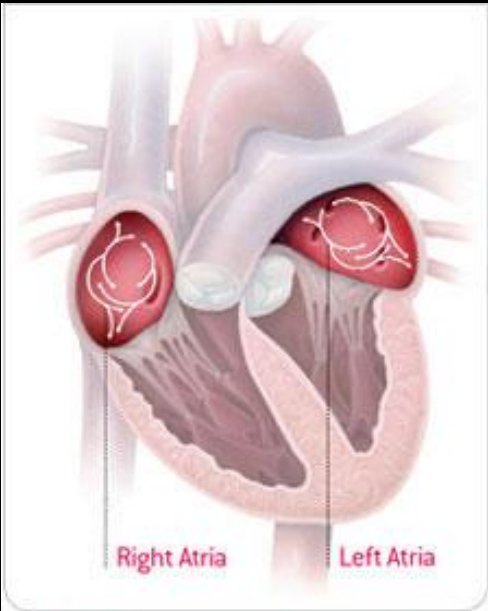
SentreHeart Lariat

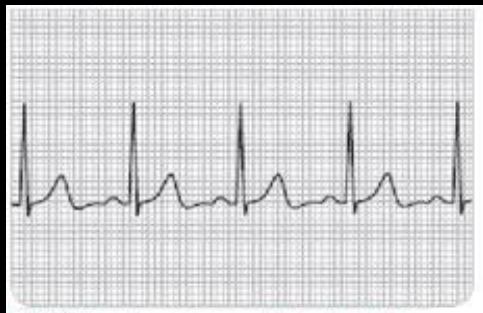
Left Atrial Appendage Suture Delivery Device

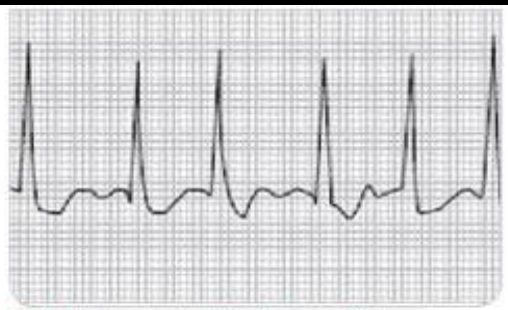
Janelle Martin Guerrero
CEPT 348 Presentation
Class of 2013

ATRIAL FIBRILLATION



AF is the irregular, chaotic beating of the upper chambers of the heart


ECG tracing a normal heart rhythm

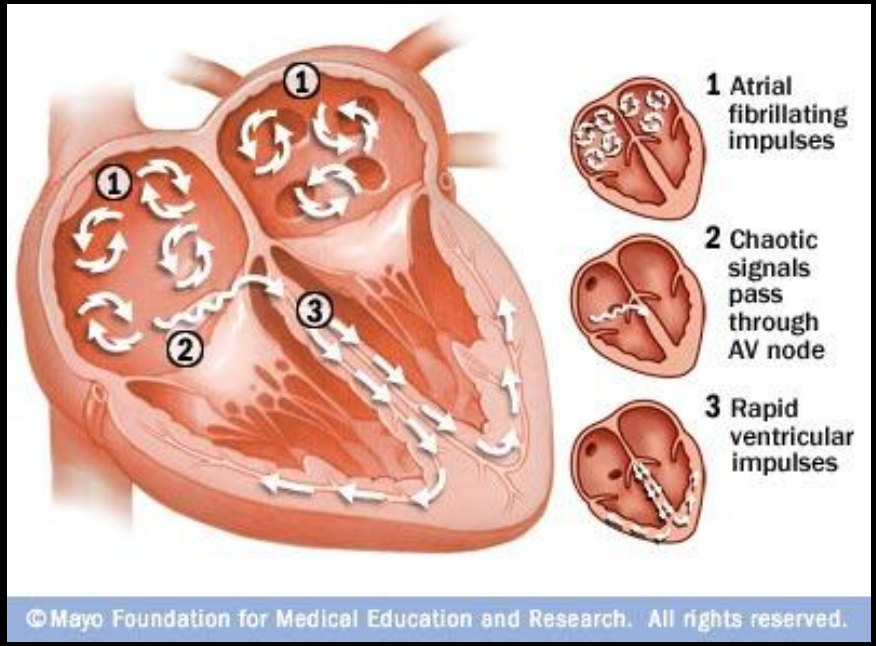

ECG tracing atrial fibrillation (AF). The rhythm is irregular and erratic.

In patients with Atrial Fibrillation (AF), blood tends to pool & form clots in an area of the heart called the left atrial appendage (LAA).

- The LAA is a pouch-like extension located in the upper left chamber of the heart.
- A blood clot that breaks loose from this area may migrate through the blood vessels & eventually plug a smaller vessel in the brain or heart resulting in a stroke or heart attack. 20% of all strokes are related to AF.
- Clinical studies show that the majority of blood clots in patients with AF are found in the LAA.

Blackshear J.L., Odell J.A., Appendage Obliteration to Reduce Stroke in Cardiac Surgical Patients with Atrial Fibrillation. Annals of Thoracic Surgery, 1996;61:755-759.

