TREO®

ABDOMINAL STENT-GRAFT SYSTEM

INSTRUCTIONS FOR USE
(IFU)

TERUMO
Aortic

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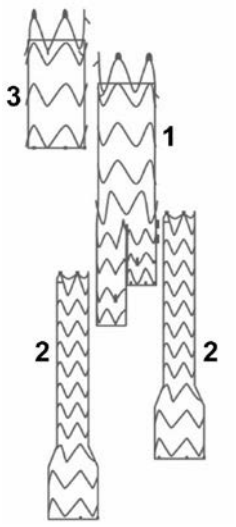
1. TREO® ABDOMINAL STENT-GRAFT SYSTEM DEVICE DESCRIPTION

The **TREO® ABDOMINAL STENT-GRAFT SYSTEM** (**TREO**) is a modular endovascular system designed to treat infrarenal abdominal aortic and aortoiliac aneurysms. The **TREO® ABDOMINAL STENT-GRAFT SYSTEM** consists of four types of implants, specifically a Main Bifurcated Stent-Graft, a Leg Extension Stent-Graft, a Proximal Cuff Stent-Graft and a Straight Iliac Extension Stent-Graft. Each stent-graft is preloaded into its own delivery system that is advanced under fluoroscopy to the location of the infrarenal aneurysm. The stent-graft is deployed at the intended location and creates a blood flow channel, excluding the aneurysm from blood pressure and flow.

1.1. STENT-GRAFTS

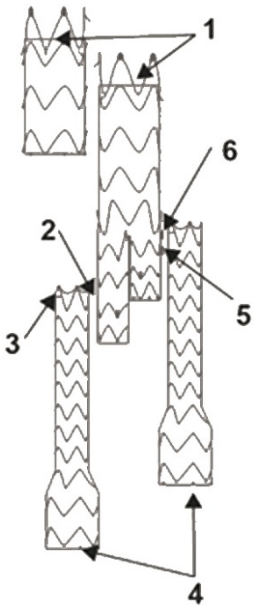
The **TREO® ABDOMINAL STENT-GRAFT SYSTEM** is typically comprised of a Main Bifurcated Stent-Graft and two Leg Extension Stent-Grafts, each delivered via an endovascular approach using their own separate delivery system. All stent-grafts consist of self-expanding Nitinol stents sutured to woven polyester fabric. The stent scaffold is a series of sinusoidal springs stacked in a tubular configuration. These stent springs are spaced along the length of the graft fabric to provide radial support and allow for the self-expansion of the stent-grafts. Radiopaque markers are placed on all stent-grafts to aid visualization and accurate placement (**Figures 1 and 2**). The radiopaque markers are cylindrical or tube in shape. Both are made of a platinum iridium alloy that is 90% platinum and 10% iridium.

Figure 1. TREO® ABDOMINAL STENT-GRAFT SYSTEM



1	Main Bifurcated Stent-Graft
2	Leg Extension Stent-Graft
3	Proximal Cuff Stent-Graft

Figure 2. Marker Band Placement



1	Proximal Markers
2	Ipsilateral Minimum Overlap Marker
3	Leg Extension Proximal Markers
4	Leg Extension Distal Markers
5	Contralateral Minimum Overlap Marker
6	Maximum Overlap Marker

Table 1 provides a summary of the materials of the **TREO** Stent-Grafts.

Table 1. TREO® ABDOMINAL STENT-GRAFT SYSTEM Materials

Implant Component	Material
Stent	Nitinol
Graft	Woven Polyester
Sutures	Braided Polyester
Radiopaque Markers	Platinum (90%) – Iridium (10%)

1.1.1. Main Bifurcated Stent-Graft

The Main Bifurcated Stent-Graft consists of three general areas: the uncovered proximal stent, the main body, and the two gates. The Main Bifurcated Stent-Graft is available in proximal diameters ranging from 20 – 36 mm. Three overall lengths are available for each diameter of the Main Bifurcated Stent-Grafts. The lengths vary in the main body of the device, as the gate lengths of the Main Bifurcated Stent-Grafts are constant across all diameters.

- The length of the ipsilateral gates is 50mm
- The length of the contralateral gates is 30mm
- The length of the transition from the main body segment to the gates is 10mm
- The lengths of the main body segments are 40, 60 or 80mm, with each length available in each diameter

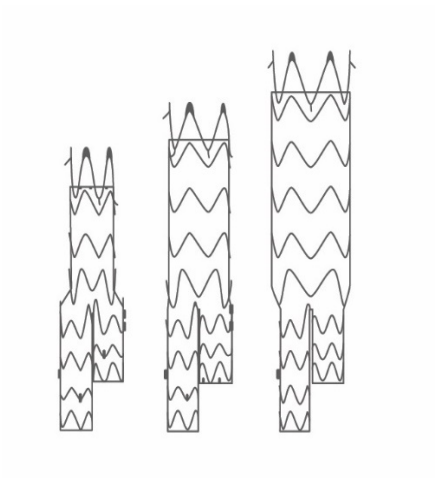
The uncovered proximal stent includes fixation barbs (suprarenal) for migration resistance. A second row of barbs are also located just distally to the start of the covered graft section, approximately at the middle of the first covered stent, to help provide infrarenal fixation. This uncovered proximal stent is composed of laser cut Nitinol and is sewn on the inside of the woven polyester graft fabric. The seal zone of the Main Bifurcated Stent-Graft consists of the distal portion of the uncovered proximal stent and the first covered proximal wireform, Nitinol stent, sewn to the inside of the graft material.

The diameter of each gate of the Main Bifurcated Stent-Graft is always the same size (14 mm), regardless of proximal diameter or length. Each gate of each Main Bifurcated Stent-Graft includes a laser cut, Nitinol lock stent that is sewn on the inside of the graft fabric. The lock stent contains dull barbs on the stent ring that are intended to engage the stent rings of the Leg Extension Stent-Graft *in-situ* and help prevent separation of the Leg Extension Stent-Graft from the Main Bifurcated Stent-Graft. The **TREO** system is designed to require a minimum overlap length of 20mm between the Main Bifurcated Stent-Graft and Leg Extension Stent-Graft.

All remaining stents on the **TREO** Main Bifurcated Stent-Graft are wireform Nitinol stents sewn on the outside of the graft fabric.

See **Figure 3** and **Table 32a** for additional information.

Figure 3. TREO Main Bifurcated Systems



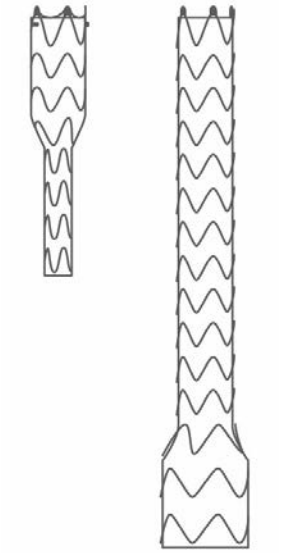
1.1.2. Leg Extension Stent-Graft

The proximal end of all Leg Extension Stent-Grafts is always the same diameter (15 mm) to allow coupling with any Main Bifurcated Stent-Graft. It is configured as shown in **Figure 1**. The system is designed to require a minimum overlap length of 20mm between the Main Bifurcated Stent-Graft and Leg Extension Stent-Graft. Additionally, the amount that each Leg Extension Stent-Graft is inserted into the gate of the Main Bifurcated Stent-Graft is adjustable. The diametric oversizing and 20mm minimum overlap length (in conjunction with the lock stent of the Main Bifurcated Stent-Graft) are designed to provide a robust overlap between the components.

The available distal diameters of the Leg Extension Stent-Grafts are 9, 11, 13, 15, 17, 20 and 24mm. Five overall lengths are available for each diameter, including 80, 100, 120, 140 and 160mm. All Leg Extension Stent-Grafts have woven polyester graft material and consist of wireform Nitinol stents sewn on the outside of the graft fabric. The distal end configuration of all Leg Extension Stent-Grafts is a closed end configuration.

See **Figure 4** and **Table 33a** for additional information.

Figure 4. TREO Leg Extension Stent-Grafts



1.1.3. Proximal Cuff Stent-Graft

The Proximal Cuff Stent-Graft consists of two general areas: the uncovered proximal stent and the main body. The Proximal Cuff Stent-Graft is available in proximal diameters ranging from 20 – 36 mm. Three overall lengths are available for each diameter of the Proximal Cuff Stent-Grafts. The three lengths are 40mm, 55mm, and 70mm.

