Summary of Safety and Effectiveness Data (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Endovascular Graft
Device Trade Name:	Ovation Abdominal Stent Graft System
Device Procode:	MIH
Applicant's Name and Address:	TriVascular, Inc. 3910 Brickway Blvd. Santa Rosa, CA 95403
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P120006
Date of FDA Notice of Approval:	October 5, 2012
Expedited:	Not applicable

II. INDICATIONS FOR USE

The TriVascular Ovation Abdominal Stent Graft System is indicated for treatment of patients with abdominal aortic aneurysms having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories,
- Non-aneurysmal proximal aortic neck:
  - with a length of at least 7 mm proximal to the aneurysm,
  - with an inner wall diameter of no less than 16 mm and no greater than 30 mm and
  - with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm,
- Adequate 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 20 mm.

III. CONTRAINDICATIONS

The Ovation Abdominal Stent Graft System is contraindicated in:

- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol)

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Ovation Abdominal Stent Graft System labeling (Instructions for Use).

V. DEVICE DESCRIPTION

The TriVascular Ovation Abdominal Stent Graft System is an endovascular device delivered via catheter to treat abdominal aortic aneurysms (AAAs). The stent graft relines the diseased vasculature, providing an endovascular blood conduit for isolating the aneurysm from the high pressure flow of blood to reduce the risk of rupture. The stent graft is comprised of an aortic body section, two iliac limbs, and iliac extensions, as required (Figure 1).

The TriVascular Ovation Abdominal Stent Graft System includes:

- An Aortic Body Stent Graft and delivery catheter
- Iliac Limb Stent Grafts and delivery catheters
- Iliac Extension Stent Grafts and delivery catheters, as required
- A Fill Polymer Kit
- An Autoinjector

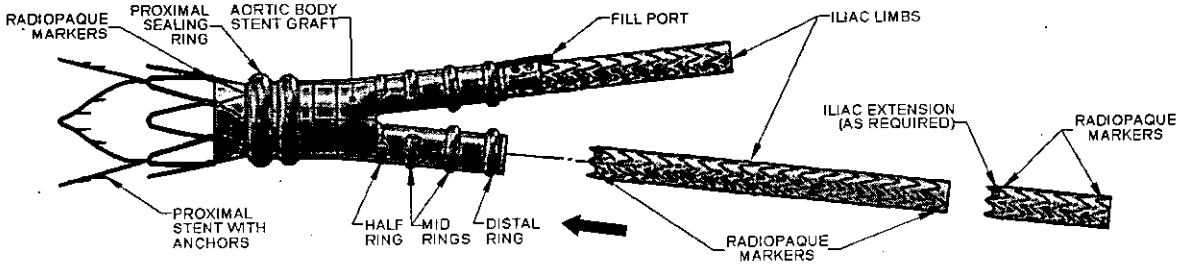

Figure 1. Schematic of Deployed TriVascular Ovation Abdominal Stent Graft System

The stent grafts are available in the sizes and configurations outlined in Tables 1-3.

Table 1. Aortic Body Stent Graft Sizes

Stent Graft Proximal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
20 mm	57 cm	14 F	80 mm
23 mm			
26 mm			
29 mm			
34 mm		15 F	

Table 2. Iliac Limb Sizes

Stent Graft Proximal Diameter	Stent Graft Distal Diameter	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
14 mm	10 mm	53 cm	13 F	80 mm
	10 mm			100 mm
	10 mm			120 mm
	10 mm			140 mm
	12 mm			80 mm
	12 mm			100 mm
	12 mm			120 mm
	12 mm			140 mm
	14 mm			80 mm
	14 mm			100 mm
	14 mm			120 mm
	14 mm			140 mm
	16 mm		14 F	80 mm
	16 mm			100 mm
	16 mm			120 mm
	16 mm			140 mm
	18 mm			80 mm
	18 mm			100 mm
	18 mm			120 mm
	18 mm			140 mm
	22 mm		15 F	80 mm
	22 mm			100 mm
	22 mm			120 mm
	22 mm			140 mm

Table 3. Iliac Extension Sizes

Stent Graft Proximal and Distal Diameters	Catheter Working Length	Delivery System Outer Profile	Covered Stent Graft Length
10 mm	53 cm	13 F	45 mm
12 mm			
14 mm			
16 mm			
18 mm		14 F	
22 mm			

Aortic Body Stent Graft

The aortic body is comprised of a proximal laser-cut stent for suprarenal fixation and a low-permeability polytetrafluoroethylene (PTFE) graft. The stent has integral anchors for fixation to the aortic wall.

For delivery, the stent is in a compressed state within the catheter. When released from the compressed state, the stent expands to engage the vessel wall. The nitinol stent is radiopaque and the implant contains nitinol radiopaque markers adjacent to the proximal graft edge for positioning during implantation. To seal the proximal end of the graft and to provide support for the aortic body legs into which the iliac limbs are deployed, the graft body contains inflatable rings that are filled with a liquid polymer that solidifies during the deployment procedure. The graft has a fill port that connects the fill network of the graft to the delivery catheter.

Iliac Limb and Iliac Extension Stent Graft

The iliac limbs and extensions are comprised of a wire-formed nitinol stent encapsulated within low-permeability PTFE. The iliac limbs are deployed into the leg section of the aortic body. Platinum radiopaque markers at the proximal and distal end of the stent graft enable visualization of the iliac limb-aortic body overlap or iliac extension-iliac limb overlap during deployment. The outward radial force of the stent provides fixation and sealing of the interface between the aortic body and each iliac limb, between the iliac limb and iliac extension, and between the iliac limb/extension and the landing zone in the iliac artery.

Aortic Body Delivery System

The aortic body stent graft is preloaded into a 14F or 15F OD delivery catheter for device introduction into the access vessel (Figure 2). The aortic body delivery catheter has a lumen that allows for the use of a guidewire for delivery of the stent graft to the deployment site.

During stent graft deployment, the device is first positioned and the sheath is retracted. The proximal stent is then deployed using stent release knobs located on the handle. The fill polymer is then delivered through the fill connector port using the autoinjector.

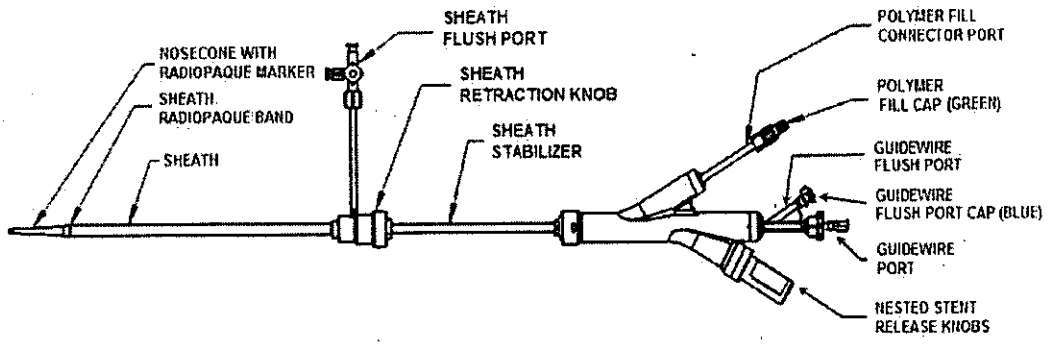

Figure 2. Schematic of TriVascular Ovation Abdominal Stent Graft System Aortic Body Delivery Catheter

Iliac Limb and Iliac Extension Delivery System

The iliac limbs and iliac extensions are preloaded into delivery catheters (13F–15F OD and 13F–14F OD respectively), as illustrated in Figure 3. The contralateral and ipsilateral iliac limbs are each deployed via iliac limb delivery catheters. After deployment of the aortic body, a guidewire is placed from the contralateral access site into the contralateral distal leg of the aortic body. The contralateral iliac limb is advanced into position and deployed into the aortic body by retracting the catheter sheath with the catheter in the appropriate position. The contralateral delivery catheter is then withdrawn from the vasculature. After the fill polymer cures within the sealing rings, the aortic body delivery catheter is disengaged from the fill port of the graft and withdrawn from the vasculature. The ipsilateral iliac limb delivery catheter is advanced over the ipsilateral guidewire and deployed using the method described above for the contralateral limb. The ipsilateral delivery catheter is then withdrawn from the vasculature.

If an iliac extension is required, the delivery system is advanced over the guidewire and the stent graft is deployed using the method described above for contralateral and ipsilateral iliac limbs.

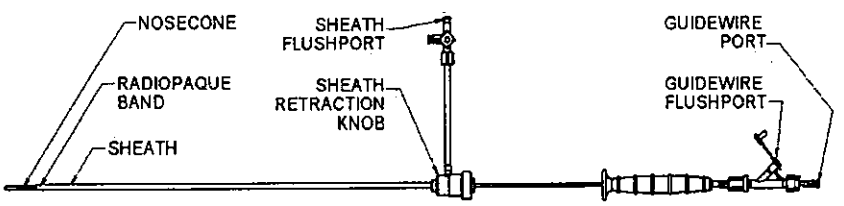

Figure 3. Schematic of TriVascular Ovation Abdominal Stent Graft System Iliac Limb / Iliac Extension Delivery Catheter

Fill Polymer and Autoinjector

The Fill Polymer Kit (Figure 4) is comprised of three materials that are mixed prior to injection. Upon mixing and injection into the graft, the components of the Fill Polymer form a radiopaque polymer that fills the sealing rings of the PTFE channels in the wall of the aortic body graft. The Fill Polymer radiopacity dissipates over time and might not be visible on fluoroscopy, X-ray, or CT beyond 1-2 months post-implant.

Prior to use, the two valves on the Fill Polymer Kit are opened and the fill polymer is mixed by alternately depressing the two syringe plungers for a minimum of 20 full strokes. Thereafter, the full syringe is disconnected from the connection tube, slipped out of the syringe support and connected to the fill polymer injection port on the catheter handle. The syringe plunger is then inserted into the autoinjector and the autoinjector is given a quarter-turn to lock it in place. The autoinjector applies controlled pressure to inject the fill polymer into the graft.

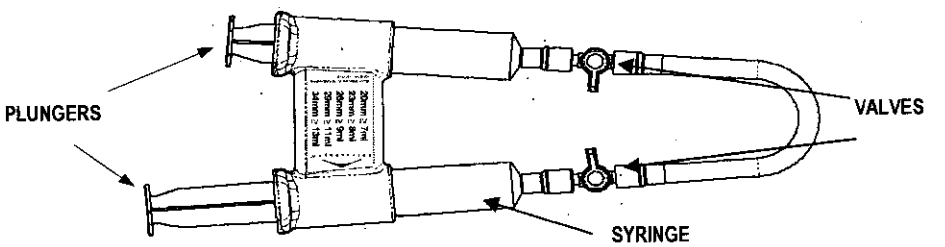

Figure 4. TriVascular Fill Polymer Kit

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the treatment of abdominal aortic aneurysms. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

The alternatives include: endovascular repair using another endovascular graft system, open surgical implantation of a synthetic graft within the aneurysmal vessel, and medical management.

VII. MARKETING HISTORY

The Ovation Abdominal Stent Graft System has been commercially available in Europe since September 2010, in the U.S. as a Humanitarian Use Device (20 mm diameter aortic body) since November 2011, in Canada through the Special Access Programme since December 2011, and commercially in New Zealand since August 2012.

The current Ovation Abdominal Stent Graft System has not been withdrawn from any market for any reason. TriVascular conducted clinical studies with a previous generation abdominal stent graft system from 2002-2004 in the U.S., Europe and

Australia but cancelled the studies in order to pursue design changes that were incorporated into the current device. The previous generation device was not commercially available in any market.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse events (e.g., complications) associated with the use of the device that may occur and/or require intervention include, but are not limited to:

- Acute and chronic renal failure, renal microembolism, renal insufficiency, renal artery occlusion, contrast toxicity;
- Allergic reaction and/or anaphylactoid response to x–ray contrast dye, anti-platelet therapy, device materials;
- Anesthetic complications and subsequent attendant problems (aspiration);
- Aneurysm enlargement or rupture;
- Blood or bleeding events such as anemia, gastrointestinal bleeding, retroperitoneal bleeding;
- Bowel events such as bowel ischemia, infarction, bowel necrosis, colon ischemia, paralytic or adynamic ileuses, obstruction, fistulas;
- Cardiac events and subsequent attendant problems such as congestive heart failure, volume overload, arrhythmias, myocardial infarction, chest discomfort or angina, elevations in creatinine phosphokinase (CPK), hypotension, hypertension;
- Cerebral events (local or systemic) and subsequent attendant problems such as change in mental status, cerebrovascular accident (hemorrhagic or embolic), reversible ischemic neurologic deficit, nerve injury, transient ischemic attacks, paraplegia, paraparesis, paralysis;
- Death;
- Device events such as deployment or device malfunction, stent fracture, loss of stent graft system component integrity, graft twisting and/or kinking, graft material wear, dilation, erosion, puncture, endograft occlusion, migration, dislodgement, endoleak;
- Embolic and thrombotic events (with transient or permanent ischemia or infarction) such as deep vein thrombosis, thromboembolism, microembolism, thrombophlebitis, phlebothrombosis, air embolism;
- General discomfort related to the procedure;
- Generalized inflammatory response that may be associated with elevated levels of systemic mediators of inflammation, elevated temperature;
- Genitourinary complications and subsequent attendant problems such as ischemia, erosion, fistula, incontinence, hematuria, infection;
- Hepatic failure;
- Insertion and other vascular access site complications such as infection, dissection, transient fever, bleeding, pain, delayed healing, abscess formation, hematoma,

dehiscence, seroma, cellulitis, nerve injury/damage, neuropathy, neuralgia, vasovagal response, pseudoaneurysm, anastomotic false aneurysm, arteriovenous fistula;

- Impotence/ sexual dysfunction;
- Lymphatic complications and subsequent attendant problems such as lymphocele, lymph fistula;
- Multi-system organ failure;
- Neoplasm;
- Operative and post–operative bleeding and hemorrhage, coagulopathy;
- Paralysis (temporary or permanent) such as paraplegia, monoplegia, paresis, spinal cord ischemia, hemiplegia, bowel or bladder incontinence;
- Pericarditis;
- Pneumothorax;
- Possible infection–urinary tract, systemic or localized, endograft;
- Pulmonary/respiratory events and subsequent attendant problems such as pulmonary insufficiency, pneumonia, respiratory depression or failure, pulmonary edema, pulmonary embolism, atelectasis, pleural effusion;
- Radiation injury, late malignancy;
- Sepsis;
- Seroma;
- Shock;
- Spinal neurological deficit;
- Surgical conversion to open repair; and/or
- Vascular spasm or vascular injury/trauma including damage to blood vessels and surrounding tissues, atherosclerotic ulcer, vessel dissection, perforation, plaque dissection, stenosis, pseudoaneurysm, vessel occlusion, embolization, ischemia, tissue loss, limb loss, gangrenous disease, worsened or new onset claudication, edema, fistula, bleeding, rupture, death.

