Safely Move the Esophagus with the EsoSure Esophageal Retractor.
The first US-patented and FDA-registered device specifically designed to move the esophagus.

The EsoSure has been used 3,400+ times in 50 EP Labs across the US and 17 times in pre-clinical trials on the EP Nurse inventor without causing injury to the esophagus.

Courtesy of Dr. Andrea Natale. California Pacific Medical Center. April, 2016.
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The EsoSure Esophageal Retractor

The EsoSure has a temperature-programmed Nitinol stylet which is flexible at room temperature for placement into the lumen of an 18 Fr Salem Sump OG tube (OGT) and assumes a firm S-shaped curve at body temperature to create esophageal deflection.

Updated EsoSure curve, released 12/2017
EsoSure’s Anatomy

Ball on tip prevents OG tube puncture.

Larger primary curve is on distal end of stylet.

.052 dia. Nitinol shaft is shorter than the distance to the OG tube’s proximal hole.

Smaller secondary curve is proximal.

Silicon plug occludes end of OG tube.

Markings on handle indicate direction of primary curve during insertion.

Clip secures handle to pillow or sheet.

Benefits of the EsoSure Esophageal Retractor

➢ Inserted into lumen of standard OG Tube in 5 seconds.
➢ Small diameter OGT does not move heart for remapping.
➢ Successful deflection > 80% of cases. Range .8 cm to 5 cm.
➢ No esophageal injury caused by EsoSure in 3,400 cases.
➢ Changes side of deflection in seconds.
➢ Mimics natural migration.
➢ Priced at $365 to $395. (Quantity dependent)
Conclusions... Mechanical displacement of the esophagus during RFA with the EsoSure device appears to be safe and efficacious in enabling adequate energy delivery to the PW for successful PVI without significant luminal temperature rise.

The EsoSure stylet update in 12/2017 has ~40% stronger force in the curve which is showing improved deflection from these results. (see next page)
**INTRODUCTION**

- Consequences of esophageal thermal injury (ETI) can be catastrophic, thus esophageal protection during LA RA must be prioritized.
- Esophageal protection by temperature monitoring is "gold standard." However, when esophageal temperature (ET), rises only option is to stop RFA.
- Esophagus is mobile structure. Multiple published experiences have demonstrated feasibility of esophageal displacement (ED) with endoscopes, TEE, etc.

We present the first study to evaluate the feasibility, effectiveness, efficiency, and safety of EsoSure, the first commercially available medical device designed to protect the esophagus by mechanically displacing it.

- We prospectively evaluated 50 consecutive patients receiving EsoSure to displace esophageus during RFA compared retrospectively to 29 consecutive controls, all receiving RFA for AF. ET was monitored in all cases; RFA ceased once ET rose 0.5°C from baseline. Fluoroscopy was used for all ED maneuvers and ET probe positioning.

**DISCUSSION & RESULTS**

- EsoSure is thin metal (nitinol) rod with two curves which smoothly esophageus laterally. Direction of displacement is changed through advancing or rotating the device. It is passed into esophagus within the lumen of an OG tube. Anesthesia performed ED with EsoSure.
- ET probe is positioned in esophagus beside EsoSure positioned on side and height closest to RFA catheter.
- EsoSure sufficiently moved the esophagus (82%), lowering peak ET rise at all PV sites (P<.011), but not at posterior LA at roofline (P=.384).
- In the case of ET rise, average time waiting for cooling was diminished in the EsoSure cohort (P<.001). Ablation time saved was greater than time spent manipulating.
- No complications were noted.

**CONCLUSION**

- This first trial of a device designed specifically to mechanically displace the esophagus has shown feasibility and effectiveness while improving the efficiency of ablation without causing patient harm.

**Follow-up Data : First 100 patients**

- Average Maximum Temperature Rise, C 0.74±0.6
- Able to Sufficiently Displace Esophagus (defined as "helpful" at all sites of RFA) 82 (82%)

**Conclusion:**

Eosophageal mechanical displacement shows promise as a valuable tool alongside temperature monitoring for protection from esophageal thermal injury. In our experience, EsoSure, in some cases, is an effective 1st generation tool for mechanical esophageal displacement.
Anatomical Review and Considerations

The EsoSure curve is designed to utilize support given to the esophagus superiorly from the inferior pharyngeal constrictor muscle and inferiorly from the diaphragm.

