Endologix

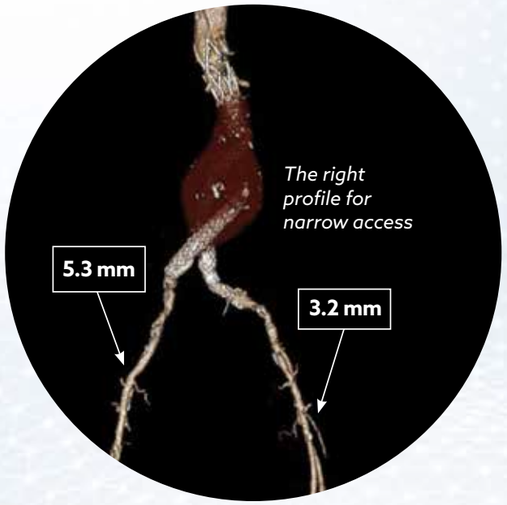
Access More Patients.
Customize Each Neck Seal.

Ovation iX™
Abdominal Stent Graft System

Access More Patients: The Least Invasive PathTowards Proven Patency

ULTRA LOW PROFILE TO EASE ADVANCEMENT

The flexible, ultra-low 12F ID Ovation iX™ delivery system enables you to navigate through tortuous and narrow anatomies, access small vessels, and deliver a stent graft to the widest on-label range of anatomies with ease and less vessel trauma.



3 year follow-up

14F OD
An ultra low profile system enables access to more patients.

1.2%
Clinically proven occlusion rate at 1 year.[1]

DEMONSTRATED PATENCY EVEN IN HOSTILE ANATOMY

The helical nitinol stent is engineered to be kink resistant even in the most tortuous anatomies. Combined with smooth, low permeability PTFE designed to reduce thrombosis and limb occlusions, the Ovation iX iliac stent grafts are clinically proven to promote patency with a low limb occlusion rate of 1.2% at 1 year[1].

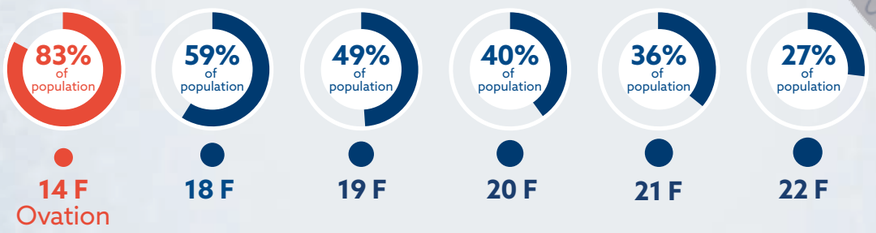
Broadened size matrix enables treatment of a wide range of AAA anatomies:

- Flared limbs up to 28 mm diameter
- Limb lengths up to 160 mm

3 month follow-up

TREAT MORE WITH LESS

Ovation iX low-profile system and its ability to address the AAA population compared with competitive systems.



Dimensions listed are system outer diameters (OD)

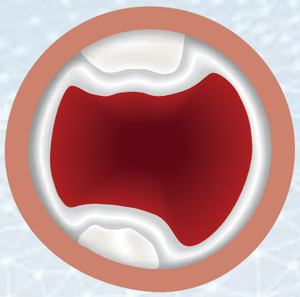
Source: Based on patient access vessel size distribution. Derived from M2S measurement database of 43,000 AAA CT scans.

Conformability
Without Compromise

PROVIDE A CUSTOMSEAL™ FOR EACH PATIENT

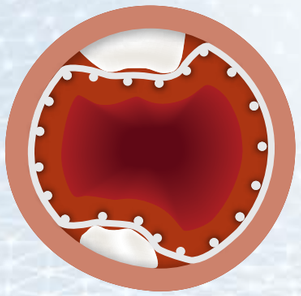
Create a customized seal that conforms to vessel wall irregularities through the CustomSeal™ polymer technology.

