Ovation Platform

(Ovation, Ovation Prime, Ovation iX)

Alto Abdominal Stent Graft System

Appendix 1
2025 Annual Clinical Update
P120006/R057

October 3, 2025

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0 TABLE OF ABBREVIATIONS

AAA	Abdominal aortic aneurysm
ARC	Aneurysm-related complications
ARM	Aneurysm-related mortality
CSSS	Case Selection and Sizing Study
DOB	Date of Birth
DTF	Device Tracking Form
ICU	Intensive Care Unit
IFU	Instructions for use
IMA	Inferior mesenteric artery
JLL	Japan Life Line (Japanese Marketing Authorisation Holder)
LAO	Left anterior oblique
LDI	Loss of Device Integrity
PAS	Post-approval study
PMDA	Pharmaceuticals and Medical Devices Agency (Japanese agency)
RCT	Randomized Controlled Trial
SAE	Serious Adverse Events

1 OVERVIEW

This annual clinical update provides a review of the ongoing experience with the Ovation platform and the Alto Abdominal Stent Graft System used in the treatment of abdominal aortic aneurysms.

The Ovation PMA (P120006) was approved on 05 Oct 2012 with subsequent approvals for Ovation Prime (P120006/S001), Ovation iX (P120006/S015, P120006/S020), and the Alto Abdominal Stent Graft System (P120006/S031). The Alto System represents the latest iteration of the Ovation platform and is the only iteration currently manufactured/commercialized by Endologix LLC as of the date of this report (Summary of Safety and Effectiveness, Instructions For Use).

In this update, 13 years of IDE clinical data, 9 1/2 years of post-approval study (PAS) data, and 13 years of worldwide commercial experience are presented. This update contains information that has become available since the reporting period of the last annual clinical update up to 31 Jul 2025.

2 WORLDWIDE DEVICE DISTRIBUTION

Please reference **Table 1** below for a summary of the worldwide commercial distribution of the Ovation platform and Alto implantable devices.

Table 1: Summary of Worldwide Commercial Distribution of the Ovation Platform*

Device	01 Sep 2024 – 31 Jul 2025	Total Lifetime Sales
Ovation Aortic Body	0	1,685
Ovation Iliac Limbs/ Extensions	0	5,116
Ovation Prime Aortic Body	0	8,715
Ovation Prime Iliac Limbs/ Extensions	0	19,903
Ovation iX Aortic Body	0	13,503
Ovation iX Iliac Limbs	6,521	65,558
Ovation iX Iliac Extensions	822	8,458
Alto Aortic Body	2513	13,246
Fill Polymer Kit	0	8,927
Autoinjector	0	23,495
CustomSeal Kit	2,418	28,434
Autoinjector 2	2,333	13,214
TOTAL	14,658	210,254

**The Ovation Abdominal Stent Graft System, Ovation Prime Abdominal Stent Graft System, Ovation iX Abdominal Stent Graft System, Fill Polymer Kit, and Autoinjector are no longer commercialized. As of the date of this report, the Alto Abdominal Stent Graft System (Alto Aortic Body Stent Graft, Ovation iX Iliac Limb/Extension Stent Grafts, CustomSeal Kit and Autoinjector 2) is the only currently commercial platform iteration in the US and OUS. The Ovation iX Abdominal Stent Graft System was discontinued in the United States on 31 October, 2020. Ovation iX was still commercial in certain OUS geographies during the reporting period but has since been discontinued.*

3 CLINICAL EVALUATIONS

3.1 Ovation Abdominal Stent Graft System Platform

Ovation IDE Study: The Ovation IDE study encompassed three subcohorts: the pivotal cohort (n=161) upon which the FDA granted approval, continued access (n=77), and de novo (n=82). Enrollment across these cohorts (n=320) spanned from November 2009 to July 2015, and each was followed through five (5) years. The final exit across all cohorts was September 2020. Pivotal cohort results may be found within the Ovation IFU (https://www.accessdata.fda.gov/cdrh_docs/pdf12/p120006c.pdf) The pivotal cohort results combined with the continued access and de novo cohorts is also referred to as the post-approval study (PAS). The PAS primary endpoint was freedom from aneurysm-related mortality at five (5) years. These results can be found on Ovation / Ovation Prime PAS FDA webpage (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=489523&c_id= 770).

