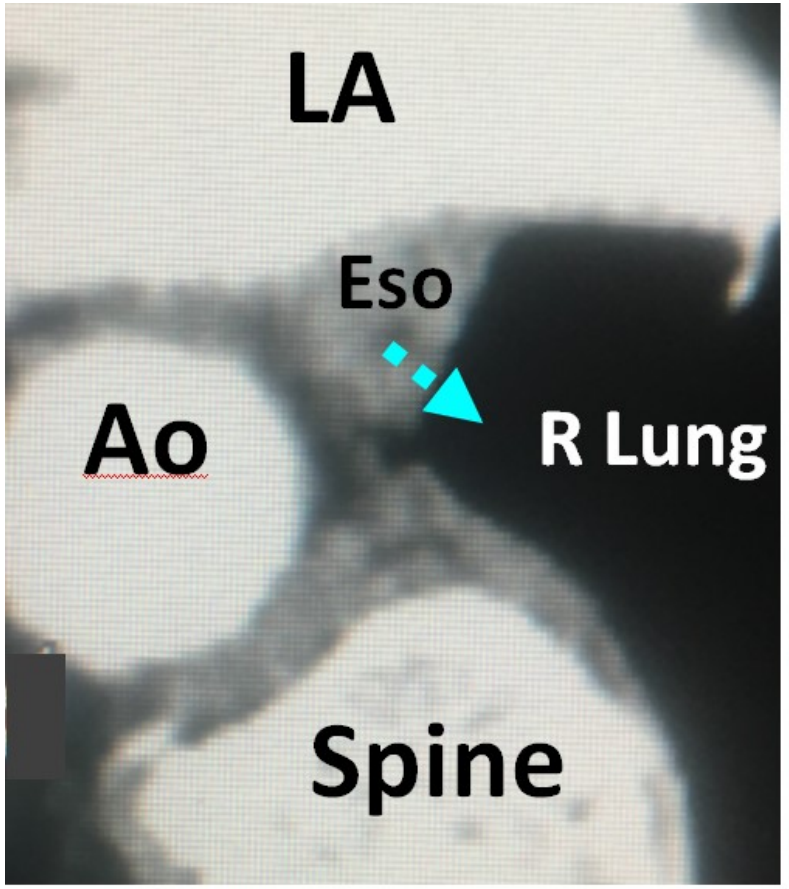
Procedure - Position

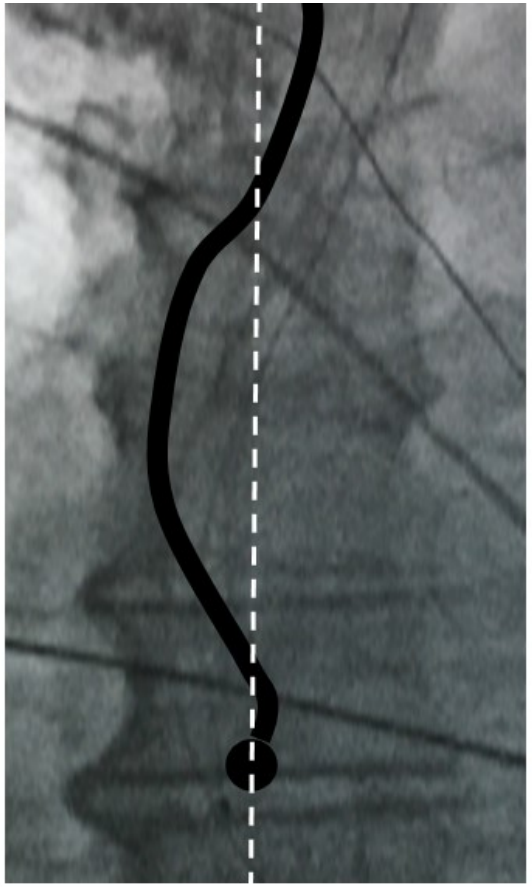
6 If the primary curve passes mid-spine but not the spine's side border:

Go apneic for 15 sec, & slide

EsoSure in & out of OGT 4" 2-3 x.

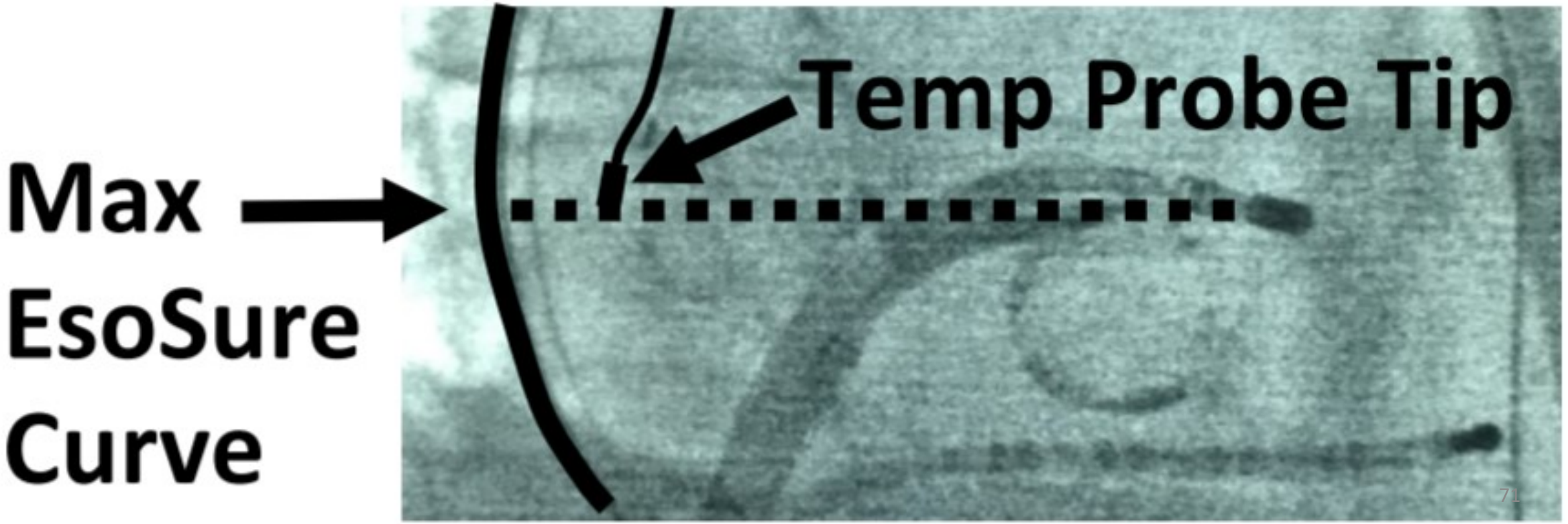
Reducing pressure in the lung and sliding the stylet in and out, frequently wiggles the esophagus between the lung and the spine for better deflection.



