

HELI-FX™ ENDOANCHOR™ SYSTEM OPERATING INSTRUCTION SUMMARY

For reference only. Refer to IFU for complete instructions.

Case Planning

- 4 EndoAnchors recommended in aortas ≤ 29 mm diameter (**Fig. 1a**)
- 6+ EndoAnchors recommended in aortas > 29 mm diameter (**Fig. 1b**)
- Modify EndoAnchor™ locations based on thrombus/calcium
- Modify anchor locations if using mobile C-arm (4 anchors: 30° RAO & 30° LAO; 6 anchors: 30° RAO, 30° LAO & 90° lateral)

Examples of fixed C-arm positioning

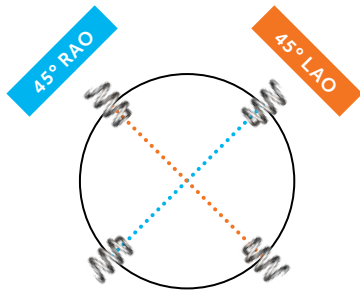


Fig 1a. 4 EndoAnchors

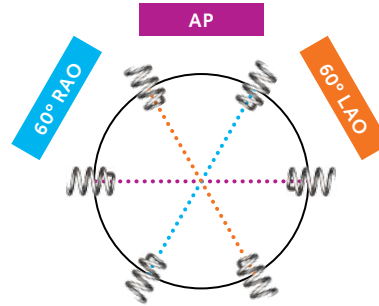


Fig 1b. 6 EndoAnchors

Device preparation

- Flush ports on guide, obturator and applicator
- Press applicator reverse button for 5 seconds to activate (**Fig. 2**)



Fig 2.

EndoAnchor™ loading

- Press applicator reverse button once
- Insert applicator tip into bottom of unused EndoAnchor™ cassette port (**Fig. 3**)
- If EndoAnchor™ is not fully loaded into applicator (**Fig. 4**), press forward button 2x then reload a new anchor



Fig 3.



Fig 4.

Inserting and Advancing the Heli-FX™ System

- AAA guide = 16F OD; TAA Guide = 18F OD; 16F or 18F long sheath is recommended
- Advance guide with obturator over 0.035" guidewire to seal zone
- Remove guidewire first, then obturator
Valve will bleed with wire only
- Insert applicator into guide and advance until white section of applicator is near guide valve (**Fig. 5**)





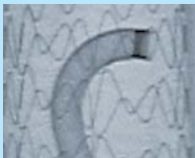






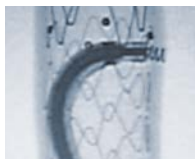


Fig 5.

TRANSFORMING ENDOVASCULAR ANEURYSM REPAIR.

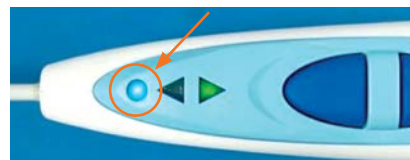
ENDOANCHORING TECHNIQUE

Eliminate parallax before anchoring.

<h2 style="color: orange;">P</h2>	<h3>Perpendicular positioning</h3> <ul style="list-style-type: none"> Rotate deflector knob on guide to visualize "C" marker as a solid line <div style="display: flex; justify-content: space-around; margin-top: 10px;"> (- Shape  - Straight line ) - Shape  </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;">    </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> Anterior Lateral Posterior </div> Position guide and applicator 90° relative to endograft <div style="display: flex; justify-content: space-around; margin-top: 10px;">    </div> 	
<h2 style="color: orange;">A</h2>	<h3>Apposition</h3> <ul style="list-style-type: none"> Stabilize guide. Advance applicator slowly until resistance is felt as it presses against the endograft and aorta wall. Under fluoro, confirm perpendicular positioning and guide recoiling against the opposite wall (Fig. 8) 	 <p style="text-align: center;">Fig. 8</p>
<h2 style="color: orange;">S</h2>	<h3>Stage 1</h3> <ul style="list-style-type: none"> Press the applicator forward button once to implant EndoAnchor™ halfway Visually confirm EndoAnchor™ tip has penetrated thru the endograft and guide/applicator position remained stable (Fig. 9) If acceptable, proceed to stage 2. Otherwise, press the reverse button and attempt again. Re-position if necessary. 	 <p style="text-align: center;">Fig. 9</p>
<h2 style="color: orange;">S</h2>	<h3>Stage 2</h3> <ul style="list-style-type: none"> Maintain constant position and pressure throughout deployment sequence Press applicator forward button again to fully implant EndoAnchor™ (Fig. 10) Slowly retract applicator under fluoro to ensure EndoAnchor™ is fully released 	 <p style="text-align: center;">Fig. 10</p>



After stage 2, if applicator does not disengage from EndoAnchor™, turn handle counter-clockwise.



If applicator detects an error, blue error light will activate. Replace applicator.

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