3.2 Alto Abdominal Stent Graft System Platform

Alto (ELEVATE) IDE Study: Endologix successfully completed the Alto IDE study in March 2019 which is reported in the Alto IFU. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120006S031C.pdf

Alto Case Selection and Sizing Study (CSSS): A multi-center clinical evaluation was initiated to compare physician selection of patients for the Alto device compared with Endologix Imaging Services using the same diagnostic, de-identified, CT scan in 100 subjects. The study endpoints include a description of any differences and concordance with respect to key anatomic measurements for Alto device sizing, general suitability for EVAR, compliance with the anatomic indications for use, and Alto Aortic Body size selected. Sites began enrolling subjects for the CSSS on 30 July 2020 and completed enrollment (n=100) on 22 December 2020. The 30-day post implant timepoint was reached for all subjects with the final subject's 30-day timepoint occurring on 21 January 2021. Reference the Alto CSSS PAS on FDA webpage: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=662675&c_id= 6009

For the 100 subjects enrolled, there has been 100% agreement and 0% disagreement among physician users and Endologix Imaging Services with respect to Alto Aortic Body sizing recommendations and suitability for EVAR.

Alto US and OUS Post-Approval Study (JAGUAR Trial): A prospective, randomized, multi-center US and OUS Post-Approval Study was initiated to collect safety, effectiveness, and neck dilatation data on the Alto Abdominal Stent Graft System and evaluate real world outcomes in comparison to commercially available comparator devices. There are two primary endpoints: a clinical endpoint and a surrogate. The clinical endpoint is a composite of aneurysm-related complications (ARC) and consists of freedom from device-related interventions (for Type I & III endoleaks, stenosis/occlusion, migration, or other device- related cause), conversion to open surgery, Type I and III endoleaks, device migration (>10 mm), aneurysm sac enlargement (>5 mm), occlusion, aneurysm rupture, and aneurysm-related death. The surrogate endpoint is the hypothesized physiologic mechanism that leads to failure of several components within the clinical endpoint: proximal neck dilation over time.

The surrogate allows for an early insight into eventual clinical sequelae. All individual components of the primary endpoint will be evaluated as separate outcomes using the Kaplan-Meier approach. Results will be stratified by device cohort. A minimum of 450 consented patients diagnosed with AAA who are considered candidates for endovascular repair and meet the study eligibility criteria, will be randomized. At least 300 will be allocated to the Alto cohort, and 150 to the comparator group.

The first subject was enrolled for the US and OUS PAS on 20 September 2021. As of 31 July 2025, 364 subjects (240 Alto arm; 124 comparator arm) had been implanted in the JAGUAR Trial. As enrollment is ongoing, no clinical conclusions can be drawn at this time. The primary endpoint is freedom from a composite of aneurysm-related complications (ARC). Currently, the rate of device-related interventions is roughly equivalent in the first (3.8% and 4.8%) and second years (2.1% and 1.1%) in the Alto and comparator cohorts, respectively. Two (2) subjects underwent conversions to open repair in the comparator arm and one (1) in the Alto arm. One (1) subject presented with bilateral type IB endoleaks [Alto arm] through year 2. There are no type III endoleaks or migrations reported. It is too early in the study to evaluate rates of sac and neck expansion. There are currently three (3) subjects with occlusions in the comparator cohort and two (2) in the Alto cohort. No ruptures are seen in the Alto cohort, but 1 event has occurred in the comparator cohort. A 0.4% 1-year aneurysm-related mortality (ARM) rate is seen in Alto, and 1.6% in the comparator cohort. There are no ARM events past 1 month. The MAE rate in the comparator cohort is roughly double that of the Alto cohort at 1 year (12.9% vs 5.8%), equivalent at year 2 (6.7% in both groups), and higher at year 3 in the comparator cohort (5.3% vs 1.9%).