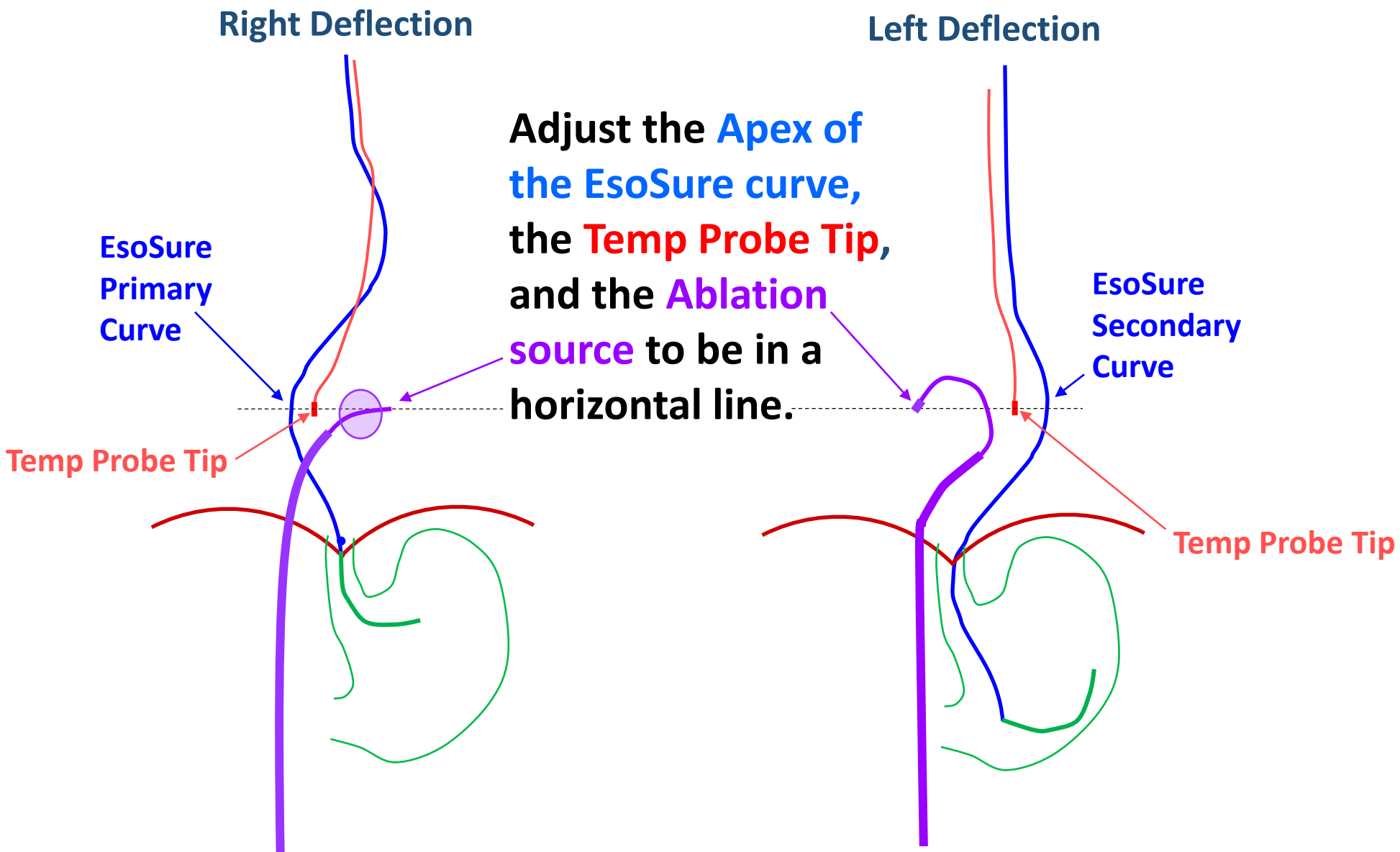


Procedure - Position

7 Temp probe is positioned inside the maximum EsoSure curve across from treatment area. (RF catheter or Cryo balloon.)



Optimal Single Thermistor TP and EsoSure Curve Position



Procedure - Assess

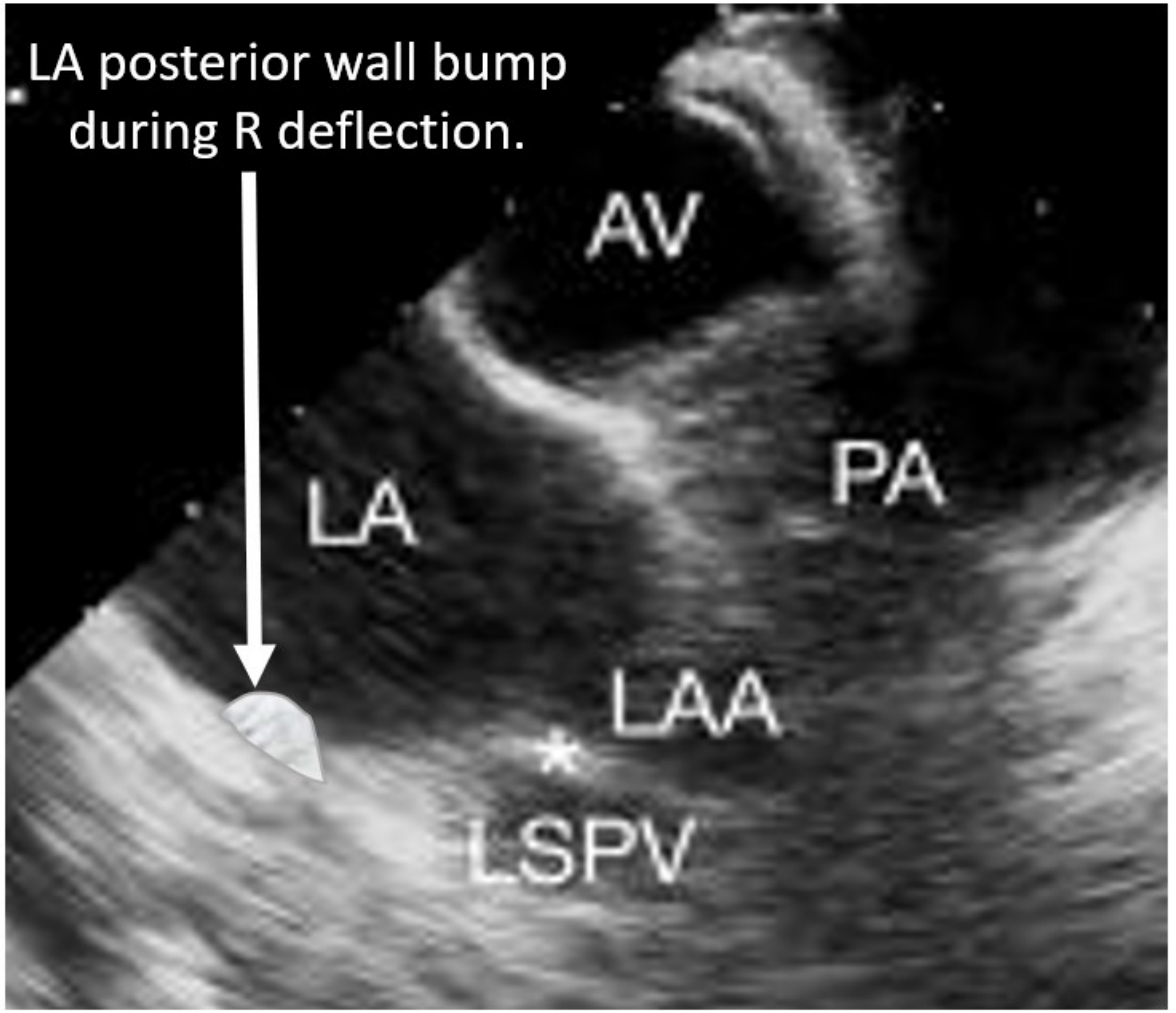
8 Assess the esophageal trailing edge with Fluoro & contrast, or with US while sliding the EsoSure in and out of the OG Tube ~1” to move the esophagus.

The trailing edge of the esophagus is of greatest concern.

Movement helps to differentiate it from the surrounding tissue.