The uncovered proximal stent includes fixation barbs (suprarenal) for migration resistance. A second row of barbs are also located just distally to the start of the covered graft section, approximately at the middle of the first covered stent, to help provide infrarenal fixation. This uncovered proximal stent is composed of laser cut Nitinol and is sewn on the inside of the woven polyester graft fabric. The seal zone of the Main Bifurcated Stent-Graft consists of the distal portion of the uncovered proximal stent and the first covered proximal wireform, Nitinol stent, sewn to the inside of the graft material. The remaining stents of the Proximal Cuff Stent-Grafts are all sewn on the inside of the graft material.

1.1.4. Iliac Extension / Straight Extension Stent-Grafts

In cases where a Leg Extension Stent-Graft needs to be extended, the following devices are available:

- For cases where the distal end of the Leg Extension Stent-Graft has a diameter of 15, 17, 20 or 24mm, then another Leg Extension Stent-Graft of a similar configuration (e.g., distal diameter that matches that of the previous stent-graft) should be used. The 15mm diameter proximal end of the added device should be placed within the 15mm diameter section of the previous device.
- For cases where the distal end of the Leg Extension Stent-Graft has a diameter of 9, 11 or 13mm, "Straight" configuration devices are available in each of these diameters. Each Straight Extension Stent-Graft has a uniform diameter of either 9, 11 or 13mm, and is intended for use with previously placed Leg Extension Stent-Graft with the same distal diameter. Straight Extension Stent-Grafts are available in 80mm lengths.

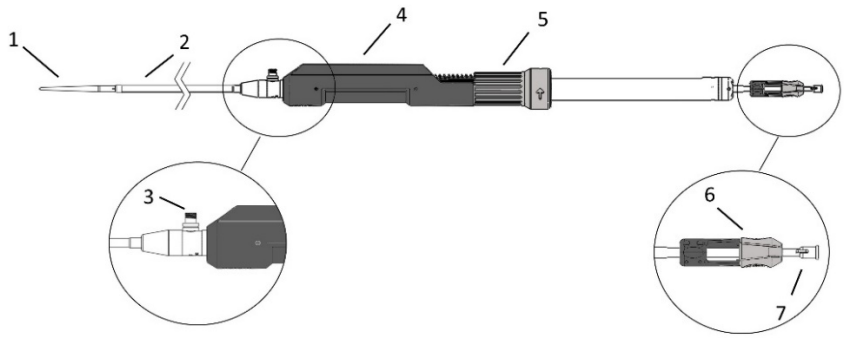
See **Table 33a** for details on the Leg Extension Stent-Grafts and **Table 33b** for details regarding Straight Extension Stent-Grafts.

1.2. DELIVERY SYSTEMS

1.2.1. Delivery System for the Main Bifurcated and Proximal Cuff Stent-Grafts

The **TREO** Main Bifurcated Stent-Graft and Proximal Cuff Stent-Graft use the same delivery system, consisting of an introducer sheath attached to a main handle assembly (**Figure 5**). The handle assembly includes a Gray Turn Knob control system for accurate placement of the Main Bifurcated Stent-Graft and Proximal Cuff Stent-Graft.

Figure 5. Main Bifurcated and Proximal Cuff Delivery System



1	Introducer Tip
2	Introducer Sheath
3	Two-Way Check Valve
4	Black Stationary Grip
5	Gray Turn Knob
6	Clasp Release
7	Guidewire Lumen

The introducer sheath and tip are hydrophilically coated. The sheath can be detached from the Black Stationary Grip and left in place while removing the rest of the Main Bifurcated Stent-Graft Delivery System so the Main Bifurcated Stent- Graft Introducer Sheath can then be used as a vascular introducer for the ipsilateral Leg Extension Stent-Graft Delivery System. The tip of the Main Bifurcated Stent-Graft Delivery System and end of the Main Bifurcated Stent-Graft Delivery System introducer sheath are radiopaque for visibility during use.

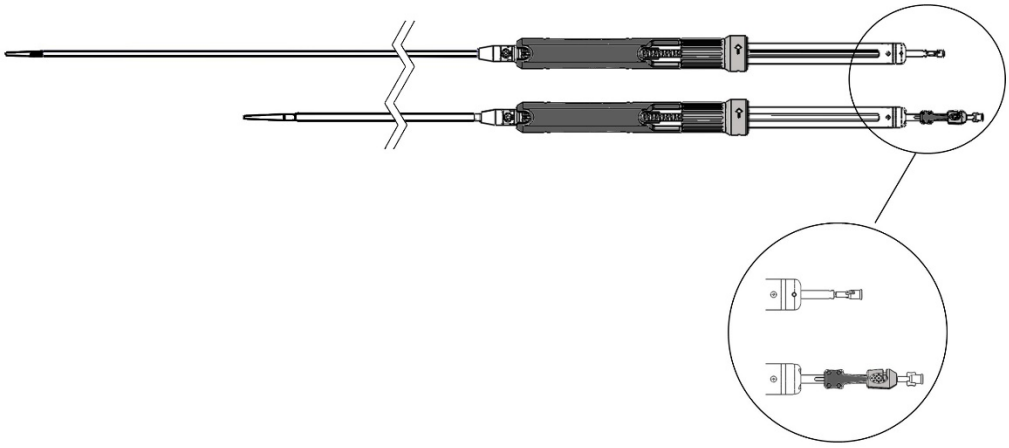
As with all **TREO** delivery systems, a 0.035" stiff guidewire is recommended. The Main Bifurcated Stent-Grafts and Proximal Cuff Stent-Graft Delivery Systems come in either 18 or 19F profiles depending on the stent-graft (see **Table 32a**). Smaller diameters (20 thru 28mm) are in 18F profile systems, while the larger diameters (30 thru 36mm) are in 19F systems. Profiles by diameter are identical for both the Main Bifurcate and Proximal Cuff Stent-Graft Delivery Systems. The working length (distance from the proximal end of the sheath [physician reference] to the proximal edge of the stent-graft fabric [patient reference]) is 49cm for all sizes.

All **TREO** delivery systems operate using either a pin and pull technique, or using the mechanical advantage. The pin and pull technique operate by the physician holding the large black stationary grip and pulling back on the gray turn knob. However, it is recommended that for better control and accuracy that the gray turn knob is initially turned as shown by the arrow to begin deployment. Regardless of technique, the physician is instructed to closely monitor the deployment under fluoroscopy. Once a Main Bifurcate or Proximal Cuff Stent-Graft is fully deployed, the bare stent is released from the delivery system using the clasp release mechanism. Full details of the deployment sequence are described in **Section 11**.

1.2.2. Delivery System for the Leg Extension Stent-Graft and Straight Extension Stent-Grafts

The **TREO** Leg Extension Stent-Grafts and Straight Extension Stent-Grafts use a similar version of the Delivery System as the Main Bifurcated Stent-Grafts and Proximal Cuff Stent-Grafts. The only difference in the delivery system from the Main Bifurcated and Proximal Cuffs as compared to the Leg Extension Stent-Graft and Straight Extension Stent-Graft Delivery System is the absence of the clasp release mechanism at the proximal end of the delivery system next to the guidewire flush port. See **Figure 6 (The delivery system for the Leg Extension and Straight Extension Stent-Grafts is on top, and the delivery system for the Main Bifurcated and Proximal Cuff Stent-Grafts is on the bottom)**.

Figure 6. Leg Extension Stent-Graft Delivery System
Leg Extension Stent-Graft Delivery System (TOP) as compared to Main Bifurcated and Proximal Cuff (BOTTOM)



The introducer sheath and tip are hydrophilically coated. The sheath can be detached from the Black Stationary Grip and left in place while removing the rest of the Leg Extension and Straight Extension Delivery System so the leave behind sheath can be used as an introducer for compatible components. The tip of the Leg Extension and Straight Extension Delivery System and end of the introducer sheath are radiopaque for visibility during use.

As with all **TREO** delivery systems, a 0.035" stiff guidewire is recommended. The delivery system for the Leg Extension Stent-Graft and Straight Extension Stent-Graft come in either 13 or 14F profiles depending on the diameter of the stent-graft (see **Tables 33a and 33b**). Smaller diameters (9 thru 15mm) are in 13F profile systems, while the larger diameters (17 thru 24mm) are in 14F systems. The working length (distance from the proximal end of the sheath [physician reference] to the proximal edge of the stent-graft fabric [patient reference]) is 80cm for all sizes.