OVATION SYSTEM

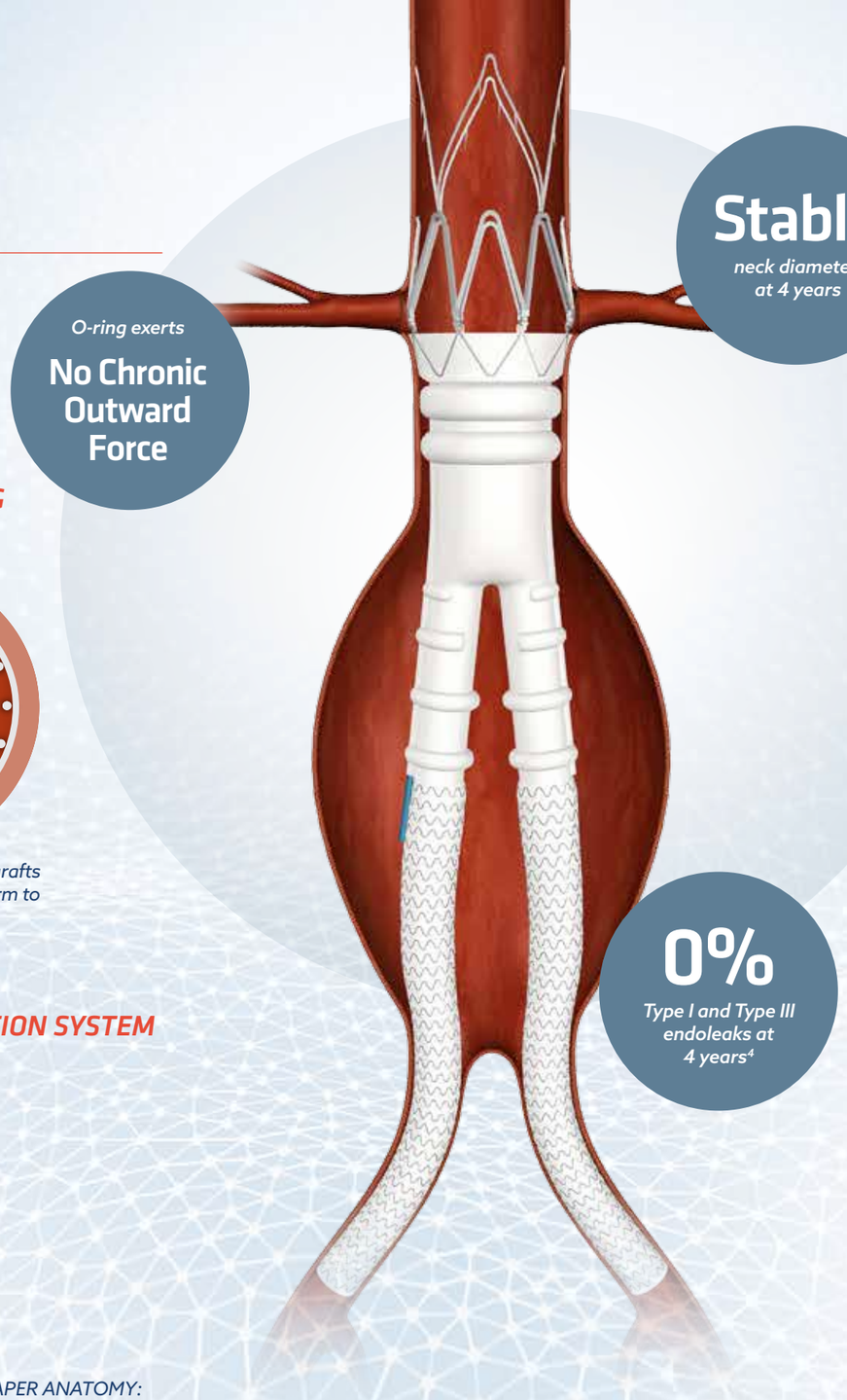


Polymer is injected in a low-viscosity liquid state, allowing sealing ring to conform to irregular luminal surfaces and create a watertight seal.