Procedure - Assess

8 Lastly, use US to check LA posterior wall for possible indentation.



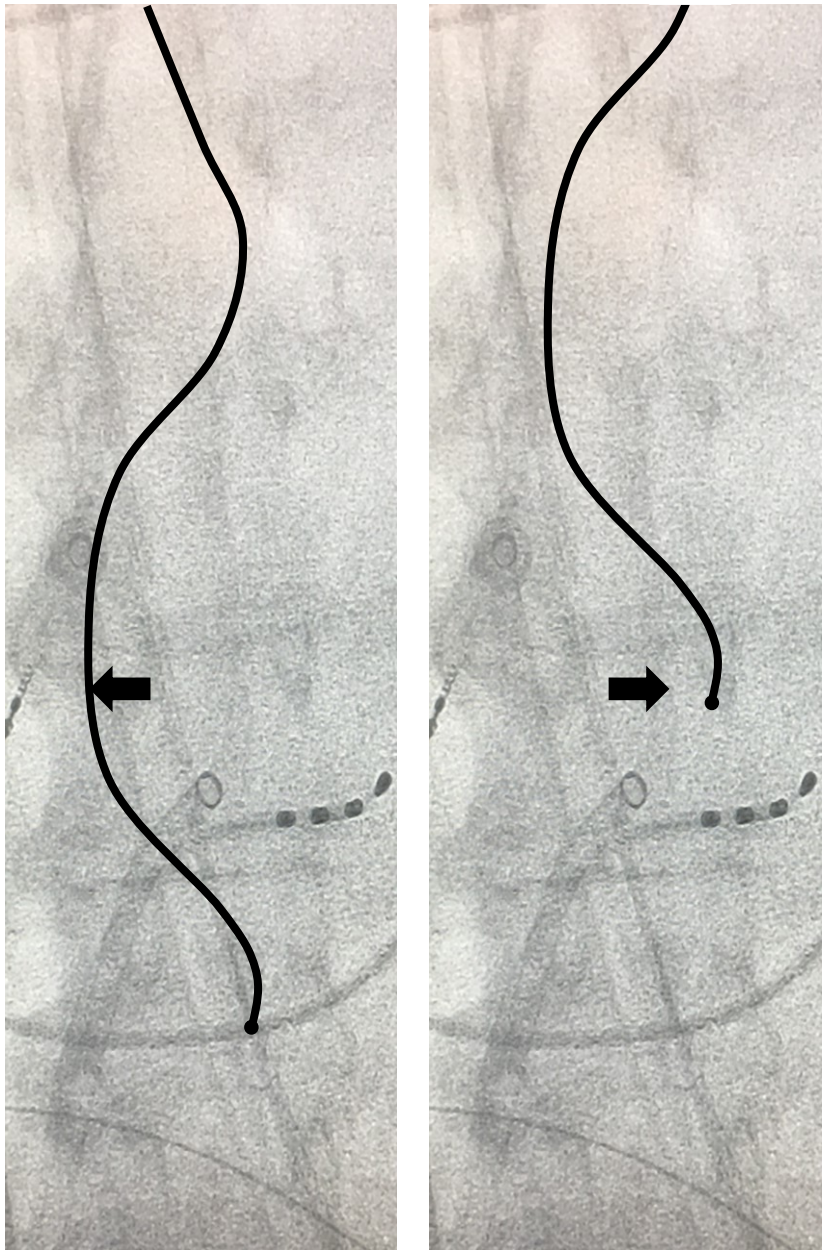
Ablation over this area should be avoided as pressure against the left atrial wall could predispose it to thermal injury.

Procedure - Removal

EsoSure Removal:

Starting with the stylet tip above the diaphragm, fix the end of the OGT and hold the stylet just above the OGT. Smoothly slide the EsoSure out and in ~4" 2X to slide the esophagus R & L behind the LA then remove. It is hypothesized that side to side esophageal movement may break potential thermal adhesions between tissue layers & reduce the potential for increased injury.

(The EsoSure tip pushes the esophagus to one side and the curve pushes it to the opposite side during in and out movement.)



Procedure – OG Tube Removal

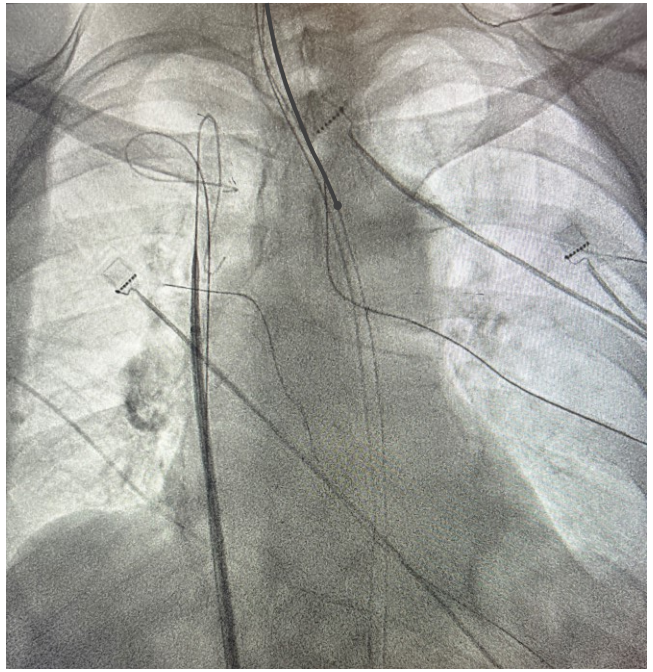
Lastly, suction the stomach and if contrast was used suction the esophagus during OG Tube withdrawal.

Contrast is extremely toxic to the lungs and if used, it needs to be suctioned from the stomach, as well as from the esophagus and upper airway. If there are pools of contrast, watch with Fluoro while suctioning to verify that it is removed.

Case Studies of Challenging Anatomy

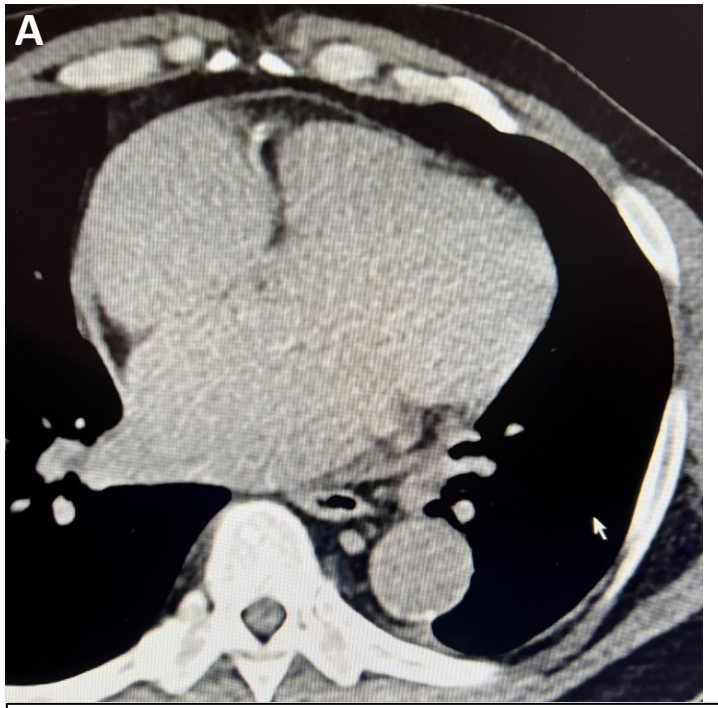
This last group of slides provides additional insight on the 20% of cases where insertion or deflection is difficult.