Behind the trachea there are only loose fibroelastic membranes and sparse, thin muscle fibers connecting the upper esophagus to the trachea. There is no restrictive tissue attached to the esophagus below the carina.
Figure 2. Axial image of esophagus and posterior LA at level of superior PVs. Between LA and esophageal lumen (A), 4 different layers are visible: radiocontrast agent within left atrium (most radiodense), a thin layer of posterior LA wall (less radiodense than LA), a thin layer of adipose tissue (radiolucent), and anterior esophageal wall (radiodense). B, There is no fat layer visible between left atrium and esophagus. Measurements were made using digital calipers. FL indicates fat layer; LA, left atrium; LA wall, posterior LA wall; Lum, lumen of esophagus; Ao, aorta; other abbreviations as in Figure 1. (Eso= Esophagus; LAA= Left Atrial Appendage) (7)

Eso – LA Distances

The total distance from the LA to the Esophagus varies and may be as little as 3.2 mm.

The mean thickness of the esophageal wall is 2.5 +/- 1 mm.

The mean thickness of the posterior left atrial wall is 2.5 +/- 1 mm.

The mean thickness of the parietal pericardium is 0.3 +/- 0.1 mm.

The mean thickness of the fat pad between the esophagus and left atrium varies from 1.3 mm to 0 mm.

Note the relationship between posterior left atrial wall, the anterior spine and the aorta. This image shows a distance between the spine and LA approximately equal to the diameter of the aorta. If this distance is narrowed and the esophagus is towards the left it may not move rightward between the LA and spine.
Physiologic Esophageal Migration

Of great significance, is the esophagus may move laterally up to 2.5 cm all by itself through physiologic migration. (8) The EsoSure is designed to create esophageal deflection in a manner that mimics physiologic migration.

Baseline Position

Migrated Position 40 min. later, without mechanical influence.
Moving the esophagus is not a new practice as there are several devices which have been used with success.

A) In 2005, the year the EsoSure was invented, the Uni. Of Michigan conducted a study using an endoscope to move the esophagus. (9)

B) An ET Stylet inside a Chest Tube was used in 2012 by Mount Sinai Hospital New York City, as well as other facilities. (3)

C) Most notable is a 2015 study in Brazil which reviewed 704 cases where TEE probes deflected the esophagus 96% of the time with a deflection range of 4 to 9 cm. In this study there were only 2 instances of superficial esophageal luminal lesions. The EsoSure, by contrast, mimics the curve of natural migration by creating movement in a gentle arc of ~3 cm rather than the right angles and corners of a TEE probe. (10)
The EsoSure stylet deflects the esophagus in the area of the mid left atrium, where there are no attachments, by utilizing support the esophagus has at the larynx and diaphragm.

*Each colored line represents data from 1 of 53 patients scanned in a 40 slice multidetector Siemens CT scanner and reconstructed from the raw data at 5 mm intervals. The point of transition from light to dark is at the mid left atrium. Measurements were obtained in the sagittal reconstructed images utilizing a GE Centricity PACS software. Data courtesy of Dr. Nino Alvarez, MD.*
Contraindications for EsoSure Use

**Absolute contraindications** are the same as those for a TEE or gastric tube insertion and include esophageal:

- Strictures
- Fistula
- Varices
- Diverticulum
- Upper GI bleeding
- Surgery of the esophagus
- Surgery of the stomach
- Other abnormalities
- Inability to place OG tube into the stomach

**Relative contraindications** include:

- Hiatal hernia, GERD, Gastric ulcer, Airway/Eso/ GI abnormalities
1) **Salem Sump gastric tube 18 Fr by 48”** - The first time the EsoSure is used it should be inserted into the hospital’s Salem Sump OGT to confirm the stylet does not extend past the proximal hole in the gastric tube. (16 Fr works, but is tighter.)

2) **3 - 20 cc luer lock syringes & 1 - 18 ga needle** - 1 for injecting OGT lumen with Tube Lube if not suctioned; 1 for contrast (if used); and 2 for cold fluid injection. The luer lock tip will fit into the end of the OGT connector that comes with the Salem Sump OGT. A Toomey syringe is necessary for injecting thick contrast agents.

3) **OG Tube Lube** - ~5 cc is used to lubricate the OG tube lumen when suctioned before placement, or flushed through the OG tube into a trash can or stomach (if OGT is already placed). Packet included with each EsoSure.