All **TREO** delivery systems operate using either a pin and pull technique, or using the mechanical advantage. The pin and pull techniques operate by the physician holding the large black grip stationary and pulling back on the gray handle. However, it is recommended that for better control and accuracy that the gray handle is initially turned as shown by the arrow to begin deployment. Regardless of technique, the physician is instructed to closely monitor the deployment under fluoroscopy.

2. INDICATIONS FOR USE

The **TREO® ABDOMINAL STENT-GRAFT SYSTEM** is indicated for use in the endovascular treatment of patients with infrarenal abdominal aortic and aorto-iliac aneurysms with the following characteristics:

- Adequate iliac or femoral access compatible with the required delivery systems and accessories
- Proximal aortic landing zone with:
  - Infrarenal landing neck length of ≥ 15mm
  - Aortic neck diameters ≥ 17 mm and ≤ 32 mm
  - Suprarenal neck angle of ≤ 45 degrees
  - Infrarenal neck angle of ≤ 60 degrees
- Distal iliac landing zone with:
  - an inside diameter of 8 mm – 13 mm and a length of ≥ 10 mm or
  - an inside diameter of > 13 mm – 20 mm and a length of ≥ 15 mm
- Minimum overall AAA treatment length (proximal landing location to distal landing location) of 13 cm
- Minimum overall length from the lowest renal artery to the aortic bifurcation of 9 cm

3. CONTRAINDICATIONS OF USE FOR THE TREO SYSTEM

The **TREO® ABDOMINAL STENT-GRAFT SYSTEM** is contraindicated for the following:

- Patients with a known allergy or intolerance to device materials listed in **Table 1 (Section 1.1)**
- Patients with a condition that threatens to infect the graft

4. WARNINGS AND PRECAUTIONS

Caution: Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

4.1. GENERAL

- The use of **TREO** requires that physicians be specially trained in endovascular abdominal aortic aneurysm repair techniques, including experience with high resolution fluoroscopy and radiation safety. Terumo Aortic will provide training specific to the **TREO** system. Specific physician training requirements are provided in **Section 10.1**.
- A team trained in vascular surgery should be available while the implant procedure is in progress in case conversion to open surgery is required.

4.2. PATIENT SELECTION

- Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications.
- Note: Key anatomic criteria that may affect successful exclusion of the aneurysm include severe infrarenal neck angulation (>60°), an infrarenal neck < 15mm in length, distal landing zones of < 10mm or < 15mm based on device selection as defined in **Section 7.2**, calcium in the proximal or distal landing zones or distal aortic segments with diameters < 70% of the combined diameters of the limbs passing through that segment of the anatomy.
- Note: Risk of bare proximal stent fracture observed in the U.S. Clinical Study (see **Section 6.4.19 Stent-Graft Integrity**) should be weighed against the risks associated with alternative treatment options for the indicated patient population.
- **TREO** should not be used in patients unable, or who will not be compliant with, the requirement to undergo preoperative

and postoperative imaging required as part of endovascular repair.

- **TREO** is not recommended in patients exceeding weight or size limits necessary to meet imaging requirements.
- Care should be taken when treating morbidly obese patients as device visualization may be compromised.
- Proximal and distal landing zones need to be considered. They are specified in Tables 32a and 33a for each device.
- Excessive aortic tortuosity may result in not being able to properly position the stent-graft or result in the stent-graft kinking.
- Significant or circumferential calcification or mural thrombus in the proximal aortic neck or the distal iliac landing zones may adversely impact sealing
- Significant or circumferential calcification or mural thrombus within the treatment length may adversely impact device patency
- The use of a bifurcated stent-graft in a patient with a narrowing of the distal aorta may result in reduced flow through the limbs. See **Section 7.1** for specific guidelines on distal aortic diameter considerations.
- Pay close attention to the iliac graft landing zone morphology to assess for proper Leg Extension Stent-Graft selection/suitability.
- When selecting an aortic bifurcate prosthesis, attention should be given to the treatment length from the lowest renal artery to the aortic bifurcation. If this length is less than the length of the contralateral length of the aortic bifurcate prosthesis, then it could result in increased difficulty when cannulating the contralateral gate. The shortest recommended treatment length for the **TREO** system is 9.0cm.
- Placement of stent-grafts in the abdominal aorta often requires proximity to the renal arteries. The distal landing area of the Leg Extension Stent-Graft may be very close to the internal iliac arteries. Care should be taken to not block these critical arteries during device deployment, with the exception of planned coverage of critical arteries.
- The 9, 11 and 13 mm Leg Extension Stent-Grafts must be extended by Straight Extension Stent-Grafts (**Table 33b**), and not additional Leg Extension Stent-Grafts.
- Iliac conduits may be used to ensure the safe insertion of the delivery system into the patient's access vessels, if determined necessary by the treating physician.
- Endovascular treatment of infrarenal abdominal aortic aneurysms requires lifelong, regular follow-up to assess patient's health as well as the performance of the implanted endovascular stent-graft. Patients with specific clinical findings, e.g., changes in structure or position of the endovascular graft should receive enhanced follow-up as described in **Section 13.**
- **TREO** is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging.
- Careful consideration should be given to treating patients with pre-existing iliac endoprostheses.

The **TREO** Stent-Graft System has not been evaluated in patients who:

- are less than 18 years old,
- are pregnant or lactating,
- have a suprarenal, juxtrarenal or pararenal aneurysm
- have a dissection in abdominal aorta, ruptured aneurysms, or symptomatic aneurysms (as determined by treating physician)
- have a patent inferior mesenteric artery that cannot be sacrificed and an occluded or stenotic celiac and/or superior mesenteric artery
- does not have at least one patent hypogastric artery left intact, unless both are occluded on pre-op imaging
- have a lesion that cannot be crossed by a guide wire
- have a proximal neck that increases by more than 10% over 15mm or more than 7% over 10mm; i.e., no trapezoidal necks
- have an active systemic infection or is suspected of having an active systemic infection (e.g., AIDS/HIV, sepsis)
- are morbidly obese (more than 100% over the ideal body weight or as defined by institutional standards) or have other clinical conditions that severely compromise or impair x-ray visualization of the aorta
- have connective tissue disease (e.g., Marfan's syndrome)
- have a mycotic aneurysm
- have significant or circumferential calcification or mural thrombus in the proximal aortic neck
- have significant or circumferential calcification or mural thrombus in the distal iliac landing zone

- have significant or circumferential calcification or mural thrombus within the treatment length, which may adversely impact device patency
- have a blood coagulation disorder or bleeding diathesis, the treatment for which cannot be suspended pre- and post-repair
- have a creatinine > 2.5 mg/dL
- have had a prior AAA repair (endovascular or surgical)
- have an untreatable allergy or sensitivity to contrast media, Nitinol/nickel, or polyester

4.3. PRIOR TO IMPLANT PROCEDURE

- Preoperative planning for access and placement should be completed prior to opening device packaging.
- Before use, carefully inspect all packaging for damage or defects. If the product or package has been damaged or the sterility of the contents is compromised, do not use the device. The product is provided double-pouched. If the outer pouch is opened, damaged, or missing, the product should not be used. Always handle devices with care. If necessary, you may work with your Endovascular Consultant to return an unused package and device to Terumo Aortic.
- For single use only. Do not re-sterilize or re-use. The re-use, reprocessing or re-sterilization of any **TREO** stent-graft system may compromise the structural integrity of the device and/or lead to device failures, which in turn may lead to injury, illness or death of the patient.
- Note product "Use By" date and do not use if the date has been exceeded.