SELF EXPANDING STENT GRAFT

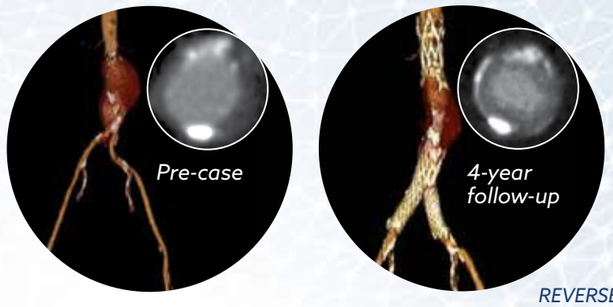


Conventional wire and fabric grafts may not be able to fully conform to an irregular luminal surface.

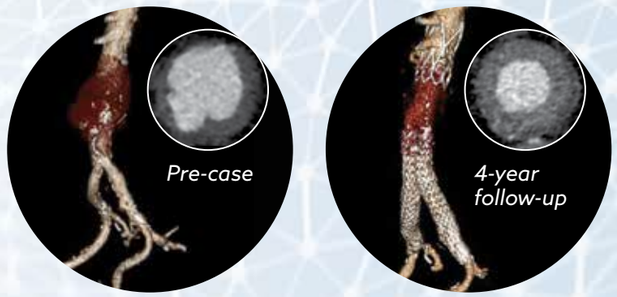


HOSTILE NECK ANATOMIES TREATED WITH OVATION SYSTEM

CALCIFIED ANATOMY:



REVERSE-TAPER ANATOMY:

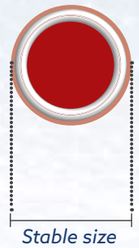


PROTECT THE NECK

The O-ring design provides a watertight, circumferential seal at the midpoint of the sealing ring, 13 mm below the inferior renal artery. It exerts no chronic outward force and insulates the neck from blood pressure, which results in stable neck diameter.[2]

OVATION SYSTEM

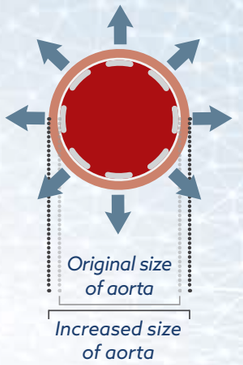
Sealing ring creates no chronic outward force and insulates the neck from blood pressure.



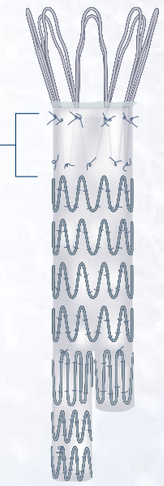
O-ring creates a circumferential seal at the midpoint of the sealing ring, and continuous wall apposition provides a watertight seal.

SELF EXPANDING STENT GRAFT

Chronic outward force from stent, combined with blood pressure, can result in neck dilatation.[3]



Seal created by chronic outward force with discontinuous points of wall apposition across a minimum 10 to 15 mm length can become compromised over time.