As of 31 July 2025, there have been no perioperative incidences of polymer leaks observed or reported in the JAGUAR Trial (n=239 Alto cases). Endologix further notes that there were no intraprocedural polymer leaks observed or reported in the Alto ELEVATE IDE study (n=75 Alto cases) or Alto Case Selection and Sizing Study (ACSSS) (n=100 Alto cases).

Reference the Alto RCT (Randomized Controlled Trial) US and OUS PAS on FDA webpage: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=662675&c_id=6010.

4 WORLDWIDE RECALLS, SAFETY COMMUNICATIONS AND FIELD SAFETY NOTICES

Please note the only iteration of the Ovation Platform that is currently commercially available is the Alto Abdominal Stent Graft System. Endologix has discontinued all previous iterations of the Ovation Platform worldwide; the Ovation iX Aortic Body and Autoinjector were discontinued in the United States on October 31, 2020.

The Ovation iX Abdominal Stent Graft System is no longer manufactured or commercialized by Endologix; however, the CustomSeal Kit and Ovation iX iliac limb and extension were still sold during the reporting period.

The historic safety communications for the Ovation iX System are included in this report for reference.

From the time of commercial launch through 31 Jul 2025, there have been two safety communications regarding the Ovation iX Abdominal Stent Graft System which are summarized below.

- On 06 Aug 2018, Endologix issued communication to physician users due to an increase in intra-operative polymer leaks identified with the Ovation iX Abdominal Stent Graft System compared to historical levels. (https://endologix.com/wp-content/uploads/2018/08/Ovation-FSN-Aug-06-Final.pdf) The polymer leaks resulted in death (AAA-related); multi-organ failure/cardiac arrest/neurological complication; local tissue necrosis; prolonged hemodynamic instability, and transient hemodynamic instability.

Investigation determined that most polymer leaks resulted from deviations to the procedural sequence related to the polymer fill and procedural steps provided in the IFU. The purpose of the safety communication was to emphasize the importance of following the polymer fill procedural sequence as instructed and provide information specifically regarding: 1) Patient Reaction; 2) Aneurysm Management; 3) Procedural Considerations; and 4) Warnings and Cautions. No changes to the IFU were required.

- On 06 May 2020, Endologix issued a communication to physician users of the Ovation iX Abdominal Stent Graft System to provide a safety update regarding polymer leaks during implantation. (https://endologix.com/wp-content/uploads/2020/05/ENDO-Ovation-FSN- FS-0012-US-Letter-Final-5-6-20.pdf) This safety update reaffirmed treatment recommendations for patients who experience a polymer leak during implantation and provided updated information on the current rate of polymer leaks, the rate of clinical harms and the root cause. FDA identified this as a Class I recall.
(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=181049)

The investigation determined that technical and procedural factors of the user (e.g. use of the cross over lumen before polymer fill, catheter manipulation) are not causative for the majority of polymer leaks, as was previously communicated. Adherence to the procedural steps within the Instructions for Use continues to be recommended and are not modified in this safety update. The root cause for most polymer leaks was determined to be a material weakness adjacent to the polymer fill channel which may become compromised during pressurization with liquid polymer.

The following was included as a part of Field Safety Notice as further risk mitigations for intravascular leak of polymer:

- Promptly treating the patient for potential severe hypersensitivity reaction if a polymer leak is identified
- Adhering to the procedural steps in the published device instructions for use (IFU) including existing IFU Caution and Warning statements and avoiding excessive device manipulation.

Endologix transitioned the US market completely from Ovation iX to the Alto Abdominal Stent Graft System at the end of October 2020. Alto incorporates design and manufacturing changes that are intended to eliminate the areas of material weakness associated with polymer leaks. Additionally, in an effort to mitigate the procedural polymer leak risk, Endologix is committed to the Alto Physician Training Program which incorporates best practices for polymer management. In accordance with our quality system and post-market surveillance procedures, Endologix will continue to closely monitor Alto device performance,

including any instances of polymer leak. As of the date of this report, Alto is the only iteration of the Ovation Platform which is manufactured or distributed by Endologix.