For the specific adverse events that occurred in the clinical studies, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

TriVascular completed comprehensive biocompatibility (Section A), *in vitro* bench and analytical testing (Section B), animal studies (Section C), and Sterility, Packaging and Shelf-Life testing (Section D) on the Ovation Abdominal Stent Graft System to support the safety and effectiveness of the device. The testing included the stent graft, iliac limbs, extensions and delivery system following recognized standards and guidance documents.

A. Biocompatibility

Biocompatibility testing was conducted on the Ovation Abdominal Stent Graft System to ensure that the finished device is biocompatible. Testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. The Ovation Abdominal Stent Graft System delivery system was categorized as an external communicating device in short-term contact with circulating blood (< 24 hours). The stent graft and fill polymer were categorized as implant devices with permanent blood contact (> 30 days). The autoinjector was categorized as a non patient contacting component. All testing was performed with finished sterile devices and met the requirements as specified within the applicable standard, and is summarized in Tables 4-6.

Table 4. Biocompatibility Test Summary - Stent Graft and Fill Polymer

Test/Study Name	Purpose	Results	Conclusion
Cytotoxicity - MEM Using L-929 Mouse Fibroblast Cells	To evaluate the ability of the test article extract to elicit a cytotoxic response in cultured mouse fibroblast cells when conducted in accordance with the test method requirements	Test article is non-toxic. Grade 0 cytotoxicity for test and negative controls Grade 2 for intermediate controls Grade 4 for positive controls	PASS
Sensitization – LLNA Albino Swiss Mice	To assess the dermal sensitization potential of a test article using the Murine Local Lymph Node Assay (LLNA).	Not a sensitizer. Differences in test article results from the negative control were not statistically significant.	PASS
Irritation - Intramuscular Implant: 28 Day	To evaluate the local toxic effects of a biomaterial in direct contact with living muscular tissue of the rabbit for twenty eight (28) days.	Slight irritant - Implant tissue had an irritant ranking score of 3.2. All animals survived to the scheduled study endpoint. Gross observations were unremarkable.	PASS
Irritation - Intramuscular Implant: 84 Day	To evaluate the local toxic effects of a biomaterial in direct contact with living muscular tissue of the rabbit for eighty four (84) days.	Non-irritant - Implant tissue had an irritant ranking score of 2.2. All animals survived to the scheduled study endpoint. Gross observations were unremarkable.	PASS
Intracutaneous Reactivity	To determine if any chemicals that may leach or be extracted from the test article were capable of causing local irritation in the dermal tissues of the rabbit.	Non-irritant - Saline and cottonseed oil extracts had an average dermal score of 0. The difference between the mean of the control and the mean of the test group was <1.0, which is acceptable.	PASS
Systemic Toxicity (Acute) – ISO Acute Systemic Injection	To screen test article extracts for potential toxic effects as a result of a single-dose system injection in mice.	Test article is non-toxic. No fatalities, signs of clinical toxicity or body weight loss > 2 grams.	PASS

Test/Study Name	Purpose	Results	Conclusion
Genotoxicity - Bacterial Mutagenicity Test - AMES Assay Using Five Salmonellea Strains and Escherichia Coli	To evaluate the mutagenic potential of the test article (or its metabolites) by measuring its ability to induce back mutations at selected loci of several strains of bacteria in the presence and absence of microsomal enzymes by a method compliant with the requirements.	Non-toxic and non-mutagenic.	PASS
Genotoxicity - *In Vitro* Mouse Lymphoma Assay	To determine the ability of a test article to induce forward mutations at the thymidine kinase (TK) locus as assayed by colony growth of L5178Y mouse lymphoma cells in the presence of trifluorothymidine (TFT).	Non-toxic and non-mutagenic.	PASS
Genotoxicity - *In Vivo* Mouse Micronucleus Assay	To evaluate the mutagenic potential of the test article (or its metabolites) by measuring its ability to induce back mutations at selected loci of several strains of bacteria in the presence and absence of microsomal enzymes by a method compliant with the requirements.	Non-toxic and non-mutagenic.	PASS
Implantation	To evaluate the local toxic effects of a biomaterial in direct contact with living muscular tissue of the rabbit for eighty four (84) days.	Test implant sites did not demonstrate any significant difference as compared to the control implant sites. Bioreactivity Rating = 1.5 (no reaction)	PASS
Hemocompatibility – Hematology: Hemolysis Test, Direct Contact Method	To evaluate the hemolytic potential of test articles according to the ASTM guideline.	Values of 2% or less are considered non-hemolytic. Test article % Hemolytic Index is 0.2%. Negative and Blank control % Hemolytic Index is 0.0%. Positive control % Hemolytic Index is 11.5%.	PASS
Hemocompatibility – Coagulation: Partial Thromboplastin Time (PTT)	To determine the time citrated plasma exposed to medical materials takes to form a clot when exposed to a suspension of phosphollipid particles and calcium chloride.	Average clotting time is comparable to negative control. At this time, there are no ranges or levels that have been established as acceptable.	N/A
Hemocompatibility – Coagulation: Platelet and Leukocyte Count	To determine if medical materials exposed to whole blood would adversely affect the make-up of the platelet and leukocyte components of the blood.	Leukocyte counts were decreased (88% of baseline) and platelet counts were increased (108% of baseline) after exposure to the test article when compared to the negative control (baseline) and reference material. No acceptable levels have been established at this time.	N/A

Test/Study Name	Purpose	Results	Conclusion
Pyrogen – Mediated Rabbit Pyrogen	To determine if a saline extract of the test article causes a febrile response in rabbits.	Non–pyrogenic.– Acceptable results are sum of temperature increase less than 3.3°C and not more than 3 rabbits with >0.5°C increase. Sum of temperature differences between 8 rabbits was 1.1°C; 1 rabbit had a >0.5°C (+0.7°C) increase.	PASS

Table 5. Biocompatibility Test Summary - Iliac Limb Stent Graft

Test/Study Name	Purpose	Results	Conclusion
Cytotoxicity - MEM Using L-929 Mouse Fibroblast Cells	To evaluate the ability of the test article extract to elicit a cytotoxic response in cultured mouse fibroblast cells when conducted in accordance with the test method requirements.	Test article is non-toxic. Grade 0 cytotoxicity for test and negative controls. Grade 2 for intermediate controls. Grade 4 for positive controls.	PASS
Sensitization – ISO Guinea Pig	To evaluate the allergic potential or sensitizing capacity of a test article.	Test article results were equivalent to the negative control.	PASS
Irritation - Intramuscular Implant: 26 week	To evaluate a test article for the potential to induce local toxic effects in the muscle tissue of New Zealand White rabbits for a period of 26 weeks.	Non-toxic – Test article was non-toxic (rating of 0.95 after 26 weeks, <1 is defined as non-toxic) when compared to the control article. All animals survived to the scheduled study endpoint.	PASS
Intracutaneous Reactivity	To determine if chemicals that may leach or be extracted from the test article were capable of causing local irritation in the dermal tissues of the rabbit.	Non-irritant - The difference between the mean of the control and the mean of the test group was <1.0, which is acceptable.	PASS
Systemic Toxicity (Acute) – ISO Acute Systemic Injection	To screen test article extracts for potential toxic effects as a result of a single-dose systemic injection in mice.	Test article is non-toxic. No fatalities, signs of clinical toxicity or body weight loss > 2 grams.	PASS
Genotoxicity - Salmonellea Typhimurium and Escherichia Coli Reverse Mutation Assay	To evaluate the potential of a test article to include histadine reversion and tryptophan reversion in the genomes of these respective organisms.	Non-mutagenic	PASS
Genotoxicity - Mouse Lymphoma Mutagenesis Assay	To evaluate the potential of a test article to induce an increase in the formation of homozygous thymidine kinase mutants over the background rate in a mouse lymphoma mutant of the L5178Y cell line, heterozygous at the thymidine kinase locus, in the presence and absence of a metabolic activation system.	Non-mutagenic	PASS

Test/Study Name	Purpose	Results	Conclusion
Genotoxicity – Rodent Bone Marrow Micronucleus Assay	To evaluate the potential of a test article and/or its metabolites to induce micronuclei in maturing erythrocytes of mice.	Non-mutagenic	PASS
Implantation	To evaluate a test article (solid material) for the potential to induce local toxic effects in the muscle tissue of New Zealand White rabbits for a period of 26 weeks.	Non-toxic – Test article was non-toxic (rating of 0.95 after 26 weeks, <1 is defined as non-toxic) when compared to the control article. All animals survived to the scheduled study endpoint.	PASS
Hemocompatibility – Hematology: Hemolysis Test, Direct Contact Method	To evaluate the hemolytic potential of test articles according to the ASTM guideline.	Values 2% or less are considered non-hemolytic. Test article % Hemolytic Index is 0.9%. Negative control % Hemolytic Index is 0.1%. Blank control % Hemolytic Index is 0.0%. Positive control % Hemolytic Index is 11.6%.	PASS
Pyrogen Mediated Rabbit Pyrogen	To evaluate the test articles for the presence of materials mediated pyrogens.	Non–pyrogenic – Acceptable result is no rabbits with a temperature increase >0.5°C. None of the 3 rabbits had an increase in temperature >0.5°C.	PASS

Table 6. Biocompatibility Test Summary - Delivery Catheter with Hydrophilic Coating

Test/Study Name	Purpose	Results	Conclusion
Cytotoxicity – MEM Using L-929 Mouse Fibroblast Cells	To evaluate the ability of the test article extract to elicit a cytotoxic response in cultured mammalian cells when conducted in accordance with the test method requirements.	Test article is non-toxic. Grade 0 cytotoxicity for test and negative controls. Grade 2 for intermediate controls. Grade 4 for positive controls.	PASS
Sensitization – ISO Guinea Pig Maximization Sensitization Test	To evaluate the allergenic potential or sensitizing capacity of a test article upon exposure to guinea pigs.	Test article sensitization response equivalent to the negative controls. No abnormal clinical signs or sensitization responses were noted for any of the animals during the study.	PASS
Intracutaneous Reactivity	To determine if chemicals that may leach or be extracted from the test article were capable of causing local irritation in the dermal tissues of the rabbit.	Test article is a non-irritant. The difference in the mean test and control scores of the 0.9% Normal Saline and Cottonseed Oil extract dermal observations were less than 1.0.	PASS
Systemic Toxicity (Acute) – ISO Acute Systemic Injection	To screen test article extracts for potential toxic effects as a result of a single-dose systemic injection in mice.	Test article is non-toxic. No fatalities, signs of clinical toxicity, or body weight loss > 2 grams in control or test animals.	PASS

Test/Study Name	Purpose	Results	Conclusion
Hemocompatibility – Hematology: Hemolysis Test, Direct Contact Method	To evaluate the hemolytic potential of test articles according to the ASTM guideline.	Corrected hemolytic index indicates test article is non-hemolytic.	PASS
Hemocompatibility – Coagulation: Partial Thromboplastin Time (PTT)	To determine the time citrated plasma exposed to medical materials takes to form a clot when exposed to a suspension of phospholipid particles and calcium chloride.	Average clotting time is comparable or equal to negative control. At this time, there are no ranges or levels that have been established as acceptable.	N/A
Hemocompatibility – Coagulation: Platelet and Leukocyte Counts	To determine if materials exposed to whole blood would adversely affect the make-up of the platelet and leukocyte components of the blood.	Leukocyte counts were decreased (83% of baseline) and platelet counts were increased (92% of baseline) after exposure to the test article when compared to the negative control (baseline) and reference material. No acceptable levels have been established at this time.	N/A
Hemocompatibility – Complement Activation C3a and SC5b Assay	To measure complement activation in Normal Human Serum (NI-IS) when serum is exposed to a test article.	The percent of normalized C3a concentration produced by the test article was 3.2% of the CVF. The percent of normalized SC5b-9 concentration produced by the test article was 0.3% of the CVF. No acceptable levels have been established at this time.	N/A
Hemocompatibility – Thrombogenicity – Thromboresistance in Beagle Dogs	To evaluate a test article for four hour thromboresistance in beagle dogs.	No adverse effects or clinical signs noted. Patency and Thrombus scores for the test article were the same as for the reference material.	PASS
Pyrogen – Mediated Rabbit Pyrogen	To determine if a saline extract of the test material causes a febrile response when administered intraveneously in rabbits using the standard USP Rabbit Pyrogen Test procedure.	Non–pyrogenic – Test material met the acceptable result of sum of temperature increase of less than 3.3°C and not more than 3 rabbits with >0.5°C.	PASS

B. Laboratory Studies: *In Vitro* Bench Testing

The testing presented in Table 7 below includes results from both baseline (T=0) and accelerated aged units. An asterisk indicates testing that was performed at the accelerated aged timepoints. The testing verified that the Ovation Abdominal Stent Graft System met product performance and design specifications.

