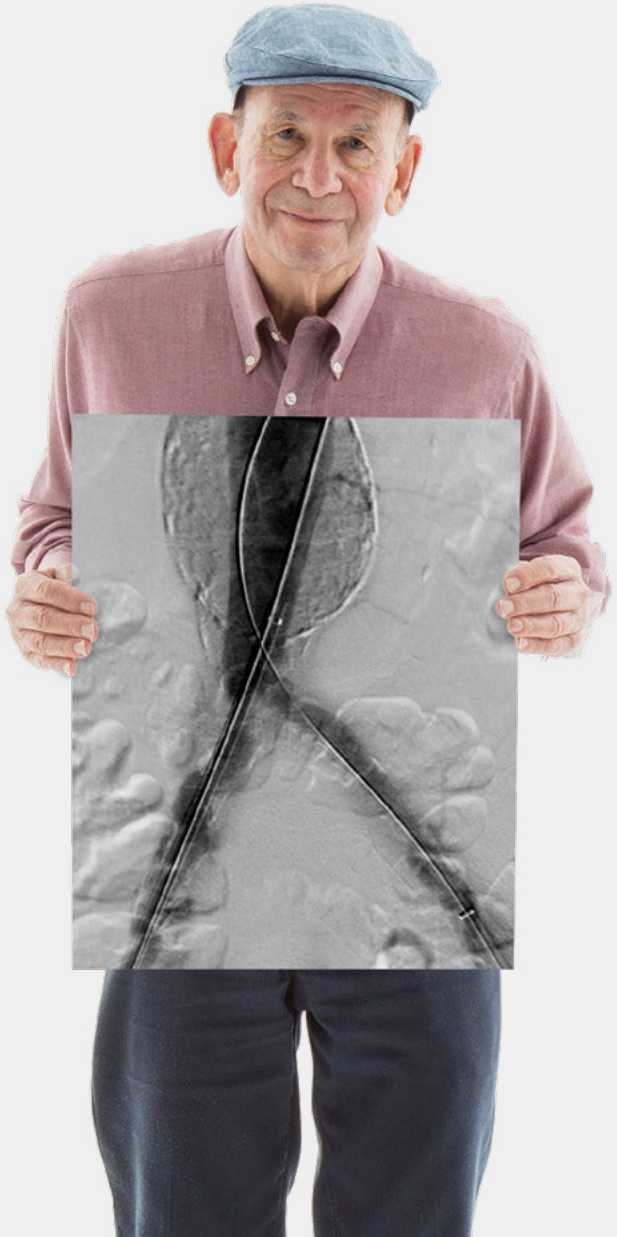
Endologix

An EVAR as unique as your patients

No two patients are alike—the **ALTO® abdominal stent graft system** provides a custom seal that conforms to the needs of specialized anatomies.

Alto®
Abdominal Stent Graft System

50% of AAA patients requiring treatment are not eligible for on-label* EVAR[1–5]



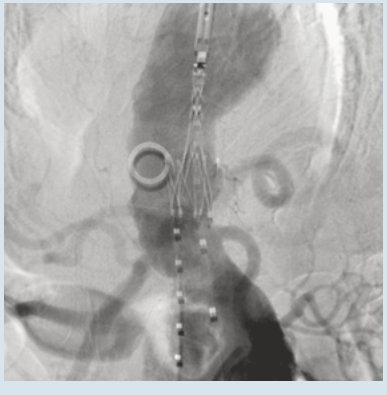
*Due to specialized anatomies

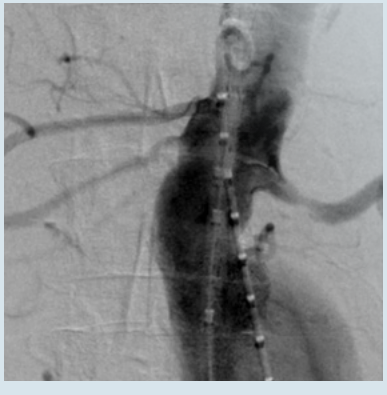
1. Barleben A, et al. Long-term outcomes of the Ovation Stent Graft System investigational device exemption trial for endovascular abdominal aortic aneurysm repair. J Vasc Surg. 2020;72(5):1667-1673. 2. Elkouri S, et al. Most patients with abdominal aortic aneurysm are not suitable for endovascular repair using currently approved bifurcated stent-grafts. Vasc Endovascular Surg 2004;38:401-12. 3. Arko FR, et al. How many patients with infrarenal aneurysms are candidates for endovascular repair? The Northern California experience. J Endovasc Ther 2004;11:33-40. 4. AbuRahma AF, et al. Aortic neck anatomic features and predictors of outcomes in endovascular repair of abdominal aortic aneurysms following vs not following instructions for use. J Am Coll Surg 2016;222:579-89. 5. Schanzer A, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation 2011;123:2848-55.