There have been no safety communications regarding the Alto Abdominal Stent Graft System since commercialization in July of 2020.

5 WORLDWIDE COMMERCIAL EXPERIENCE

5.1 Ovation iX Abdominal Stent Graft System

As part of continuous monitoring of Ovation iX lifetime device performance, the most common global product complaint category from commercialization to the current data cut (08 Aug 2015 – 31 Jul 2025) was Type IA endoleak. During this time period there were 343 Type IA events that occurred out of a total of 13,503 devices sold [343/13,503], which equals a rate of 2.54%. The root cause analysis identified that the majority of Type IA endoleaks are acute (<30 days) and the variables associated with Type IA endoleaks include the anatomical variances of reverse taper neck and juxtarenal angle.

5.2 Alto Abdominal Stent Graft System

As part of continuous monitoring of Alto lifetime device performance, the most common global product complaint category from commercialization to the current data cut (22 Jul 2020 – 31 Jul 2025) was Type IA endoleak. During this period there were 156 Type IA events that occurred out of a total of 13246 devices sold [156/13246], which equals a rate of 1.17%. The root cause analysis identified that the majority of Type IA endoleaks are associated with patient selection, cautionary product use, and indeterminate.

Endologix will continue to closely monitor Ovation and Alto device performance, including Type IA endoleak trend.

6 POLYMER LEAK TRENDS

Over the lifetime of the Alto System through the current reporting period, there have been a total of twenty-one (21) polymer leaks reported to Endologix (July 2020 – July 2025). Of those polymer leaks, eighteen (18) events had transient hemodynamic instability, two (2) had prolonged hemodynamic instability, two (2) had local tissue necrosis, two (2) had cardiac arrest, one (1) had spinal cord infarction, and one (1) resulted in the death of the patient. With respect to intra-operative aneurysm-related complications associated with polymer leaks, four (4) events experienced an unresolved Endoleak Type Ia, and one (1) event experienced an occlusion.

As of July 2025, the lifetime complaint rate for the commercial Alto Abdominal Stent Graft System is 0.16%, as compared with 0.89% for the predecessor Ovation iX Abdominal Stent Graft System. It is noted that the reported event rates are calculated based on voluntary complaint reporting and units sold, which may underestimate the true rate of occurrence and may contain less information than would be typical of an analysis from a clinical trial. Due to the nature of voluntary complaint reporting, some data may be incomplete.

7 EXPLANT ANALYSIS

Endologix monitors the performance of its products to ensure their ongoing quality, safety, and efficacy. When a product is explanted and returned, a thorough review is conducted that includes a historical analysis, an engineering evaluation, and histopathological examinations of the explanted stent grafts. Endologix strives to make at least three good faith attempts to retrieve any device associated with a reported adverse event or incident, along with relevant medical records and imaging. It is important to note that explant analyses can only be performed on devices that have been returned.

From the launch of the Alto system (July 2020) through 31 July 2025, there have been sixteen (16) explants out of a total of 13,246 implant procedures performed worldwide, representing an explant rate of 0.12%. This compares favorably to the cumulative lifetime explant rate of 0.26% observed with the previous Ovation iX platform. Of the sixteen (16) Alto devices that were explanted, two (2) were returned for explant evaluation thus 12.5% of explanted Alto devices were returned as the only devices available for explant analysis. See below for a summary of both cases for their intra-operative complications:

- PR57214: A polymer filling issue was visually confirmed. Excessive manipulation of the delivery system was noted and may have contributed to the complication. The delivery system was not returned, and the stent graft was dissected during the explant procedure.
- PR57264: There was a kink present on the sheath approximately 7mm proximal to the proximal end of the sheath fitting. There is a slight "S" shaped bend to the sheath over the proximal end of the 270mm length of the sheath. The flush valve presented with one wing sheared off. The remainder of the device remains unremarkable. Based on visual inspection the complaint is confirmed.