4.4. DURING THE IMPLANT PROCEDURE

- Exercise care during handling and delivery to help prevent vessel rupture.
- Excessive use of contrast agents, emboli or a misplaced stent-graft may result in renal complications.
- Ensure that the delivery system handle and delivery system sheath are parallel with the patient's leg. Excessive angulation where the handle meets the delivery system sheath may prevent delivery system sheath retraction.
- Prosthesis components cannot be re-sheathed or drawn back into the delivery system without compromising the system, even if the prosthesis component is only partially deployed.
- If the outer sheath is accidentally withdrawn exposing the prosthesis, the device will prematurely deploy and may be incorrectly positioned.
- Failure to position the bifurcate proximal edge markers within the healthy infrarenal aortic neck may result in prosthesis leaks or require a further procedure such as the placement of a Proximal Cuff.
- Failure to position the prosthesis distal to the lowest renal ostium may result in occlusion of the renal arteries.
- Do not re-advance the clasp. Re-advancement of the clasp may cause capture of a bare stent strut resulting in an unintended movement of the stent-graft during system withdrawal. The device is designed to withdraw with the clasp fully open. The black release grip is locked in place when fully retracted over the gray thumb grip.
- Failure to position the Leg Extension Stent-Graft distal edge marker proximal to the internal iliac artery origin may result in occlusion of the internal iliac artery.
- Failure to position the proximal markers of the Leg Extension Stent-Graft at or distal to the maximum overlap marker on the Main Bifurcated Stent-Graft could lead to blockage of the opposite gate.
- Failure to position the proximal markers of the Leg Extension Stent-Graft at or proximal to the minimum overlap marker on the Main Bifurcated Stent-Graft could lead to modular dis-junction.
- Always use fluoroscopy to verify the prosthesis is completely released from the delivery system. Incomplete retraction of the delivery system sheath or incomplete retraction of the clasp release mechanism could lead to dislodgement of the prosthesis when the delivery system is removed from the patient.
- Use fluoroscopic guidance to advance the delivery system and to detect kinking or alignment problems with the stent-graft system. Do not use excessive force to advance or withdraw the delivery system when resistance is encountered. If the delivery system kinks during insertion, do not attempt to deploy the stent-graft component. Carefully remove the device and insert a new delivery system.
- An inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent-graft.
- Prosthesis migration or incorrect prosthesis deployment may require surgical intervention.

- Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification or tortuosity, or where excessive resistance is experienced, as vessel or catheter damage could occur. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system. Also exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity and/or angulation which can affect successful initial treatment of the aneurysm.
- High pressure injections of contrast media made at the edges of the stent-graft immediately after implantation can cause endoleaks.
- Endovascular techniques such as kissing balloons should be considered in the graft flow divider and native aortic bifurcation zone as the anatomy warrants.
- It is recommended that balloon modeling be done with a compliant balloon. Balloon inflation should not exceed 1 atm.
- Over inflation of compliant balloon can cause graft tears and/or vessel dissection or rupture.
- When expanding the prostheses, there is an increased risk of vessel injury and/or rupture, and possible patient death, if the compliant balloon's proximal and distal radiopaque markers are not completely within the covered (graft fabric) portion of the prosthesis.
- Do not expand the bare proximal stent of the Main Bifurcated Stent-Graft as expansion of the bare proximal stent may cause vessel injury or rupture and the balloon could snag onto the bare proximal stent of the Main Bifurcated Stent-Graft.
- Be careful not to displace the prostheses upon introducing and retracting the compliant balloon catheter.
- Always recheck position of stent-graft following ballooning.
- Care should be taken when inflating the compliant balloon, especially with calcified, tortuous, stenotic, or otherwise diseased vessels.
- Inflate the compliant balloon slowly. It is recommended that a backup compliant balloon be available.
- Do not use power/pressure injections through the delivery systems.

4.5. TREATMENT AND FOLLOW UP

- The long-term performance of **TREO** has not yet been established.
- Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.
- All patients with endovascular aneurysm repair should undergo periodic imaging to evaluate the stent-graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (> 5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or stent-graft migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.
- Patients experiencing reduced blood flow through the stent-graft limb or due to endoleaks may be required to undergo secondary interventions or surgical procedures.
- Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:
    - aneurysm growth > 5 mm, with or without endoleak, since last follow-up,
    - change in aneurysm pulsatility, with or without growth or endoleak,
    - persistent Type I/III endoleak, with or without aneurysm growth,
    - persistent Type II endoleak with aneurysm growth,
    - stent-graft migration resulting in an inadequate seal zone,
    - decrease in renal function due to renal artery occlusion (migration or poor placement).
- Following endovascular aneurysm repair (EVAR), spinal cord ischemia (SCI) may result in a rare complication of paraplegia or paraparesis. Cerebrospinal fluid (CSF) drain is advised if spinal cord ischemia is suspected.

4.6. MAGNETIC REASONANCE IMAGING (MRI) SAFETY INFORMATION

Nonclinical testing has demonstrated that **TREO** is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems only, with the parameters specified in **Section 10.6**. Additional MRI safety information is also provided in **Section 10.6**.

5. ADVERSE EVENTS

5.1. POTENTIAL ADVERSE EVENTS

Adverse events that may occur in conjunction with endovascular procedures include, but are not limited to, those listed in the following section. For the specific adverse events that occurred in the clinical study, please see **Section 6.**

Table 2. Potential Adverse Events	
Amputation	Hemorrhage
Anesthetic reactions/complications (e.g., aspiration)	Hepatic failure
Aneurysm Sac Enlargement	Impotence
Aneurysm / Lesion Rupture	Infection
Aortic damage (perforation, dissection, bleeding, rupture)	Ischemia (spinal cord, perfusion pathways)
Arteriovenous fistula / aorto-duodenal fistula	Limb ischemia
Blood Loss	Open surgical conversion
Bowel complications (e.g., adynamic ileus, transient ischemia, infarction, necrosis)	Paralysis/Paresthesia/Paraparesis
Cardiac events (e.g., arrhythmia, congestive heart failure, myocardial infarction, hypotension, hypertension)	Post Implantation Syndrome
Cerebral vascular accident (stroke)	Pseudoaneurysm
Claudication (e.g., buttock, lower limb)	Radiation overexposure or reaction
Coagulopathy	Renal failure or Complications
Contrast toxicity / anaphylaxis	Stenosis of native vessel
Death	Stent fracture / break
Delivery system failure	Stent-Graft failure (e.g., improper component placement, graft material wear, suture break, dilatation, erosion, graft twisting or kinking, puncture, perigraft flow)
Deployment failure (partial or inaccurate deployment)	Stent-Graft migration
Embolism (micro and macro) with transient or permanent ischemia or infarction	Transient Ischemic Attack
Endoleak	Vascular Trauma (perforation / dissection)
Fever and localized inflammation	Vessel Damage
Gastrointestinal complications	Vessel Dissection
Genitourinary complications (e.g., ischemia, erosion, femoral-femoral artery thrombosis, fistula, incontinence, hematuria, infection)	Vessel Occlusion/Thrombosis
Hematoma (surgical)	Wound complications (dehiscence, infection, hematoma, seroma, cellulitis)

5.2. ADVERSE EVENT REPORTING

Any adverse event or clinical incident involving the **TREO® ABDOMINAL STENT-GRAFT SYSTEM** in the United States should be immediately reported to Terumo Aortic using the email address qualityus@terumoaortic.com.

6. SUMMARY OF CLINICAL STUDY

6.1. INTRODUCTION

The primary objectives of the pivotal study were to evaluate the safety and effectiveness of the **TREO® ABDOMINAL STENT-GRAFT SYSTEM** in subjects with infrarenal aortic and aorto-iliac aneurysms. The study was a multi-center, prospective, single-arm, non-randomized, and non-blinded investigation. One hundred and fifty (150) subjects were treated between November 25, 2013 and February 10, 2016 at 29 investigational sites in the United States. Subjects are being followed at 1 month, 6 months, 1 year, and annually thereafter for 5 years. Subjects identified with fracture(s) within the first 5 years of follow-up will be followed for an additional 5 years (annually through 10 years post index procedure).

Although the primary effectiveness analysis was completed at 1 year, at the time of the data lock on February 14, 2019, partial 4-year data were available and are described in the subsequent sections.

6.2. ENDPOINTS

6.2.1. Primary Endpoints

The primary safety endpoint is the composite major adverse event (MAE) rate, defined when any of the following occur within 30 days:

- All-cause mortality
- Myocardial infarction
- Stroke
- Renal Failure requiring renal replacement therapy
- Respiratory Failure
- Paraplegia
- Bowel Ischemia
- Procedural blood loss of ≥ 1000 cc

The primary safety endpoint was compared to a performance goal of 19%. The performance goal was derived using published data on open surgical controls.

The hypothesis tested for the primary safety endpoint at a one-sided alpha level of 0.025 was:

Null hypothesis (H_0): $p_{saf} \geq 0.19$

Alternative hypothesis (H_1): $p_{saf} < 0.19$

where p_{saf} was the proportion of **TREO** subjects with major adverse events through 30 days post procedure and 19% was the performance goal for this endpoint.

The proportion of subjects in the safety sample with composite MAE at 30 days post procedure was summarized as number, percentage and an exact 95% confidence interval (Clopper-Pearson method). The probability of experiencing at least one MAE in the 30 days post procedure was tested versus the performance goal for the endpoint using an exact binomial test.