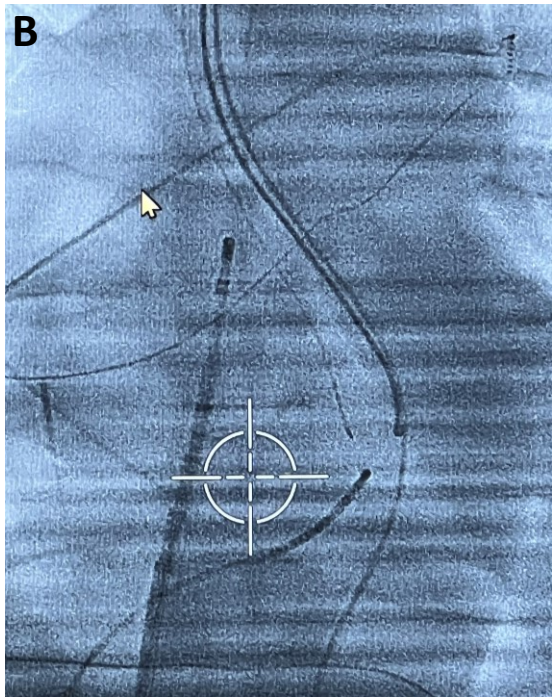
Case Studies of Challenging Anatomy: Resistance While Advancing



In this procedure the EsoSure met resistance at this point. If during EsoSure insertion, the stylet stops advancing and a loop in the OG tube is not seen on Fluoro, do not advance it further.

It is most likely an esophageal stricture or anatomically confined space. Remove the EsoSure as you do not want to cause trauma in the patient, especially when they are anticoagulated.

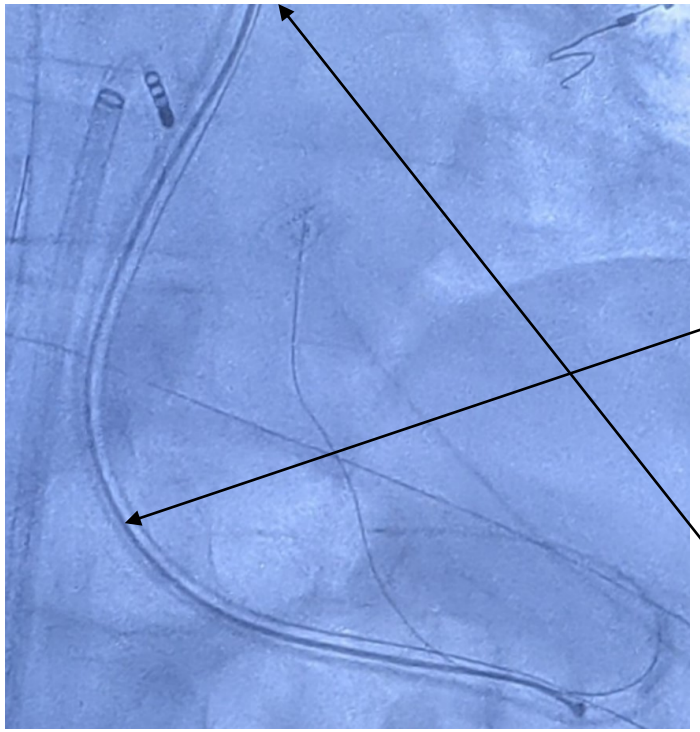




If a CT is available, knowledge of the intrathoracic anatomy is helpful. In the above case, the tight space between the LA and spine (A) required a Valsalva in order to slide the primary curve behind the heart. A small amount of resistance was felt at this point of advancement (B), which was expected, as the narrow space squeezes the OG Tube. The straight OG tube below the EsoSure tip shows that there is no a bend in the esophagus preventing advancement. Slow and gradual advancement along with a Valsalva will usually be successful.

Case Studies of Challenging Anatomy: Resistance While Advancing

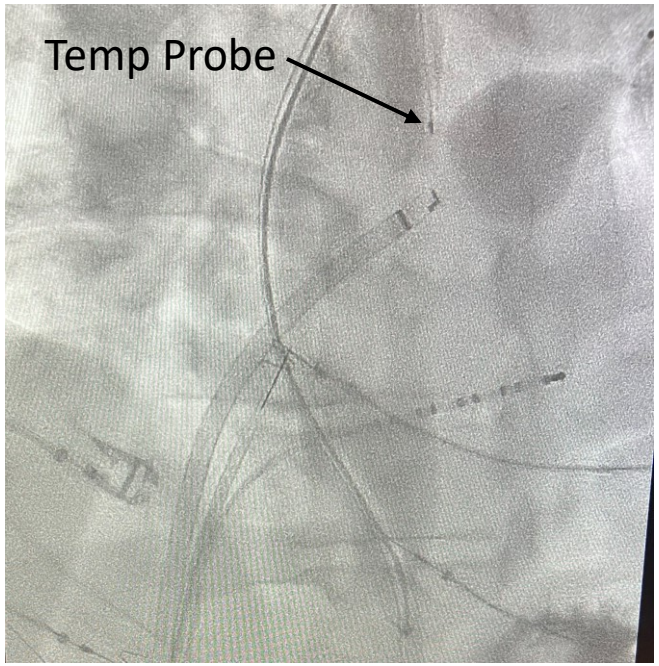
Difficulty advancing the EsoSure to use the secondary curve to the left.



Sometimes the curve in the esophagus, below the diaphragm, is sharp and the EsoSure cannot be advanced far enough to use the secondary curve for left deflection. In this situation the secondary curve should not be used. Instead, retract the EsoSure for left deflection with the tip of the stylet or rotate the EsoSure to use the primary curve to the left.

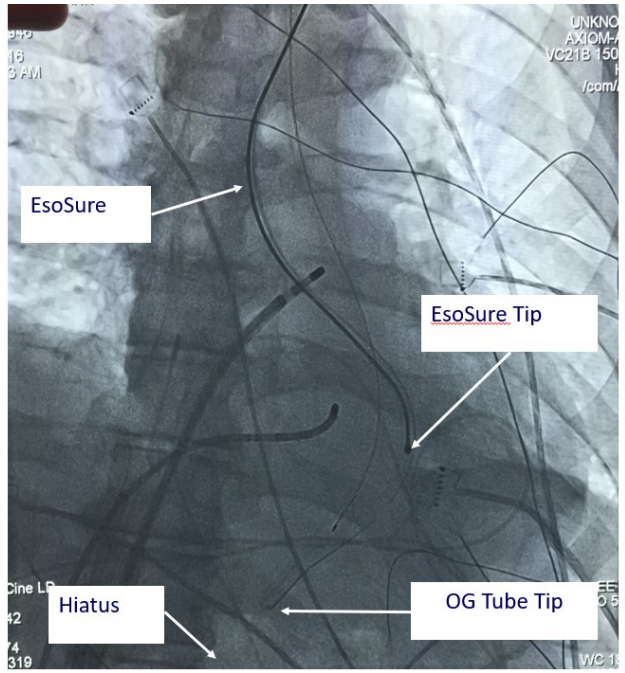
These are the three scenarios where advancement of the EsoSure was difficult and occur infrequently.

Case Studies of Challenging Anatomy: Dilated Esophagus



Contrast was used in this procedure and a ~4 cm dilated esophagus was identified at the start. Later in the procedure most of the contrast flushed out, but the width could still be estimated.

If the Temp Probe is all that is used to determine the width of the esophagus, and it is not positioned along the trailing edge, the size of the esophagus is unknown, as is the position of the Temp Probe relative to the edge of the esophagus closest to the ablation device.