RISKS OF ATRIAL FIBRILLATION



Risks of Afib include:

- Stroke
- Cardiac Dysfunction
  - Increased LA pressure & volume
  - Decreased stroke volume
  - Shortened diastolic ventricular filling period
  - Regurgitation of AV valve
  - Irregular, rapid ventricular rate → potential LV systolic dysfunction
- Poor Quality of Life
- All-Cause Mortality

ATRIAL FIBRILLATION PREVALENCE

Prevalence:

- 2.2 million people in the U.S. have Afib
  - Median age: 75 (65-85 are 70% of Afib population)
  - For those older than 40, the prevalence averages 2.3%
  - For those older than 65, the prevalence averages 5.9%
- Diseases associated with Afib include:
  - Heart disease, coronary artery disease, heart valve disease, hypertrophy cardiomyopathy, congenital heart disease, obesity, diabetes mellitus, metabolic syndrome, hyperthyroidism, chronic kidney disease and status post cardiac surgery

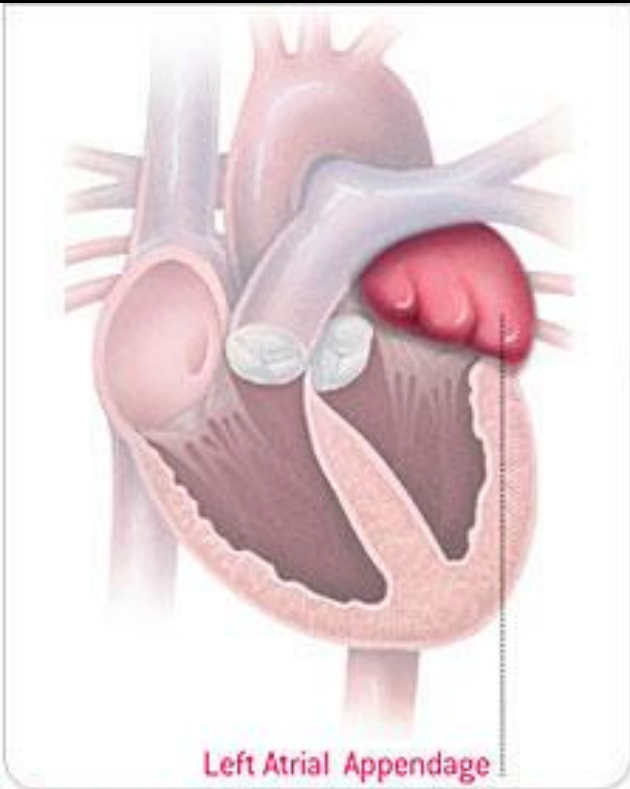
Risk Factors:

- Family history of CAD, polygenic & monogenic inheritance, birth weight, inflammation & infection, pericardial fat, autonomic dysfunction, prolonged QT interval, supraventricular tachycardias, decreased Mg levels, alcohol & caffeine, medications and decrease activity.

Afib & Stroke:

- A person with Afib is five times more likely to have a stroke than someone without Afib.
- 15% of people who have a stroke, have Afib
- 3 out of 4 Afib-related strokes can be prevented

STROKE PREVENTION



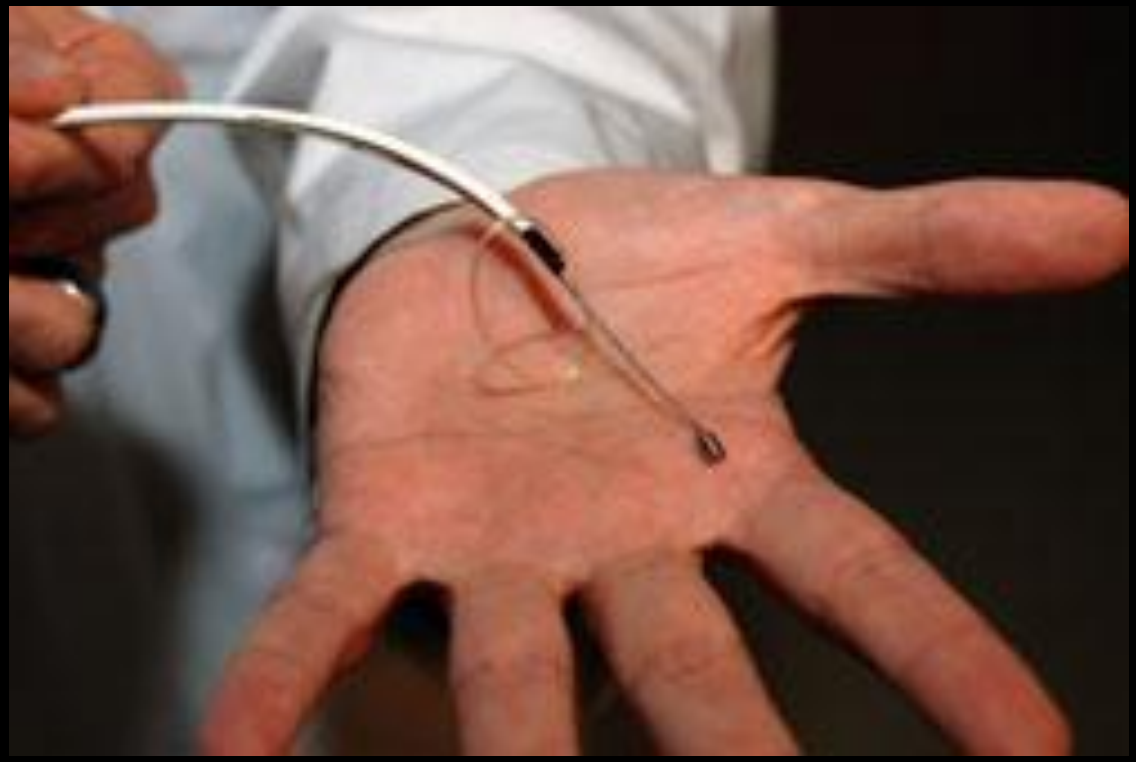
The Left Atrial Appendage (LAA) is a pouch like extension on the left side of the heart

- Since the majority of blood clots are found in the LAA, it is believed that closing off the appendage may reduce the risk of stroke & potentially eliminate the need for long term anticoagulation therapy.

- The LARIAT device occludes the LAA from heart circulation, & thus, the tissue becomes necrotic & dies. Therefore, blood clots from the LAA no longer increase the risk of stroke, CV death & systemic embolization. It also eliminates the need for long term anticoagulation therapy.

- An obvious patient benefit is the elimination of anticoagulants, which may reduce bleeding-related-events such as bruising, nose bleeds, GI bleeding, or more importantly, hemorrhagic strokes.