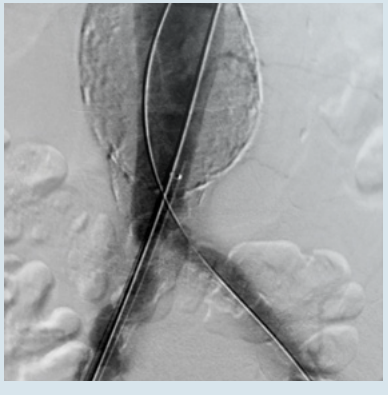
Off-label EVAR is mostly due to:

- Short neck length
- Small access vessel diameter
- Excessive neck angulation

A short proximal neck is the most common excluding factor for EVAR[6] with approximately 33% of patients presenting with necks <10 mm.



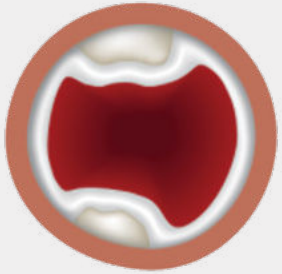




6. Picel, AC, Kansal N. Essentials of endovascular abdominal aortic aneurysm repair imaging: preprocedural assessment. AJR Am J Roentgenol. 2014;203(4):W347-357.

You need an EVAR solution as unique as they are

Featuring adaptive sealing technology—only on the **ALTO abdominal stent graft system.**

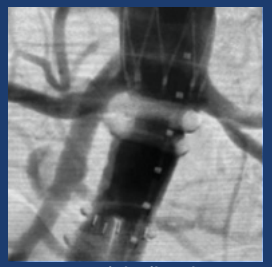


ALTO's exclusive **adaptive sealing technology** creates an effective seal around the vessel wall, conforming to the patient's anatomy.

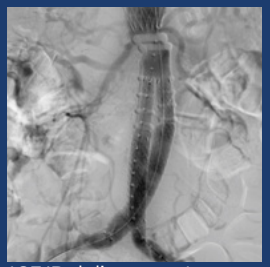
This technology eliminates chronic radial force in the seal zone* and results in stable neck diameters out to 5 years[1,2]

Integrated compliant balloon optimizes molding of the sealing ring

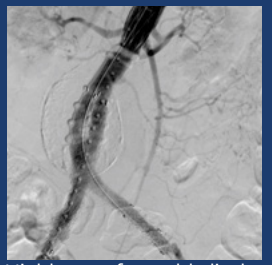
A blueprint for the **future of EVAR**



7 mm neck indication



13F ID delivery system



Highly comformable limbs

*Seal zone for the ALTO stent graft is defined as a location 7mm down for the lowest renal.

1. Swerdlow NJ, et al. Five-year results of endovascular abdominal aortic aneurysm repair with the Ovation abdominal stent graft. J Vasc Surg. 2020;71(5):1528-1537
2. Core Lab evaluation, Ovation Global Pivotal Trial. N=94. Data from Aug 2, 2016. ALTO was not included in the Ovation Global Pivotal Trial.

A personalized experience to meet the needs of each patient's anatomy

ALTO provides **on-label treatment** of the broadest range of patient anatomies.

Women are underserved by conventional EVAR

One in five AAA patients are women[1], yet only 34% of women with AAA are eligible for EVAR treatment due to anatomical restrictions, including[2,3]:

- Neck length
- Neck angulation
- Iliac access diameter

*Due to lack of significant calcification at the level of 7mm below the inferior renal artery.

1. Derubertis BG, et al. Abdominal aortic aneurysm in women: prevalence, risk factors, and implications for screening. J Vasc Surg. 2007;46(4):630-635. 2. Ulug P, et al. Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intactabdominal aortic aneurysm repair: systematic reviews with meta-analysis. Lancet. 2017;389(10088):2482-2491. 3. Sweet MP, et al. The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair.