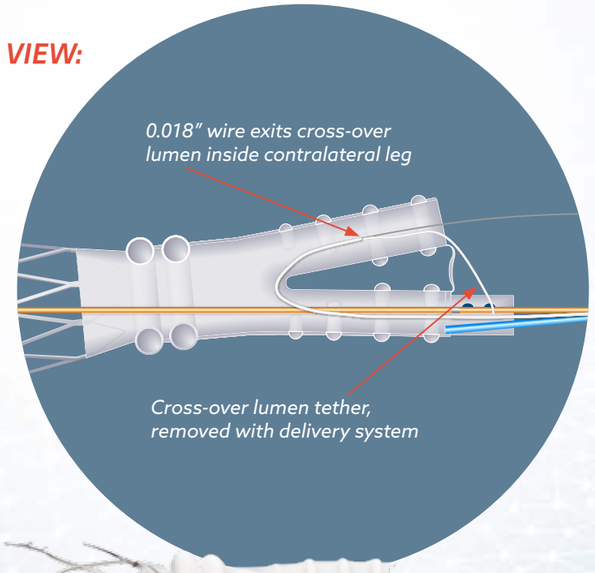


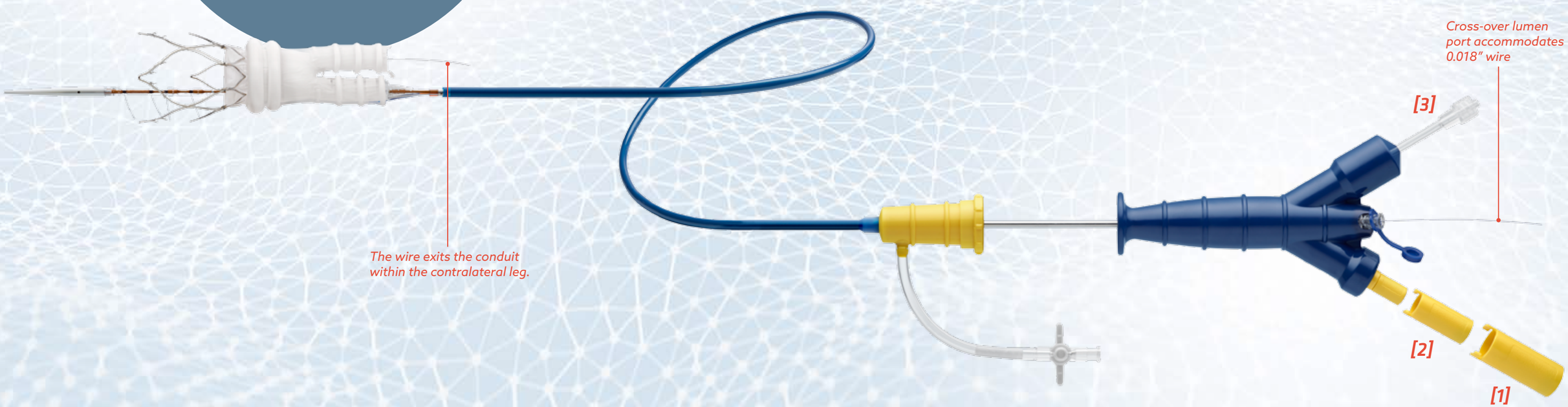
Ovation iX Offers Simplified Delivery and Precise Placement

CROSSOVER LUMEN FOR OVATION IX – THE SOLUTION TO GATE CANNULATION

The crossover lumen provides an alternative to retrograde cannulation. Designed for predictable procedure times, increased efficiencies, and reduced ancillary device usage, the crossover lumen simplifies the delivery of Ovation iX™.

CROSS-SECTION VIEW:

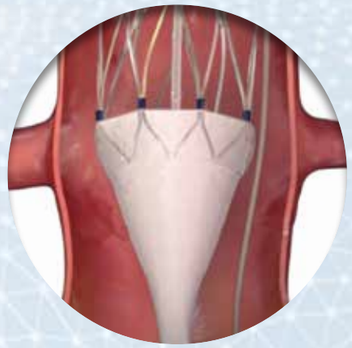




The wire exits the conduit within the contralateral leg.

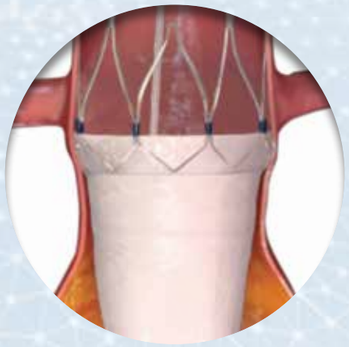
SIMPLE, STAGED DEPLOYMENT PROMOTES PRECISE PLACEMENT

With a simple, staged deployment and eight radiopaque markers, the Ovation iX system is designed to deliver precise placement and accurate deployment.