The primary effectiveness endpoint is successful aneurysm treatment 12 months post-implant, defined as a composite of the following:

- Technical success at the conclusion of the procedure defined as endograft patency, absence of Type I/III endoleak, or treated aneurysm rupture
- Absence of aneurysm enlargement (>5mm) or stent-graft migration (>10mm) through 12 months (compared to 30-day)

- Absence of fracture, conversion to open surgical repair, treated aneurysm rupture, Type I/III endoleak, or stent-graft occlusion (i.e., loss of patency requiring secondary intervention) through 12 months.

The primary effectiveness endpoint was compared to a performance goal of 88%. The performance goal was based on clinical study data reported for commercially available endovascular grafts.

The hypothesis tested for the primary effectiveness endpoint at a one-sided level of 0.025 was:

Null hypothesis (H_0): $p_{eff} \leq 0.88$

Alternative hypothesis (H_1): $p_{eff} > 0.88$

where p_{eff} was the proportion of **TREO** subjects with successful aneurysm treatment at 12 months post procedure and 88% was the performance goal defined for this endpoint.

The proportion of **TREO** subjects with successful aneurysm treatment at 12 months post procedure was summarized as count and percentage, and an exact 95% confidence interval. The observed proportion was tested against the performance goal for this endpoint using an exact binomial test.

6.2.2. Sample Size

The sample size for the **TREO® ABDOMINAL STENT-GRAFT SYSTEM** pivotal study was driven by both the primary effectiveness and primary safety endpoints.

Primary Safety Endpoint:

Assuming that the proportion of subjects with at least one adverse event included in the definition of the composite MAE up to 30 days post-implant was 10.2%, 150 endovascular subjects (receiving the **TREO** device) provided 80% power for an exact binomial test at a one-sided alpha level of 0.025 against the performance goal of 19%

Primary Effectiveness Endpoint:

Assuming that the proportion of subjects with a successful aneurysm treatment at 12 months post-implant was at 95.6%, 127 endovascular subjects (receiving the **TREO** device and with 12-month follow-up) provided greater than 80% power for an exact binomial test at a one-sided alpha level of 0.025 against an 88% performance goal. The goal of 127 subjects with 12-month follow-up was achieved with 150 enrolled subjects including an assumed 15% attrition rate.

With the assumed attrition rate, a final sample size of 150 subjects satisfied the power requirements for both the primary safety and effectiveness endpoints.

Secondary Endpoints

Secondary safety endpoints include the following

- The rate of each individual component of the composite MAE, determined at 30 days, 6 months, and 12 months
- The composite MAE rate at 12 months and annually to 5 years
- Procedure-related complications through 30 days, 6 months, 12 months, and annually to 5 years

Secondary effectiveness endpoints include the following:

- Technical success at 30 days confirmed by an imaging modality
- Clinical utility measures (type of anesthesia, procedure duration, time in the intensive care unit and length of hospital stay)
- Aneurysm-related Mortality (ARM) at 12 months and annually through 5 years
- Secondary interventions through 12 months, and annually through 5 years
- Major device-related events through 30 days, 12 months, and annually through 5 years. Events include Type I/III endoleak, stent-graft migration, fracture, aneurysm sac expansion, conversion to open surgery and occlusion requiring intervention.

6.3. PATIENTS

Patients enrolled in the pivotal study met the following criteria:

- Age between 18 and 85
- Infrarenal AAA with or without iliac artery involvement:
  - ≥ 4.5 cm in diameter for males, or ≥ 4.0 cm in diameter for females, or
  - increased in diameter by 0.5 cm in the last 6 months
- AAA anatomy including:
  - infrarenal landing neck length of 10mm or greater and an angle of less than 60 degrees relative to the long axis of the aneurysm (centerline at lowest renal to centerline at bifurcation) and a suprarenal neck angle of less than 45 degrees relative to the infrarenal neck axis and an outside diameter of 17mm – 32mm, or
  - infrarenal landing neck length of 15mm or greater and an angle of between 60 and 75 degrees relative to the long axis of the aneurysm and a suprarenal neck angle of less than 45 degrees relative to the infrarenal neck axis and an outside diameter of 16mm – 30mm
  - Patient had lowest renal artery at least 9 cm from the aortic bifurcation. Patient had a distal iliac landing neck that had an inside diameter of 8 mm – 13 mm and a length of at least 10 mm, or an inside diameter of >13 mm – 20 mm and a length of at least 15 mm
- Patient's distal iliac landing neck met the vessel size requirements specified for the corresponding devices in the IFU
- Patient had a total treatment length of at least 13 cm
- Patient had a distal aortic diameter above the iliac bifurcation ≥70% of the sum of the selected Leg Extension Stent-Graft diameters that would pass through the same
- Patient was willing and able to comply with 1-month, 6-month, and 12-month follow-up visits, as well as annual visits out to 5 years
- Patient had adequate renal function to tolerate required follow-up contrast enhanced CTs
- Patient had adequate vascular access (e.g., patent iliac or femoral arteries) for introduction of the delivery system, which is 18F (6.0 mm) or 19F (6.3 mm) outer diameter, based on size of device used. Alternatively, patient's anatomy was suitable for creation of an iliac conduit
- Patient or Legally Authorized Representative agreed to sign Informed Consent Form

Patients were excluded from enrollment in the pivotal study if they had any of the following anatomic or physiologic characteristics:

- Patient was pregnant or lactating
- Patient had a dissection in abdominal aorta, ruptured aneurysm, or symptomatic aneurysm (as determined by treating physician)
- Patient had a patent inferior mesenteric artery that could not be sacrificed and an occluded or stenotic celiac and/or superior mesenteric artery
- Implant procedure as planned did not allow for at least one patent hypogastric artery left intact, unless both were occluded on pre-op imaging
- Patient had a lesion that could not be crossed by a guide wire
- Proximal neck could not increase by more than 10% over 15mm or more than 7% over 10mm (i.e., no trapezoidal necks)
- Patient had severe untreated coronary artery disease and/or unstable angina, significant areas of myocardium at risk (based on coronary angiogram or radionuclide scans), left ventricular ejection fraction < 20%, or recent diagnosis of CHF
- Patient had a stroke or myocardial infarction within 6 months of the planned treatment date
- Patient had chronic obstructive pulmonary disease requiring routine need for oxygen therapy outside the hospital setting (e.g., daily or nightly home use)
- Patient had an active systemic infection or was suspected of having an active systemic infection (e.g., AIDS/HIV, sepsis)
- Patient was morbidly obese (more than 100% over the ideal body weight or as defined by institutional standards) or had other clinical conditions that had the potential to severely compromise or impair x-ray visualization of the aorta
- Patient had connective tissue disease (e.g., Marfan syndrome)
- Patient had a mycotic aneurysm
- Patient had significant or circumferential calcification or mural thrombus in the proximal aortic neck
- Patient had significant or circumferential calcification or mural thrombus in the distal iliac landing zone

- Patient had significant or circumferential calcification or mural thrombus within the treatment length, which could have adversely impacted device patency
- Patient had a blood coagulation disorder or bleeding diathesis, the treatment for which could not be suspended pre- and post-repair
- Patient was in acute or chronic renal failure (creatinine $\geq$ 2.5 mg/dL), unless patient was stable on dialysis
- Patient had less than two-year life expectancy as evidenced by factors prohibiting major medical intervention (e.g., presence of malignancy, severe cardiopulmonary disease)
- Patient was participating in another research study, had received investigational study drug within 30 days of planned procedure, or had received an investigational device within one year of planned procedure
- Patient was confronted with other medical, social or psychological issues that the investigator believed could have interfered with study treatment or follow-up. These reasons had to be documented. An example included adherence to a theological or personal doctrine with aversion or opposition to blood transfusion
- Patient had a prior AAA repair (endovascular or surgical)
- Patient had an untreatable allergy or sensitivity to contrast media, Nitinol/nickel, or polyester
- Patient had undergone other major surgical or medical intervention within 45 days of the planned procedure or was planning to undergo other major surgical or medical intervention within 45 days post implantation (e.g., coronary artery bypass grafting, organ transplantation, renal stenting)

All patients enrolled in the pivotal study met the selection criteria based on site-reported imaging measurements. One subject had pre-existing chronic obstructive lung disease for which he denied daily oxygen use prior to enrollment and treatment with the **TREO** stent-graft, as he used oxygen only as needed during the day. However, following enrollment, the subject clarified that he used oxygen every night, which constituted routine oxygen use, and was therefore an exclusion criterion. The subject remained active in the study until his death prior to the 2-year follow-up visit.