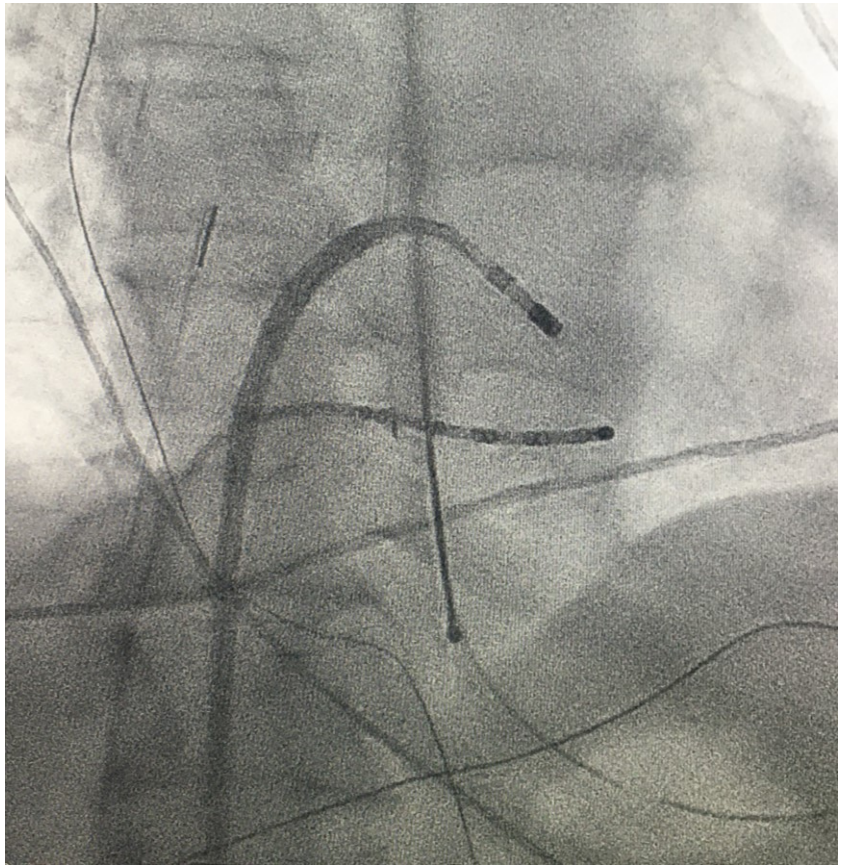


If the tip of the EsoSure extends more than the width of the spine lateral to the right or left spinal border, then the esophagus is most likely dilated or there is a hiatal hernia. Especially if the tip of the stylet prolapses on the diaphragm when it is advanced to the hiatus.

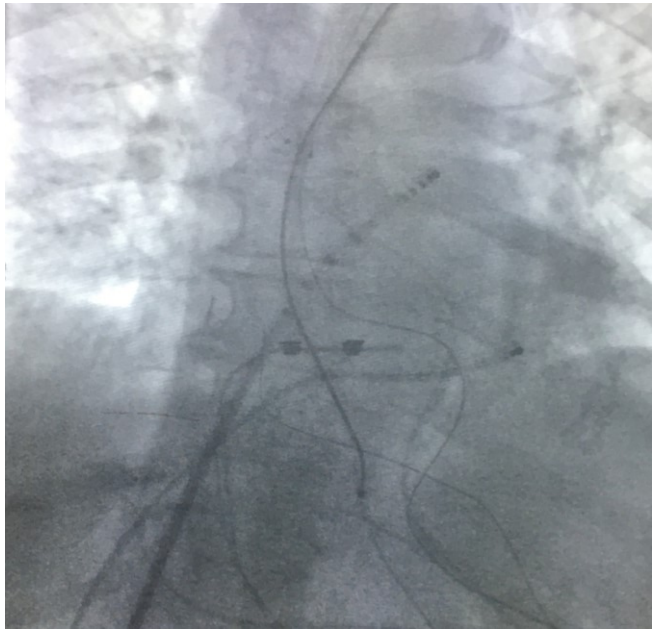
If you are not able to clearly visualize the esophagus with contrast or ICE, estimate that the esophagus covers the entire posterior wall of the left atrium.

Case Studies of Challenging Anatomy: Narrow LA>Spine

EsoSure looks straight



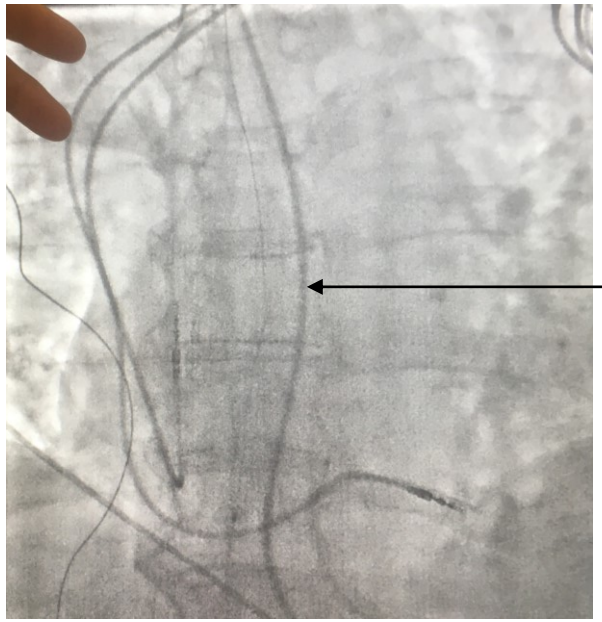
In this view, the EsoSure looks straight. What sometimes happens is the curve goes posteriorly. This is frequently seen when there is no space between the LA and spine. Rotate and retract the EsoSure primary curve to the right above the heart, Valsalva, then slowly advance for right deflection.



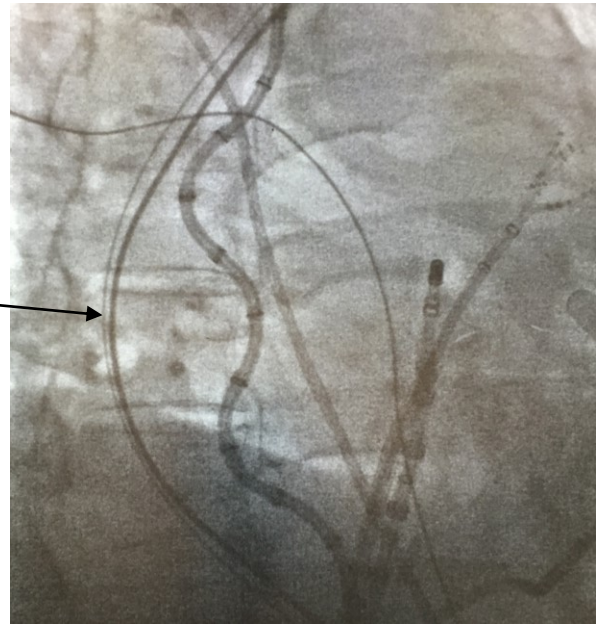
Another common trait of a narrow LA to spine space is the EsoSure primary curve gets stuck between them.

Retract the primary curve above the heart, perform a Valsalva then slowly advance the EsoSure behind the heart. If the curve gets forced back to the left, pause for a few seconds, repeat the Valsalva and continue 1 cm at a time with a few second pause between advancements. This works 75% of the time.