4) **Contrast** - Injected through OGT into esophagus behind left atrium. E-Z-HD Barium Sulfate (Bracco Diagnostics) is preferred & adheres to esophagus.

5) **Temperature Probe (TP)** - Without balloon over thermistor is recommended.
To lubricate the OGT lumen, tear off the top of Tube Lube packet and suction Tube Lube while pinching the edges. Or, a 20 cc. luer lock syringe may be inserted into OGT connector with the OGT outside or inside the body (if OGT already placed) to flush the OGT lumen with 5 cc. Tube Lube, & 15 cc. of air.

Insert EsoSure into OGT outside body (first use only), to verify stylet does not extend past proximal OGT hole of your hospitals OGT. Wipe stylet and replace into holder after test.

Use abundant lubrication on the outside of the Temperature Probe (TP) and OGT to ease insertion, repositioning and keep them from sticking to each other during positioning.
➢ For easier insertion, rotate the head 30° away from the side of the mouth where the ET is taped.

➢ A Peds 5 or 6 Fr uncuffed ET tube or a nasal trumpet airway inserted orally will help as an introducer for the smaller diameter 9 Fr TPs which are more flexible and challenging to place.

➢ Curve the oropharynx by pulling the jaw towards the chest while the head is rotated 30°.
➢ Insert and advance the TP to the stomach and then the OGT, or insert and advance both together. (TP after OGT may stick and stop)

➢ Use Fluoro to confirm position of both in stomach as soon as possible, as advancing either after they have warmed in the body may create a loop in the throat or upper esophagus.

➢ Adjust OGT so that the radiopaque gap at proximal hole is near diaphragm.

* The most common difficulty with EsoSure insertion is when the OGT is not placed into the stomach during the initial insertion.
EsoSure Equipment - Contrast

Types of Contrast

Barium pudding, cream and paste- Difficult to inject, due to thickness, and made to slide through the esophagus resulting in a shorter coating time.


Gastrographin- Clear liquid is easiest to inject. Spreads easily but passes through for a shorter coating time. Lubricates OGT in lieu of Tube Lube.
Steps for Better Contrast Results

Contrast Injection with 20 cc Luerlock or Toomey Syringe

1) Verify OGT tip is in stomach with Fluoro and OGT has been flushed with Tube Lube.

2) Mix EZ-HD Barium Sulfate with water per instructions. Gastrografin has been used as well. It passes through esophagus quickly but acts as a lubricant, negating the use of Tube Lube. Both contrasts are pulmonary toxic.

3) After transeptal (to avoid obscuring cardiac anatomy under fluoro) withdraw OGT to place tip above diaphragm. Gap in OGT radiopaque strip indicates proximal hole.

4) Withdraw and slowly inject 10 to 20 cc of contrast under fluoro while moving OGT 1”-2” up and down behind heart until lumen is visible. Do not over fill.

5) Re-advance OGT into stomach.

6) Inject 30 cc of air to flush Barium Sulfate through OGT into stomach. (If this is omitted, the barium sulfate will harden and prevent the movement of the stylet inside the OGT or use of the OGT for suctioning.)

7) Insert EsoSure stylet per protocol.

8) *** Suction stomach & esophagus while slowly withdrawing OGT at end of case.
It has come to our attention that an esophagram is a billable procedure and the Physician and Hospital may be compensated for the materials and time it takes to evaluate the esophagus in it’s baseline state and during deflection to reduce the chance of injury.

“There are also many clinical situations where an esophagram (code 74220) by itself (without an upper GI examination) is an appropriate diagnostic imaging procedure.”

Also reference the AMA/ACR Clinical Examples in Radiology, Summer 2006, pp. 4-5, for more information on the coding of an esophagram.

New Esophageal Enhancement Agents for Consideration

Iotrolan Contrast:

• To date, Barium Sulfate products and Gastrografin have been the only contrast materials I am aware of to be used in the esophagus during AF ablations.

• The primary reason that contrast is not used more frequently, is that these products are pulmonary toxic and pose a small risk for aspiration. There is a product called Iotrolan (trade name Isovist) which is not pulmonary toxic according to the studies I have read. If you would be interested in investigating Iotrolan, I think it has the potential for assisting with esophageal visualization, especially to determine the baseline luminal diameter and the distance from the ablation catheter to the esophageal border.

Lawson & Definity Ultrasound Enhancement:

• A number of practitioners are working to reduce or eliminate fluoro usage during their procedures. Ultrasound visualization of the esophagus yields marginal results most of the time.