6.4. STUDY RESULTS

6.4.1. Subject Accountability and Follow-Up

In total, 226 potential subjects underwent imaging screening by the sites and Imaging Review Committee (IRC). There were 150 subjects enrolled in the Pivotal Study. Site investigators reviewed each potential subject to determine whether they meet all inclusion/exclusion criteria. In addition, an independent imaging review committee, made up of a team of vascular surgeons, assessed each potential study subject for anatomic suitability. If there was a difference of opinion on a subject's anatomical eligibility, additional reviews would be performed by other members of the imaging review committee, and the consensus of all reviewers would be shared with the study site by the Sponsor. The investigators were ultimately responsible for considering both medical and anatomic criteria and determining patient's eligibility for the study. The most common reasons for a patient not being enrolled in the Pivotal Study were anatomical criteria (n=48) such as infrarenal landing neck length, distal iliac landing zone diameters and lengths and significant calcification or thrombus. An additional 11 patients were excluded for other medical criteria, 13 were eligible but declined participation, and 4 patients were dropped due to inadequate screening imaging.

The post-procedure follow-up regimen involved evaluations at hospital discharge as well as 1, 6, and 12 months post-procedure and annual visits thereafter. The 1, 6, and 12-month visits were comprehensive visits requiring physical examination and imaging. At the 1-month visit, the first series of post-procedure imaging data was collected. These data provided the baseline measurements for aneurysm enlargement and migration, against which all subsequent visits were compared. **Table 3** summarizes the visit windows as defined in the Protocol. In some instances, subjects may return for follow-up outside the protocol-defined windows.

Table 3. Follow-Up Interval Summary and Windows

Interval	Protocol Visit Window	Analysis Window
Operative	N/A	Procedure date
1-Month Follow-up	30 days +/- 4 weeks	Day 1 through Day 123

Table 3. Follow-Up Interval Summary and Windows

Interval	Protocol Visit Window	Analysis Window
6-Month Follow-up	6 months +/- 8 weeks	Day 124 through Day 275
12-Month Follow-up	12 months +/- 8 weeks	Day 276 through Day 635
2-Year Follow-up	24 months +/- 12 weeks	Day 636 through Day 995
3-Year Follow-up	36 months +/- 12 weeks	Day 996 through Day 1355
4-Year Follow-up	48 months +/- 12 weeks	Day 1356 through Day 1715
5-Year Follow-up	60 months +/- 12 weeks	Day 1716 through Day 1884
Analysis windows were utilized for effectiveness endpoint reporting. *Primary safety endpoint was limited to data through 30 days.*		

Aneurysm sac enlargement, endoleak, and migration are evaluated by Core Laboratory review of CT imaging. Similarly, stent fractures were evaluated by Core Laboratory review of x-rays. Imaging was considered adequate to assess the parameter if a response for the parameter was documented by the Core Laboratory. Although evaluations of endoleak and fracture are conducted during the procedure, these evaluations are made using intraoperative angiography rather than CT or x-ray. As such, imaging during the operative period is listed as "Not Applicable; however, events detected angiographically are included in the respective secondary endpoint reporting.

Detailed subject compliance and imaging follow-up data are presented in **Table 4** for 150 subjects in the Pivotal Study. One hundred and fifty subjects (150) were implanted with the **TREO® ABDOMINAL STENT-GRAFT SYSTEM** and seen through discharge. All of these subjects completed the 1-month follow-up visit (minimum of 97% of subjects had imaging adequate to evaluate endovascular graft parameters). The follow-up compliance rate at 6 months and 1 year was at least 88.9% of subjects with imaging adequate to evaluate endovascular graft parameters. There were four subjects that died within the first year; none of these deaths were aneurysm-related.

Beyond the 1-year visit, there was at least 83% of subjects with imaging adequate to assess endovascular graft parameters at 2-years, 71% at 3 years (with 5.8% of subjects still in the follow-up window with visit not yet completed), and 40.6% at 4 years (with approximately 31.9% of subjects still in the follow-up window with a visit not yet completed).

Table 4. Summary of Compliance and Core Lab Imaging Follow-Up

Analysis Window		Subject Follow-Up[c]			Imaging Performed[c]		Imaging Adequate to Assess the Parameter[d]				Events Occurring Within Window[e]				
	Eligible for Visit[a]	No Visit, Still in Window[b]	Missed Visit	Visit Performed	CT Scan	X-Ray	Sac Diameter	Endoleak	Migration	Fracture	Death	Surgical Conversion	LTFU	Early Withdrawal	Not Due for Next Visit
Proc	150	0	0	150/150 (100.0%)	NA	NA	NA	NA	NA	NA	0	0	0	0	0
1 Mo	150	0	0	150/150 (100.0%)	150/150 (100.0%)	147/150 (98.0%)	NA[d]	146/150 (97.3%)	NA[d]	148/150 (98.7%)	1	0	0	0	0
6 Mos	149	0	10/149 (6.7%)	139/149 (93.3%)	138/149 (92.6%)	133/149 (89.3%)	137/149 (91.9%)	134/149 (89.9%)	134/149 (89.9%)	133/149 (89.3%)	2	0	0	3	0
1 Yr	144	0	7/144 (4.9%)	137/144 (95.1%)	137/144 (95.1%)	131/144 (91.0%)	136/144 (94.4%)	133/144 (92.4%)	128/144 (88.9%)	131/144 (91.0%)	7	0	2	3	0
2 Yrs	132	0	13/132 (9.8%)	119/132 (90.2%)	119/132 (90.2%)	113/132 (85.6)	116/132 (87.9%)	113/132 (85.6%)	111/132 (84.1%)	110/132 (83.3%)	6	0	1	5	0
3 Yrs	120	7/120 (5.8%)	15/120 (12.5%)	98/120 (81.7%)	95/120 (79.2%)	88/120 (73.3%)	94/120 (78.3)	94/120 (78.3%)	91/120 (75.8%)	86/120 (71.7%)	2	0	2	3	44
4 Yrs	69	22/69 (31.9%)	8/69 (11.6%)	39/69 (56.5%)	32/69 (46.4%)	30/69 (43.5)	30/69 (43.5)	31/69 (44.9%)	28/69 (40.6%)	30/69 (43.5%)	0	0	2	5	49
5 Yrs	13	10/13 (76.9%)	2/13 (15.4%)	1/13 (7.7%)	1/13 (7.7%)	1/13 (7.7%)	1/13 (7.7%)	1/13 (7.7%)	1/13 (7.7%)	1/13 (7.7%)	0	0	0	1	0

NA – Not Applicable

[a] Eligible for Visit reflects those subjects eligible for follow-up calculated as: (previous eligible for follow-up) – (previous death + conversion + lost to follow-up + early withdrawal + not due for follow-up)

[b] Subjects who did not have a visit within the window but who had not yet reached the end of the analysis window. This value is used for the denominator for calculating the percentage of visits performed.

[c] Based on site-reported data

[d] Based on Core Laboratory analysis. Sac Diameter and Migration assessments use 1 month as baseline, and are therefore not reported at 1 month. Eligible subjects require valid value at 1 month and at the specified time point.

[e] These columns reflect subjects who had visits within the specified window but were not eligible at the start of the next window due to death, surgical conversion, lost to follow-up or early withdrawal.

6.4.2. Subject Demographics

The demographics of the study population are typical for a pivotal EVAR study performed in the United States. In the Pivotal Study, 88% (132/150) subjects were male. The mean age was 71.7 years and approximately one-half of the cohort was between 65 and 74 years of age. Almost all subjects were Caucasian, 98.0% (147/150). **Table 5** summarizes the subject demographics for the Pivotal Study.

Table 5. Summary of Subject Demographics

Characteristic	Statistics	Pivotal
Sex		
Female	% (n/N)	12.0% (18/150)
Male	% (n/N)	88.0% (132/150)
Age (years)	Mean ± SD (N) Median (IQR) Min - Max	71.7 ± 7.4 (150) 72.0 (67.0, 78.0) 52 - 85
Age Groups		
18-64 years	% (n/N)	16.7% (25/150)
65-74 years	% (n/N)	48.0% (72/150)
75-80 years	% (n/N)	24.7% (37/150)
81-85 years	% (n/N)	10.7% (16/150)
Ethnic Group		
Hispanic or Latino	% (n/N)	1.3% (2/150)
Not Hispanic or Latino	% (n/N)	96.7% (145/150)
Not Reported	% (n/N)	1.3% (2/150)
Unknown	% (n/N)	0.7% (1/150)
Race		
American Indian/Alaskan Native	% (n/N)	0.7% (1/150)
Black or African American	% (n/N)	1.3% (2/150)
White	% (n/N)	98.0% (147/150)

6.4.3. Baseline Medical History

Table 6 summarizes the comorbidities of enrolled subjects. Most of the subjects in the Pivotal Study had a history of hypertension or received treatment for hypertension 90.0%, (135/150), 73.3% (110/150). A history of hyperlipidemia was reported in 73.3% (110/150) and smoking in 85.3% (128/150).