Table 7. Ovation Abdominal Stent Graft System In Vitro Bench Test Summary

Test	Purpose / Objectives	Acceptance Criteria	Results
Mechanical Testing: Implant			
Stent Radial Force*	For the aortic body, the purpose is to determine the radial force of the stent graft	Aortic Body Radial Force: When the stent is compressed after being deployed to its maximum	PASS The stent grafts met

Test	Purpose / Objectives	Acceptance Criteria	Results
	components to fixate to the vessel wall and thereby prevent migration of the graft. For the iliac limbs, the purpose is to determine the radial force of the stent graft component to seal and fixate the iliac vessel and prevent migration of the graft.	diameter, the stent will have a radial force of at least 0.4 lbf; when the stent is expanded back to its maximum vessel diameter it will have a radial force greater than 0.2 lbf. <u>Iliac Limb and Iliac Extensions Radial Force:</u> >0.1 lbf and <4.5 lbf for the 10mm diameter size; >0.2 lbf and <5.8 lbf for the 12mm diameter size; >0.2 lbf and <7.0 lbf for the 14mm diameter size; >0.2 lbf and <8.2 lbf for the 16mm diameter size; >0.3 lbf and <9.4 lbf for the 18mm diameter size; >0.3 lbf and <10.6 lbf for the 22mm diameter size.	the radial force requirements.
Dimensional Verification (diameter and length)*	To confirm the as-built devices meet the pre-determined range adequate to treat a broad number of patients.	The implant must treat patients within the following diameter and lengths: <u>Aortic Body Diameter:</u> Sized to treat 15.5mm to 17.4mm diameter vessels for the 20mm nominal diameter size. Sized to treat 17.5mm to 20.4mm diameter vessels for the 23mm nominal diameter size. Sized to treat 20.5mm to 23.4mm diameter vessels for the 26mm nominal diameter size. Sized to treat 23.5mm to 26.4mm diameter vessels for the 29mm nominal diameter size. Sized to treat 26.5mm to 30.4mm diameter vessels for the 34mm nominal diameter size. <u>Iliac Limb and Extensions Diameter:</u> Sized to treat 7.5mm to 9.4mm diameter vessels for the 10mm nominal diameter size. Sized to treat 9.5mm to 11.4mm diameter vessels for the 12mm nominal diameter size. Sized to treat 11.5mm to 13.4mm diameter vessels for the 14mm nominal diameter size. Sized to treat 13.5mm to 15.4mm diameter vessels for the 16mm nominal diameter size. Sized to treat 15.5mm to 17.4mm diameter vessels for the 18mm nominal diameter size. Sized to treat 17.5mm to 20.4mm diameter vessels for the 22mm nominal diameter size. <u>Aortic Body Length:</u> Length tolerance = +5 / -5 mm <u>Iliac Limb Length:</u> Length tolerance = +5 / -5 mm <u>Iliac Extension Length:</u>	PASS The stent grafts met the treatment diameter and length specifications.

Test	Purpose / Objectives	Acceptance Criteria	Results
		Length tolerance = +3 / -3 mm	
Stent Graft Conformability to Vessel Wall	To confirm the stent adequately conforms to the arterial wall in diseased, non-uniform vessels.	Aortic Body: Appropriately-sized stent grafts will seal in 16 and 30mm simulated vessels. Iliac Limb and Extensions: Appropriately-sized stent grafts will seal in 8 and 20mm simulated vessels.	PASS Testing was augmented by clinical data. The stent grafts tested created a conformable seal.
Stent Graft Length to Diameter Relationship	To characterize the stent graft length to diameter relationship.	To characterize any foreshortening (length to diameter relationship) of the aortic body, iliac limb and iliac extension graft during deployment.	PASS The stent grafts tested demonstrated that the dimensional changes during deployment did not influence the final stent length (i.e. foreshortening).
Stent Graft Modular Joint Integrity	To confirm the stent graft junctions do not separate when subjected to a worst-case blood pressure value (320 mmHg).	The aortic body with iliac limb and iliac limb with iliac extension junctions must not separate when subjected to an internal pressure of 320 mmHg.	PASS The various combinations of stent grafts tested demonstrated that the stent grafts do not separate at the load corresponding to the specified blood pressure.
Stent Graft Lumen Burst Strength	To confirm that the stent grafts do not burst when subjected to a worst-case blood pressure value (320 mmHg).	The aortic body, iliac limb, and iliac extension stent grafts must not burst below 320 mmHg.	PASS The stent grafts tested demonstrated that the stent grafts do not burst below the specified blood pressure.
Stent Graft Longitudinal Tensile Strength	To confirm that the stent grafts have adequate longitudinal tensile strength for both hemodynamic loads and delivery.	Aortic Body: The aortic body graft must have adequate longitudinal tensile strength to withstand the maximum of either hemodynamic loads resulting from a transient systolic pressure of 320 mmHg or a delivery system pull force of 2 lbf. Iliac Limb and Extensions: The iliac limb and extension graft must have longitudinal tensile strength for hemodynamic loads resulting from a transient systolic pressure of 320 mmHg.	PASS The stent grafts tested demonstrated that the stent grafts have adequate longitudinal tensile strength for both hemodynamic loads and delivery.
10-yr Device Integrity	The stent grafts must demonstrate 10-year equivalent device integrity.	Stent Graft Creep: Aortic Body and Iliac Limb Graft must not burst below a pressure of 320mmHg after 10 years simulated creep testing. Changes in either diameter or length must not affect the ability of the device to function. Aortic Body Graft Material Cyclic Loading: Material must maintain structural integrity under cyclic loading for an	PASS The stent graft samples satisfied all of the acceptance criteria for 10-year device integrity.

Test	Purpose / Objectives	Acceptance Criteria	Results
		equivalent of a 10 year life under simulated physiologic conditions. Stent Graft Pulsatile Fatigue: The modular graft system (aortic body and limbs) should provide structural integrity under pulsatile internal pressure for 400 million cycles. Aortic Body Stent Dilatation Fatigue: Aortic Body Graft Stents should provide structural integrity under pulsatile dilatation for 400 million cycles. Iliac Limb Dilatation Fatigue: Iliac Limb stent grafts should maintain structural integrity under pulsatile dilatation for 400 million cycles. Graft Stent Attachment Fatigue: The proximal aortic body graft - stent attachment sites must be able to transfer load from the graft to the stent for 400 million cycles of cyclical load. The following test conditions define the anticipated clinical extreme conditions: 1) Angulated Graft-Stent Attachment Fatigue: The graft-stent attachment must withstand 400 million cycles of cyclic load under worst case angulated conditions of inner radius of curvature. 2) Lesser Curve Graft-Stent Attachment Fatigue: The graft-stent attachment must withstand 400 million cycles of cyclic load on the lesser curve of an angulated aorta. 3) Asymmetric Greater Curve Graft-Stent Attachment Fatigue: The graft-stent attachment must withstand 400 million cycles of cyclic load assuming a worst-case anchor engagement into the greater curve of an angulated aorta. Iliac Limb Asymmetric Axial Fatigue: Maintain structural integrity for the equivalent of a 10 year life. Stent Anchor Fatigue: The aortic body stent anchors must withstand without fracturing 400 million cycles of axial loading at physiologic conditions. Iliac Limb/Extension Overlap Fatigue: Iliac limbs with extensions in an overlap condition should maintain structural integrity without excessive wear under pulsatile radial dilatation for 400M cycles.	

Test	Purpose / Objectives	Acceptance Criteria	Results
Stent Corrosion Resistance	To demonstrate that the stents and attachment rings have adequate corrosion performance.	The stents and attachment rings must have in-vitro corrosion performance that is at least equivalent to a commercialized stent-graft device.	PASS All tested samples met the corrosion requirement.
Stent Graft Radiopacity	To confirm the implant is visible under fluoroscopy during the implant procedure to allow for proper placement.	The implant must be visible under fluoroscopy during the implant procedure to allow for proper placement.	PASS All tested samples met the radiopacity specification.
Stent Graft Kink Resistance	To confirm the iliac limb and extension stent grafts have sufficient flexibility to conform to tortuous anatomy.	Iliac Limb and Iliac Extension will accommodate curvature not exceeding 90° with a minimum inner radius of curvature of 1 cm without kinking.	PASS There was no observance of kinking at the specified radius of curvature in any of the stent grafts tested.
Stent Graft Permeability	To confirm the stent grafts maintain adequate permeability.	Aortic Body and Iliac Limb graft water entry pressure must not be less than a differential pressure of 817 mmHg.	PASS All samples met the permeability specification.
Stent Graft Inflation Channel Burst Strength	To confirm the aortic body graft inflation channels will not burst during graft inflation.	The aortic body graft inflation channels must not burst at a pressure differential less than 16psig (827mmHg).	PASS All samples met the minimum burst pressure.
Durability – Stent Maximum Strain by FEA	To confirm the stent design has adequate mechanical properties for manufacturing, delivery and fatigue performance.	The peak strains should not exceed 9% in the aortic body stent during catheter loading or under *in vivo* conditions. The peak strains should not exceed 9% in the iliac limb or extension stents during catheter loading or under *in vivo* conditions. The fatigue safety factors computed from the maximum FEA-predicted cyclic fatigue strains under challenging *in vivo* conditions and nitinol material fatigue data should be >1.	PASS All of the computed peak strains were less than the design limit. All of the computed fatigue safety factors were >1.
Mechanical Testing: Fill Polymer			
Fill Polymer Degradation Resistance*	To confirm the fill polymer has adequate degradation resistance in a test representative of 10 years in vivo duration.	The fill polymer must not degrade as measured by a loss of less than 10% mass in an *in vitro* degradation test representative of 10 years *in vivo* duration inside the graft.	PASS All samples met the fill polymer degradation resistance specification.
Fill Polymer Radiopacity	To ensure adequate visibility to aid in verifying the complete deployment of the implant.	The fill polymer must have adequate radiopacity at time of deployment to indicate filling of the graft with fill polymer.	PASS All deployments met the visibility acceptance criteria.
Fill Polymer Dimensional Stability*	To ensure dimensional stability such that exclusion of the aneurysm and sufficient aortic bloodflow is maintained throughout the life of the implant.	The fill polymer must not shrink during cure by an amount sufficient to cause loss of seal. It also must not swell during or after cure by an amount sufficient to cause loss of graft patency or structural integrity.	PASS All samples met the dimensional stability specifications. Testing was augmented by clinical data.

Test	Purpose / Objectives	Acceptance Criteria	Results
Fill Polymer Ease of Mixing	To confirm the fill polymer mixing force is within ergonomic limits.	The maximum syringe plunger force to mix the fill polymer must not exceed 16 lbf and an average value of 11 lbf.	PASS All samples met the mix force specification.
Fill Polymer Cure Time*	To confirm the fill polymer, once mixed, consistently cures (gels) within a pre-determined range.	The fill polymer kit must provide adequate mixing to the fluid as it passes from one syringe to another as verified through a fill polymer cure time of 13±2 minutes.	PASS The fill polymer mixing was confirmed through acceptable cure time.
Fill Polymer Balloonability Time	To confirm that the stent graft is balloonable within 15 minutes of mixing the fill polymer.	The stent graft must be balloonable under test protocol conditions within 15 minutes after detach of the delivery system from the graft with a properly sized balloon.	PASS Testing demonstrated that all filled grafts maintained structural integrity when ballooned after the filling process in accordance with IFU recommendations.
Fill Polymer Modulus*	To confirm the fill polymer provides mechanical support and seal conformability between the stent graft and the aortic wall.	The fill polymer must have mean elastic modulus (200– 500 psi when cured) and storage modulus (87-109 psi [6.0-7.5X10^{5}Pa]).	PASS All samples met the modulus criteria.
Mechanical Testing: Delivery System			
Delivery System Placement Accuracy of Stent Graft*	To confirm successful placement of the stent graft in the in vivo environment.	The system must permit consistent and accurate deployment of the implant to within: +5/-0 mm of the intended proximal aortic landing site ±5 mm of the distal iliac landing site	PASS All samples were successfully deployed within the specification requirements of the proximal deployment target.
Delivery System Hemostasis*	To confirm the hemostatic seals on the proximal end of the sheath and the guidewire lumen will not leak.	The hemostatic seals on the proximal end of the sheath and the guidewire lumen shall not leak water at a rate greater than 7 ml/min.	PASS All samples satisfied the water leak rate specification limit.
Delivery System Radiopacity	To ensure adequate visibility to aid in the accurate placement of the implant.	The delivery system must have sufficient radiopacity as evaluated under fluoroscopy to orient the implant, to confirm sheath retraction, to confirm fill tube detach (aortic body) and to confirm catheter withdrawal from the implant.	PASS Visibility for all deployments met the acceptance criteria.
Delivery System Unsheathing Force (Force to Deploy)*	To confirm the force required to retract the sheath is within appropriate ergonomic limits.	The unsheathing force shall not exceed the minimum tensile strength of the sheath tubing and shall not exceed an ergonomic limit of 12 pounds.	PASS All stent graft samples were successfully deployed with unsheathing forces below specification.