• Lumason (Sulfur hexafluoride lipid-type A microshperes by Bracco) and Definity (Perfluten liquid Microspheres) for intravenous or intravesical use to enhance the quality of US images. If you would be interested in exploring either one, it may offer benefits as the vast majority of EPs utilize US during their procedures. (Please let me know if you try either of these products.)
Use EsoSure Movement with ICE to Identify the Esophagus

An unrecognized...
- dilated esophagus
- hiatal hernia
- abnormally stretchy esophagus

... may give the EP Physician a false sense of awareness of the esophageal borders. Always verify the esophageal borders with ICE if contrast not used.

Movement facilitates ICE evaluation of the Esophagus

1) While the EP Physician is actively scanning the esophagus with ICE;
2) Smoothly slide the EsoSure stylet 2”-3” in and out of the OG Tube several times to create movement in the esophagus;
3) During this time, have the mapping person record the esophageal position and place it on the 3D map;
4) In the same manner, slide the temperature probe in and out ~1” to better identify the position of the temperature probe within the esophageal image.
Temperature Probes- Poor

All of the 50+ EP Labs I have visited use Temperature Probes (TP) during their AF ablations. Unfortunately, the most common TP provided by anesthesia has a balloon over the thermistor (A) and is a poor choice. Many Electrophysiologists are not aware that this TP is being used and it’s negative aspects.

TPs with a balloon have three negative consequences:

1) Air between thermistor and sheath and sheath and the balloon, which enclose the thermistor, insulate the thermistor and have been demonstrated to significantly delay rapid temperature increases. (13)

2) The balloon has a larger diameter than the TP itself. The standard 18 Fr TP has a 27 Fr balloon (9 mm in diameter). This enlarges the esophagus AP and laterally (B & C), pressing it against the LA, increasing the potential for thermal injury. (15)

3) When used during deflection with the EsoSure, the balloon does not slide over the OG tube, which makes optimal TP positioning more difficult.
These manufacturers and models of single pole TPs do not have the balloon over the thermistor and this gives them three benefits over the balloon models. (Covidien, DeRoyal, Novamed, Smith Medical, Truer, et al)

1) Less insulation around the thermistor provides a quicker response to increases in temperature. (13)

2) The 9 Fr or 12 Fr TP is much smaller in diameter than the 18 Fr TP with 27 Fr balloon and does not stretch the esophageal lumen. (B1 vs B2). Do not ablate over an OGT or TP as they have been shown to press the anterior wall of the esophagus against the posterior wall of the LA and increase the incidence of thermal injury. (15) An orally inserted Nasal Trumpet or Peds ET tube may be used as an introducer.

3) The smooth surface makes for easier and better TP positioning along the side of the esophagus closest to the thermal source during esophageal deflection as distance is of great importance. (C)

Multi-pole TPs are also available. However, their higher cost and hardware requirements need to be weighed against their potential benefits. (D) Temperature probes with exposed metal thermistors are discouraged. (14)
Ordering Information for Single Pole Temperature Probes:

* DeRoyal Industries, Inc.
  Ref # 81-020409 for 9 Fr model
  They also make a 12 Fr model.

Novamed, Inc.
Ref # 10-1620-001 for 12 Fr model.
* An EP catheter can be placed inside this sheath for location on a 3D map.

Smiths Medical ASD, Inc.
Ref # ER400-9 for 9 Fr model or
#ER400-12 for 12 Fr model

Truer Medical, Inc.
General Purpose Probe Ref # GP14400 14 Fr
(EsoSure’s manufacturer and distributor have no financial relationship with any of these companies.)

• The DeRoyal 9 Fr model is recommended due to a combination of quick temperature response, small diameter, low friction coating and firmest 9 Fr shaft for ease of placement.
Who is the best choice for inserting the EsoSure?