LARIAT SUTURE DELIVERY DEVICE



- The LARIAT device was invented by Dr. William E. "Billy" Cohn, Director of Minimally Invasive Surgical Technology at the Texas Heart Institute at St. Luke's Episcopal Hospital.
- The LARIAT snare device has been approved by the FDA in the treatment of Afib.
  - A "noose device" which closes off the LAA is inserted from outside the heart, (unlike the Watchman device which is inserted into the LAA from inside the heart).
- It is used in cases where the patient cannot tolerate anticoagulants.

LARIAT SUTURE DELIVERY DEVICE

The LARIAT is a teflon-coated, braided-polyester suture device designed to permanently cutoff the LAA from cardiac circulation. The Lariat leaves only a small remnant of braided polyester suture behind.

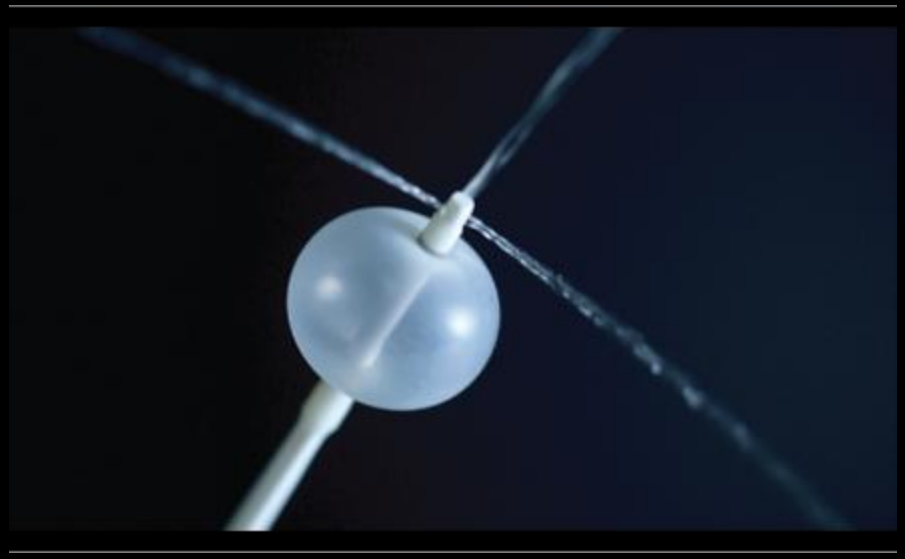
It consists of a six part system:

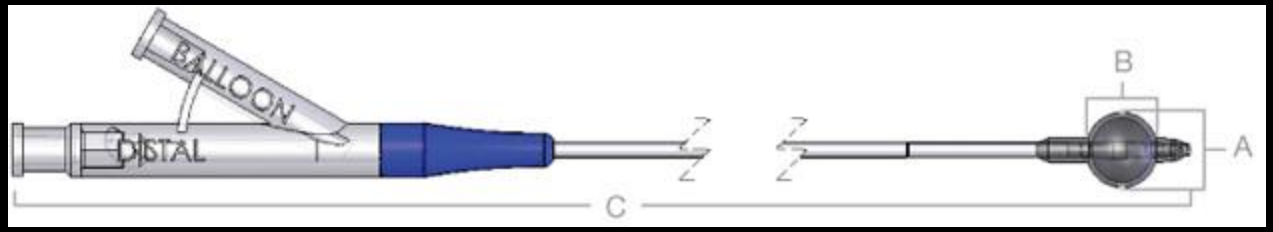
1) LARIAT suture delivery device
2) EndoCATH large occlusion balloon
3) FindrWIRZ guide wire system
4) SofTIP guide cannula
5) TenSURE suture tightener
6) SureCUT suture cutter

LARIAT SUTURE DELIVERY DEVICE

- Precise, user-controlled remote delivery of a 40mm pre-tied suture loop through access of 4.3mm or greater.
- Meltzer knot tightened with Tensure suture tightner.
- Collapsible snare retains suture until ready to deploy.
- Compatible with wide range of anatomical shapes & sizes (up to 40mm width, 20mm height & 70mm length)
- Braided polyester suture is left behind to maintain closure of the LAA.