Case Studies of Challenging Anatomy: Lungs



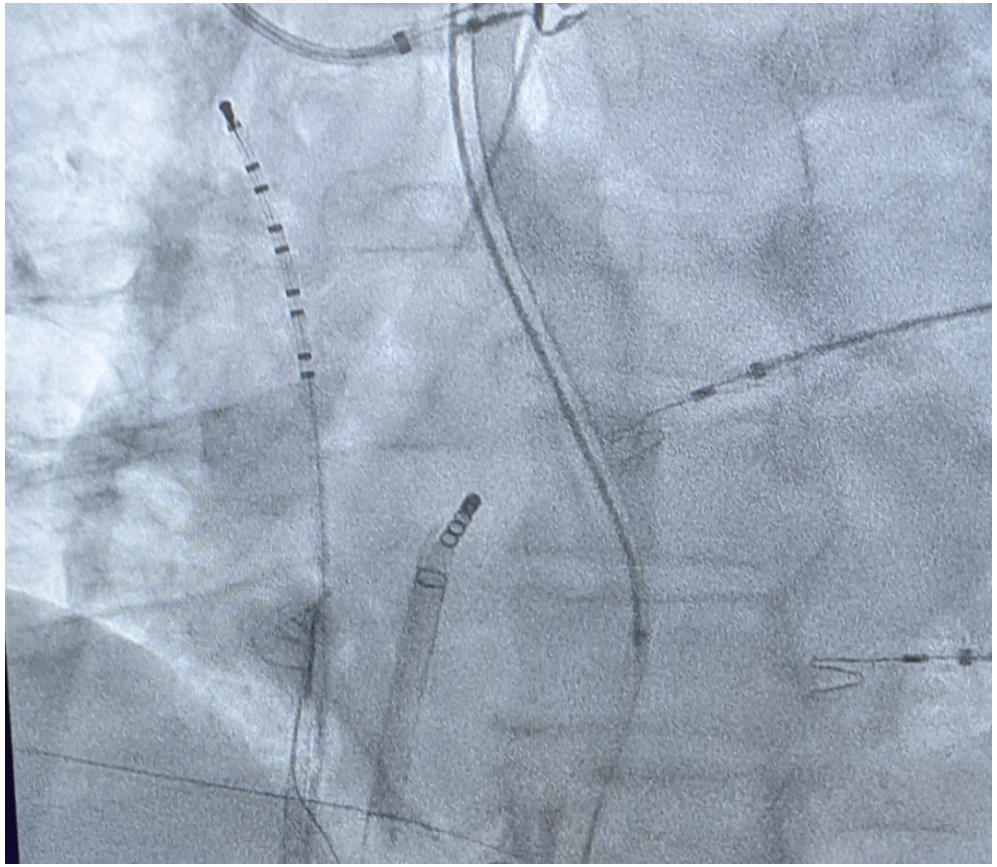
EsoSure curve apex

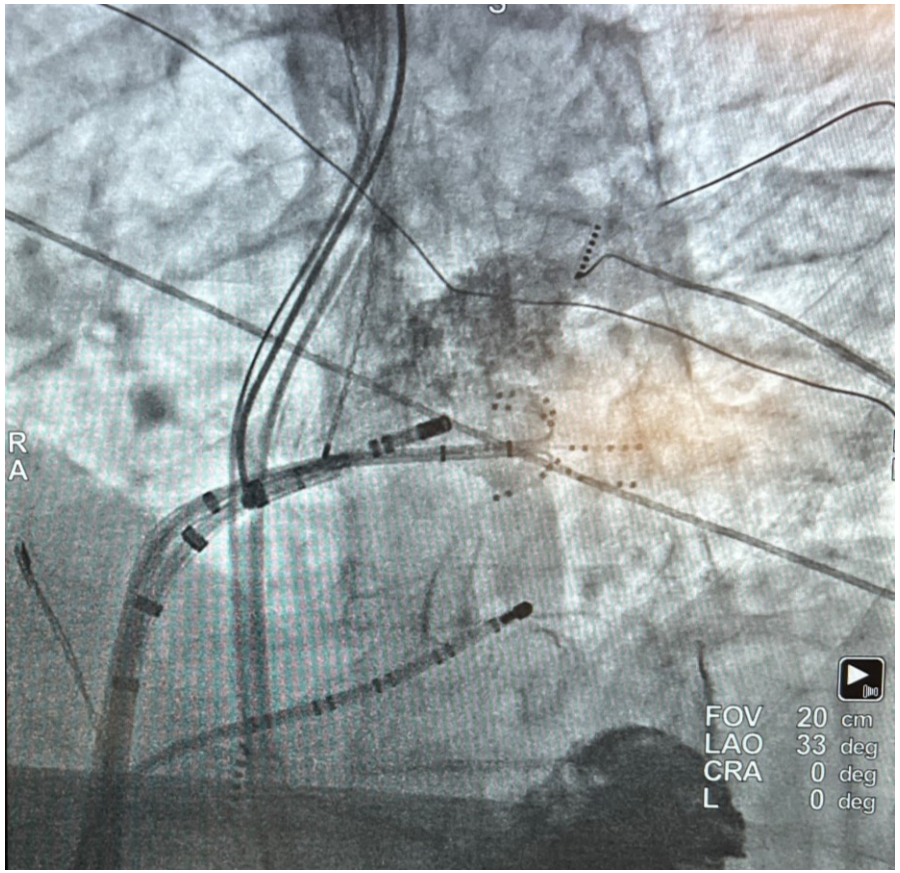


If the apex of the primary or secondary curve does not reach the lateral border of the spine, in an AP view, the most likely deterrent is the lung. Have Anesthesia disconnect the ET Tube from the vent tubing for ~10 seconds to deflect the lungs and reduce resistance. Just flipping the switch on the ventilator will stop breathing and won't allow for exhalation. Then slide the EsoSure in and out of the OG Tube 4-6" several times. One rotation of poster rotation may help the OG Tube slide between the lung and spine for better deflection.

Also, as the EsoSure curve sits in position for 5-10 minutes the force of the curve against the surrounding anatomy frequently gains another .5 to 1 cm of deflection.