Test	Purpose / Objectives	Acceptance Criteria	Results
Delivery System Kink Resistance*	To confirm the catheter can be advanced to the implant site such that it does not kink, compromise the deployment, or damage the implant.	The catheter can be advanced through a tortuous model and does not kink in a way that compromises the deployment or damages the implant.	PASS All devices were advanced through the tortuous flow model without kinking. No deployments were compromised by delivery system kinks, nor were any implants found to be damaged during post-simulated use inspection.
Delivery System Profile*	To confirm the delivery system profiles are within labeled requirements.	The delivery system outer diameters (ODs) must not exceed the labeled OD.	PASS All delivery system samples passed the attribute profile test.
Delivery System Length*	To confirm the as built delivery system lengths will provide positioning of the implant to the target location within most anatomical settings.	Working Length: Aortic Body delivery system: 52cm - 58cm Iliac Limb / Iliac Extension delivery system: 50cm - 55cm	PASS The delivery systems met the dimensional specifications for length.
Delivery System Pushability*	To confirm the delivery system transmits sufficient pushability to position the catheter to the correct target location for an accurate placement of the stent graft.	The delivery system must transmit sufficient pushability to position the catheter at the correct elevation within the model for an accurate placement of the stent graft.	PASS All delivery system samples met the pushability specifications.
Delivery System Trackability*	To confirm the delivery system has sufficient trackability to position the catheter, track over the guide wire and accurately position the implant.	The delivery system must have sufficient trackability to position the catheter and accurately position the implant within the model. When placed in a tortuous model, the delivery system can sufficiently track over the guide wire to locate the implant at the intended deployment location.	PASS All delivery system samples met the trackability specifications.
Delivery System Torquability*	To confirm the aortic body delivery system has sufficient torquability to position the catheter and accurately position and orient the implant.	The Aortic Body delivery system must have sufficient torquability to position the catheter and accurately position and orient the implant within the model. When placed in a tortuous model, the distal end of the sheathed catheter must rotate an amount to match the rotation of the handle and flushport.	PASS All delivery system samples met the torquability specifications.

Test	Purpose / Objectives	Acceptance Criteria	Results
Delivery System Bond Strengths*	To confirm the delivery system has adequate bond tensile strengths to permit access, deployment and withdrawal of the stent graft.	Sheath to Sheath Fitting: Minimum Tensile Strength: 15 lbf Radiopaque Marker Band on Lumens: Minimum Tensile Strength: 1.5 lbf All other bonded components: Minimum Tensile Strength: 5 lbf Nosecone: Minimum Torsional Strength: 5 lbf after rotational test Sheath to Sheath Fitting: Minimum Torsional Strength: 12.2 in-oz Inner Catheter Proximal Band (Aortic Body only) Minimum Torsional Strength: 12.2 in-oz	PASS The delivery system bonds have adequate strength to reliably meet functional specifications.
Delivery System Detach Stop Force*	To confirm that the aortic body delivery system fill tube does not disconnect from the aortic body graft at a force below the designated specification.	The system must not allow the fill tube to detach from the aortic body graft at a force less than 2 lbs prior to releasing the stop.	PASS All aortic body delivery systems passed the detach stop force requirement.
Delivery System Detach Force*	To confirm the aortic body permits consistent withdrawal of the delivery system without causing damage to or dislodgement of the implant.	The system must permit consistent withdrawal of the delivery system without causing damage to or more than 5 mm dislodgement distance of the implant.	PASS The delivery system samples met the detach force specification: No movement of the stent-graft was observed during detach for any of the aortic body samples.
Simulated Use*	To confirm the delivery system can deploy and fill the stent graft within an *in vitro* model without failure to: access, deploy the stents, fill the graft or withdraw the catheter.	The delivery system shall deploy and fill the stent graft within the *in vitro* model without failure to: access, deploy the stents, fill the graft or withdraw the catheter.	PASS In all devices tested, access, deployment, fill, and catheter withdrawal were successful.
Delivery System Auto-Injector Pressure Range*	To confirm the autoinjector supplies adequate force to the syringe in order to fill the stent graft with fill polymer while not exceeding the burst pressure of the stent graft inflation channels.	The autoinjector must supply a 12-16 psig soon after insertion of syringe into autoinjector.	PASS All auto-injector samples met the specifications.
Catheter Guidewire Compatibility*	To confirm the device can track over a commonly available guidewire size in order to aid in advancing the device to the treatment site.	The guidewire lumen must accept a 035" guidewire with little or no resistance.	PASS All delivery system samples met the guidewire compatibility specifications.
Catheter Luer Compatibility*	To confirm compatibility with a commonly available connector type for elements of the catheter which interface with other accessories.	The catheter must be compatible with standard luer fittings in order to interface with other accessories.	PASS All delivery system samples met the luer compatibility specifications.

Test	Purpose / Objectives	Acceptance Criteria	Results
Introducer System Compatibility*	To confirm that, in the event an introducer is required, delivery system can fit through commercially available introducers.	Delivery system must fit through a commercially available introducer.	PASS All delivery system samples passed through the appropriately-sized introducer sheath.
Graft Magnetic Resonance Imaging Safety	To confirm the implant will not migrate or heat significantly in the presence of magnetic resonance.	The implant must pose no known hazards in an MR environment pursuant to an "MR Conditional" label status.	PASS The implants are deemed MR Conditional.

C. *In vivo* Animal Studies

The objectives of the animal studies were to evaluate device deployment and chronic implant performance in ovine models. Preclinical *in vivo* GLP and non-GLP animal testing utilizing early and final versions of the fill material was conducted in 27 animals to meet these objectives. The stent grafts used in the animal study were prototypes of the final device design of the Ovation Abdominal Stent Graft System. Although not conducted on the final design of the stent graft, the performance of the devices used in the animal studies was considered indicative of the current system performance. The results demonstrated successful device delivery, graft patency, absence of migration or kinking, absence of abnormalities on end-organ histopathology, and/or normal healing. The results support the safety and expected performance of the Ovation Abdominal Stent Graft System. Table 8 outlines the *in vivo* animal studies conducted.

Table 8. Ovation Abdominal Stent Graft System In vivo Animal Studies

Study Number / Study Name	GLP / Non-GLP	Type / Number of Animals	Follow-up Duration / Procedure	Objectives	Results
DVP-2144; Chronic GLP study of in ovine Stent Graft and Fill Polymer Vasculature utilizing a prototype delivery system to the final marketed delivery system[a]	GLP	Ovine/ 18	30 day and 90 day	Evaluate the deployment of the stent grafts for the following items: • Successful device placement • Ease of delivery • Deployment accuracy • Device radiopacity • Delivery system flexibility Verify that the stent grafts maintain luminal patency and physiological function. Evaluate the stent grafts for migration and kinking. Determine the response of the host and the prosthesis in the vascular system.	The test devices were deployed successfully, maintained patency, did not migrate, kink significantly, or elicit an abnormal host response when deployed in the ovine vascular system.
DVP-2150: a 30-day chronic GLP safety study of Stent Graft and Fill Polymer in ovine vasculature	GLP	Ovine/ 3	30 day	Evaluate the deployment of the stent grafts and fill polymer. Verify that the stent grafts maintain patency and physiological function. Evaluate the stent grafts for migration and kinking. Determine the response of the host and the prosthesis in the vascular system.	The study endpoints were successful delivery, graft patency, absence of migration or kinking, and normal healing. Delivery was successful in all animals treated. All endpoints of the study were satisfied.

Study Number / Study Name	GLP / Non-GLP	Type / Number of Animals	Follow-up Duration / Procedure	Objectives	Results
DVP-2151: a 90-day chronic GLP study of Stent Graft and Fill Polymer in ovine vasculature	GLP	Ovine/ 3	90 day	Evaluate the deployment of the stent grafts and fill polymer. Verify that the stent grafts maintain patency and physiological function. Evaluate the stent grafts for migration and kinking. Determine the response of the host and the prosthesis in the vascular system.	The study endpoints were successful delivery, graft patency, absence of migration or kinking, and normal healing. Delivery was successful in all animals treated. All endpoints of the study were satisfied.
DVP-2154: a 30-day non-GLP chronic study of Fill Polymer in ovine vasculature[b]	Non-GLP	Ovine/ 3	30 day	Determine the outcome resulting from a bolus release of soluble fill material into the ovine vasculature during the cure process.	A bolus release of the fill polymer did not produce angiographic changes either acutely or chronically, and did not produce any abnormalities evident on end organ histopathology. There did not appear to be any adverse response of the ovine vascular system or organs to the worst-case fill polymer spill exposure.

[a] *The delivery system used in the animal studies was determined to be similar to the system tested in clinical investigation. Differences included the addition of lubricous coating, switch from PEBAX to ABS handle material, and the addition of a Detach prevention feature (release of one additional wire before withdrawal).*

[b] *The FDA was not obliged to accept this non-GLP study and utilized regulatory discretion and additional scrutiny in deciding whether it could be utilized. This study provided adjunctive, supporting data to the additional GLP studies. It was conducted to address a risk evaluation of a device fault condition and is not relevant to the normal/intended use of the device*

D. Sterility, Packaging, and Shelf-Life

The Ovation Abdominal Stent Graft System is sterilized by a validated ethylene oxide (EtO) or E-Beam sterilization process to achieve a minimal sterility assurance level (SAL) of 10^{-6}. Packaging performance and stability testing (summarized in Table 9) demonstrated that the Ovation Abdominal Stent Graft System maintains functionality and packaging integrity through 3 year shelf life.

Table 9. Ovation Abdominal Stent Graft System Sterility, Packaging, and Shelf-Life

Test	Requirement	Results	Analysis Type
Sterilization Aortic Body, Iliac Limbs, Iliac Extensions	100% EtO sterilization process is used. It is considered an overkill sterilization cycle in accordance with ISO 11135-1:2007 Annex B. Validation of the sterilization cycle demonstrates that the devices achieve a sterility assurance level of 10^{-6}. Sterilization validation was performed by identifying the worst case or challenge location on the product.	PASS	Biological indicators were placed in the challenge location in 60 full test units (20 units/cycle x 3 half cycles).

Test	Requirement	Results	Analysis Type
Sterilization Fill Polymer Kit and Autoinjector	E-Beam radiation sterilization process is used on the Autoinjector and Fill Polymer Kit. Both products are validated in accordance with the VDmax method detailed in AAMI TIR33:2005 and allowed per ISO 11137-2:2006. Validation of the sterilization cycle demonstrates that the devices achieve a sterility assurance level of 10^{-6}. Sterilization validation was performed by demonstrating product sterility at a fraction of the routine sterilization dose based on the average product bioburden level.	PASS	Thirty (30) full products were tested for bioburden levels. The verification dose was determined using AAMI TIR33:2005 from the average product bioburden results. Ten (10) full products were tested for sterility after the products were subjected to the verification dose.
Packaging Performance and Stability	The packaging designs of the Ovation Abdominal Stent Graft System must be sufficient to adequately protect the device and maintain the integrity of the Ovation Abdominal Stent Graft System package throughout its shelf life claim of up to three years.	PASS	Attribute

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The applicant performed a prospective, international, single-arm, nonrandomized pivotal clinical study to establish a reasonable assurance of safety and effectiveness of endovascular aneurysm repair with the Ovation Abdominal Stent Graft System for the treatment of abdominal aortic aneurysms (AAA). The study was conducted in the U.S. (under IDE G090239), Germany, and Chile under an identical treatment and follow-up protocol. Information from a feasibility study of a previous generation device was also considered in evaluating the longer-term safety of the unique device characteristic (i.e., polymer stability). The feasibility study and the Ovation Abdominal Stent Graft System Pivotal Clinical Study are summarized in Table 10.

Table 10. Clinical Use of the Ovation Abdominal Stent Graft System

Clinical Study	Device Design	Study Design	Objective	Number of Sites	Number of Patients
Ovation Abdominal Stent Graft System Pivotal Clinical Study	Ovation Abdominal Stent Graft System	Prospective, consecutively enrolling, single-arm, non-randomized multi center, international clinical study	Evaluate safety and effectiveness	28 (US) 8 (OUS)	111 (US) 50 (OUS)
Feasibility	ENOVUS Abdominal Stent Graft System	Prospective, consecutively enrolling, non-randomized multi center international feasibility study	Evaluate the preliminary safety of the first generation device	7 (US) 7 (OUS)	43 (US) 36 (OUS)

Data from the pivotal clinical study to support the PMA approval decision are summarized in below.

A. Study Design

Patients were treated between November 2009 and March 2011. The database for this PMA reflected data collected through June 6, 2012 and included 161 patients (111 in the United States, 30 in Germany and 20 in Chile). There were 36 investigational sites.

The sample size of the study was calculated using the normal approximation with nQuery Advisor 6.02 (Statistical Solutions, Saugus, MA) and was based upon the primary safety evaluation. It was estimated that 150 patients with evaluable data at 30 days would provide 96% statistical power to test the primary safety hypothesis (major adverse event [MAE] incidence of 11%) at the one-sided 0.05 level. A 15% attrition rate was anticipated through 12 months, which would yield approximately 128 patients available to assess the primary effectiveness endpoint at 12 months. Should the rate for the primary effectiveness composite endpoint equal 88.2%, then 128 patients would provide 80% power to test the primary effectiveness hypothesis at the one-sided 0.05 alpha level. Therefore, the sample size of n=161 provides adequate statistical power for the evaluation of safety and effectiveness.

The analysis included endpoints that were consistent with current literature on endovascular stent grafts. The primary safety hypothesis was tested by comparing the 30-day major adverse event (MAE) incidence in patients treated with the Ovation device to a target performance goal of 21%[1], which was established based upon the 30 day MAE rate published in the literature for a recently-approved FDA device. The primary effectiveness hypothesis was tested by comparing the 12-month composite treatment success rate in patients treated with the Ovation device to a target performance goal of 80%. For effectiveness endpoint evaluation, an independent core lab reviewed CT scans and abdominal x-rays to assess aneurysm changes, device position and integrity, and endoleaks. The statistical analyses included standard descriptive statistics and the Kaplan-Meier method, with Kaplan-Meier curves generated for outcomes through 12 months.

The following external evaluation groups were used for the study:

- Core Laboratory: In order to provide independent verification of imaging findings, images required by protocol were sent by the study sites to a central imaging core laboratory with processes and systems that are GMP/GCP, HIPAA, and 21 CFR Part 11 compliant. The imaging core laboratory is housed in an ISO 13485 certified facility, which adheres to all applicable federal regulations.
- Clinical Events Committee (CEC): An independent CEC adjudicated all MAEs, SAEs, device-related AEs, and deaths for event type and device and procedure relatedness. Members included physicians with relevant endovascular AAA experience who were

[1] Turnbull IC, Criado FJ, Sanchez L, et al. Five-year results for the Talent enhanced Low Profile System abdominal stent graft pivotal trial including early and long-term safety and efficacy. *J Vasc Surg.* Mar 2010;51(3):537-544

not directly involved in the conduct of the study and who had no conflicts of interest related to the study sponsor or the study investigators.