<table>
<thead>
<tr>
<th>Anesthesia Provider- No</th>
<th>EP Nursing Staff- Yes</th>
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<tr>
<td><strong>Pros:</strong></td>
<td><strong>Pros:</strong></td>
</tr>
<tr>
<td>➢ Experienced with OG and airway management</td>
<td>➢ Will have regular use of device</td>
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<tr>
<td>➢ Positioned at head of table</td>
<td>➢ Experienced inserting OG/NG tubes</td>
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<tr>
<td>➢ Rotating staff will have infrequent experience (Consistent staff is good)</td>
<td>➢ Frequent use will make for easier and quicker insertion and positioning</td>
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<tr>
<td>➢ Takes 2-3 procedures to become comfortable, and</td>
<td>➢ More familiar with fluro images</td>
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<tr>
<td>➢ Takes regular use to become proficient</td>
<td><strong>Cons:</strong></td>
</tr>
<tr>
<td>➢ Infrequent use makes for lower efficiency and competency</td>
<td>➢ May not be allowed by Hospital</td>
</tr>
<tr>
<td></td>
<td>➢ May not feel comfortable with procedure (Once done, this abates)</td>
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*Equate learning to use the EsoSure to learning to start an IV. It needs to be done regularly in order to become familiar with the feel and the process.*
Insertion- EP Staff Assisted by Anesthesia

- Insertion is most effectively done when EP Staff inserts the EsoSure and Anesthesia performs a good head tilt-jaw thrust to straighten and open the airway. This will assist the stylet in passing through the oropharynx and upper esophagus.

- Rotation of the primary curve from one side to the other is also easier with one person rotating the OGT at the mouth and the another simultaneously rotating the handle in the same direction.

- Anesthesia and EP Nursing Staff collaborating with both of these tasks is very helpful.
### Workflow Options - When to deflect the Esophagus

*The OGT should to be inserted prior to anticoagulation to limit the possibility of bleeding. It can be removed if deflection is not needed.*

#### Deflect Prior to Transeptal

**Pros:**
- Does not interrupt procedure flow
- Done in all first time AF ablation cases as Eso is of concern in most all cases
- Insertion done after ET intubation, as residual anesthetics at higher level for easier passage
- Gives stylet time to become firmer and respirations time to massage deflection further
- Gives staff time to rotate to R side if initial deflection is to L, without interrupting flow

**Cons:**
- Increased expense when used in every case
  - ($365 - $395 ea)
- Separate fluoro. (May be placed during CS placement.)

#### Deflect After LA Mapping

**Pros:**
- Will only be used in cases where needed

**Cons:**
- Insertion with deflection to L will need to be rotated to R which takes 1-2 min depending upon Staff familiarity
- Will take a few minutes for stylet to warm and create maximum deflection
- A dose of anesthetics may need to be given to ease insertion

*If contrast is used in the esophagus, it is prudent to inject the contrast after the transeptal is completed, as the contrast may obscure fluoro views of anatomy during the transeptal.*
EsoSure Insertion Tips

- Use Fluoro to verify the TP and OGT are in the stomach before insertion. Identifying and advancing OGT and TP later, after warming, may create a loop.

- Short acting muscle relaxants (Succinylcholine) facilitate passage of the EsoSure stylet and relax the esophagus for greater deflection. Beware that muscle relaxants (especially non-depolarizers) may affect phrenic nerve testing. Rocuronium may be reversed with Sugammadex. If paralytics are contraindicated or not desired...

- Deepening anesthesia before EsoSure insertion will reduce bucking and ease insertion, if paralytics not desired, but may not increase esophageal deflection.

- Have a second staff open the airway with a head tilt - jaw thrust maneuver. (The single most helpful step for easy insertion.) DO NOT force the stylet if it stops.

- Inject 20 cc. of room temp or cold water or IV fluid immediately before insertion.

- The angle of stylet insertion should be in a cranial-to-caudal direction.

- A Miller 3 or 4 blade or Glidescope may facilitate passage when the airway is restricted.
Cooling the OGT Makes for Easier Insertion and Rotation

The temperature programmed Nitinol stylet assumes a firm curved shape ~3 seconds after entering the body.

Injecting 20 cc of room temp water or IV fluid into the OGT delays curve formation to ~10 seconds and 20 cc of ice cold water delays curve formation to ~20 seconds.

This makes both insertion and rotation easier. Keep 2-3 20 cc syringes in a cup of ice.
Using the EsoSure - Collect Items and Practice

➢ 18 Fr 48” Salem Sump OG Tube (OGT);
➢ 3- 20 cc syringes filled with water or IV Fluid. Placed into a cup of ice is optimal for better cooling.
➢ 1 - 18 ga needle.
➢ Tube Lube (included in each EsoSure box).
➢ EsoSure.
➢ Temp Probe (TP) if used. (Smooth shaft TPs without a balloon are much better.)
➢ Contrast, if used.
➢ Practice inserting EsoSure into holder. Same feel as into OGT.
Endotracheal **Intubation** is required for EsoSure use.