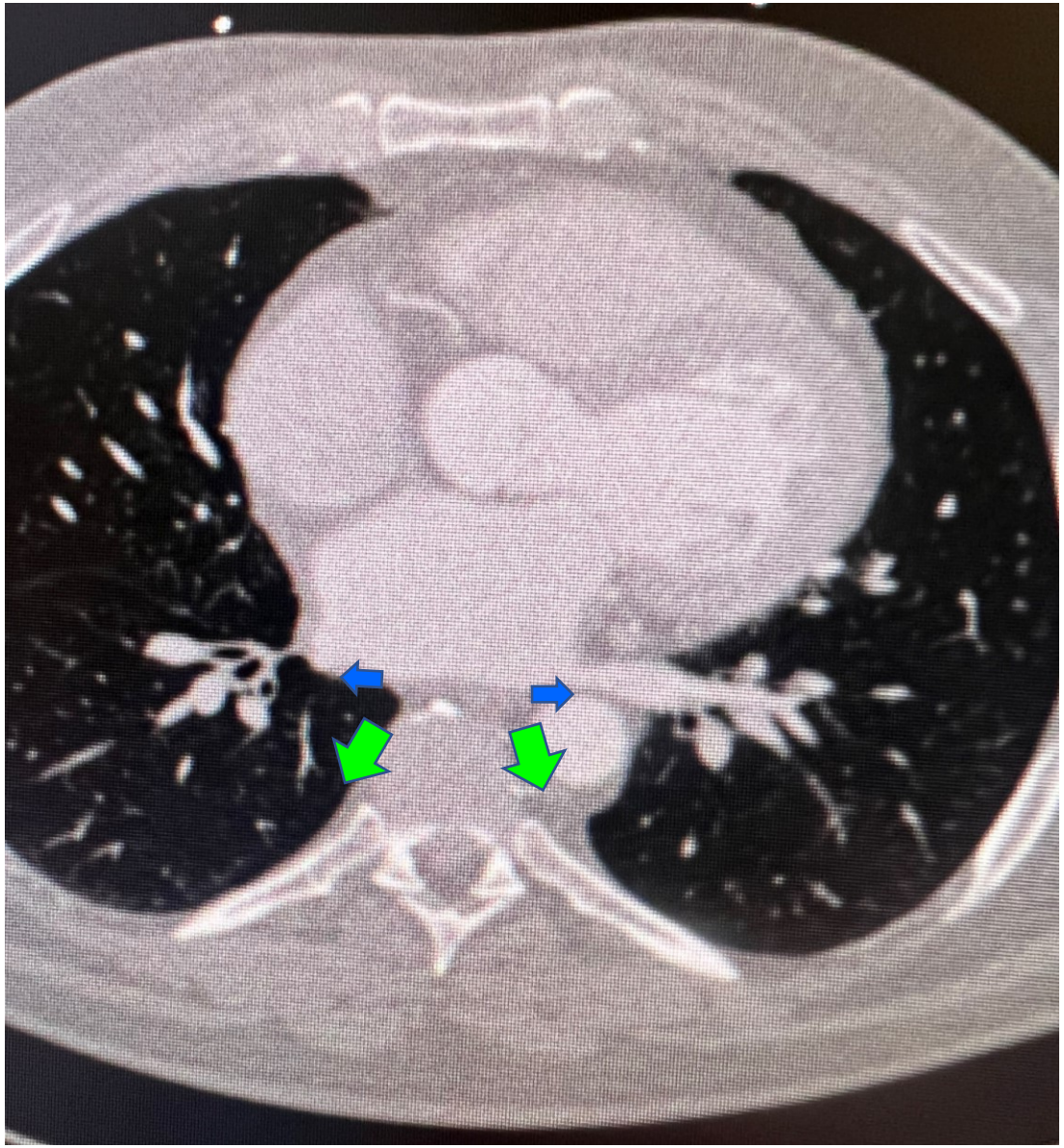
Case Studies of Challenging Anatomy: Using the Tip for Deflection





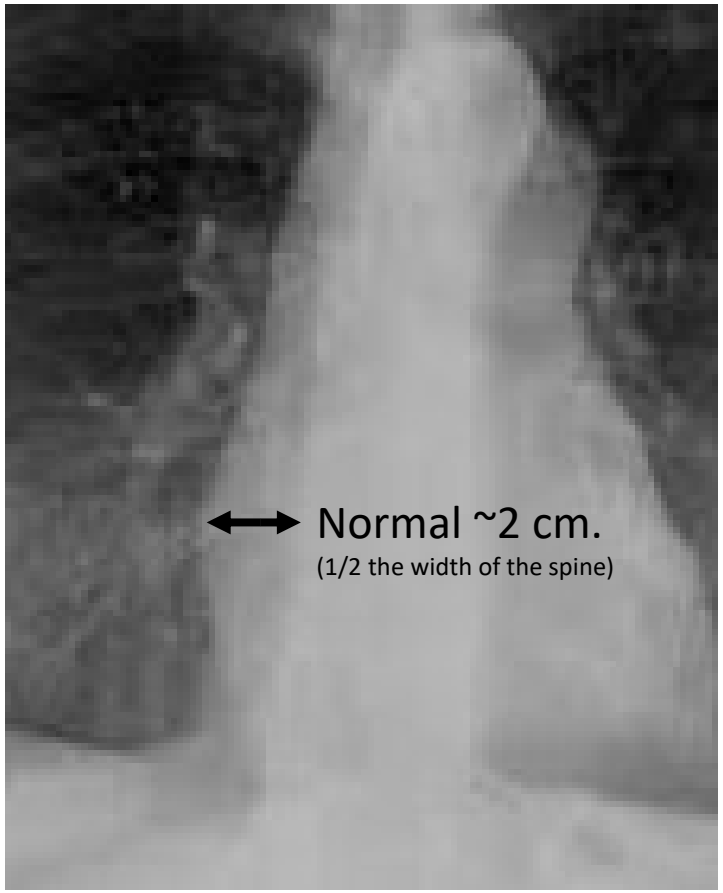
One option, when the baseline esophagus is left sided or right sided, and positioning of the EsoSure primary curve back to that side is difficult, is to use the tip of the EsoSure for deflection.

Case Studies of Challenging Anatomy: Deflection Pathways

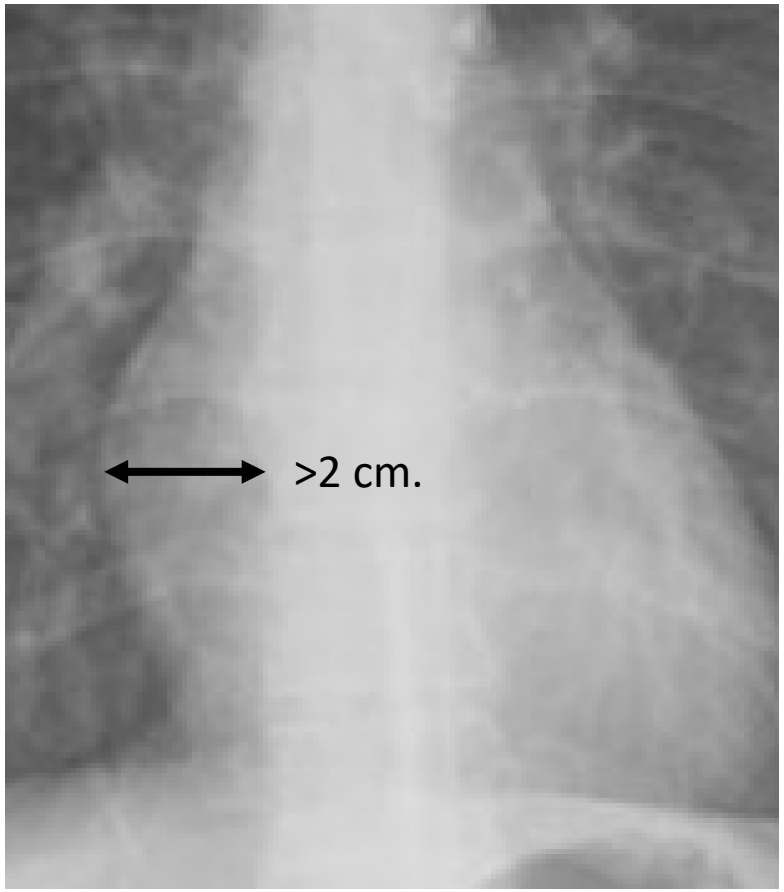


As a reminder, picture the EsoSure in 3D as you position the stylet. To help the primary curve work its way posterior-laterally between the lung and the spine you may use one posterior rotation as you slide the EsoSure in and out of the OG tube 4-6". Sometimes it may be helpful to take the lateral path.