Summaries of complaints that did not include analysis have been removed from this update.

8 LITERATURE REVIEW

The current systematic review of the literature from April 11, 2024 - April 30, 2025 identified a total of two (2) device specific articles providing clinical safety/performance outcomes on the Ovation Platform and Alto Abdominal Stent Graft System. See **Table 2** below.

Table 2: Safety and Performance Outcomes in Ovation/Alto Platform

Author, Title, Publication Date	Study Design Mean follow-up (range)	Treatment/Indication Population Mean Age (range)	Safety and Performance Outcomes	Annual Clinical Update Year	Conclusion
Ichihashi S, et al. Less Aortic Neck Dilatation of the ALTO Stent Graft compared to the Self-Expanding Stent Grafts after Endovascular Aortic Repair for Abdominal Aortic Aneurysms. Cardiovasc Intervent Radiol. 2025 Apr;48(4):438-446.	• Retrospective multi-center observational study • Outcomes measured through 12 months	• Utilizes Alto device • Patients undergoing EVAR • N=111 Alto patients propensity matched to N=111 self-expanding stents • Mean age 78 in both cohorts • On-label status of patients was not provided for analysis in the clinical literature, therefore on/off label use of the device is unknown.	• Proximal neck enlargement of 3mm at 12 months (2.3% in Alto vs 26.7% in comparators, p<0.001) • AAA sac shrinkage at 12 months (30.2% in Alto vs 41.4% in comparators, p<0.021)	2025	• Alto had less neck expansion than self-expanding stents at 12 months. • At 12 months, there was no significant difference in survival, reintervention, and AAA-related adverse events.
Konert M. ELECT: prospective, randomized trial comparing microvascular plug (MVP) versus platinum-fibered microcoils for embolization of aneurysm sac side branches before endovascular aortic aneurysm repair. CVIR Endovasc. 2024 May 3;7(1):42.	• Single-center prospective 1:1 Randomized study • Average follow-up 4-6 weeks	• Utilizes Ovation and other devices • N=60 patients scheduled for EVAR, randomized to coils or microvascular plugs. Includes n=9 Ovation patients • Mean age 71 years • On-label status of patients was not provided for analysis in the clinical literature, therefore on/off label use of the device is unknown.	• Procedure time 55 minutes (MVP) vs 67 minutes (Coils) p=0.018 • Contrast volume 34 mL (MVP) vs 35 (coils) p=0.87 • Radiation (Gray/cm^2): 119 (MVP) vs 140 (coils), p=.45	2025	• Coils and MVP are both safe and effective for embolizing sac side branches. • MVP is associated with shorter procedure times.
Mazzacccaro. Low profile endografts for the endovascular treatment of abdominal aortic aneurysms. Expert Rev Med Devices. 2023	• Meta-analysis • Median follow-up: 5y	• Patients treated with low profile endografts • Mean age: Ovation 73.9, Incraft 74.6, Zenith LP/Alpha 74.8 • On-label status of patients is not provided, however, the tables suggest off label	• Perio-operative AAA-mortality: Zenith LP/Alpha 0%, Ovation 0.3-0.4%, Incraft 0% • 3 year survival: Zenith LP/Alpha 87-91.1%,	2024	• Survival rates, reintervention rates, and sac enlargement rates were comparable across all three low profile endovascular devices. • The Zenith device had the highest rate of limb stenosis and kinking.

