

# Endografts: Thoracic Aortic Aneurysm (TAA) & Abdominal Aortic Aneurysm (AAA)

October 2024

## Device Overview

An AAA happens when the wall of the aorta in the abdomen weakens and bulges outward.[1] Similarly, a TAA is the same condition, but occurring in the section of the aorta located in the chest cavity.[2] When the aortic wall weakens, it becomes more prone to rupture. There are surgical treatment options for both abdominal aortic aneurysms (AAAs) and thoracic aortic aneurysms (TAAs). Both endovascular stent grafting and open surgery aim to prevent an AAA from rupturing. The main distinction is that the endovascular stent graft is placed inside the aneurysm without removing any aortic tissue and does not require open-chest or open-abdominal surgery.[3] Several suppliers provide a range of grafts for these repairs. Each endograft comes with specific instructions for use (IFU) from the manufacturer, detailing various anatomical characteristics of the aneurysm that should be assessed through preprocedural imaging.[4]

## Actions for Consideration



### PARTNER

#### ENGAGE SUBJECT MATTER EXPERTS

Assess current utilization of grafts and engage key physician specialties, including vascular and cardiothoracic surgeons, and interventional radiologists.

#### CONSIDER GUIDELINES FOR USE

With various treatment options available, consider evaluating the criteria for suitable indications and target populations, in particular in patients with specific anatomical requirements.

#### UNDERSTAND CONCERNS

Continue conversations with key specialties, leverage physician peer to peer conversations to understand decision making.



### CONNECT

#### SEEK CLINICAL IMPACT

Analyze data and physician usage by procedure to enhance care quality and patient outcomes.

#### CONDUCT ANALYSIS

Evaluate the costs of grafts, including reimbursement and outcomes data, to inform decision-making. Assess whether a primary supplier can be identified.

#### DETERMINE POPULATION

Work with key stakeholders to determine appropriate patient & procedures for utilization.



### COMMUNICATE

#### EDUCATE AND TRAIN

Share details about the available initial and ongoing training. Collaborate with suppliers to assess the necessity of in-person support during surgical cases.

#### PLAN AHEAD

Consider developing a process for selecting endografts that takes into account the primary supplier and the patient's anatomical requirements.

#### FOLLOW-UP FOR FEEDBACK

Create a continuous feedback loop to evaluate and address safety, effectiveness, and patient outcomes. Ensure metrics are reported regularly.

## Clinical Insights: HealthTrust Physician Advisors

A panel of vascular, cardiothoracic surgeons, and interventional vascular radiologists within our HealthTrust Physician Advisor Network offered the following insight with regard to endografts for AAA and TAA repairs.[5]

### Physician Advisor Insights



#### Graft Selection (Features and Factors)

- Appropriateness for individual aortic anatomy
- Ease of use
- Effectiveness
- Durability
- Postoperative rate of end and migration
- Approximately 75% of cases will be able to utilize any suppliers' grafts
- Certain cases require specific type of grafts based on patient anatomy
- Patient condition/anatomy is key in selection of graft

#### Supplier Selection

- Matching patient anatomy to the advantages of each specific graft
- Supplier rep support in cases
- Breadth of inventory
- Supplier customer service
- Future pipeline of innovation
- Cost of grafts

#### Niche Features/Products

- Fenestrated
- Branched grafts
- Grafts for specialized anatomy

#### Impactful Differences

- Ease of use allowing for decrease in OR time
- Suppliers that offer clinical support during implantation

#### Additional Feedback

- It is reasonable to have a predominate supplier for the majority of cases
- Very straightforward infrarenal case, any of the suppliers would be reasonable
- Availability of access to use all suppliers based on those with anatomical need

## Professional Society Statements & Clinical Practice Guidelines

### The American Heart Association (AHA)/American College of Cardiology (ACC) Joint Committee on Clinical Practice Guidelines

The 2022 AHA/ACC Guidelines for the Diagnosis and Management of Aortic Disease: A Report of the AHA/ACC Joint Committee on Clinical Practice Guidelines noted: “There is an increasing role for thoracic endovascular aortic repair in the management of uncomplicated type B aortic dissection. Clinical trials of repair of thoracoabdominal aortic aneurysms with endografts are reporting results that suggest endovascular repair is an option for patients with suitable anatomy.”[6] Full context of guidelines can be found [here](#).

### The Society for Vascular Surgery

Concerning the use of endografts, the Society for Vascular Surgery advises “using Food and Drug Administration (FDA) approved branch endograft devices in anatomically suitable patients to maintain perfusion to at least one internal iliac artery”.[7] Guidelines can be found [here](#).



See Reference section for complete listing of research sources.