Made to Conform

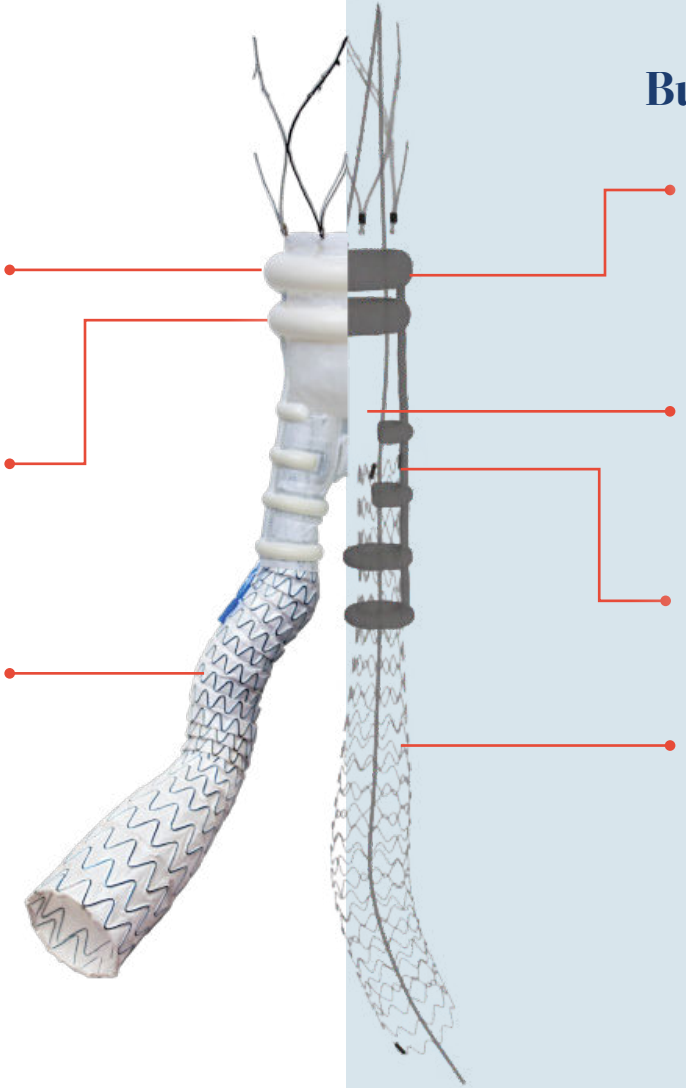
Adaptive with sealing ring conforming to irregular surface, creating a **patient-specific seal**

Treat infrarenal neck lengths as short as 7mm and ≤60° juxtarenal angulation without adjunctive devices

PTFE iliac limbs with helical nitinol architecture provide **flexibility** and minimal luminal encroachment

Lowest profile AAA device on market

13F inner diameter
15F outer diameter



Built to Perform

Separation of fixation and seal allows you to fixate graft in healthy tissue and seal closest to renals

Integrated compliant balloon **enables timesaving interoperative deployment**

Proprietary crossover lumen allows **easy cannulation**

97.2% freedom from secondary intervention due to graft occlusion at 5 years[†]

[†]ENCORE Data File: April 12, 2018.

Where versatility and durability meet

The ENCORE* analysis—a pooled, retrospective analysis of six trials—demonstrated **favorable clinical outcomes over five years.**