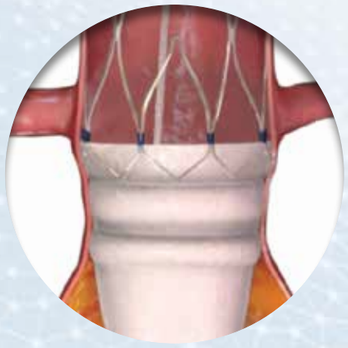
[1]

The midcrown is deployed enabling visualization of the 8 radiopaque markers and adjustment for parallax. Repositioning is possible if necessary to ensure precise placement.



[2]

Once proper positioning is confirmed, the integral anchors on the proximal crown are deployed radially with minimum force. This enhances placement accuracy while reducing the risk of migration.

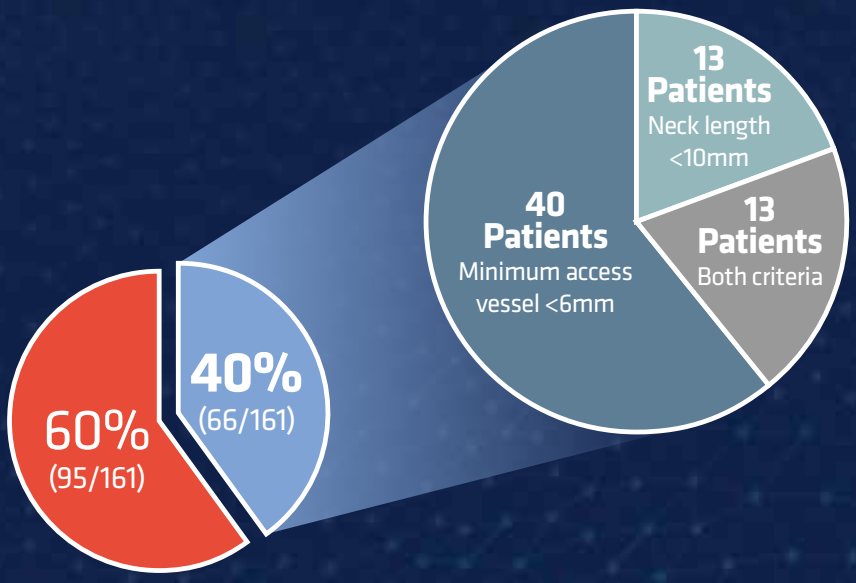


[3]

With the device anchored exclusively above the aneurysm, the O-rings are filled with CustomSeal™ polymer to provide a sustained seal without exerting chronic outward force on the critical aortic neck segment.

ACCESS MORE PATIENTS, CUSTOMIZE EACH NECK SEAL

In the Ovation Pivotal trial, approximately 40% of patients (66/161) treated had access vessels <6 mm in diameter, aortic neck length <10 mm, or both. Patients within this anatomically challenging group had a 0% MAE rate at 0 to 30 days and a 3.0% MAE rate at 31 to 365 days.[1]



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NOTES:

1. Ovation® pivotal trial reintervention rate due to Ovation limb occlusions, N=159. Data as of July 25, 2014.
2. Neck dilatation in proximal neck defined as growth > 3 mm at 10 mm below renals, 13 mm below renals and 15 mm below renals. Core Lab evaluation, Ovation Global Pivotal Trial. N=94. Data as of July 31, 2015.
3. Rodway AD et al. Eur J Endovasc Surg 2008; 35: 685-93 EVAR: N=67, Open: N=56. Data available for up to 2 years. Devices: Cook Zenith and Medtronic Talent
4. Endoleaks and Migration rates based on Core Lab Data (M2S)

INDICATIONS FOR USE: The Endologix Ovation iX™ Abdominal Stent Graft System is indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including: adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories; proximal aortic landing zone: with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery, and with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm; 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, fluorinated ethylene propylene [FEP] or nitinol). Also consider the information in Section 4 Warnings and Precautions of the systems' Instructions for Use.

Refer to Instructions for Use for more information concerning Indications, Contraindications, Warnings and 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.

CE Marked. Please refer to current Ovation iX Instructions for Use.

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