

TRANSFORMING EVAR

ANATOMICALLY ADAPTIVE, UNIQUELY POWERFUL

Results from the ENCORE* analysis demonstrate favorable midterm durability at 5 years as evidenced by successful aneurysm exclusion and low aneurysm-related mortality.



A PLATFORM WORTHY OF AN ENCORE

5 CLINICAL TRIALS | 1 EU POST MARKET STUDY | 1296 PATIENTS

Adaptive sealing technology in endovascular aneurysm repair is the foundation for the ALTO abdominal stent graft platform which creates a personalized seal for every patient's unique anatomy.



E·N·C·O·R·E

EffectiveNess of Custom Seal with Ovation: Review of the Evidence

AT 5-YEARS, THE POOLED, RETROSPECTIVE ANALYSIS DEMONSTRATED:

99%

FREEDOM FROM

AAA-RELATED

⊘ CONVERSION

ORUPTURE

98%

FREEDOM FROM

REINTERVENTION
FOR TYPE IA
ENDOLEAK

90%

FREEDOM FROM

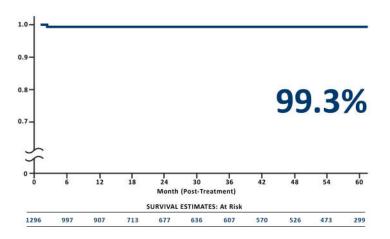
DEVICE-RELATED REINTERVENTION

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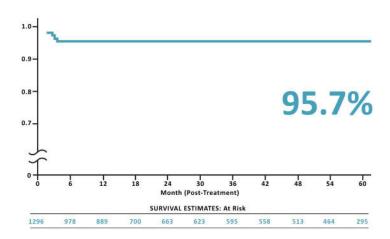
THE ADAPTIVE SEALING TECHNOLOGY FEATURED IN THE ALTO STENT GRAFT WAS DESIGNED TO ADDRESS DURABILITY ISSUES IN EVAR

A primary cause of loss of proximal seal is a ortic neck dilatation, often due to constant radial force, exerted on the aneurysm neck.

FREEDOM FROM AAA-RELATED MORTALITY



FREEDOM FROM TYPE IA ENDOLFAK



The ENCORE analysis presents favorable clinical outcomes even in wide neck anatomies, proving that adaptive sealing technology is designed for durability.

LEARN MORE AT ENDOLOGIX.COM/ENCORE

*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.

The ALTO® Abdominal Stent Graft System

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,
 - o Lack of significant calcification at the level of 7 mm below the inferior renal artery,
 - o Conicity < 10% as measured from the inferior renal artery to the aorta 7 mm below the inferior renal artery,

- o 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
- o An aortic angle of ≤ 60 degrees
- A distal iliac landing zone:
 - o With a length of at least 10 mm, and
 - o 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: Endologix products and associated components are not available in all countries or regions. Please consult with your Endologix representative regarding product availability.

Products and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the "Instructions for Use" for complete and specific indications, contraindications, all warnings and precautions. Rx only.

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