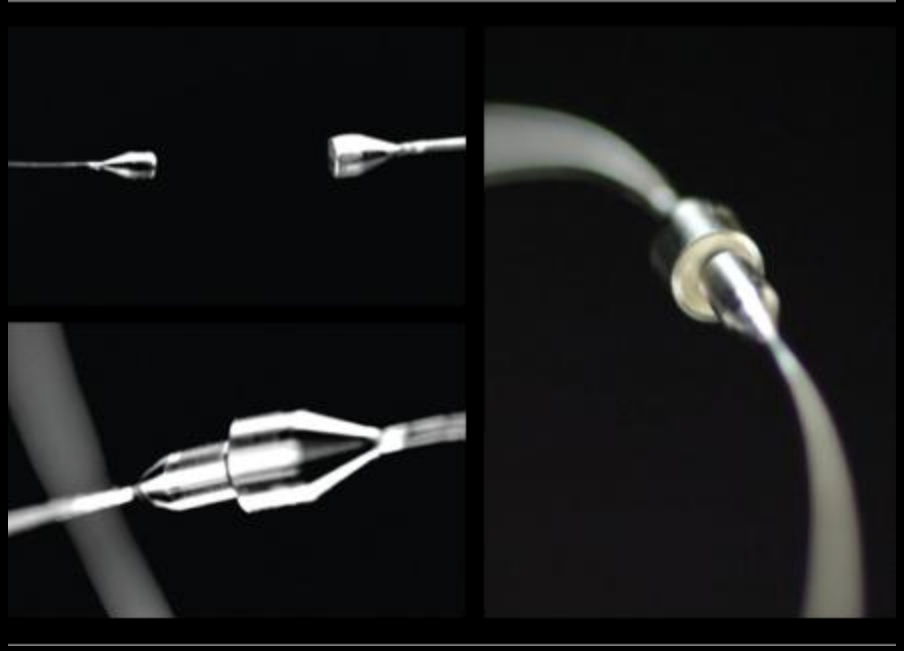
ENDOCATH OCCLUSION BALLOON

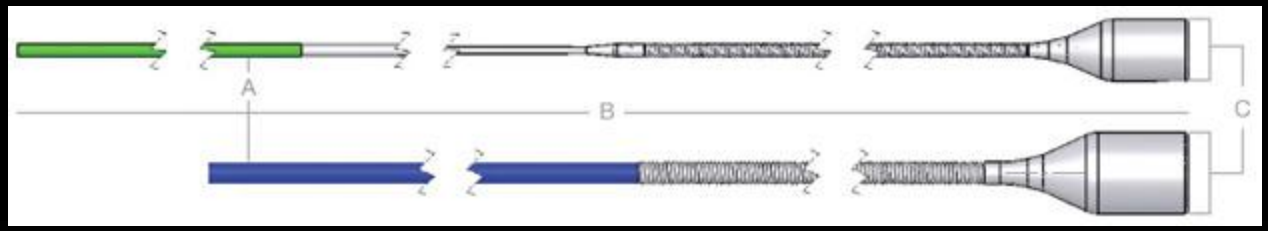




- Low profile, 15mm diameter x 12mm length balloon compatible with 9F access
- Distal perfusion holes for diffusion of contrast during angiogram
- Non-latex, polyisoprene balloon material allows elasticity with compliance
- 0.35" guide wire lumen for over-the-wire delivery
- Compatible with fluoroscopic & echographic imaging for proper placement

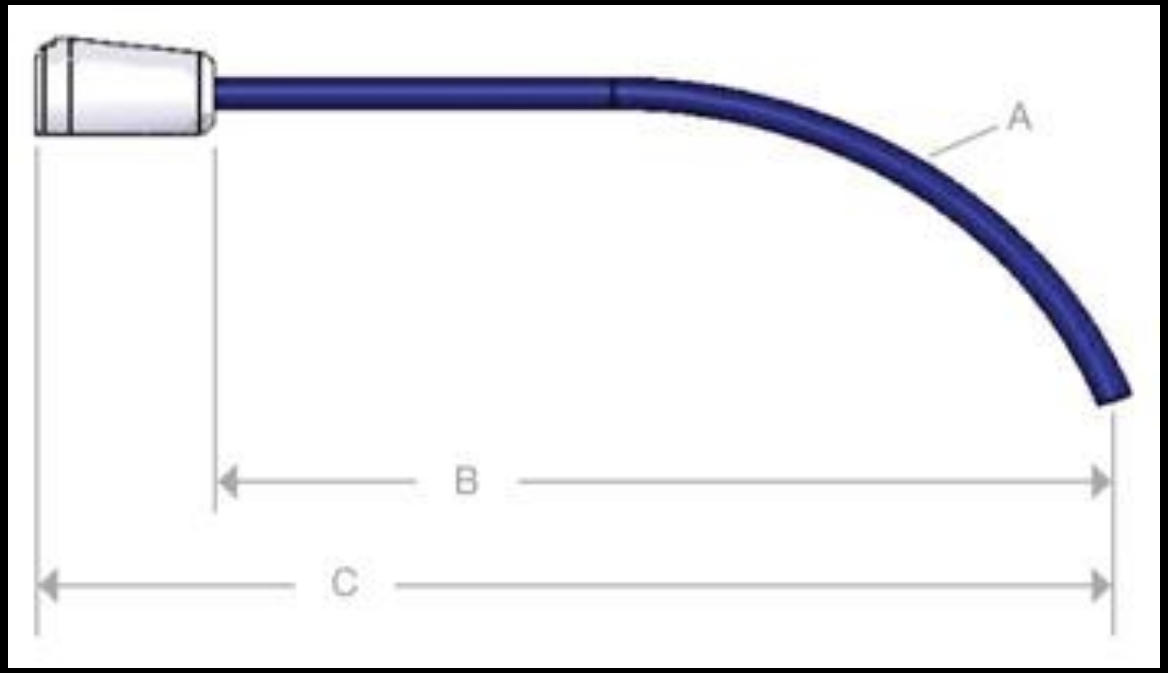
FINDRWIRZ GUIDE WIRE SYSTEM





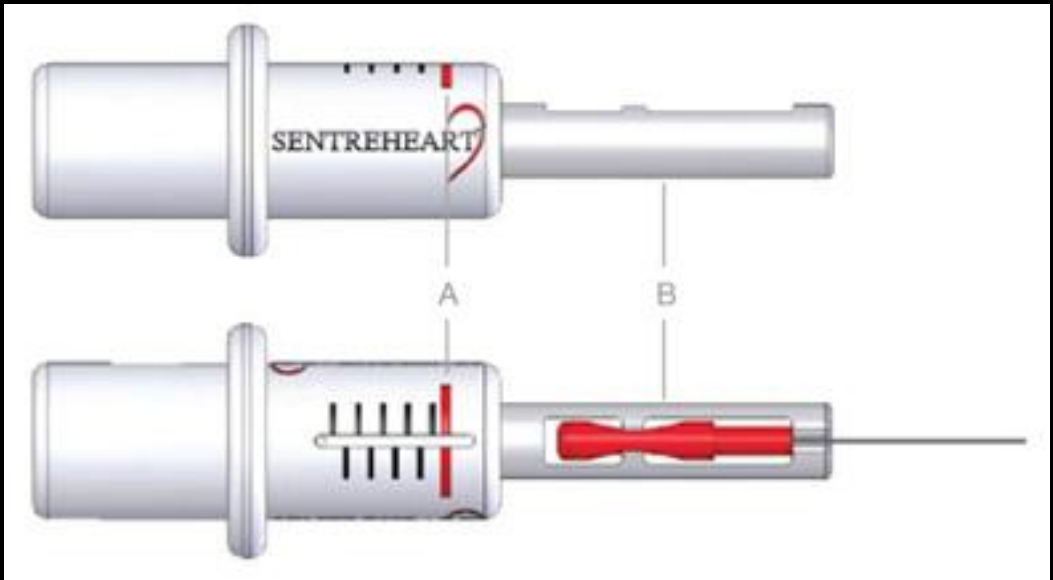
- 0.025" & .035" PTFE-coated, steerable guide wires enable positioning & placement at desired anatomic location
- Magnetic tipped guide wires locate each other when in close proximity & will attach
- Minimizes guide wire management requirements for diagnostic &/or therapeutic procedures
- Ideally suited for dual access procedures where control of positioning & placement are required
- Guide wire diameter: 0.25" & .035"; wire length: 220cm& 150cm; magnet diameter: 2.7mm & 3.5mm; introducer size requirement: 8F & 11F