Suction Tube Lube from packet through 18 Fr 48” Salem Sump OGT to **lubricate OGT lumen** or flush with 20 cc syringe. (Olive/mineral oil OK.)

GENEROUSLY **lubricate TP & OGT and insert** orally prior to anticoagulation. Insert TP before OGT, or insert together.

**Confirm with Fluoro** that BOTH TP and OGT are in stomach.
#1
➢ Ask anesthesia to give a bolus of anesthetics/paralytics before EsoSure insertion to reduce gag reflex and ease placement.
➢ Stand in a position to watch the fluoro screen, if possible.
➢ A head tilt - jaw thrust maneuver by another staff is essential for rapid advancement of the stylet.
➢ Flush OGT with 20 cc cold fluid immediately before insertion of stylet. This will allow for rotation before firming of curve, if needed.

**Insertion of the EsoSure in 4 steps**

A good head tilt – jaw thrust opens and aligns the airway for easier insertion.
#2

- Insert EsoSure into OGT lumen holding the end of the OGT in one hand so it is straight.
- Quickly advance the stylet 2”-3” at a time to diaphragm.
- Use AP Fluoro past the throat.
- Stop advancing when stylet tip reaches the diaphragm.
- If the stylet stops advancing during insertion, **don’t force it**, fix the stylet position and ...

Strain OGT and align towards feet for easier insertion.

Rotating the head 30° away from the ET tube makes for easier insertion of OGT, temp probe and EsoSure stylet.
#3

- Quickly retract the OG tube back over the fixed stylet ~2” at a time for 3 times to pull out the loop.
- Then advance the stylet until the tip of the stylet is at the diaphragm.
- If the stylet will still not advance, pan up with fluoro. *DO NOT FORCE THE STYLET.* Remove if it will not advance.
Seat Stylet in OGT & Position

#4

➢ If the white stopper at the handle seals the OGT first, and the stylet tip is not to the diaphragm, advance the OGT/stylet together so tip is at diaphragm.

➢ If the stylet tip is at the diaphragm and the stopper is not seated in the OGT, retract OGT.

➢ If curve is not on correct side, rotate immediately to the desired side before stylet takes on firm state.
3 Curve Positions: 1- Primary Curve to Right  2- Secondary Curve to Left

The larger Primary/Distal curve is usually oriented to the right (1) after insertion.

If deflection is desired to the left, there are two ways to achieve this.

White side of handle up for Primary curve orientation to right. Not 100% correlation. Verify with fluoro.

When the Primary curve is to the right, advance the EsoSure/OG to create leftward deflection with the smaller Proximal curve.

First- Advance the OGT/stylet & TP together so that the tip passes through the diaphragm and angles left towards the stomach. This will position the Secondary/Proximal curve to the left. (2).

* If needed, gently push the stylet further in to bow out the secondary curve under fluoro, to increase deflection. Retract TP if deflection adequate.
If the secondary curve does not provide adequate leftward deflection, retract the stylet inside the OGT (This leaves the TP at the diaphragm, as retracting the OGT often pulls the TP back and will hinder optimal positioning).

**Procedure:**

1) Withdraw the stylet until the tip is at diaphragm;
2) Inject 20 cc cold water into OGT;
3) then immediately rotate the OG tube at the mouth and the EsoSure handle 2-3 revolutions in the same direction.
4) If the stylet does not rotate or if it spins 360 degrees, try rotating it in the opposite direction.
5) Release pressure as soon as rotation occurs. Anatomy may prevent deflection.

Rotate handle and OGT clockwise towards the spine (R>L), and if that does not work try counterclockwise. It may take a few attempts to get the feel. One person rotating the handle while another rotates the OGT is helpful.

Inject 20 cc. cold water or IV fluid through the OGT to cool and soften the stylet just before rotation.
The primary curve towards the left is in position 3. With the stylet in this position, it MUST NOT be advanced past the diaphragm as it curves away from the stomach. To change the side of deflection from left to right, inject 20 cc cold fluid into OGT, then rotate the stylet and OG tube together from the 3 position, to the 1 position, or the stylet may be removed, allowed to cool and reinserted with the handle reversed.
To remove the stylet simply hold the end of the OG tube and smoothly withdraw the EsoSure by the handle.

Leave the OG in place to suction out gastric contents and the esophagus during removal of the OG tube. If esophageal contrast was used this is particularly essential as contrast is pulmonary toxic. Ensure that airway reflexes return prior to extubation.