- Data Safety and Monitoring Board (DSMB): An independent DSMB reviewed the progress of the study at intervals during enrollment. Based on the safety data, the DSMB could have recommended that TriVascular continue, modify, or stop the study in accordance to previously agreed parameters. The committee was composed of physicians with relevant endovascular AAA experience and one biostatistician who were not directly involved in the conduct of the study and who had no conflicts of interest related to the study sponsor or the study investigators.

1. Inclusion and Exclusion Criteria

Enrollment in the TriVascular Ovation Abdominal Stent Graft System study was limited to patients who meet the inclusion criteria as outlined in Table 11.

Table 11. Inclusion Criteria

Inclusion Criteria
Patient is ≥ 18 years of age.
Patients who are male or non-pregnant female (females of child bearing potential must have a negative pregnancy test prior to enrollment into the study).
Patient has signed an Institutional Review Board (IRB)/Ethics Committee (EC) approved Informed Consent Form.
Patient is considered by the treating physician to be a candidate for elective open surgical repair of the AAA (i.e., category I, II, or III per American Society of Anesthesiology (ASA) classification). ASA category IV patients may be enrolled provided their life expectancy is greater than 1 year.
Patient has an infrarenal abdominal aortic aneurysm that meets at least one of the following: • Abdominal aortic aneurysm ≥ 5.0 cm in diameter • Aneurysm has increased in size by 0.5 cm in last 6 months. • Maximum diameter of aneurysm exceeds 1.5 times the transverse dimension of an adjacent non-aneurysmal aortic segment
Patient has patent iliac or femoral arteries that allow endovascular access with the TriVascular Ovation Abdominal Stent Graft System.
Patient has a suitable non–aneurysmal proximal aortic neck length of ≥ 7 mm inferior to the most distal renal artery ostium.
Patient has a suitable non-aneurysmal distal iliac artery length (seal zone) of ≥10 mm. The resultant repair should preserve patency in at least one hypogastric artery.
Patient has a suitable non–aneurysmal proximal aortic neck luminal diameter between 16 and 30 mm.
Patient has suitable non–aneurysmal distal iliac luminal diameters between 8 and 20 mm.
Patient meets the following anatomic criteria: the distance from the most distal renal artery to most superior internal iliac artery measurement is at least 13 cm.
Patient has juxtarenal aortic neck angulation ≤ 60° if proximal neck is ≥10 mm and ≤ 45° if proximal neck is <10 mm.

Inclusion Criteria
Patient must be willing to comply with all required follow-up exams.

Patients were not permitted to enroll in the TriVascular Ovation Abdominal Stent Graft System study if they met any of the exclusion criteria outlined in Table 12.

Table 12. Exclusion Criteria

Exclusion Criteria
Patient has a dissecting aneurysm.
Patient has an acutely ruptured aneurysm.
Patient has an acute vascular injury.
Patient has a need for emergent surgery.
Patient has a known thoracic aortic aneurysm or dissection.
Patient has a mycotic aneurysm or has an active systemic infection.
Patient has unstable angina (defined as angina with a progressive increase in symptoms, new onset or nocturnal angina, or onset of prolonged angina).
Patient has had a myocardial infarction (MI) and/or stroke (CVA) within the past 6 months.
Patient has a major surgical or interventional procedure planned ≤30 days of the AAA repair.
Patient has history of connective tissue disease (e.g., Marfan's or Ehler's–Danlos syndrome).
Patient has history of bleeding disorders or refuses blood transfusions.
Patient has dialysis dependent renal failure or baseline serum creatinine level >2.0 mg/dl.
Patient has a known hypersensitivity or contraindication to anticoagulation or contrast media that is not amenable to pre-treatment.
Patient has a known allergy or intolerance to polytetrafluorethylene (PTFE), PEG-based polymers, fluorinated ethylene propylene (FEP) or nitinol.
Patient has a body habitus that would inhibit X–ray visualization of the aorta.
Patient has a limited life expectancy of less than 1 year.
Patient is currently participating in another investigational device or drug clinical trial.
Patient has other medical, social or psychological conditions that, in the opinion of the investigator, preclude them from receiving the pre-treatment, required treatment, and post-treatment procedures and evaluations.

2. Follow-up Schedule

The study follow-up schedule for patients consisted of imaging and clinical assessments (described below) at post-procedure (pre-discharge), 1 month, 6 months and 1 year, and yearly thereafter through 5 years. Patients who returned for unscheduled visits were incorporated into the clinical data set.

Preoperatively, patient demographics, medical/surgical history, physical exam, Ankle-Brachial Index (ABI) measurement, and laboratory testing, which included renal and coagulation assessment, as well as serum pregnancy for female patients of childbearing

potential, were collected for each patient. Postoperatively, the objective parameters measured during the study included the following assessments and testing, prior to discharge:

- Physical exam
- Ankle-Brachial Index (ABI) measurement
- Laboratory testing, which includes renal and optional coagulation assessment
- Length of hospital stay
- Abdominal X-ray (KUB), including AP, lateral, left oblique and right oblique views. This X-ray served as the baseline for all future evaluations of device integrity.
- Concomitant medications (anticoagulants, antiplatelets and antibiotics only)
- Adverse events
- Other relevant data as indicated on the CRF, including optional wound assessment.

The following objective parameters were measured at the 1 month, 6 month, and yearly follow-up visits:

- Physical exam
- Laboratory testing, which includes renal and optional coagulation assessment
- Contrast Enhanced Spiral Abdominal/Pelvic CT
- Abdominal X-ray (KUB), including AP, lateral, left oblique and right oblique views
- Device/aneurysm assessment based on imaging (endoleak, migration, integrity, patency, AAA dimensions)
- Concomitant medications (anticoagulants, antiplatelets and antibiotics only)
- Adverse events
- Other relevant data as indicated on the CRF including optional wound assessment.

As noted above, adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

3. Clinical Endpoints

The primary safety endpoint for this study was the proportion of patients who experienced a Major Adverse Event (MAE) within 30 days of the initial procedure compared to a target performance goal. Other secondary endpoints and analyses included mortality rates at 30 days and 12 months; AAA-related mortality at 30 days and 12 months; AAA rupture through 12 months; and conversion to open repair through 12 months. All MAEs were adjudicated by an independent clinical events committee (CEC).

The primary effectiveness endpoint for this study was the proportion of patients that achieved Treatment Success. Treatment Success is a composite endpoint of technical success (defined as successful delivery and deployment of one aortic body and two iliac limbs) and freedom from the following assessed at 12 months: Type I and III endoleaks,

stent graft migration, AAA enlargement, and AAA rupture and conversion to open repair. Other secondary endpoints and analyses included evaluation of technical success and through 12 months, freedom from: Type I and III endoleaks, stent graft migration, AAA enlargement, and loss of device integrity.

Study success was defined as meeting the primary safety and effectiveness endpoints. The Ovation pivotal study was considered successful if the null hypotheses for the test of primary safety ($\geq 21\%$) and effectiveness ($\leq 80\%$) were rejected.

B. Accountability of PMA Cohort

At the time of database lock, of 161 patients enrolled in the PMA study, 152 (94%) were evaluable for primary endpoint analysis at the 12-month follow-up visit. Detailed patient accountability and follow-up are presented in Table 13. The numbers found in Table 13, as well as subsequent sections, represent those patients that had data available to assess the relevant parameters.

Table 13. Patient and Imaging Accountability Through 12-Month Follow-up Visit

Interval (Analysis Window)	Patient follow-up			Patients with imaging performed (Core Lab)		Patients with adequate imaging to assess the parameter (Core Lab)				Patient events occurring before next visit					
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Imaging	KUB imaging	Aneurysm size increase	Endoleak	Migration	Stent Integrity	No implant	Conversion to surgery	Death	Withdrawal	Loss to follow-up	Not due for next visit yet
Originally Enrolled	161									0					
Events after implant but before a 1 Month visit												1			
1 Month (Day 1 - 90)	160	160 (100%)	161 (101%)[1]	160 (100%)	157 (98%)		153 (96%)		157 (98%)						
Events after 1 Month visit but before a 6 Month visit												1	1	1	
6 Month (Day 91 - 304)	157	156 (99%)	155 (99%)	154 (98%)	150 (96%)	154 (98%)	150 (96%)	154 (98%)	150 (96%)						

Interval (Analysis Window)	Patient follow-up			Patients with imaging performed (Core Lab)		Patients with adequate imaging to assess the parameter (Core Lab)				Patient events occurring before next visit					
	Eligible	Clinical Follow-up	Imaging Follow-up	CT Imaging	KUB imaging	Aneurysm size increase	Endoleak	Migration	Stent Integrity	No implant	Conversion to surgery	Death	Withdrawal	Loss to follow-up	Not due for next visit yet
Events after 6 Month visit but before a 12 Month visit												2	3		
12 Month (Day 305 - 547)	152	152 (100%)	152 (100%)	150 (99%)	146 (96%)	150 (99%)	143 (94%)	150 (99%)	146 (96%)						

Data analysis sample size varies for each of the timepoints above and in the following tables. This variability is due to patient availability for follow-up as well as quantity and quality of images available from specific timepoints for evaluation. For example, the number and quality of images available for evaluation of endoleak at 6 months is different than the number and quality of images available at 12 months due to variation in the number of image exams performed, the number of images provided from the clinical site to the Core Lab, and or the number of images with acceptable evaluation quality

[1]One patient expired before hospital discharge and is not eligible for 1 month visit, but has Imaging follow-up in 1-90 days time period post procedure.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an endovascular stent graft study. Baseline data regarding patient demographics, medical history and baseline aortoiliac aneurysm characteristics are summarized in Tables 14-16.

Table 14. Patient Demographics

Variable	Statistics	Ovation Treatment Group
	N	161
Age (yr)	Mean ± std	73 ± 8
	Median	73
	Min, Max	54, 95
Gender		
- Male	% (n/N)	87.6% (141/161)
- Female	% (n/N)	12.4% (20/161)
Race		
- White	% (n/N)	92.5% (149/161)
- Black	% (n/N)	2.5% (4/161)
- Asian	% (n/N)	0.0% (0/161)
- American Indian or Alaska Native	% (n/N)	0.0% (0/161)
- Native Hawaiian or Other Pacific Islander	% (n/N)	0.0% (0/161)

Variable	Statistics	Ovation Treatment Group
- Unknown/Other	% (n/N)	5.0% (8/161)
Ethnicity		
- Hispanic or Latino	% (n/N)	9.3% (15/161)
- Not Hispanic or Latino	% (n/N)	89.4% (144/161)
- Unknown	% (n/N)	1.2% (2/161)

Table 15. Patient Medical History

Variable	Ovation Treatment Group % (n/N)
ASA Grade	
- I	5.6% (9/161)
- II	28.0% (45/161)
- III	59.6% (96/161)
- IV	6.8% (11/161)
Cardiovascular Disease	
- Coronary artery disease	44.7% (72/161)
- Valvular heart disease	11.8% (19/161)
- Angina	6.8% (11/161)
- Cardiomyopathy	6.8% (11/161)
- Congestive Heart Failure	7.5% (12/161)
- Myocardial infarction	20.5% (33/161)
- Arrhythmia	21.7% (35/161)
- Hypertension	84.5% (136/161)
- Hypotension	0.6% (1/161)
- Hyperlipidemia	70.2% (113/161)
Peripheral Vascular Disease, Stroke and Aneurysm History	
- Peripheral vascular disease	23.6% (38/161)
- Carotid artery disease	13.0% (21/161)
- Transient ischemic attack (TIA)	5.0% (8/161)
- Stroke (CVA)	8.1% (13/161)
- Family History of aneurysms	6.2% (10/161)
Pulmonary History	
- Smoking	70.2% (113/161)
- Chronic obstructive pulmonary disease (COPD)	27.3% (44/161)
Gastrointestinal, Genitourinary, Reproductive History	
- Renal failure/insufficiency	13.7% (22/161)
- Diabetes	21.1% (34/161)
- Alcohol abuse	1.9% (3/161)
Hematological Problems (hemorrhage, coagulopathy disorder, anemia, platelet disorder)	7.5% (12/161)
Other Significant Medical Condition	75.8% (122/161)

The primary safety hypothesis of the clinical study was tested by comparing the 30-day major adverse event (MAE) incidence in patients treated with the Ovation device to a target performance goal of 21%[2], which was established based upon a published 30 day MAE rate for a recently-approved FDA device. For comparison purposes, the baseline patient characteristics for Ovation and the device are provided in Table 16 below.

Table 16. Comparison of Selected Baseline Patient Characteristics With Ovation Device and Talent Device

Baseline Patient Characteristic	Ovation device (n = 161)	Talent Device* (n = 166)
Demographics		
Age (yr, mean±SD)	73 ± 8	74 ± 7
White ethnicity (%)	92.5	92.8
Female gender (%)	12.4	8.4
Medical history (%)		
Angina	6.8	16.9
Arrhythmia	21.7	44.0
Cardiac revascularization	na	38.6
Congestive heart failure	7.5	28.3
Coronary heart disease	44.7	56.0
Hypertension	84.5	83.7
Myocardial infarction	20.5	38.6
Peripheral vascular disease	23.6	46.4
Diabetes	21.1	15.7
Chronic obstructive pulmonary disease	27.3	39.2
Smoking	70.2	84.9
Aortic morphology (mm, mean±SD)		
Maximum AAA diameter	53.6 ± 9.0	55.0 ± 9.3
Proximal neck length	23.0 ± 12.5	22.9 ± 12.5
Proximal neck diameter	22.5 ± 2.7	25.3 ± 3.6

*Data from reference[1].

Table 17 provides the baseline aneurysm and anatomical measurements of the study population.