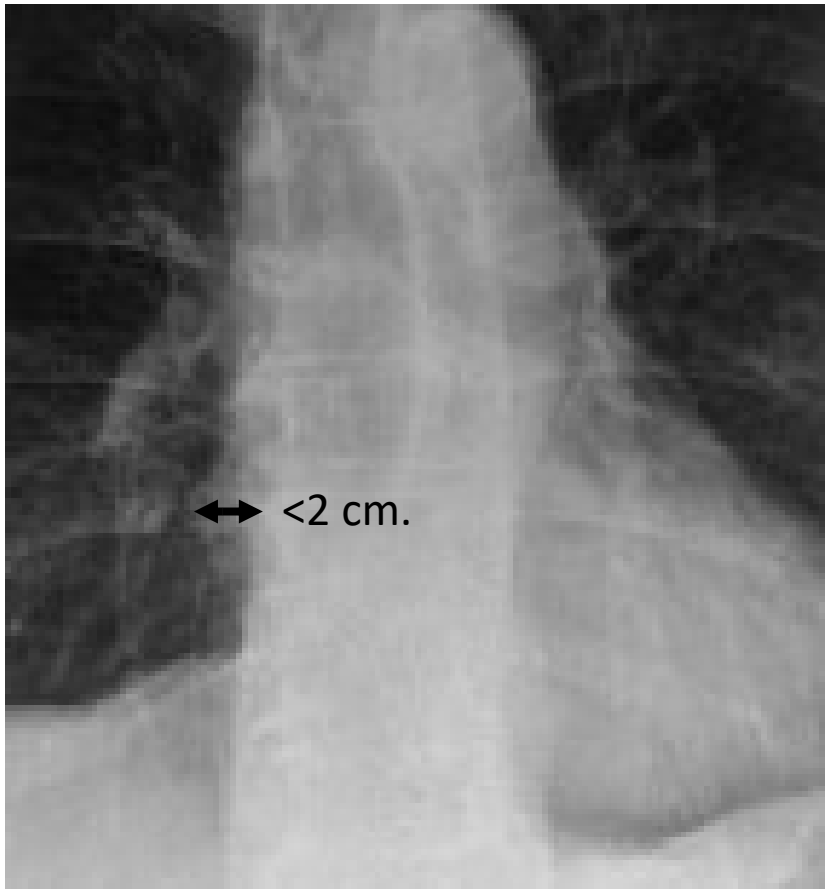
Case Studies of Challenging Anatomy: Heart Rotation & Size



The position of the heart relative to the spine gives an indication of the heart's rotation. There is usually ~2 cm of the right heart border to the right of the spine.

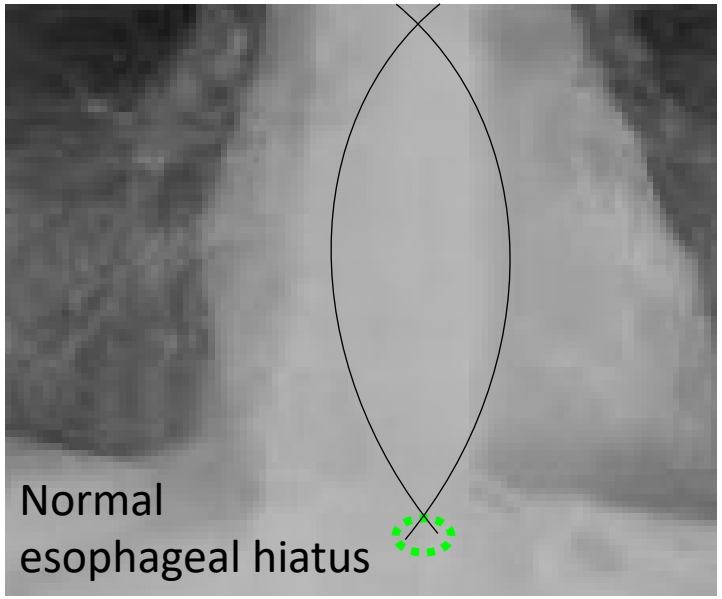


If the heart extends >2 cm further to the right of the spine the heart is likely enlarged or rotated to the right. If there was no CT scan anticipate that a Valsalva will be needed, and that right deflection will be difficult.

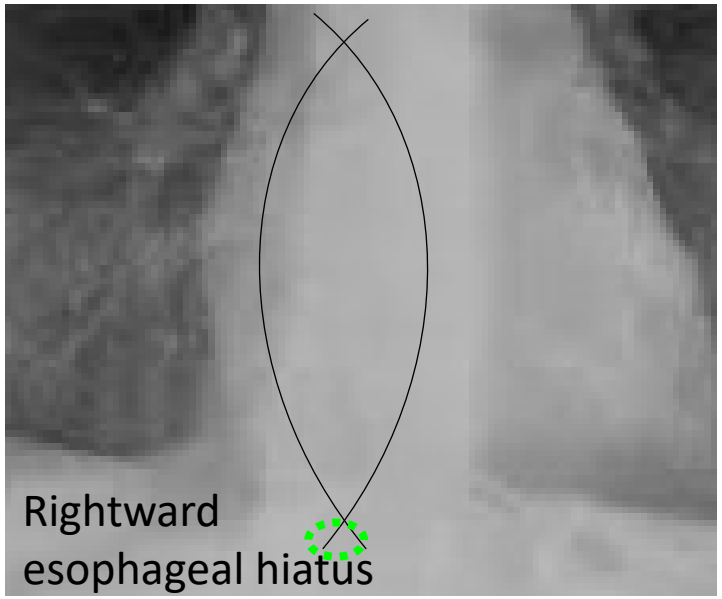


If there is <2 cm of heart to the right of the spine then the heart is most likely rotated to the left and left deflection will be more challenging as the right PVs will be closer to the left border of the spine.

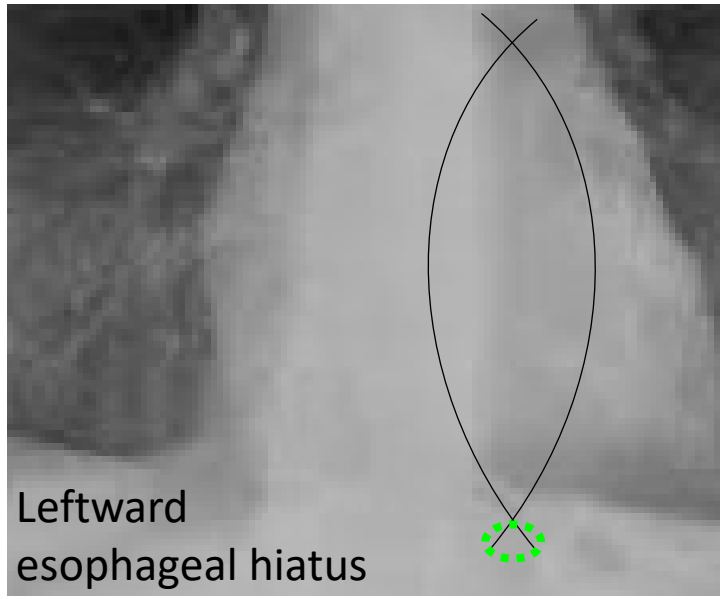
Case Studies of Challenging Anatomy: Esophageal Hiatus



The esophageal hiatus, where the esophagus passes through the diaphragm, is usually over the left half of the spine. However, it may be shifted to the right or left which has a bearing upon where the tip of the EsoSure gets support and the amount of esophageal deflection to the side opposite the hiatus.



If the esophageal hiatus is shifted to the right, then the left deflection will be reduced. Options are to deflect further to the right, away from the right PVs.



If the hiatus is shifted to the left, then the right deflection away from the left PVs will be minimized. Options are to try deflection further to the left, lateral to the left PV ostia, or straight posterior deflection away from the left PVs.

Closing

Much of the information shared here was gained through feedback from EP Techs, Nurses, Anesthesia providers and EP Physicians… just like you.

We welcome and encourage your questions and comments as your input will help us teach others.

Please email steve@epreward.com or call me any time at 561-779-1040.

Thank you. Steve

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