SOFTIP GUIDE CANNULA



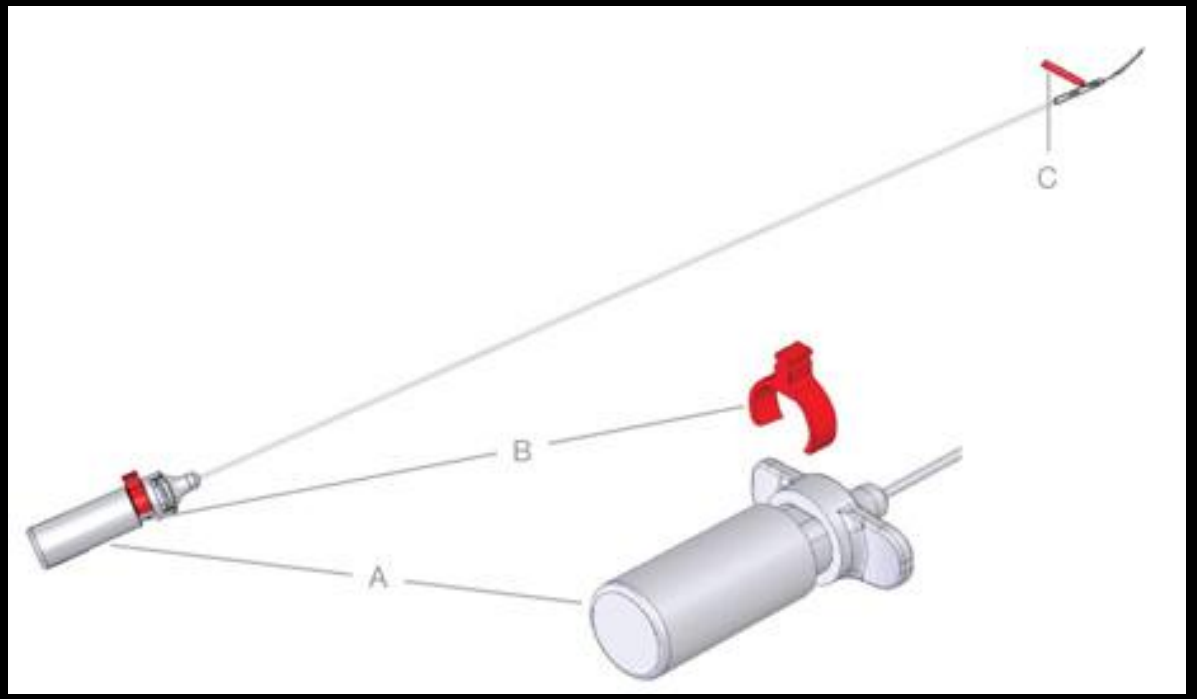
- The SofTIP guide cannula is designed to provide control during delivery & placement of the LARIAT.
- The SofTIP enables guidance & orientation of the LARIAT through a 4.3mm access for positioning at the targeted closure location.
    A. Diameter: 4.3mm (12.9F)
    B. Working Length: 22.5cm
    C. Overall Length: 25cm