Table 17. Baseline Aortoiliac Characteristics

Variables	Statistics	Ovation Treatment Group
Proximal Aorta		
Aortic diameter 35 mm proximal to proximal renal artery (mm)[1]	N	160
	Mean ± SD	25.0 ± 2.7
	Median	25.0
	Min, Max	19.0, 32.2

[2] Turnbull IC, Criado FJ, Sanchez L, et al. Five-year results for the Talent enhanced Low Profile System abdominal stent graft pivotal trial including early and long-term safety and efficacy. *J Vasc Surg.* Mar 2010;51(3):537-544

Variables	Statistics	Ovation Treatment Group
Aortic diameter at distal renal artery (mm)[2]	N	161
	Mean ± SD	22.5 ± 2.7
	Median	22.5
	Min, Max	17.5, 31.0
Aortic diameter 7 mm distal to distal renal artery (mm)[1]	N	161
	Mean ± SD	22.1 ± 2.9
	Median	21.9
	Min, Max	16.0, 30.0
Aortic diameter 13 mm distal to distal renal artery (mm)[1]	N	161
	Mean ± SD	22.7 ± 3.1
	Median	22.0
	Min, Max	16.6, 32.3
Proximal neck length (mm)[2]	N	161
	Mean ± SD	23.0 ± 12.5
	Median	21.9
	Min, Max	1.0, 50.0
Juxtarenal angle (degrees)[1]	N	161
	Mean ± SD	19.1 ± 13.5
	Median	16.0
	Min, Max	0.0, 60.0
Aortic Aneurysm		
Maximum aortic aneurysm diameter (mm)[2]	N	161
	Mean ± SD	53.6 ± 9.0
	Median	52.5
	Min, Max	37.8, 90.0
Maximum aortic aneurysm diameter distribution (mm)		
	40.0-49.9	35.4% (57/161)
	50.0-59.9	50.3% (81/161)
	60.0-69.9	8.7% (14/161)
	70.0-79.9	3.1% (5/161)
	80.0-89.9	1.2% (2/161)
	90.0-99.9	1.2% (2/161)
Distal Aorta		
Aortic bifurcation diameter (mm)[2]	N	161
	Mean ± SD	20.3 ± 6.9
	Median	18.5
	Min, Max	11.5, 53.5
Left iliac diameter (mm)[2]	N	161
	Mean ± SD	13.7 ± 3.3
	Median	13.0
	Min, Max	8.7, 34.0
Left iliac minimum access diameter (mm)[2]	N	159

Variables	Statistics	Ovation Treatment Group
	Mean ± SD	7.0 ± 1.6
	Median	6.8
	Min, Max	3.2, 11.5
Right iliac diameter (mm)[2]	N	161
	Mean ± SD	13.9 ± 3.0
	Median	13.3
	Min, Max	8.3, 23.4
Right iliac minimum access diameter (mm)[2]	N	159
	Mean ± SD	7.0 ± 1.6
	Median	7.0
	Min, Max	3.5, 11.4

[1] Data provided by site imaging
[2] Data provided by imaging core lab

D. Devices Implanted

A total of 161 aortic bodies and 366 iliac limbs were implanted in 161 patients during the initial implant procedure. The design of this device requires implantation of at least one aortic body and two iliac limbs. Additional iliac limbs and iliac extensions could be used to extend the length of the device, where indicated. Aortic body and iliac limb (including iliac extensions) delivery and deployment were successful in all patients. The total number of Ovation devices implanted in each patient is presented in Table 18, and device use by diameter is presented in Table 19. The entire spectrum of available aortic body and iliac limb diameters were used in this study.

Table 18: Number of Devices Implanted

Total Number of Ovation Devices Implanted per Patient	Ovation Treatment Group % (n/N)
3[1]	78.3% (126/161)
4	16.1% (26/161)
5	5.6% (9/161)

[1] Technical success was defined as implantation of one Ovation aortic body and a minimum of two Ovation iliac limbs (minimum of 3 Ovation devices). Additional Ovation Iliac limbs and/or iliac extensions may be implanted as extensions if additional vessel coverage is needed.

Additional accessory devices were implanted in the treatment area of 11 subjects during the index procedure as outlined in section 2.2 Technical success.

Table 19. Distribution of Implanted Device Sizes

Variables	Diameter (mm)	Ovation Treatment Group % (n/N)
Ovation aortic body	Overall	161
	20	2.5% (4/161)
	23	21.7% (35/161)
	26	36.0% (58/161)

Variables	Diameter (mm)	Ovation Treatment Group % (n/N)
	29	28.0% (45/161)
	34	11.8% (19/161)
Ovation iliac limbs (devices)	Overall	366
	10	5.5% (20/366)
	12	21.9% (80/366)
	14	35.0% (128/366)
	16	16.9% (62/366)
	18	14.2% (52/366)
	22	6.6% (24/366)

The Ovation Abdominal Stent Graft System aortic body is 80 mm in length, the iliac limbs are available in four lengths (80 mm, 100 mm, 120 mm, and 140 mm), and the iliac extension is 45 mm in length as outlined in section V. Note that the iliac limbs can also be used as extensions when additional coverage is required in the iliac artery.

E. Safety and Effectiveness Results: Summary of Key Outcomes

Table 20 presents the key outcomes of the Ovation Abdominal Stent Graft System clinical studies; detailed analyses may be found in the following sections.

Table 20. Summary of Key Outcomes

Variable	Aneurysm Rupture	Conversion to Surgical Repair	All-cause Mortality	AAA-related Mortality[1]	Major Adverse Event (MAE)
Treatment to 30 Days	0	0	1	1	4
31 to 365 Days	0	0	3	0	6
Treatment to 365 Days	0	0	4	1	10
Total Patients	0% (0/161)	0% (0/161)	2.5% (4/161)	0.6% (1/161)	6.2% (10/161)
Kaplan-Meier Summaries	**Freedom from Aneurysm Rupture**	**Freedom from Conversion**	**Freedom from All-cause Mortality**	**Freedom from AAA-related Mortality**	**Freedom from Major Adverse Event**
365-Day Estimate	100%	100%	97.2%	99.4%	93.0%

[1] AAA-related mortality defined as death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA or within the hospital stay if the patient was not discharged within 30 days, then it is presumed to be aneurysm-related.

1. Safety Results

The analysis of safety was based on the study cohort of 161 patients available for the evaluation through 12 months. The primary safety endpoint was defined as the

proportion of patients who experience a Major Adverse Event (MAE) within 30 days of the initial procedure.

The secondary safety endpoints were:

- Mortality rates at 30 days and 12 months
- AAA related mortality at 30 days and 12 months
- MAE through 12 months
- AAA rupture through 12 months
- Conversion to open repair through 12 months

1.1. Major Adverse Events through 30 Days (Primary Safety Endpoint)

The primary safety hypothesis was that the incidence of MAEs through 30 days post-treatment would meet a pre-defined target performance goal of 21%. The incidence of MAEs through 30 days in patients treated with the Ovation device was 2.5% (4 of 161) with an upper-bound 95% confidence interval of 5.4%. Therefore, the primary safety endpoint of this study was met.

Table 21. Primary Safety Endpoint: MAE through 30 Days

Variable	Ovation Treatment Group % (n/N)	Upper One-Sided 95% Confidence Limit	Target Performance Goal	Study endpoint
Major adverse events[1]	2.5% (4/161)	5.4%	21%	met

[1] A major adverse event was defined as any of the following: death, myocardial infarction, stroke, renal failure, respiratory failure, paralysis, bowel ischemia, or procedural blood loss ≥ 1,000 cc

Table 22. MAE Components Through 30 Days

Variable	Ovation Treatment Group % (n/N)
Number of patients with one or more major adverse events[1,2]	2.5% (4/161)
- All-cause death	0.6% (1/161)
- Myocardial infarction	1.2% (2/161)
- Renal failure	1.2% (2/161)
- Respiratory failure	0.6% (1/161)
- Paralysis	0.0% (0/161)
- Stroke	0.0% (0/161)
- Bowel ischemia	0.6% (1/161)
- Procedural blood loss ≥ 1000 cc	1.2% (2/161)

[1]A major adverse event was defined as any of the following: death, myocardial infarction, stroke, renal failure, respiratory failure, paralysis, bowel ischemia, or procedural blood loss ≥ 1,000 cc
[2]A patient may report multiple MAEs; hence, number of patients with any MAE may not be the sum of those in each MAE category

1.2. All-cause Mortality rates at 30 days and 12 months

All-cause mortality through 365 days post-treatment was 2.5% (4 of 161): 1 death occurred within 30 days of the index procedure and 3 deaths occurred after 30 days post-treatment.

Table 23. All-cause Mortality Through 365 Days

Variable	Treatment to 365 days % (n/N)	Treatment to 30 days % (n/N)	31 to 365 days % (n/N)
All-cause mortality	2.5% (4/161)	0.6% (1/161)	1.9% (3/159)

The Kaplan-Meier estimate of freedom from all-cause mortality through 365 days was 97.2%.

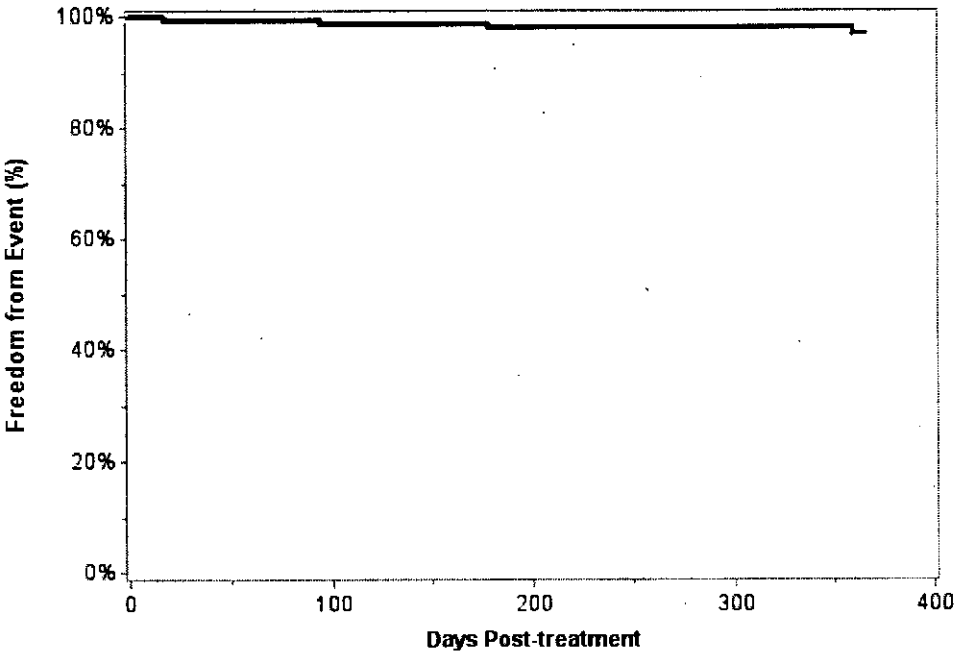

Figure 5. Freedom from All-cause Mortality Through 365 Days: Kaplan-Meier Estimate

Table 24. Freedom from All-cause Mortality Through 365 Days: Kaplan-Meier Estimate

Variable	Treatment to 30 days	31 to 182 days	183 to 365 days
Number at risk[1]	161	159	157
Number of events	1	2	1
Number censored[2]	0	0	156
Kaplan-Meier estimate[3]	0.994	0.981	0.972
Standard error[3]	0.006	0.011	0.014

[1] Number of patients at risk at beginning of interval
[2] Patients are censored because their last follow-up has not reached the end of the time interval or because they are lost to follow-up. In addition, all patients followed beyond 365 days are censored at 365 days.
[3] Estimate made at end of time interval

1.3. AAA-related Mortality at 30 days and 12 Months (365 Days)

AAA-related mortality through 365 days post-treatment was 0.6% (1 of 161): 1 AAA-related death occurred within 30 days of the index procedure due to abdominal sepsis and disseminated intravascular coagulation. During the index procedure, the site reported a polymer leak from the Aortic Body, and the patient experienced a hypersensitivity reaction. The device component responsible for the disconnection between the Aortic Body and the Fill Polymer Kit was modified, and no additional disconnections have been reported since then.

Table 25. AAA-related Mortality Through 365 Days

Variable	Treatment to 365 days % (n/N)	Treatment to 30 days % (n/N)	31 to 365 days % (n/N)
AAA-related mortality[1]	0.6% (1/161)	0.6% (1/161)	0.0% (0/159)

[1]AAA-related mortality defined as death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA, then it is presumed to be aneurysm-related.

The Kaplan-Meier estimate of freedom from AAA-related death through 365 days was 99.4%

Table 26. Freedom from AAA-related Mortality Through 365 Days: Kaplan-Meier Estimate

Variable	Treatment to 30 days	31 to 182 days	183 to 365 days
Number at risk[1]	161	159	157
Number of events	1	0	0
Number censored[2]	0	2	157
Kaplan-Meier estimate[3]	0.994	0.994	0.994
Standard error[3]	0.006	0.006	0.006

[1] Number of patients at risk at beginning of interval

[2] Patients are censored because their last follow-up has not reached the end of the time interval or because they are lost to follow-up. In addition, all patients followed beyond 365 days are censored at 365 days.

[3] Estimate made at end of time interval

[4] AAA-related mortality defined as death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA or within the hospital stay if the patient was not discharged within 30 days, then it is presumed to be aneurysm-related.

1.4. AAA Rupture through 12 months

No AAA rupture was reported through 365 days post-treatment.

1.5. Conversion to Open Repair through 12 months (365 Days)

No surgical conversion was reported through 365 days post-treatment.

1.6. Adverse Events

Adverse events (AEs) for all enrolled patients were categorized by the Medical Dictionary for Regulatory Activities[3] (MedDRA) codes. MedDRA coding provides a standard category of event terms allowing health authorities to readily exchange and analyze data related to the safe use of medical products.

The adverse event data are displayed as the number of patients with one or more events in the category and time interval, and the total number of patients with one or more AEs in each category, along with their relative percentages. Serious adverse events (SAEs), device-related AEs, and procedure-related AEs by MedDRA code are summarized below.

