Access More Patients.
Customize Each Seal.

Ovation iX™
Abdominal Stent Graft System
The Least Invasive Path Towards 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.

12F ID
An ultra low profile system enables access to more patients.

CustomSeal™
Polymer-filled O-ring conforms to and protects the aortic neck

3 year follow-up
Staged deployment of suprarenal stent allows easier, precise placement

Low profile, kink-resistant catheter built for maneuverability and flexibility

Low-permeability PTFE enables effective aneurysm exclusion and device patency

1.2%
Clinically proven occlusion rate at 1 year.

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 versus Medtronic’s Endurant IDE that yielded a 2.7% limb occlusion rate.

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

14 F Ovation
83% of population

18 F Endurant®
59% of population

19 F AFX®
49% of population

20 F Excluder®
40% of population

21 F Zenith®
36% of population

22 F Aorfix™
27% of population

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.

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

83% of population
14 F Ovation

59% of population
18 F Endurant®

49% of population
19 F AFX®

40% of population
20 F Excluder®

36% of population
21 F Zenith®

27% of population
22 F Aorfix™

HELPS OVERCOME CHALLENGES OF TORTUOUS ANATOMY
Pre-case
3 month follow-up

Highly conformable, kink-resistant iliac limbs designed to reduce the risk of occlusion

CUSTOM SEAL™
Polymer-filled O-ring conforms to and protects the aortic neck

83% of population
80%
75%
70%
65%
60%
55%
50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%

Dimensions listed are system outer diameters (OD)
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
SELF EXPANDING STENT GRAFT
Polymer is injected in a low-viscosity liquid state, allowing sealing ring to conform to irregular luminal surfaces and create a watertight seal.
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:

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.

Stable neck diameter at 4 years

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

Increased size aorta

Original size aorta

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.

Stable size aorta

0% Type I and Type III endoleaks at 4 years

REVERSE-TAPER ANATOMY:

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

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

4-year follow-up

4-year follow-up

4-year follow-up

4-year follow-up
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.

0.018" wire exits cross-over lumen inside contralateral leg

CROSSOVER LUMEN TETHER, REMOVED WITH DELIVERY SYSTEM

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. 0.018" wire exits cross-over lumen inside contralateral leg

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

3. 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.

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.

Cross-over lumen port accommodates 0.018" wire

The wire exits the conduit within the contralateral leg.

[1] [2] [3]
ACCESS MORE PATIENTS, CUSTOMIZE EACH 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