Table 6. Summary of Subject Comorbidities

Comorbidity	Pivotal
Peripheral Vascular Disease	25.3% (38/150)
Documented Coronary Artery Disease	56.0% (84/150)
Myocardial Infarction	18.0% (27/150)
Stable Angina	0.7% (1/150)
Unstable Angina	6.0% (9/150)
Arrhythmias	24.0% (36/150)
Congestive Heart Failure	8.7% (13/150)
Other	32.2% (48/149)
Diabetes Mellitus	28.0% (42/150)
Hypertension (HTN) and/or Treatment of HTN	90.0% (135/150)
Hypercholesterolemia	44.7% (67/150)
Hyperlipidemia	73.3% (110/150)
Smoking	85.3% (128/150)
Current	31.3% (40/128)
Former	68.8% (88/128)
Renal Insufficiency	13.3% (20/150)
Currently on Antiplatelet/Anticoagulant Medications	78.7% (118/150)
Limb Ischemia	7.3% (11/150)
Limb Ischemia: Left Claudication	6.0% (9/150)
Limb Ischemia: Left Ischemic Rest Pain	0.7% (1/150)
Limb Ischemia: Left Asymptomatic	2.0% (3/150)
Limb Ischemia: Right Claudication	5.3% (8/150)
Limb Ischemia: Right Ischemic Rest Pain	0.7% (1/150)
Limb Ischemia: Right Asymptomatic	2.7% (4/150)
Vascular Intervention	18.0% (27/150)
Gastrointestinal	20.0% (30/150)
Cholecystitis	4.0% (6/150)
Ischemic Colitis	0% (0/150)
Complications: Small Bowel Ischemia	0.7% (1/150)
GI Bleed	4.7% (7/150)
Impotence	16.0% (24/150)

- *All values expressed as % (n/N)* -

6.4.4. Baseline Aneurysm Characteristics

Subjects with aortic or aortoiliac aneurysms were enrolled in the study. All subjects met the anatomic criteria for enrollment, as assessed by the Imaging Core Laboratory. Of the 150 subjects enrolled in the study, 19 (12.7%) had iliac artery involvement. A comparison of the Core Laboratory and site reported anatomic characteristics are presented in **Table 7**.

Table 7. Comparison of Core Laboratory and Site Reported Anatomic Characteristics

Characteristic	Statistics	Core Laboratory	Site Reported	Difference (Core Lab - Site)
Angle between Suprarenal Aorta and Proximal AAA Neck (degrees) (Suprarenal Neck Angle)	Mean ± SD (N) Median (IQR) Min - Max	18.6 ± 11.1 (149) 16.4 (10.1, 25.8) 0.0 - 51.9	13.0 ± 11.1 (149) 10.0 (3.0, 20.0) 0.0 - 40.0	5.6 ± 11.2 (149) 4.9 (-1.1, 12.8) -23.6 - 51.9
Angle between Proximal AAA Neck and Main Axis of AAA (degrees) (Infrarenal Neck Angle)	Mean ± SD (N) Median (IQR) Min - Max	35.8 ± 13.2 (149) 35.4 (27.2, 42.0) 5.2 - 72.2	25.0 ± 16.5 (149) 22.0 (12.0, 35.0) 0.0 - 70.0	10.8 ± 15.1 (149) 11.4 (0.8, 21.2) -42.3 - 47.2
Diameter of Proximal Neck (mm)	Mean ± SD (N) Median (IQR) Min - Max	23.0 ± 3.1 (150) 22.3 (21.0, 24.7) 15.0 - 33.5	23.7 ± 3.0 (150) 24.0 (21.5, 25.0) 17.0 - 32.0	-0.7 + 3.1 (150) -2.4 (-6.2, 7.5) -16.4 – 31.3
Length of Infrarenal Proximal Neck (mm) (Proximal Landing Zone)	Mean ± SD (N) Median (IQR) Min - Max	43.1 ± 13.0 (150) 43.1 (33.9, 50.7) 14.4 - 80.4	28.4 ± 11.2 (150) 27.8 (20.0, 34.0) 10.0 - 60.0	14.6 ± 11.0 (150) 13.0 (7.1, 20.9) -16.6 - 50.8
Length from Lowest Renal Artery to Aortic Bifurcation (mm)	Mean ± SD (N) Median (IQR) Min - Max	119.5 ± 14.2 (150) 118.5 (110.6, 127.5) 85.1 - 160.8	116.8 ± 16.0 (150) 114.0 (107.5, 124.0) 90.0 - 200.0	2.6 ± 12.8 (150) 3.1 (-2.5, 7.7) -88.4 - 35.4
Length from Aortic Bifurcation to Right Internal Iliac Artery (mm)	Mean ± SD (N) Median (IQR) Min - Max	59.4 ± 15.3 (150) 59.5 (47.9, 71.8) 25.9 - 95.5	64.1 ± 30.4 (150) 58.2 (46.0, 73.0) 25.0 - 185.0	-4.7 ± 29.3 (150) -1.1 (-6.8, 7.5) -143.1 - 35.2
Length from Aortic Bifurcation to Left Internal Iliac Artery (mm)	Mean ± SD (N) Median (IQR) Min - Max	58.5 ± 15.7 (149) 57.7 (48.8, 66.7) 26.9 - 107.9	64.5 ± 29.4 (149) 58.0 (47.0, 71.0) 30.0 - 192.0	-6.0 ± 28.5 (149) -1.6 (-7.9, 7.6) -142.2 - 27.2
Length of Right Iliac/Femoral Landing Zone (mm)	Mean ± SD (N) Median (IQR) Min - Max	48.9 ± 19.8 (136) 48.6 (33.5, 63.8) -14.9 - 94.0	37.6 ± 21.6 (136) 30.0 (20.0, 50.5) 4.0 - 120.0	11.3 ± 26.6 (136) 8.0 (-1.7, 31.2) -95.2 - 79.0
Length of Left Iliac/Femoral Landing Zone (mm)	Mean ± SD (N) Median (IQR) Min - Max	50.6 ± 19.1 (140) 51.3 (35.8, 61.8) 13.7 - 107.9	38.6 ± 21.3 (140) 37.5 (20.0, 50.0) 6.0 - 120.0	12.0 ± 25.1 (140) 8.2 (-0.7, 26.8) -55.7 - 92.9
Total Treatment Length (Core Lab = One Measure, Site = Left) (mm)	Mean ± SD (N) Median (IQR) Min - Max	187.9 ± 20.2 (150) 186.9 (172.9, 202.6) 139.3 - 265.4	181.0 ± 32.8 (150) 174.0 (158.0, 194.0) 137.0 - 336.0	7.0 ± 31.7 (150) 10.0 (0.9, 20.2) -144.9 - 67.1
Total Treatment Length (Core Lab = One Measure, Site = Right) (mm)	Mean ± SD (N) Median (IQR) Min - Max	187.9 ± 20.2 (150) 186.9 (172.9, 202.6) 139.3 - 265.4	181.0 ± 33.8 (150) 174.0 (160.0, 198.0) 130.0 - 329.0	6.9 ± 31.5 (150) 9.8 (1.4, 24.0) -137.9 - 62.1
Maximum Aneurysm Diameter (mm)	Mean ± SD (N) Median (IQR) Min - Max	54.0 ± 7.7 (150) 52.8 (50.0, 56.4) 39.2 - 113.3	54.4 ± 6.6 (150) 53.2 (51.0, 57.0) 42.4 - 108.0	-0.4 ± 3.2 (150) -0.7 (-1.8, 1.0) -11.9 - 18.6
Diameter of Distal Aorta (mm) (Aortic Diameter at Bifurcation)	Mean ± SD (N) Median (IQR) Min - Max	30.4 ± 9.5 (150) 28.2 (23.3, 35.7) 16.7 - 72.1	26.5 ± 6.3 (150) 25.0 (22.0, 30.0) 15.0 - 47.0	3.9 ± 7.9 (150) 2.3 (-0.3, 5.7) -14.6 - 48.0

Table 7. Comparison of Core Laboratory and Site Reported Anatomic Characteristics

Characteristic	Statistics	Core Laboratory	Site Reported	Difference (Core Lab - Site)
Diameter of Right Iliac Landing Zone Neck (mm)	Mean ± SD (N) Median (IQR) Min - Max	16.9 ± 3.0 (145) 16.6 (14.7, 18.7) 9.6 - 27.3	14.1 ± 2.8 (145) 14.0 (12.0, 16.0) 9.0 - 23.0	2.8 ± 2.5 (145) 2.8 (1.4, 4.1) -8.1 - 10.2
Diameter of Left Iliac Landing Zone Neck (mm)	Mean ± SD (N) Median (IQR) Min - Max	17.4 ± 3.8 (145) 16.4 (15.0, 19.1) 11.1 - 36.1	13.7 ± 2.6 (145) 14.0 (12.0, 15.0) 8.0 - 20.0	3.7 ± 3.8 (145) 3.1 (1.7, 4.7) -4.4 - 23.1

The distribution of baseline aneurysm diameters as measured by the Imaging Core Laboratory is presented in **Table 8**. The majority of subjects (100/150, 66.7%) had aneurysms with maximum sac diameter ranging from 50-59 mm.