99% freedom from

- AAA-related mortality
- Conversion
- Rupture

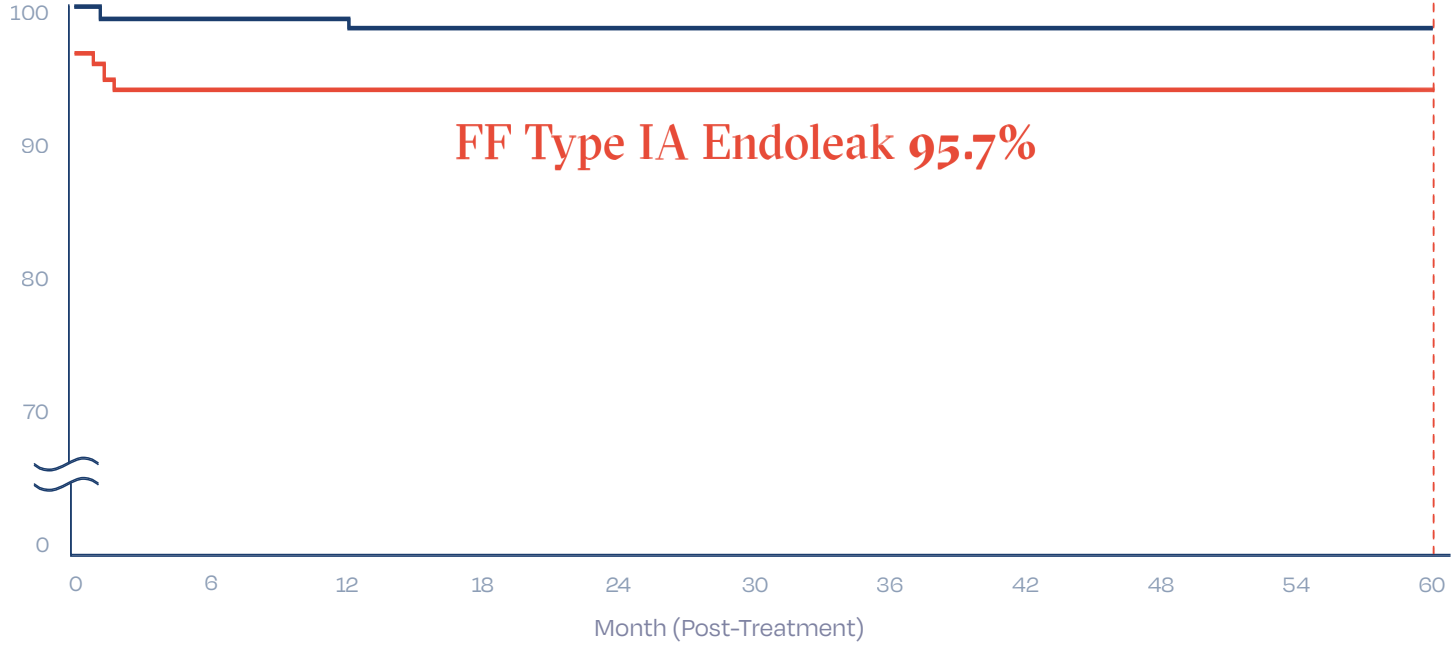
98% freedom from

- Reintervention for type 1A endoleak

90% freedom from

- Device-related intervention

FF AAA-Related Mortality **99.3%**



Survival Estimates: At Risk

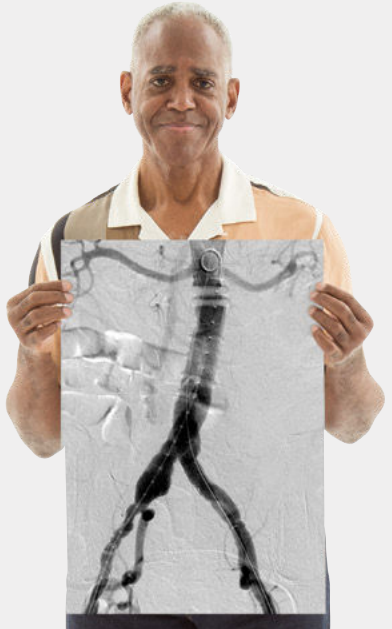
1296	997	907	713	677	636	607	570	526	473	299
1296	978	889	700	663	623	595	558	513	464	295

*The Ovation platform product family includes a series of device iterations using adaptive neck sealing technology such as Ovation, Ovation Prime, Ovation iX, and ALTO. The devices included in the studies used in the ENCORE analysis all include adaptive sealing technology. ALTO was not included in the ENCORE data set.

ENCORE includes results from real-world patient population. 3% of patients had neck characteristics beyond the FDA-approved anatomic IFU. Safety and effectiveness of Ovation and ALTO when used outside the IFU have not been established. The ENCORE analysis pools data on file from March 20, 2019.

Choose an EVAR solution as unique as your patients

ALTO features adaptive sealing technology, the lowest profile delivery system, and the shortest neck indication.



Indications for use

The ALTO® Abdominal Stent Graft System is indicated for treatment of patients with infrarenal abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair with the device, which includes the following:

- Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories,
- A proximal aortic landing zone for the sealing ring 7 mm below the inferior renal artery.
- An aortic sealing zone comprised of healthy aorta defined as:
  - Lack of significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7mm below the inferior renal artery,
  - Lack of significant calcification at the level of 7 mm below the inferior renal artery,
  - Conicity < 10% as measured from the inferior renal artery to the aorta 7 mm below the inferior renal artery,
  - An inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery, and
  - An aortic angle of ≤ 60 degrees
- A distal iliac landing zone:
  - With a length of at least 10 mm, and
  - With an inner wall diameter of no less than 8 mm and no greater than 25 mm.

Contraindications

The system is contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, contrast agents, fluorinated ethylene propylene [FEP], titanium, nickel, platinum, or iridium.

Refer to Instructions for Use for more information concerning Indications, Contraindications, Specific Anatomic Considerations, Warnings, Precautions, and Adverse Events.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: Not all product components are available in every country. Please consult with your Endologix representative to confirm product availability.

These are a portrayal of typical EVAR patients and not real patients.

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