Author, Title, Publication Date	Study Design Mean follow-up (range)	Treatment/Indication Population Mean Age (range)	Safety and Performance Outcomes	Annual Clinical Update Year	Conclusion
		patients are included with hostile neck features	Ovation 86.9-100%, Incraft 84.4-94.5% • Technical success: Zenith LP/Alpha 92.1-100%, Ovation 89.2-100%, Incraft 90-99.3% • 3 year intervention: Zenith LP/Alpha 86.6-91%, Ovation 90.8-100%, Incraft 91.8-96.1% • 3 year sac enlargement: Zenith LP/Alpha 87-98.4%, Ovation 90.3-97.1%, Incraft 96.1-100% • Limb occlusion: Zenith LP/Alpha 2.2%, Ovation 3.2%, Incraft 2.9% • Type Ia endoleaks: Zenith LP/Alpha 2.2%, Ovation 3.3%, Incraft 4.1% • Type Ib endoleaks: Zenith LP/Alpha 0.7%, Ovation 0.4%, Incraft 1.4% • Type II endoleaks: Zenith LP/Alpha 7.3 %, Ovation 16.3%, Incraft 25.6% • Type III endoleaks: Zenith LP/Alpha 1.1%, Ovation 2.3%, Incraft 0.5%		• The Incraft device had the lowest occurrence of type III endoleaks, and Ovation and the highest. • Reintervention was not impacted by neck thrombus, neck calcification, and small iliac access
Varkevisser. The Impact of Proximal Neck Anatomy on the 5-Year Outcomes Following Endovascular Aortic Aneurysm Repair With	• Retrospective analysis of the ENCORE dataset, consisting of 6 clinical studies • Follow-up through 5 years	• 1020 EVAR patients treated with the Ovation Platform (Ovation/Ovation Prime/Ovation iX), including 402 with at	• 5 year type IA rate in: favorable anatomy (4.3%), short neck (1.7%), wide neck (7.1%), taper neck (3.2%), angulated neck (6.1%)	2024	• Risk of type IA endoleaks is not increased in anatomies with short, angulated, or reverse tear-shaped necks. • Wide necks are associated with increased risk of type IA endoleaks

Author, Title, Publication Date	Study Design Mean follow-up (range)	Treatment/Indication Population Mean Age (range)	Safety and Performance Outcomes	Annual Clinical Update Year	Conclusion
the Ovation Stent Graft. J Endovasc Ther. 2023		least 1 hostile neck characteristic • Mean age: favorable anatomy 73.2, short neck 74.7, wide neck 74.0, tapered neck, 73.5, angulated neck 76.3 • Off label treatment occurred in 14% of short necks, 13% of wide necks, 4.9% with reverse taper, and 16% of angulated necks, compared with 0.2% in patients with favorable neck anatomy			
Efthymiou. Endovascular juxtarenal aortic aneurysm repair using the ALTO abdominal stent graft system: the first case series. Vasc Specialist Int 2022	• Single-center Prospective study describing characteristics and deployment procedures of the ALTO device and early outcomes • Follow-up 1 month	• Patients included were generally eligible to be treated for AAA. • N=6 males • Mean age 67 years (range: 60-77 yrs) • 4 infrarenal; 2 juxtarenal • On-label status of patients is not provided	• 100% technical success • At 1 month, CTA showed no evidence of type I or III endoleaks, device migration, graft thrombosis, or structural graft failure • No deaths • No polymer leaks • 2 type II endoleaks	2023	• This clinical series demonstrates that the use of the ALTO stent graft system is associated with promising initial outcomes
Jensen. "Aortic balloon molding" during ovation endograft implantation expands graft use for hostile neck anatomy. Ann Vasc Surg 2022.	• Single-site retrospective review of patients who underwent EVAR with Ovation iX stent graft between March 2019 and December 2020 • Mean follow-up was 7.9±6 months • **No Alto devices**	• Challenging aortoiliac anatomy is responsible for EVAR ineligibility in up to 50% of cases • The technique was preferentially performed in patients with hostile neck anatomy • Aortic Balloon Molding" or ABM is a novel endovascular technique in which the graft is pre-cannulated	• 1-year freedom from type Ia endoleak 100% • 1-year freedom from stent. migration 100% • No polymer leaks • 1 Type Ia endoleak at completion • 6 neck related adjunctive procedures	2023	• ABM is a safe and effective adjunctive technique for the treatment of AAA the Ovation iX stent graft. The technique may allow for optimal endograft sizing. The technique also ensures adequate seal in complex aortic anatomy, particularly in patients who do not meet IFU criteria for EVAR.

