The technical success of FEVAR is contingent upon meticulous preoperative planning and is not applicable in some morphological situations. The indication for FEVAR devices limits neck angulation to less than 45 degrees relative to the long axis of the aneurysm and less than 45 degrees relative to the axis of the suprarenal aorta. Commercially available FEVAR graft delivery systems are larger than many of the standard EVAR counterparts. With larger delivery systems, fenestrated grafts may require conduits or be unsuitable for patients with narrow, calcified, or tortuous access vessels.

The ENDOVASCULAR TEAM

The complexity of the FEVAR procedure requires advanced training and skills from the operators. Optimal FEVAR results have been reported by single-center studies with operators with significant FEVAR experience (over 10 years), a modern hybrid suite, and a high volume of high-risk patients available. Suboptimal FEVAR therapy outcomes have been published in a multicenter trial in which investigators emphasized learning curve issues as a cause of these results. Endovascular teams looking to develop a FEVAR practice should have a sustainable volume of appropriate patients to refine their skills and shorten the learning curve.

The economic burden

The true financial implications of FEVAR are best understood when all aspects of the therapy are calculated, including: device costs, technical fees, hospital charges, personnel fees, and radiation doses. Frequently, EVAR has been shown to have significant need for secondary procedures over time. Controlled Mode with a maximum whole body averaged SAR of 4 W/kg.

MRI Safety and Compatibility:

• Not secured to other EndoAnchor devices or any other medical device, system, or implant.

Contraindications

• In patients with known allergies to the EndoAnchor implant material (MP35N-L Ti).

• In patients with signs of ongoing infection, sepsis, or systemic inflammatory response.

• In patients with a clinically relevant pulmonary embolism.

• In patients with known or suspected malignancy.

• In patients for whom the placement of an EndoAnchor is contra-indicated for any other reason.

• In patients who are pregnant or likely to become pregnant.

• In patients with aortic dissection.

• In patients who have already undergone an open repair or who have aortic graft infection.

• In patients who have undergone a failed endovascular repair with more than one type I endoleak.

• In patients who have undergone a failed endovascular repair with multiple endoleaks.

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

• Vessel damage, including dissection, perforation, and spasm.

• Vascular access complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula.

• Surgical conversion to open repair.

• Stroke.

• Renal complications (renal artery occlusion/dissection or contrast-induced AKI).

• Failure to correct/prevent Type I endoleak.

• EndoAnchor embolization.

• Death.

• Aneurysm rupture.

The performance of the Aptus EndoAnchor has not been evaluated for securing multiple endograft components to one another. Not securing EndoAnchor implants into aortic tissue could result in implantation difficulty and suboptimal endograft fixation and/or sealing.

In patients with known allergies to the EndoAnchor implant material (MP35N-L Ti), the EndoAnchor implants should be used with caution if there is a high risk of allergic reactions. Prolonged exposure to the implant material could result in local inflammation and discomfort. The Aptus EndoAnchor implant material (MP35N-L Ti) is not recommended for use until the manufacturer’s validation studies have been completed.

Hybrid technique

• Surgical conversion to open repair.

• Placement of multiple stent grafts due to fenestration failure, pararenal or pararenal extension, cranial or caudal extension.

• Vessel damage including dissection, perforation, and spasm.

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• Medtronic Aorto—Peripheral Stent Graft System

• Medtronic Heli-FX EndoAnchor System

• Medtronic Zenith TX2

• Endostent

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• In patients with a clinically relevant pulmonary embolism.

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• In patients for whom the placement of an EndoAnchor is contra-indicated for any other reason.

• In patients who are pregnant or likely to become pregnant.

• In patients with aortic dissection.

• In patients who have already undergone an open repair or who have aortic graft infection.

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