Discard the EsoSure.
**Unilateral Deflection for a Lateral Esophagus: Primary Curve to One Side**

A) The OG tube must be inserted before anticoagulation. The EsoSure may be inserted at any time during the procedure.

B) Prior to insertion of the EsoSure for left deflection, the temperature probe was advanced to the stomach and then retracted to this position after left deflection.

C) The LAO 43 view demonstrates posterior as well as lateral displacement of the esophagus. The temperature probe assists with visualizing esophageal luminal diameter during deflection. 

Courtesy of Dr. Bruce Lindsay, Cleveland Clinic Hospital. Cleveland, OH. June, 2016.
Bilateral Deflection : Rotating the Primary Curve

A) The baseline OG Tube lies along the right side of the vertebrae. 

B) The EsoSure was inserted for rightward esophageal deflection to increase the deflection distance to the right.

C) After right deflection, the EsoSure was rotated for left deflection. The temperature probe should have been advanced before rotation of the EsoSure, and then retracted to the inside of the curve.
Bilateral Deflection for a Medial Esophagus: Advancing and Rotating the Primary Curve

For additional deflection, the stylet tip was retracted to the diaphragm and the larger primary curve was rotated to the left for better deflection outside the left border of the spine.

Baseline esophagus was inside the left spinal border in the AP view.

To go from right to left deflection, the distal half of the primary curve was advanced past the diaphragm to the stomach bringing the secondary curve inferior for left deflection near mid spine. The stylet could have been advanced further to bow out the curve further.

Improved deflection with new version of EsoSure stylet introduced December, 2017.

These were the first two cases where the new stylet with greater curve strength was used.
Inserting the stylet and allowing it to sit 5-10 minutes while other tasks are being done, gives breathing motion time to massage the esophagus and allow for more movement.

Muscle relaxants relax the airway and esophagus for easier insertion and greater deflection. Coordination between the Physician and Anesthesia is necessary to not interfere with phrenic nerve testing. Short-acting Succinylcholine has a quick recovery time, or Rocuronium may be reversed with Sugammadex.

With the secondary curve giving left deflection, push the OGT/stylet 1”-2” towards the stomach to bow the stylet and esophagus further towards the left to increase deflection. Tape the OGT to the corner of the mouth, if needed, to keep the OGT/stylet from springing back.

Always slide the OGT/stylet and TP in and out to place the curve apex at the optimal position.

Change the course of deflection from posterior-lateral to lateral or vice versa (next pg).

If deflection past the midline does not occur give a deep inspiration and hold it for 5 seconds to see if increasing the AP chest diameter and the distance between the posterior LA and spine will assist.
The esophagus slides between the aorta and left atrium. Best seen in AP view. Infrequent.

1 Right Lateral: Esophagus slides between the right lung and left atrium. Best in AP view. Infrequent.

2 Right Posterior-Lateral: The esophagus slides between the right lung and right side of the vertebrae. Best in RAO view. Frequent.

3 Left Posterior-Lateral: Where the esophagus slides between the aorta and the vertebrae. Best visualized in LAO view. Frequent.

4 The esophagus slides between the aorta and left atrium. Best seen in AP view. Infrequent.

Each person's anatomy is different and most individuals will not have all 4 courses.
Right Posterior-Lateral: Where the esophagus slides between the right lung and right side of the vertebrae. Best in RAO view. Frequent.

Left Lateral: Where the esophagus slides between the aorta and the left atrium. Best in AP view. Infrequent.

Left Posterior-Lateral: Where the esophagus slides between the aorta and the vertebrae. Best visualized in LAO view. Frequent.

Right Lateral: Esophagus slides between the right lung and left atrium. Best in AP view. Infrequent.

Technique to change the deflection course:

1- Retract stylet 4-6” inside OGT
2- Rotate the handle and 180° in the direction of the desired new course (2-3 revolutions is often required to change sides of deflection);
3- Re-advance the stylet so the primary curve follows the new course.

*Accessing a new course for deflection is not assured due to anatomical variations.
1- Prior to anticoagulation, insert **OGT** and **TP** into stomach & confirm with Fluoro.

2- Insert **EsoSure** for R or L deflection, as needed.

3A- Retract **TP** to optimal position.