TENSURE SUTURE TIGHTENER



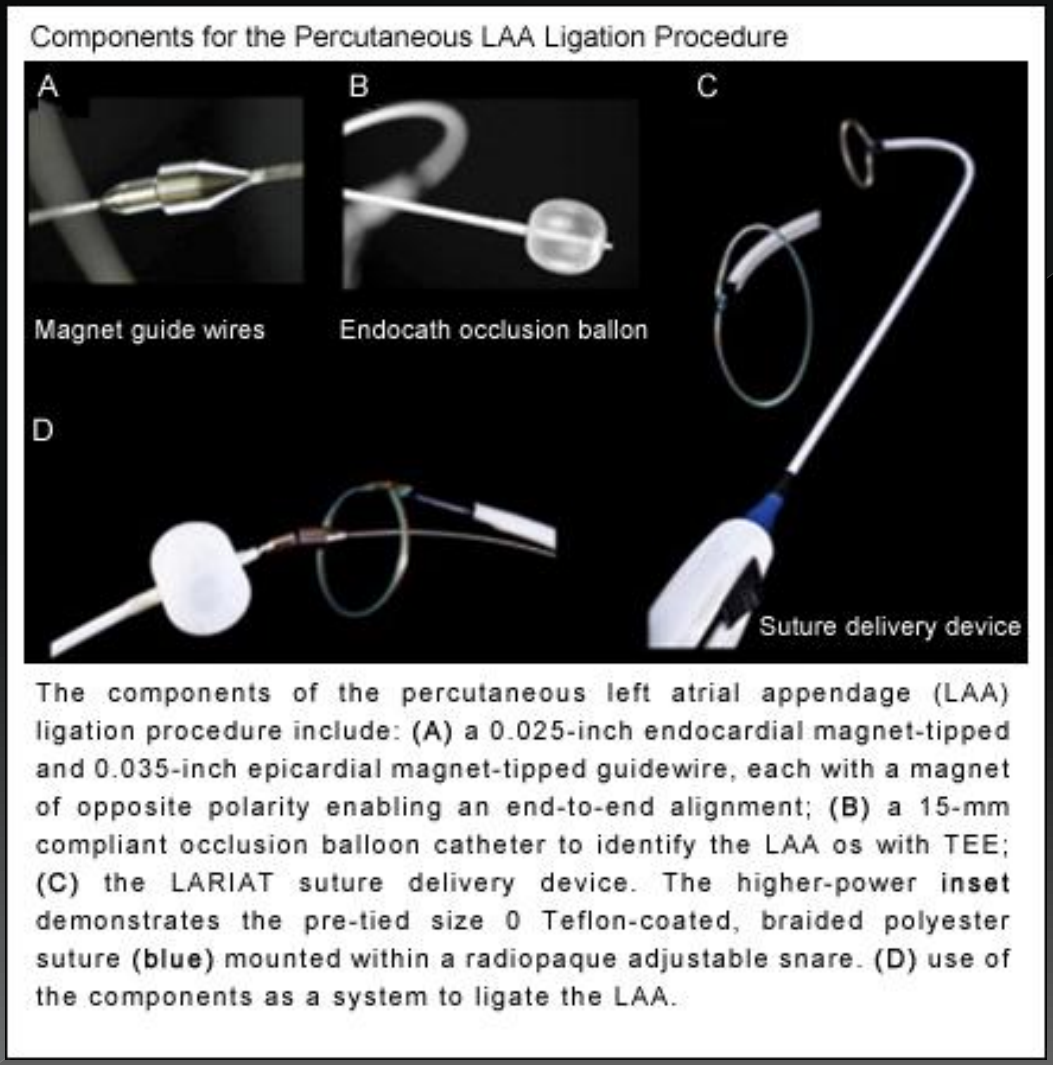
- Optimizes tactile feedback during tightening & minimize operator variability.
- Provides consistency in tightening.
    A. Tension indicator
    B. LARIAT suture release tab holder

SURE CUT SUTURE CUTTER



- The SureCUT suture cutter is designed to cut the multifilament suture included in the LARIAT system. The design enables rapid termination of excess suture without risk of cutting the tightened knot, as the cutting mechanism is placed behind the distal tip.
    A. Handle with cutting actuator
    B. Plunger lock
    C. Suture threader

Procedural overview



The components of the percutaneous left atrial appendage (LAA) ligation procedure include: **(A)** a 0.025-inch endocardial magnet-tipped and 0.035-inch epicardial magnet-tipped guidewire, each with a magnet of opposite polarity enabling an end-to-end alignment; **(B)** a 15-mm compliant occlusion balloon catheter to identify the LAA os with TEE; **(C)** the LARIAT suture delivery device. The higher-power **inset** demonstrates the pre-tied size 0 Teflon-coated, braided polyester suture **(blue)** mounted within a radiopaque adjustable snare. **(D)** use of the components as a system to ligate the LAA.

- Angiography is used to assess LAA anatomy, orientation, size & *proximity* to left circumflex coronary artery prior to procedure.
- TEE probe is inserted into the esophagus & images are obtained.
- Epicardial access is then achieved into the LAA via subxiphoid approach.
- Once epicardial space is accessed, a 0.035" wire is placed & the access is dilated to 14 Fr.
- Transseptal access in the LA is gained using 8.5 Fr SL1 guide catheter & BRK needle via femoral vein.