Author, Title, Publication Date	Study Design Mean follow-up (range)	Treatment/Indication Population Mean Age (range)	Safety and Performance Outcomes	Annual Clinical Update Year	Conclusion
		and a compliant aortic balloon is inflated at the site of the graft's sealing rings during polymer administration • 43 patients total; 26 in ABM group. • Mean age 75 years; 38 male; 5 female • 65.4% of patients in the molding group were off label			
Mathlouthi. The correlation of aortic neck length to late outcomes following EVAR with the Ovation stent graft. J Vasc Surg 2022	• Multi-center, international prospective Ovation stent graft trials • Median follow-up 58 months	• Aim of study was to evaluate 5-year outcomes after EVAR in patients with short aortic necks (<10mm) • 238 total patients; 41 had proximal neck length <10mm • 81% male • Mean age 73+/- 8 years • Patient population is on-label	• The 5-year overall survival estimates were 77.8% for the standard neck group compared with 59.5% for the short neck group (P =.03). • No differences in the 5-year freedom from ARM (99.2% vs 100% • No differences in freedom from type Ia endoleak (96.3% vs 96.3%; • No differences in freedom from reintervention (77.9% vs 79.7% • After adjusting for age and other potential confounders, short proximal neck was associated with a two-fold increase in 5-year all-cause mortality • No data on polymer leaks	2023	• The Ovation endograft performed well in short AAA neck with no difference in 5-year type Ia endoleak, • reintervention, and ARM rates. • However, short proximal neck was independently associated with a two-fold increase in • the risk of all-cause mortality at 5 years.
Berczeli. Time-resolved CT angiography after EVAR: a quantitative approach to accurately characterize aortic endoleak type and	• Retrospective analysis of 48 patients, 24 had abdominal EVAR and both d-CTA and DSA b/w March 2019 and January 2021	• Patient with Ovation stent graft was 72 years old. No indication whether male or female • Patients who underwent d-CTA after abdominal EVAR for endoleak diagnosis and	• Type III endoleak reported from defect in polymer sealing ring	2023	• No conclusions relevant to Ovation devices

Author, Title, Publication Date	Study Design Mean follow-up (range)	Treatment/Indication Population Mean Age (range)	Safety and Performance Outcomes	Annual Clinical Update Year	Conclusion
identify inflow vessels. J Endovasc Ther 2023	• Only one ovation device (not specified)	had DSA imaging available within a 3-month period to confirm the findings of d-CTA • On-label status of patients is not provided			
Cuozzo. Early experience with ovation alto stent-graft. Ann Vasc Surg 2023	• Single-center Prospective study of patients undergoing EVAR with Ovation Alto stent-graft between June 2021 and February 2022. • Follow-up at 1, 3, and 6 months • Mean follow-up 8.8 months (range 4.9-12.9)	• Infrarenal abdominal aortic aneurysms. Hostile aortic neck anatomy was defined as unfavorable neck shape (tapered, reversed tapered), >50% calcification, and circular or semicircular thrombus; a narrow iliac-femoral axis was defined as an external iliac artery (EIA) of <6 mm diameter • n=7 males • Mean age 76.1 +/- 6.2 years • Patient population is on-label	• Technical success 100% • No cases of polymer leak • No major aneurysm-related complications occurred during follow-up; • No type IA/IB and type III endoleaks were observed. • 3 Type II endoleaks (42.8%) registered. • No reinterventions • No stent-graft thrombosis • No migration	2023	• Authors conclude that Initial experience suggests that Ovation Alto stent-graft seemed to have promising early technical and clinical success rates
Lyden. One-year safety and effectiveness of the Alto abdominal stent graft in the ELEVATE IDE trial. J Vasc Surg 2023.	• Prospective multi-center trial • Mean follow-up 16.5 months (range 12-30)	• AAAs, with sealing 7 mm below the top of the fabric in aortic neck diameters from 16 to 30 mm • N=75 (70 males) • Mean age 72.5 (65-83 years) • On-label patient population	• 30 day MAE was 5.3% • At 1 year, treatment success was 96.7% • All-cause mortality was 4.0%; no AAA-related mortality occurred • AAA enlargement was 1.6% • type I endoleak rate was 1.4% • 100% freedom from type III endoleaks, device migration, device fracture, stent occlusion, or AAA rupture • Device-related secondary intervention rate was 2.7% • No polymer leaks	2023	• The current evidence demonstrates that endovascular repair of AAAs with the Alto device yields a favorable effectiveness profile through 1-year post-treatment
Kontopodis. Late neck related adverse events are rare among patients with wide aortic neck underground endovascular repair with	• Retrospective single-center with patients undergoing EVAR with Ovation system from May 2011 to April 2021 • Median follow-up was 36 months (range from 6 to 106 months)	• Patients with wide aortic necks undergoing EVAR included to examine outcomes with an endograft exerting minimal outward pressure (Ovation Endologix) • 281 patients total; Group 1 –	• No overall differences between groups • Freedom from mortality was 95, 86, and 75% at 12, 36, and 60 months follow-up • Freedom from neck related adverse events was 98, 94, and 94% at 12, 36, and 60	2023	• Low rates of neck related adverse events are observed among patients undergoing EVAR with the Ovation endograft during mid-term follow-up