## Clinical Evidence

Research directly comparing the safety and efficacy of endograft suppliers is mainly restricted to industry-sponsored studies.

**A 2023 Australian retrospective cohort study by Falster et al.** assessed mortality, rupture rates, and secondary interventions after endovascular repair (EVAR) of intact AAAs using modern endograft devices from three manufacturers: Cook, Medtronic, and Gore.[8] The study included 2,874 eligible EVAR patients who underwent repair of intact AAA between January 2010 and June 2019. The study concluded “there was no statistically significant difference” across devices in secondary rupture rates, which ranged between 0.4 and 0.5 per 100 person years. Patients receiving Medtronic and Gore devices tended to have higher crude rates of subsequent aneurysm repair than those receiving the Cook devices (1.5 vs. 0.8 per 100 person years, respectively). This finding remained in the adjusted analysis but was only statistically significant for Medtronic devices [Hazard ratio (HR) 1.57, 95% Confidence Interval (CI) 1.02 – 2.47; HR 1.73, 95% CI 0.94 – 3.18, respectively].”[8] Limitations included the exclusion of certain clinical and morphological characteristics of aneurysms that could affect endograft selection. Additionally, conflicts of interest were identified, as one author served as a consultant for Abbott Vascular, Medtronic, Intervene, Surmodics, Philips Medical, Boston Scientific, and BD Bard.[8]

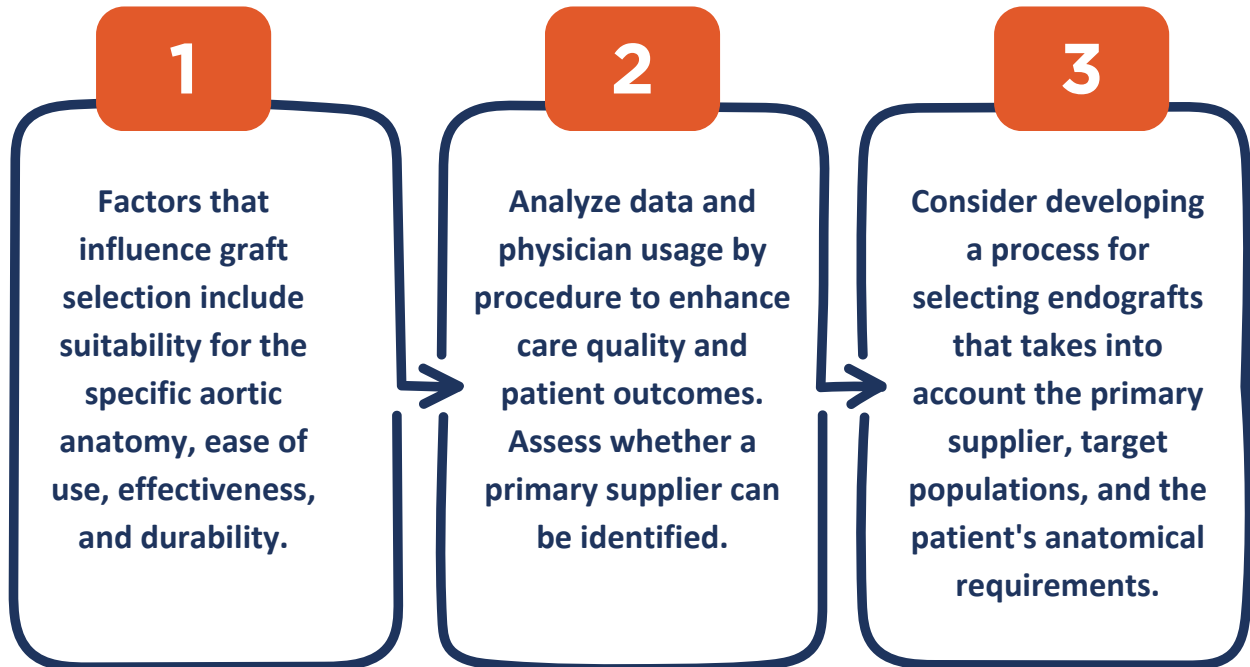


**Systematic search terms:** Endografts, Thoracic Aortic Aneurysm (TAA) & Abdominal Aortic Aneurysm (AAA) **Databases:** PubMed, Medline, CINAHL. **Studies published from:** 2019 to 2024.

## FDA Approval

Individual endografts utilized for TAA and AAA repair FDA approval can be searched through the Premarket Approval (PMA) data base found [here](#). [9]

## Summary



### HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis, physician engagement, and product trials.

ASK A QUESTION

PROVIDE YOUR FEEDBACK

SHARE YOUR VOICE

NETWORK WITH PEERS



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App store: "HealthTrust Huddle"

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