CONFIDENTLY TREAT WIDE NECKS WITH ESAR

EndoSuture Aneurysm Repair (ESAR) offers a durable, reinforced seal and protects against neck dilatation to minimize Type Ia endoleaks

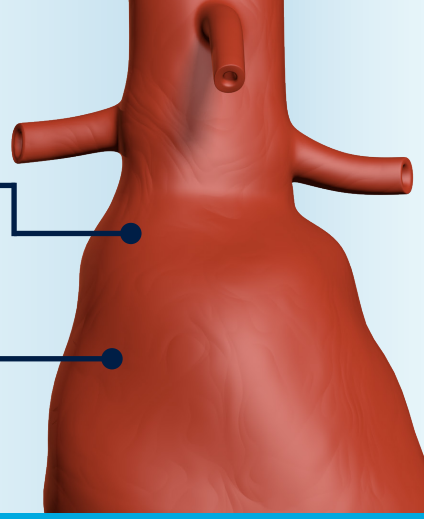
What are the challenges after EVAR in wide necks?

Neck Dilatation

Neck diameter is an independent risk factor for neck dilatation.[1] Diameter ≥25mm has greater risk of dilatation after Endovascular Aneurysm Repair (EVAR) (p=0.02).[2]

Type Ia Endoleaks

Wide necks are more likely to develop Type Ia endoleaks (p=0.049);[3] which transmit the highest pressures into the sac.[4]



Neck diameter predicts Type Ia endoleak risk*:

*observed with multiple endografts

GREAT Registry (n = 2678)

≥25mm predicts greater Type Ia risk (p=0.007)[5]

Device Included: Excluder™* graft

ANCHOR Registry (n = 221)

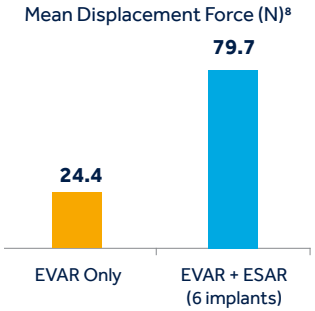
≥26mm (at lowest renal) predicts development of Type Ia (p=0.013)[6]

Devices Included: Endurant™ system, Excluder™*, Zenith™*, Talent™*, AneuRx™* grafts

™*Third party brands are trademarks of their respective owners.

ESAR enhances the proximal seal zone competency over standard EVAR

A Creates a durable, reinforced seal[7-9]



Tested in human cadaveric model

STRONGER ATTACHMENT[8,9]

Over EVAR[8] alone, via secure transmural wall fixation[10]

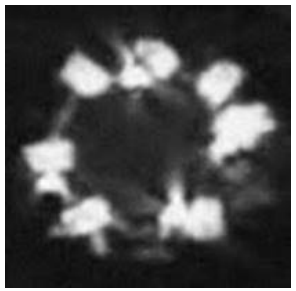


Image courtesy of Dr. Giovanni Pratesi

RADIAL FIXATION[11]

95.9% implants with adventitial penetration[7*]

Radial support just as with sutures[11]

*ANCHOR Primary AAA, at intended location

B Protects against neck dilatation[1]

Benchtop data on file at Medtronic

LOSS OF APPOSITION WITH EVAR

Neck expansion beyond nominal graft diameter[1,12]

Benchtop data on file at Medtronic

MAINTAIN APPOSITION WITH ESAR

Stability of a surgical anastomosis[8]

EndoAnchor™ implants protect where they are deployed[1]

C Minimizes Type Ia endoleaks

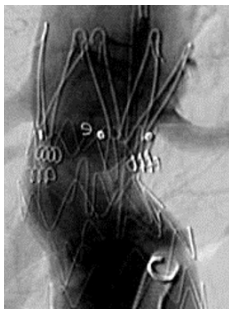


Image courtesy of Dr. Jean-Paul De Vries

MINIMAL TYPE IA IN HOSTILE NECKS

	ANCHOR Primary AAA[13] n = 712	EVAR Only[14] n = 199
Type Ia	3.4% (4/117)	9.5% (19/199)
Time	at 4 years	4.1 years (avg)
Hostile*	88.6%	100%