[3] Refer to http://www.meddramsso.com/.

1.7. Serious Adverse Events

Table 27. Serious Adverse Events Through 365 Days Using MedDRA Codes

Variable	Treatment to 365 Days % (n/N)	Treatment to 30 Days % (n/N)	31 to 365 Days % (n/N)
Serious adverse events [1]	38.5% (62/161)[2]	13.0% (21/161)[2]	29.7% (47/158)[2]
Blood and lymphatic system disorders	1.9% (3/161)	0.6% (1/161)	1.3% (2/158)
Cardiac disorders	6.8% (11/161)	1.9% (3/161)	5.1% (8/158)
Gastrointestinal disorders	6.8% (11/161)	1.9% (3/161)	5.7% (9/158)
Hepatobiliary disorders	0.6% (1/161)	0.0% (0/161)	0.6% (1/158)
Immune system disorders	1.2% (2/161)	1.2% (2/161)	0.0% (0/158)
Nervous system disorders	1.9% (3/161)	0.0% (0/161)	1.9% (3/158)
Renal and urinary disorders	4.3% (7/161)	1.9% (3/161)	2.5% (4/158)
Respiratory, thoracic and mediastinal disorders	8.1% (13/161)	3.1% (5/161)	5.1% (8/158)
Surgical and medical procedures (hip arthroplasty)	0.6% (1/161)	0.0% (0/161)	0.6% (1/158)
Vascular disorders	6.8% (11/161)	2.5% (4/161)	4.4% (7/158)
Other[3]	22.9% (37/161)	4.9% (8/161)	18.9% (30/158)

[1]A serious adverse event (SAE) was defined as any event that is fatal, is life-threatening, requires or prolongs (>48 hours) inpatient hospitalization, is a persistent or significant disability or incapacity, or is considered an important medical event.
[2]A patient may report multiple SAEs: hence, number of patients with any SAE may not be the sum of those in each SAE category.
[3]The most common "Other" events were in the MedDRA categories of "infections/infestations" and "injury/procedural complications," which include events such as: wound infection, pneumonia, urinary tract infection, bleeding, and pseudoaneurysm.

1.8. Device-Related Adverse Events

Device-related AEs were reported in 3.7% (6 of 161) of patients through 365 days post-treatment.

Table 28. Device-related Adverse Events Through 365 Days

Variable	Treatment to 365 Days % (n/N)	Treatment to 30 Days % (n/N)	31 to 365 Days % (n/N)
Device-related events [1]	3.7% (6/161)[2]	2.5% (4/161)[2]	1.3% (2/158)[2]
General disorders and administration site conditions[3]	1.9% (3/161)	1.9% (3/161)	0.0% (0/158)
Immune system disorders[4]	1.2% (2/161)	1.2% (2/161)	0.0% (0/158)
Injury, poisoning and procedural complications[5]	1.2% (2/161)	0.0% (0/161)	1.3% (2/158)
Vascular disorders[6]	0.6% (1/161)	0.0% (0/161)	0.6% (1/158)

[1] A device-related adverse event was defined as any event that was adjudicated by the CEC as potentially related to the device
[2] A patient may report multiple adverse events and in different categories; hence, number of patients in each category may not be the sum of those in each subcategory.
[3] Device damage, stent graft endoleak.
[4] Anaphylactic shock, hypersensitivity.

Variable	Treatment to 365 Days % (n/N)	Treatment to 30 Days % (n/N)	31 to 365 Days % (n/N)

[5] In-stent arterial restenosis, vascular pseudoaneurysm.

[6] Supra-renal aneurysm rupture.

1.9. Procedure-Related Adverse Events

Procedure-related AEs were reported in 44.1% (71 of 161) of patients through 365 days post-treatment.

Table 29. Procedure-related Adverse Events Through 365 Days

Variable	Treatment to 365 Days % (n/N)	Treatment to 30 Days % (n/N)	31 to 365 Days % (n/N)
Procedure-related events [1]	44.1% (71/161)[2]	35.4% (57/161)[2]	13.3% (21/158)[2]
Blood and lymphatic system disorders	1.2% (2/161)	1.2% (2/161)	0.0% (0/158)
Cardiac disorders	1.9% (3/161)	1.9% (3/161)	0.0% (0/158)
Gastrointestinal disorders	2.5% (4/161)	2.5% (4/161)	0.0% (0/158)
General disorders and administration site conditions[3]	29.8% (48/161)	22.4% (36/161)	8.2% (13/158)
Infections and infestations (wound infection)	0.6% (1/161)	0.6% (1/161)	0.0% (0/158)
Injury, poisoning and procedural complications[4]	12.4% (20/161)	9.9% (16/161)	2.5% (4/158)
Nervous system disorders	0.6% (1/161)	0.6% (1/161)	0.0% (0/158)
Renal and urinary disorders	2.5% (4/161)	1.9% (3/161)	0.6% (1/158)
Respiratory, thoracic and mediastinal disorders	3.1% (5/161)	3.1% (5/161)	0.6% (1/158)
Vascular disorders	7.5% (12/161)	6.2% (10/161)	1.3% (2/158)
Other	3.1% (5/161)	2.4% (4/161)	0.6% (1/158)

[1] A procedure-related adverse event was defined as any event that was adjudicated by the CEC as related to the procedure for adjudicated events, or was procedure related in the investigator's opinion for events not adjudicated

[2] A patient may report multiple adverse events and in different categories; hence, number of patients in each category may not be the sum of those in each subcategory.

[3] The most common event was type II endoleak.

[4] The most common events were operative blood loss, in-stent restenosis, and pseudoaneurysm.

1.10. Unanticipated Adverse Events

One (1) UADE occurred from two (2) SAEs (polymer leak from the aortic body of the stent graft and anaphylactic shock) reported by an investigator for one patient. The patient was receiving an implant of a 26 mm Ovation device and fill polymer discharge occurred due to a disconnection of the fill tube that injects the fill material polymer into the aortic body stent graft. There were no embolic consequences and the AAA was successfully excluded. The patient was transferred to ICU post procedure. On post-operative day 16, the patient experienced disseminated intravascular coagulation and abdominal sepsis and died the following day. Upon review by the DSMB, the members recommended that the events be reported to FDA as an unanticipated adverse device

effect (UADE). In response, TriVascular temporarily suspended patient enrollment until appropriate modifications could be made to the distal stop component on the aortic body delivery catheter and its connection to the delivery system to address the fill tube disconnection. Following this corrective action, no additional UADEs or disconnections of the fill tube have been reported.

Table 30. UADEs Through 365 Days

Variable	Treatment to 365 Days % (n/N)	Treatment to 30 Days % (n/N)	31 to 365 Days % (n/N)
Unanticipated adverse device effects [1]	0.6% (1/161)	0.6% (1/161)	0.0% (0/158)

[1]An unanticipated adverse device effect (UADE) was defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of patients.

2. Effectiveness Results

The analysis of effectiveness was based on the major effectiveness study cohort of 161 patients available for the evaluation through 12 months. The primary effectiveness endpoint is proportion of patients that achieve Treatment Success, which is a composite endpoint assessed at 12 months that requires the following criteria to be met:

- Technical Success, defined as successful delivery and deployment of one aortic body and two iliac limbs.
- Freedom from Type I & III endoleaks at 12 months
- Freedom from stent graft migration at 12 months
- Freedom from AAA enlargement at 12 months
- Freedom from AAA rupture and conversion to open repair through 12 months

The secondary effectiveness endpoints are an evaluation through 12 months:

- Technical success, defined as successful delivery and deployment of one aortic body and two iliac limbs.
- Freedom from Type I & III endoleaks
- Freedom from stent graft migration
- Freedom from AAA enlargement
- Freedom from loss of device integrity

2.1. Treatment success

Treatment success, defined as technical success (successful delivery and deployment of once Ovation aortic body and a minimum of two Ovation iliac limbs) and freedom from AAA enlargement, migration, type I or III endoleak, AAA rupture, or surgical conversion post-index procedure and through 12 months, was 99.3%. The primary effectiveness endpoint of this clinical study was met.

Table 32. Primary Effectiveness Endpoint: Treatment Success Through 12-Month Follow-up

Variable	Ovation Treatment Group %(n/N)	95% Lower Confidence Limit	Target Performance Goal	Study endpoint
Treatment Success [1,2]	99.3% (137/138)	96.8%	80.0%	met

[1] Treatment success was defined as the proportion of patients that met all of the following criteria: technical success (defined as successful delivery and deployment of one aortic body and two iliac limbs), freedom from type I and III endoleak at 12 months (core lab assessed), freedom from stent graft migration at 12 months (core lab assessed), freedom from AAA enlargement at 12 months (core lab assessed), freedom from AAA rupture through 12 months (site assessed), and freedom from conversion through 12 months

[2] The 12-month analysis window ranges from 305 to 547 days

2.2. Technical success

Technical success, defined as successful delivery and deployment of one Ovation aortic body and a minimum of two Ovation iliac limbs, was 100% (161 of 161).

Additional accessory devices were implanted in the treatment area of 11 subjects during the index procedure as outlined in Table 33 below.

Table 33: Accessory devices used, location, and reason for implantation

Accessory device	Number of Patients	Implant location	Reason for implantation
Balloon expandable stent	3	Proximal aortic neck	Type IA endoleak
	1	Right iliac	Dissection
Self-expanding stents	1	Left iliac	Small type II endoleak
Stent graft	2	Proximal aortic neck	Type IA endleak
	1	Iliac limb	Dissection
Embolization coil	1	Proximal aortic body	Type IA endoleak
	1	Right internal iliac	Type IB endoleak
Multiple balloon-expandable and self-expanding stents	1	Aortic neck and iliac limbs	Type IA endoleak/stenosis in left proximal iliac limb

2.3. AAA Enlargement

Aneurysm diameter enlargement, identified by the imaging core laboratory at 12 months post-treatment (compared to the 1-month imaging), was reported in a patient. The patient with enlargement at 6 months had an increase slightly greater than 5 mm. At the 12 month visit, the patient's aneurysm diameter decreased to an overall diameter change of < 5 mm during the 12 month period. An additional patient had AAA diameter increase reported by the imaging core laboratory at the 12 month assessment, but the site reported a 3 mm decrease in AAA diameter at the 12 month assessment. This patient has a type II site-reported endoleak but no required intervention.

Table 34. AAA Diameter Change Through 12-Months

Variable	6 months % (n/N)[2]	12 months % (n/N)[2]
AAA diameter increase > 5 mm[1]	0.6% (1/154)	0.7% (1/150)
AAA diameter change ≤ 5 mm[1]	83.1% (128/154)	67.3% (101/150)
AAA diameter decrease > 5 mm[1]	16.2% (25/154)	32.0% (48/150)

Data provided by imaging core lab

Analysis windows are: 6 months (91 to 304 days), and 12 months (305 to 547 days)

[1] 1-month imaging serves as the baseline measure. If 1-month imaging was missing the first available postoperative image served as the baseline measure

[2] Denominator at each time point is the number of patients with at least one readable scan in the time interval

2.4. Migration

The proportion of patients with a device migration (evidence of proximal or distal movement of the stent graft > 10 mm relative to fixed anatomic landmarks) identified by the imaging core laboratory through 12 months post-treatment was 0% (0 of 161).

2.5. Endoleak

No type I, III, or IV endoleaks were identified by the imaging core laboratory through 12 months post-treatment. Concordance of imaging results at the 12-month follow-up visit between the core laboratory and the site-reported data was 89.5%. Type II endoleak incidence at the 1-year follow-up visit was 34.3%. The protocol-specified CT methodology may have influenced endoleak detection rates, thereby increasing the reported rates. Slice thicknesses of 0.6 to 2.0 mm were recommended in the protocol, which were ultimately reconstructed by the imaging core laboratory to 2.0 mm for analysis. In contrast, 3-5 mm slices are commonly utilized in the follow-up of patients treated with endovascular stent grafts, which are not as effective in detecting small leaks. As the typical type II endoleak identified in this study was small (median volume: 1.1 cc), the endoleak detection rate in this study was likely due, in part, to high-quality imaging.

Three (3) patients (3/158, 1.9%) were treated with secondary interventions for type II endoleak between 31 to 365 days. Sites reported 1 patient (1/158, 0.6%) that was treated for type IA endoleak and 1 patient (1/158, 0.6%) that was treated for type IA and type IB endoleaks, all between 31-365 days. These type I endoleaks were not detected during review by the imaging core laboratory.

Table 35. Imaging Core Lab-reported Endoleaks Through 12-months

Variable	Treatment to 12 months % (n/N)[1,2]	1 month % (n/N)[1,2]	6 months % (n/N)[1,2]	12 months % (n/N)[1,2]
Endoleaks	47.1% (74/157)	44.4% (68/153)	42.0% (63/150)	38.5% (55/143)
- Type I	0.0% (0/157)	0.0% (0/153)	0.0% (0/150)	0.0% (0/143)
- Type II	42.0% (66/157)	40.5% (62/153)	38.0% (57/150)	34.3% (49/143)
- Type III	0.0% (0/157)	0.0% (0/153)	0.0% (0/150)	0.0% (0/143)

Variable	Treatment to 12 months % (n/N)[1,2]	1 month % (n/N)[1,2]	6 months % (n/N)[1,2]	12 months % (n/N)[1,2]
- Type IV	0.0% (0/157)	0.0% (0/153)	0.0% (0/150)	0.0% (0/143)
- Indeterminate origin	8.9% (14/157)	3.9% (6/153)	4.0% (6/150)	4.2% (6/143)

Data provided by imaging core lab

Analysis windows are: 1 month (1 to 90 days), 6 months (91 to 304 days), and 12 months (305 to 547 days)

[1] Denominator at each time point is the number of patients with at least one readable scan in the time interval

[2] Numerator may not equal the sum of type endoleaks if more than one type was identified in the same patient

2.6. Loss of Stent Graft Integrity

Loss of stent graft integrity was identified by the imaging core laboratory through 12 months post-treatment in 2.5% (4 of 159) of patients. The time to initial event identification was 30 days (n=1), 6 months (n=1), and 12 months (n=2). Each event was identified as stent fracture in the mid-strut area of the proximal stent and none were associated with clinical sequelae. Furthermore, the sponsor evaluated the nature of the stent fractures and did not identify any specific anatomic patient criteria that were associated with fractures, such as severe angulation or short neck lengths.