Author, Title, Publication Date	Study Design Mean follow-up (range)	Treatment/Indication Population Mean Age (range)	Safety and Performance Outcomes	Annual Clinical Update Year	Conclusion
the ovation endograft. Ann Vasc Surg 2023		aortic neck diam 20-29mm (n=222); Group 2 – 34 mm (n=59) • mean age was 72 years; 99% male • note: Only "a few" Alto devices used • On-label patient population	months • 2 distal migration • 4 neck dilation • **Endoleaks**: 8 early Type Ia 4 late Type Ia 5 Type Ib • 78 Type II • 3 Type III • No data on polymer leaks		

9 CONCLUSION

Based on available clinical study data and worldwide clinical experience to date, endovascular therapy with the currently marketed Alto Abdominal Stent Graft System continues to be a viable treatment option for abdominal aortic aneurysms.

Adverse Event Reporting:

Any adverse event involving the Ovation or Alto devices should be reported immediately to the Endologix Customer Service Department at 800-983-2284 (24 hours message service). Outside the US, contact your local Endologix representative. Accurate and timely reporting of adverse events by the physician users to the device manufacturer and FDA (MedWatch Form 3500) is critical for monitoring device performance and detection of potential device-related safety issues.

Patient Follow-Up and Selection:

Regular follow-up of all patients treated with the Ovation and Alto Abdominal Stent Graft Systems is required. Physicians should tailor follow-up to the needs and circumstances of each individual patient.

Endologix recommends the following imaging schedule in **Table 3** for patients treated with the Alto Abdominal Stent Graft System. The appropriate follow-up imaging and imaging modalities for a particular patient are the responsibility of the clinician.

Table 3: Recommended Patient Imaging Schedule

Interval	Contrast Enhanced Spiral CT [1]	Abdominal X-rays [2]
Pre-procedure (baseline)	X	
Pre-discharge		X
1 month	X	X
6 months	X	X
12 months (annually thereafter)	X	X

[1] Abdominal / Pelvic. Used to assess graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, stent graft patency, AAA size, occlusion of branch vessels, and endoleak (including source and type, if present).

[2] AP, lateral, left oblique and right oblique views. Used to assess the presence of stent fracture. Ensure the entire device is captured on images for device assessment.

Patients should be counseled on the importance of adhering to the recommended follow-up schedule during the first year and annually thereafter. More frequent follow-up may be required for some patients based on clinical evaluation.

Refer to the ***Instructions for Use*** for detailed patient follow-up and selection recommendations, e.g., for patients with impaired renal function.