Results from separate trials; head to head data may differ

*hostile necks per SVS criteria

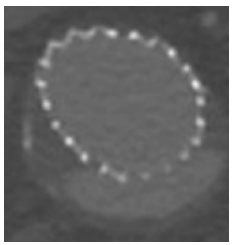


Image courtesy of Dr. Apostolos Tassiopoulos

MINIMAL TYPE IA REINTERVENTIONS

97.2% FF reinterventions for Type Ia endoleak (through 4 years)[7]

"EndoAnchor™ implants are an opportunity for EVAR improvement"[15]

Dr. William Jordan Jr., M.D.
Professor and Chief of Vascular Surgery, Emory University

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HELI-FX™& HELI-FX™ THORACIC ENDOANCHOR™ SYSTEMS

Indications for Use

The Heli-FX™ EndoAnchor™ system is intended to provide fixation and sealing between endovascular aortic grafts and the native artery. The Heli-FX™ EndoAnchor™ system is indicated for use in patients whose endovascular grafts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion. The EndoAnchor™ implant may be implanted at the time of the initial endograft placement, or during a secondary (i.e. repair) procedure.

Contraindications

Treatment with the Heli-FX™ EndoAnchor™ system is contraindicated for use in the following circumstances:

- In patients with known allergies to the EndoAnchor™ implant material (MP35N-LT)
- In conjunction with the Endologix Powerlink™* endograft

Warnings

- The long-term performance of the EndoAnchor™ implant has not been established. All patients should be advised endovascular aneurysm treatment requires long-term, regular follow-up visits to assess the patient's health status and endograft performance. The EndoAnchor™ implant does not reduce this requirement.
- The EndoAnchor™ implant and the Heli-FX™ EndoAnchor™ system have been evaluated via in vitro testing and determined to be compatible with the Cook Zenith™*, Cook Zenith™* TX2™*, Gore Excluder™*, Gore TAG™*, Medtronic AneuRx™, Medtronic Endurant™, Medtronic Talent™ AAA, Medtronic Talent™ TAA, Medtronic Valiant Xcelerant™, Medtronic Valiant™ Captivia™, and Medtronic Valiant Navion™ endografts. Use with endografts other than those listed above has not been evaluated.
- The performance of the EndoAnchor™ implant has not been evaluated for securing multiple endograft components together. Not securing EndoAnchor™ implants into aortic tissue could result in graft fabric damage, component separation, and resultant Type III endoleaks.
- The performance of the EndoAnchor™ implant has not been evaluated in vessels other than the aorta. Use of the EndoAnchor™ implant to secure endografts to other vessels may result in adverse patient consequences such as vascular perforation, bleeding, or damage to adjacent structures.
- The performance of the EndoAnchor™ implant has not been evaluated for securing multiple anatomical structures together. Such use could result in adverse patient consequences such as vascular perforation, bleeding, or embolic events.

MRI Safety and Compatibility

- The EndoAnchor™ implants have been determined to be MR Conditional at 3T or less when the scanner is in Normal Operating Mode with whole-body-averaged SAR of 2 W/kg, or in First Level Controlled Mode with a maximum whole-body-averaged SAR of 4 W/kg.
- Please refer to documentation provided by the endograft system manufacturer for MR safety status of the endograft system with which the EndoAnchor™ implants are being used.

Potential Adverse Events

Possible adverse events that are associated with the Heli-FX™ EndoAnchor™ system, include, but are not limited to:

- Aneurysm rupture
- Death
- EndoAnchor™ implant embolization
- Endoleaks (Type III)
- Enteric fistula
- Failure to correct/prevent Type I endoleak
- Failure to prevent endograft migration
- Infection
- Renal complications (renal artery occlusion/dissection or contrast-induced acute kidney injury)
- Stroke
- Surgical conversion to open repair
- Vascular access complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vessel damage, including dissection, perforation, and spasm

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events. Additional potential adverse events may be associated with endovascular aneurysm repair in general. Refer to the *Instructions for Use* provided with the endograft for additional potential adverse events.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a licensed healthcare practitioner.

See package inserts for full product information.

CAUTION: EndoAnchor™ implant locations should be based upon a detailed examination of the preoperative CT imaging in cases involving irregular or eccentric plaque in the intended sealing zones. EndoAnchor™ implants should be implanted only into areas of aortic tissue free of calcified plaque or thrombus, or where such pathology is diffuse and less than 2mm in thickness. Attempting to place EndoAnchor™ implants into more severe plaque or thrombus may be associated with implantation difficulty and suboptimal endograft fixation and/or sealing.

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