* Adjust **TP** and **OGT/Stylet** up and down together to be adjacent to ablation catheter tip.
Optimal Temp Probe Placement for Subsequent Deflections

4- Advance TP and EsoSure Stylet/OGT together.

5a- If L deflection is adequate, retract TP to inside of curve.

5b- If deflection with the secondary curve is not adequate, withdraw the stylet INSIDE the OGT, to not pull the TP back with the OGT, and ... or Slide stylet inside OGT if you do not want to move the TP.

6- Retract EsoSure Stylet inside OGT so tip is at diaphragm, inject 20 cc cold water, then rotate for L deflection.

*Slide stylet inside OGT if you do not want to move the TP.
Optimal TP and EsoSure Curve Position relative to Ablation energy.

Adjust the Apex of the EsoSure curve, the TP Tip, and Ablation source in a horizontal line.
**Optimal Circa-S Placement for Initial & Subsequent Deflections**


2- Advance EsoSure/OGT to deflect L with secondary curve.

3- Retract EsoSure Stylet inside OGT so stylet tip is at diaphragm (this avoids pulling the Circa back as it may stick to the OGT), then rotate stylet/OGT for L deflection.

*The curves of the Circa may catch on the OGT and be pushed outward.*
Reasons for Minimal or Unsuccessful Deflection

Anatomical differences between patients lead to different outcomes.

Minimal deflection may occur to the right, left or both sides. There is a higher probability of reduced deflection in patients with:

- A history of smoking or COPD creates increased lung density & stiffness.
- Left atrial enlargement may compact the area where the Eso is deflected.
- Inflammation & sclerosis post CABG/thoracic surgery may stiffen tissues.
- With GERD, eosinophils may infiltrate the esophageal walls and make it stiffer.
- A posterior PV takeoff may block deflection towards that side.
- Restricted distance between the LA posterior wall and vertebrae (Pg 46)
- RIPV & LIPV deflection is difficult when they are close to the diaphragm.

Unsuccessful deflection of the esophagus may be due to a dilated or stretchy esophagus, a hiatal hernia, or an inability to pass the OGT into the stomach. This image shows the EsoSure tip in a far L lateral position. When the OGT and TP were advanced, they prolapsed on the diaphragm.
When the space between the anterior aspect of the Spine and the posterior Left Atrial wall is +/- 0.5 cm, deflection of the left sided esophagus to the right may be prevented. This was true involving patients on the right.
Complications: The same potential for complications as with a TEE or gastric tube including trauma to the upper airway, esophagus, stomach or surrounding organs and tissues.

If EsoSure advancement stops, fix the stylet and retract the OGT back 6”, then advance the OGT/stylet together. Here, the OGT was advanced because it was not verified in the stomach immediately after initial insertion. Advancing a cool and stiffer OGT outside the body, when the OGT in the body is warm and soft, frequently results in curling.

Trauma to the posterior oropharynx is possible during insertion of the stylet or with advancement of the stylet/OG tube. No instances of airway trauma have been reported when appropriate lubrication on the OGT and airway opening was used during insertion.
Review case. **Pre Deflection evaluation:**

A) The CT shows a decreased space for deflection between the anterior surface of the spine and the posterior surface of the LA at the level of this slice. The Aorta's position may limit leftward deflection.

B) The LA image shows the RIPV angled posteriorly (it is hard to tell how much in this view) which may or may not interfere with rightward deflection towards this PV.

C) The OGT Fluoro image confirms with the CT in A that the Eso is midline over the spine, though it is unclear without contrast or further US evaluation if the OGT is in the R, L or middle of the Eso.

D) The blue dotted line is extend superiorly from the baseline OGT image in C as there was not a more superior AP image. Right deflection with the EsoSure has pulled the right edge of the Eso to the R border of the spine.

E) Left deflection with the secondary curve is to spine left.

F) Right deflection is best seen in RAO, as the most common path of movement is in a posterior-lateral direction along the spine and RAO is perpendicular to the plane of the stylet’s curve.

G) Right deflection in LAO is in plane with the curve and provides little information.

H) RAO is in plane with the L deflection curve.

I) This L deflection is with the secondary curve. Left deflection is best viewed from LAO, as the course of deflection is most frequently along the spine posterior-medial to the Aorta. This less than optimal deflection may be due to the proximity of the of the Aorta to the Spine and Left Atrium as seen in A.

Images courtesy of Dr. Thomas Dewland. Oregon Health Sciences University. Portland, OR. Sept. 2017
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