PROCEDURAL OVERVIEW

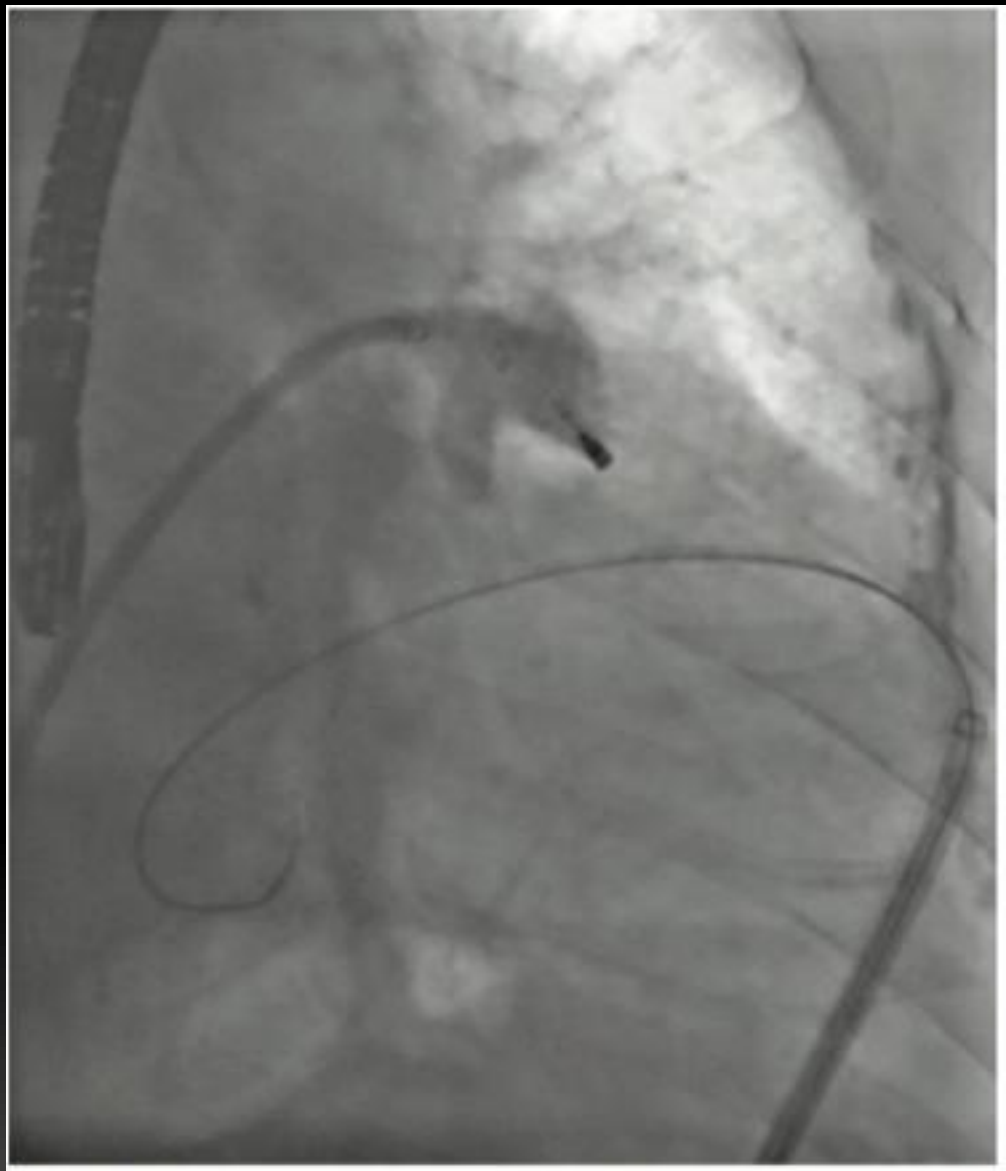


Figure 1. *Left atrial appendagram through the guidewire lumen of the EndoCATH with the endocardial FindrWIRE magnet at the apex of the left atrial appendage.*

- EndoCATH occlusion balloon & endocardial FindrWIRE are advanced together, through the 8.5Fr SL1 transseptal catheter with the use of fluoro in AP view.
- It is then guided to the LAA.
- The endocardial FindrWIRE is advanced to the anterior-most aspect of the LAA.
- Position is confirmed via TEE & angiography via lumen of the EndoCATH.
- Endocardial FindrWIRE is secured by closure of the rotating hemostasis valve.

PROCEDURAL OVERVIEW

Figure 2. *Endocardial and epicardial FindrWIRZ magnetically attached and occlusion balloon inflated at the ostium of the left atrial appendage.*

- Once the FindrWIRE is placed in the LAA apex, the 0.035" epicardial FindrWIRE is back-loaded into the LARIAT delivery system & both are advanced through the 14 Fr soft-tipped epicardial guide cannula.
- The distal tip of the LARIAT & FindrWIRE are advanced with fluoro guidance until the magnet located on the endocardial & epicardial sides attract & attach to each other.
- Occlusion balloon is then inflated at the ostium of the LAA & confirmed via angiography & TEE.

PROCEDURAL OVERVIEW

Figure 3. *Radio-opaque snare of the LARIAT device containing pre-tied suture fully opened and advanced over the left atrial appendage.*

- The radiopaque snare of the LARIAT that contains the pre-tied suture is fully opened & advanced over the appendage.
- A radio-opaque marker on the distal tip of the LARIAT is aligned with the proximal marker of the EndoCATH occlusion balloon that should have been positioned at the origin of the LAA.
- This is the initial placement for the closure of the LAA.
- With the snare still open around the LAA, the EndoCATH is inflated at the LAA ostium & visualized using TEE & fluoro.