Table 35. Loss of Stent Graft Integrity Through 12-Months

Variable	Treatment to 12 months % (n/N)[1,2]	1 month % (n/N)[1,2]	6 months % (n/N)[1,2]	12 months % (n/N)[1,2]
- Stent fracture	2.5% (4/159)	0.6% (1/157)	1.3% (2/150)	2.7% (4/146)

Data provided by imaging X-ray core lab

Analysis windows are: 1 month (1 to 90 days), 6 months (91 to 304 days), and 12 months (305 to 547 days)

[1] Denominator at each time point is the number of patients with at least one readable scan in the time interval. Missing or unreadable 1 month measures were imputed with available discharge X-ray measures

[2] Numerator is number of patients with a stent fracture reported in the time interval. Once a stent fracture is reported it will also be reported at each subsequent time interval.

3. AAA-related Secondary Interventions

A total of 12 AAA-related secondary procedures were performed in 10 (6.2%) patients for endoleak (2 procedures for type IA, 1 for type IB and 3 for type II), aortic body stenosis (3 procedures), iliac limb occlusion (2 procedures), and iliac limb stenosis (1 procedure). Two patients had a single intervention to treat two outcomes (one patient with type IA and type IB and one patient with type IA and aortic body stenosis).

Table 36. Patients with AAA-related Secondary Procedures through 365 Days

Variable	Treatment to 365 Days % (n/N)	Treatment to 30 days % (n/N)	31 to 365 days % (n/N)
AAA-related secondary procedures[1]	6.2% (10/161)	1.2% (2/161)	5.1% (8/158)

4. Clinical Utility Endpoints

The secondary Clinical Utility endpoints were evaluated:

- Blood loss
- Duration of procedure
- Length of hospital stay
- Type of anesthesia
- Type of vascular access

Table 37. Clinical Utility

Variable	Statistics	Ovation Treatment Group
Procedure time (min)	N	161
	Mean ± SD	110 ± 41
	Median	105
	Min, Max	46, 264
Procedural blood loss (cc)	N	158
	Mean ± SD	231 ± 264
	Median	150
	Min, Max	15, 2500
Hospital stay (days)[2]	N	161
	Mean ± SD	2 ± 3
	Median	1
	Min, Max	0, 33
Anesthesia type[1]		
- General	% (n/N)	65.8% (106/161)
- Regional	% (n/N)	16.8% (27/161)
- Local	% (n/N)	23.6% (38/161)
- Conscious sedation	% (n/N)	11.2% (18/161)
Vascular access type		
- Cutdown	% (n/N)	52.2% (84/161)
- Percutaneous	% (n/N)	42.9% (69/161)
- Cutdown and percutaneous	% (n/N)	5.0% (8/161)

[1] Numerator may not equal the sum of types if more than one type occurred in the same patient
[2] Date of death was used as discharge date for patients who expired prior to discharge

5. Patient Accountability and Follow-up Beyond 12 Months

Eighty-five (85) patients have been followed beyond12 months, including 55 with completed follow-up visit and imaging assessed by the site; 41 with CTs assessed by the Core Lab; and 26 with X-rays assessed by the Core Lab. Study follow-up is ongoing. No aneurysm ruptures, conversions to surgical repair, MAEs, device-related adverse events (AE), type I or III endoleaks or migrations were reported beyond 12 months. One patient with stent fracture and two patients with AAA enlargements were reported at the 2 year follow up. There were no clinical sequelae in the patient with the reported stent fracture, and type II endoleaks were reported in the patients with the AAA

enlargements. No interventions have been required for these patients. One patient death was determined to be AAA-related because it was a supra-renal aneurysm rupture superior to the stent graft but in the target vessel segment. The additional 5 deaths beyond 12 months were not AAA-related.

6. Subgroup Analysis

The following preoperative characteristics were evaluated for potential association with outcomes.

6.1. Gender Analysis

Despite the wide utilization of endovascular therapy, females with AAA requiring intervention remain an underserved population. Although nearly 1 in 3 AAAs are diagnosed in females [36], they comprise only 6.5% to 13.2% of patients enrolled in endovascular AAA IDE trials [14-18]. Female enrollment in the current study was 12.4%, a proportion higher than that reported in most [15-18], but not all [14], IDE trials of currently marketed AAA endografts. The MAE rate for males was 2.1% and for females was 5.0%. For treatment success, the rates were comparable at 99.2% and 100% for males and females, respectively. An equivalent percentage of females (1/20, 5%) and males (5/141, 3.5%) received accessory devices during the index procedure, described in section 2.2 Technical Success. No other differences were found regarding endovascular treatment between males and females; however, due to the small sample size, there are limitations to the interpretation of this subanalysis.

Table 38. Primary Safety Endpoint Subanalysis: Major Adverse Events Through 30 Days by Gender

Variable	Male	Female
Major adverse events[1]	2.1% (3/141)	5.0% (1/20)

[1]A major adverse event was defined as any of the following: death, myocardial infarction, stroke, renal failure, respiratory failure, paralysis, bowel ischemia, or procedural blood loss ≥ 1,000 cc

Table 39. Primary Effectiveness Endpoint Subanalysis: Treatment Success Through 12-Month Follow-up Visit by Gender

Variable	Male	Female
Treatment Success [1,2]	99.2% (121/122)	100.0% (16/16)

[1] Treatment success was defined as the proportion of patients that met all of the following criteria: technical success (defined as successful delivery and deployment of one aortic body and two iliac limbs), freedom from type I and III endoleak at 12 months (core lab assessed), freedom from stent graft migration at 12 months (core lab assessed), freedom from AAA enlargement at 12 months (core lab assessed), freedom from AAA rupture through 12 months (site assessed), and freedom from conversion through 12 months

[2] The 12-month analysis window ranges from 305 to 547 days

XI. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Treatment success, defined as technical success and freedom from AAA enlargement, migration, type I or III endoleak, AAA rupture, or surgical conversion through 12 months, was 99.3%. Note that 11 patients received additional accessory devices during the index procedure. The primary effectiveness endpoint of this clinical study was met, and these data demonstrate a reasonable assurance of effectiveness of endovascular repair of AAA with the Ovation device through 12 months post-treatment.

B. Safety Conclusions

The primary safety endpoint of this clinical study was met. Patients treated with the Ovation device had a MAE rate of 2.5%, meeting the target performance goal of 21%. All-cause mortality through 12 months was 2.5%. No AAA ruptures or conversions to open surgery were reported through 12 months. No device-related AEs were reported in patients with available data between days 366 and 730. These data demonstrate a reasonable assurance of safety of endovascular repair of AAA with the Ovation device through 12 months post-treatment.

The risks of the device are based on non-clinical laboratory and animal studies as well as data collected in the clinical study to support PMA approval as described above. The non-clinical testing supports the safety and expected performance of the Ovation Abdominal Stent Graft System and provided the basis for initiating a pivotal study to further support the safety conclusions.

C. Benefit-Risk Conclusions

As stated above, the safety and effectiveness endpoints were met in the clinical study, with a 30-day MAE rate of 2.5% (with a target performance goal of 21%) and treatment success through 12 months of 99.3% (with a target performance goal of 80%). For the patient, this means that they will likely not experience a major adverse event in the first 30 days after receiving this device and that their aneurysm will very likely remain excluded from blood flow and pressure such that it will not rupture and cause death.

Additional outcome benefits include 12-month MAE rate of 6.2%, and no AAA rupture or surgical conversion. Again, for the patient, these benefits will extend beyond the short time period after treatment. These results, combined with the Ovation Abdominal Stent Graft System indications, result in a reasonable assurance of safety and effectiveness for patients in the general population as indicated, including those with small access diameters, $\geq$ 7 mm proximal aortic neck, and an aortic angle of $\leq$ 60 degrees if proximal neck is $\geq$ 10 mm and $\leq$ 45 degrees if proximal neck is < 10 mm. Patient follow up beyond 12 months continues to support the safety and effectiveness conclusions through 12 months.

In conclusion, the data provided in this PMA application demonstrate that the possible benefits of the Ovation Abdominal Stent Graft System outweigh the probable risks for the endovascular treatment of abdominal aortic aneurysms. Additional information will be provided from the post approval study.

D. Overall Conclusions

The data in the PMA Application provide reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

The combination of preclinical and clinical experience with the Ovation Abdominal Stent Graft System supports the safety of the device. Preclinical bench testing was performed on the Ovation Abdominal Stent Graft System in accordance with applicable guidance documents and national and international standards. The testing confirmed that the Ovation Abdominal Stent Graft system met performance and design specifications.

Preclinical *in vivo* GLP and non-GLP animal studies utilizing early and final versions of the fill polymer were performed to evaluate the acute and chronic performance of the device design. The study endpoints were successful delivery, graft patency, absence of migration or kinking, normal healing and an evaluation of a bolus release of the fill polymer. The results support the safety of the Ovation Abdominal Stent Graft System.

Biocompatibility testing was performed on the materials of the Ovation Abdominal Stent Graft System in accordance with the applicable international standard. All testing met the requirements as specified in the applicable standard, ensuring the finished device is biocompatible.

Sterilization, packaging, and shelf life testing were performed on the Ovation Abdominal Stent Graft System. The testing demonstrated that the Ovation Abdominal Stent Graft System maintains a Sterility Assurance Level of 10^{-6}. The results of shelf life testing confirmed that the Ovation Abdominal Stent Graft System maintains functionality and packaging integrity throughout 3 year shelf life.

The results of the clinical study demonstrate that the primary safety and effectiveness endpoints were met. The 30-day outcomes in patients treated with the Ovation device included: 0.6% rate for both all-cause and AAA-related mortality;, a 2.5% MAE rate;

and 100% freedom from delivery or deployment failure, type I or III endoleak, AAA rupture, or surgical conversion. Through 12 months post-treatment, all-cause mortality was 2.5%, AAA-related mortality was 0.6%, MAE rate was 6.2%, with 100% freedom from type I or III endoleak, device migration, AAA rupture, or surgical conversion.

These data confirm that the overall clinical benefit outweighs the overall clinical risk.

XIII. CDRH DECISION

CDRH issued an approval order on October 5, 2012. The final conditions of approval cited in the approval order are described below.

You agree to provide the following information as part of the Annual Report to your PMA application:

1. You will provide a clinical update to physician users at least annually. At a minimum, this update will include, for your long-term post-approval study cohort, a summary of the number of patients for whom data are available, with the rates of aneurysm-related mortality, aneurysm rupture, secondary endovascular procedures, conversion to surgical repair, complications, endoleak, aneurysm enlargement, prosthesis migration, and patency. Reports of losses of device integrity, reasons for conversion and causes of aneurysm-related death and rupture are to be described. A summary of any explant analysis findings are to be included. Additional relevant information from commercial experience within and outside of the U.S. is also to be included. The clinical updates for physician users and the information supporting the updates must be provided in the Annual Report.

In addition to the Annual Report requirements outlined above, you agree to conduct a post-approval study (PAS) to evaluate the long-term safety and effectiveness of the Ovation Abdominal Stent Graft System for the treatment of infra-renal abdominal aortic aneurysms.

2. *Long-Term Follow-up Study:* This will be a prospective, consecutively enrolling, single-arm, multicenter study that will consist of continued follow-up of all available subjects from the pivotal study and the continued access study, as well as newly enrolled (*de novo*) subjects from this PAS and the HDE PAS (H100008). A total of 320 subjects will be enrolled with at least 192 evaluable at five years post-implantation. A minimum of 59 *de novo* subjects will be enrolled from a minimum of 15 investigational sites across the U.S.

   The primary safety endpoint of the study is freedom from aneurysm-related mortality at five years post implantation, which will be compared to a performance criterion of 92%. Aneurysm-related mortality is defined as:

Death from rupture of the abdominal aortic aneurysm or from any procedure intended to treat the AAA. If a death occurred within 30 days of any procedure intended to treat the AAA or within the hospital stay if the patient was not discharged within 30 days, then it is presumed to be aneurysm-related.
Secondary endpoints through five years will include mortality rates (AAA-related and all-cause), serious adverse events (SAE), device patency, conversion to surgical repair, endoleak, AAA enlargement, stent graft migration, device integrity, secondary endovascular procedures and aneurysm rupture.

3. *Evaluation of training program:* This analysis will evaluate your training program by comparing the incidence of the following as a function of physician experience:

   - at implant: technical failure, type I endoleak, and the use of accessory devices implanted in the treatment area; and
   - through 30 days: secondary endovascular procedures, device-related serious adverse events, and the following events: thromboembolic, paralysis, paraparesis, renal, stroke, claudication, and ischemic colitis,

   as a function of physician experience. The physicians involved in this comparison include all those who treated the subjects included in the PAS, the previously enrolled subjects and *de novo* subjects. The physicians' experience will be categorized into two groups:

   a. those who have completed fewer than 20 endovascular repairs of AAA with any current marketed device in the 2 years preceding participation in the Ovation physician training program, and
   b. those who completed equal to or more than 20 said cases.

   Additionally, if any insights are obtained regarding your training program, you will provide a discussion of that in the post-approval study report. Should modifications be necessary to the training program, you will describe and provide the appropriate rationale for each modification within an annual report to your PMA.

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study. Your PMA supplement should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

Please be advised that the results from this study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.
FDA would like to remind you that you are required to submit PAS Progress Reports every six months during the first two years of the study and annually thereafter. The

reports should clearly be identified as Post-Approval Study Report. Two copies, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm.

The applicant's manufacturing facility was inspected and was found to be in compliance with the device Quality System (QS) Regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See Approval Order.