PROCEDURAL OVERVIEW

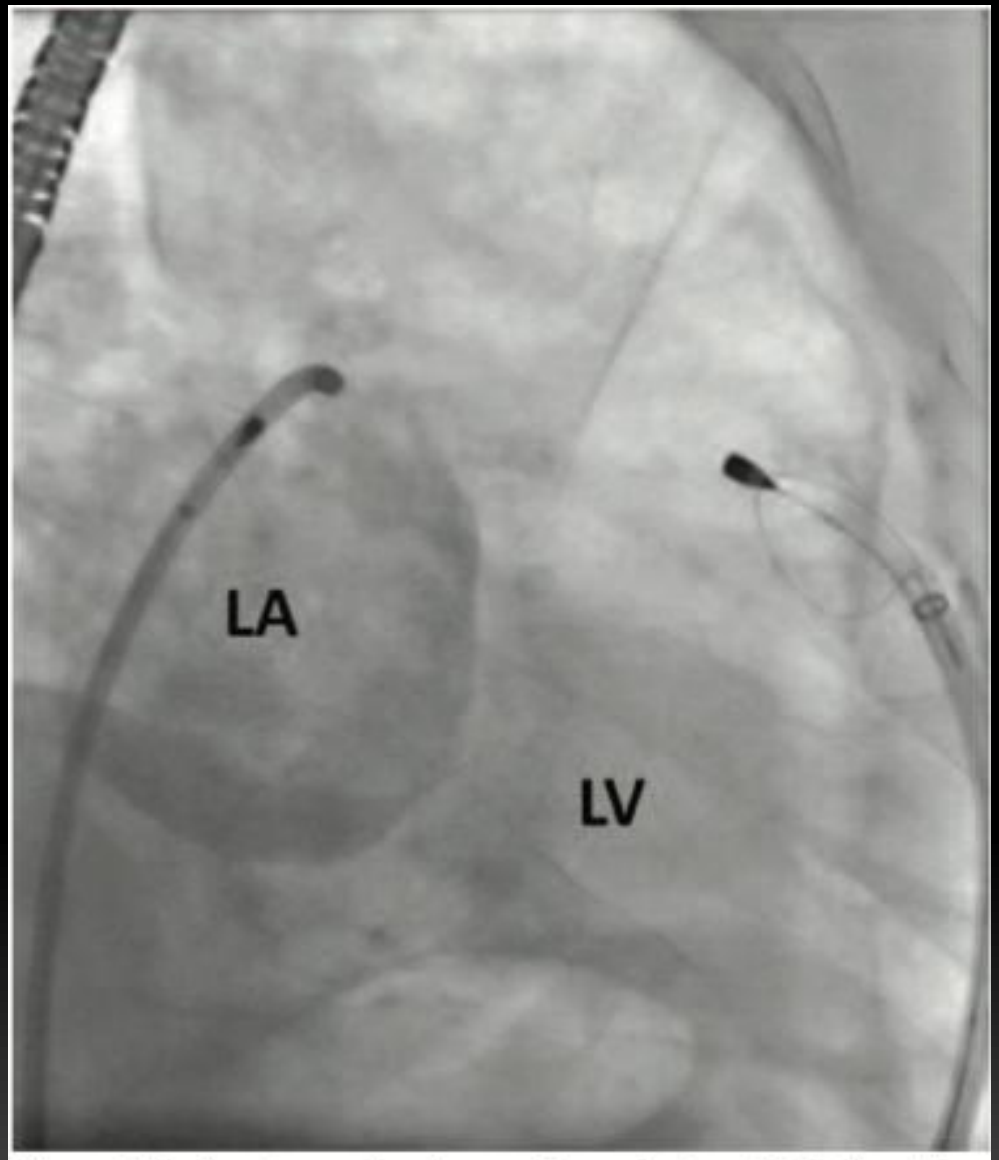


Figure 5. *Left atriagram showing complete exclusion of the left atrial appendage and no extravasation of contrast into the pericardial space.*

- The snare is then closed to ligate the LAA .
- Once there is confirmation of LAA capture & closure in the desired location, the EndoCATH is reinflated before suture is released.
- The inflated occlusion balloon acts as a platform for the suture release position & ensures that slippage off of the LAA cannot happen during tightening.
- The EndoCATH balloon is deflated & appendagram through EndoCATH lumen confirms primary closure.

PROCEDURAL OVERVIEW

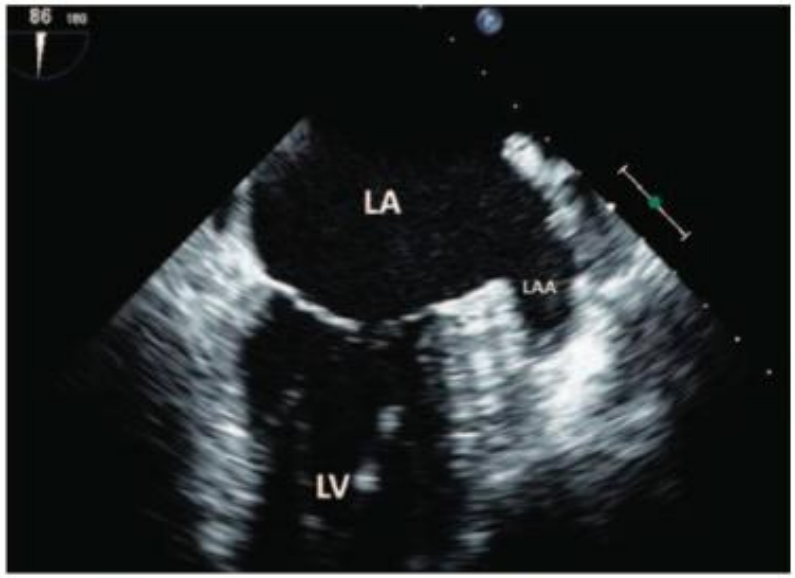


Figure 6. *Transesophageal echocardiography with color Doppler showing left atrial appendage preprocedure.*

Figure 7. *Transesophageal echocardiography with color Doppler showing complete exclusion of the left atrial appendage postprocedure.*

- The EndoCATH & FindrWIRE are withdrawn from LAA as a single unit & withdrawn from transseptal guide catheter.
- Final result is confirmed with left atriagram and color doppler TEE.
- The LARIAT device & 0.035" FindrWIRE are then removed & are exchanged for pigtail catheter, which is left in the pericardium for drainage.

VIDEO OF LARIAT DEVICE

- http://www.youtube.com/watch?v=CCKqayXzLDA
- From the *inside* of the heart a balloon is placed inside the LAA to expand it & make it accessible to the "noose" device which is inserted from the *outside* of the heart.
- The positioning balloon is withdrawn before the LARIAT noose is closed around the base of LAA.
- The "noose" completely closes off the LAA which dies & is no longer electrically active.

LARIAT PROS VS. CONS

Advantages of LARIAT:

- Complete control of the pericardial space in the event of cardiac perforation
- Lack of any endovascular hardware left behind
- Possible elimination of the need for post-procedure anticoagulation

Disadvantages of LARIAT:

- Need for simultaneous transseptal & pericardial access, which requires access to O.R. until staff are confidently able to perform procedure in the EP/Cath Lab. However, even in the EP lab, the O.R. team should be on standby in case of emergency cardiac surgery.
- Anatomic variables can limit candidacy for the device, such as LAA diameter > 40 mm, posteriorly rotated LAA, or pericardial adhesions from prior cardiac surgery or pericarditis.
- Risk of chronic pericarditis, due to infection of the percardium.

References

- "*Percutaneous Catheter-Based LAA Ligation & Management of Perioprocedureal LAA Perforation with the LARIAT Suture Delivery System*"; Drs. Ranjith Shetty, Joshua Leitner, & Ming Zhang. The Journal of Invasive Cardiology; Vol 24; Issue 11, November 2012.
- LARIAT Suture Delivery Device website: http://www.sentreheart.com/us/products/lariat
- "*Prevalence, Age Distribution, and Gender of Patients with Atrial Fibrillation*"; Drs. Feinberg, Blackshear, Laupacis, Kronmal & Hart. Arch Intern Med; 2013 Mar 13; 155(5): 469-73
- Journal of the American College of Cardiology website: http://content.onlinejacc.org/journal.aspx