Table 8. Distribution of Baseline Aneurysm Diameters – Core Lab Reported

Maximum Aneurysm Diameter (mm)	Pivotal Study N = 150
< 45 mm	3/150 (2.0%)
45-49 mm	27/150 (18.0%)
50-59 mm	100/150 (66.7%)
60-69 mm	15/150 (10.0%)
70-79 mm	4/150 (2.7%)
80-89 mm	0
> 90 mm	1/150 (0.7%)

6.4.5. **TREO** Stent-Grafts Implanted

A total of 565 **TREO** Stent-Grafts were implanted in the Pivotal Study. The number of **TREO** Stent-Grafts implanted in the initial procedure are shown in **Tables 9, 10 and 11**. No competitor devices were implanted during any of the initial procedures. All subjects received at least 3 **TREO** Stent-Grafts; namely, a single Main Bifurcated Stent-Graft and 2 Leg Extension Stent-Grafts. Ten percent of subjects received additional stent-grafts (13 subjects received 1 additional stent-graft, 1 subject received 2 additional stent-grafts and 1 subject received 3 additional stent-grafts). Overall, 98.7% of the subjects were treated with 3 or 4 total **TREO** Stent-Grafts.

Table 9. TREO Stent-Grafts Implanted

TREO Components	Pivotal Study N = 150*
Main Bifurcated Stent-Graft	150/150 (100.0%)
Proximal Cuff Stent-Graft	6/150 (4.0%)
Ipsilateral Leg Extension Stent-Graft	150/150 (100.0%)
Ipsilateral Leg/Straight Extension Stent-Graft	3/150 (2.0%)
Contralateral Leg Extension Stent-Graft	150/150 (100.0%)
Contralateral Leg/Straight Extension Stent-Graft	7**/150 (4.7%)
Denominator includes all subjects who received the test device.* * Seven subjects received 9 contralateral Leg Extension Stent-Grafts / Straight Extension Stent-Grafts*	

Table 10. Number of Devices Implanted During the Index Procedure

Number of Devices Implanted	Pivotal Study N = 150*
1	NA
2	NA
3	135/150 (90.0%)
4[a]	13/150 (8.7%)
5[b]	1/150 (0.7%)
6[c]	1/150 (0.7%)

Denominator includes all subjects who received the **TREO device.*

[a]*The following 13 subjects received 4 devices during the index procedure:*

Subject received 4 devices, including a Proximal Cuff Stent-Graft, which corrected an unspecified type endoleak. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 60 months.

Subject received 4 devices, including a contralateral Leg Extension Stent-Graft to extend the treatment area. At 36 months, the subject experienced two bare stent fractures, connecting to a single eyelet, at the proximal aspect of the uncovered portion of the Main Bifurcated Stent-Graft. There were no reported clinical sequelae through the subject's last visit at 48 months; specifically, no evidence of endoleak, aneurysm sac expansion, patency compromise, or migration.

Subject received 4 devices, including an ipsilateral Leg Extension Stent-Graft, which corrected an unspecified type endoleak. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 24 months. Prior to the 36-month follow-up, this subject expired due to respiratory failure.

Subject received 4 devices, including an ipsilateral Leg Extension Stent-Graft to optimize the seal. The stent-graft remains patent, with no evidence of endoleak, migration, or sac expansion, through 48 months.

Subject received 4 devices, including an ipsilateral Leg Extension Stent-Graft, which corrected an unspecified type endoleak. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 60 months.

Subject received 4 devices, including a Proximal Cuff Stent-Graft, which corrected an unspecified type endoleak. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 36 months. Prior to the 48-month visit, this subject expired due to pancreatic cancer.

Subject received 4 devices, including a Proximal Cuff Stent-Graft to optimize the seal. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 60 months.

Subject received 4 devices, including a contralateral Leg Extension Stent-Graft, which corrected an unspecified type endoleak. The stent-graft remains patent, with no evidence of endoleak, migration, or sac expansion, through 48 months.

Subject received 4 devices, including a Proximal Cuff Stent-Graft, which corrected an unspecified type endoleak. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 48 months.

Subject received 4 devices, including a Proximal Cuff Stent-Graft, which corrected an unspecified type endoleak. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 60 months.

Subject received 4 devices, including a contralateral Leg Extension Stent-Graft to extend the treatment area. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 12 months. Prior to the 24-month follow-up, this subject expired due to hemorrhagic stroke.

Subject received 4 devices, including a contralateral Leg Extension Stent-Graft to extend the treatment area. The stent-graft remained patent, with no evidence of endoleak, migration, or sac expansion, through 36 months. Prior to the 48-month follow-up, this subject expired due to unknown type of cancer.

Subject received 4 devices, including a contralateral Leg Extension Stent-Graft to extend the treatment area. The stent-graft has remained patent, with no evidence of endoleak, migration, or sac expansion, through 36 months.

[b]*Subject received 5 devices, including 1 Proximal Cuff Stent-Graft and 1 contralateral Leg Extension Stent-Graft to treat endoleaks. The investigator reported a Type II endoleak at the end of the procedure which persisted at 1 month. Prior to the 6-month follow-up, this subject expired due to Creutzfeldt-Jakob Disease.*

Table 10. Number of Devices Implanted During the Index Procedure

Number of Devices Implanted	Pivotal Study N = 150*
[c] Subject received 6 devices, including 3 contralateral Leg Extension Stent-Grafts. Two Leg Extension Stent-Graft were implanted due to tortuosity of the left iliac system and subsequent limb shortening. The third Leg Extension Stent-Graft was implanted to treat a balloon-induced left iliac artery rupture. This subject experienced a fracture in the uncovered portion of the Main Bifurcated Stent-Graft at 24 months. The subject had a Type II endoleak present at 1 month through 24 months; however, no evidence of endoleak at 36, 48, or 60 months. The stent-graft remained patent, with no evidence of migration, through 60 months.	

Table 11. Diameter of TREO Devices Implanted During the Index Procedure

TREO Stent-Graft Type	Outer Diameter (mm)	Pivotal Study N = 150*
Main Bifurcated Stent-Graft		150/150 (100.0%)
	20	1/150 (0.7%)
	22	5/150 (3.3%)
	24	12/150 (8.0%)
	26	34/150 (22.7%)
	28	48/150 (32.0%)
	30	24/150 (16.0%)
	33	19/150 (12.7%)
	36	7/150 (4.7%)
Proximal Cuff Stent-Graft		6/150 (4.0%)
	20	0/150 (0.0%)
	22	0/150 (0.0%)
	24	0/150 (0.0%)
	26	2/150 (1.3%)
	28	2/150 (1.3%)
	30	0/150 (0.0%)
	33	2/150 (1.3%)
	36	0/150 (0.0%)
Ipsilateral Leg Extension Stent-Graft		150/150 (100%)
	9	2/150 (1.3%)
	11	4/150 (2.7%)
	13	23/150 (15.3%)
	15	45/150 (30.0%)
	17	36/150 (24.0%)
	20	26/150 (17.3%)
	24	14/150 (9.3%)
Contralateral Leg Extension Stent-Graft		150/150 (100%)
	9	1/150 (0.7%)
	11	12/150 (8.0%)
	13	25/150 (16.7%)
	15	39/150 (26.0%)
	17	34/150 (22.7%)
	20	17/150 (11.3%)
	24	12/150 (8.0%)

Table 11. Diameter of TREO Devices Implanted During the Index Procedure

TREO Stent-Graft Type	Outer Diameter (mm)	Pivotal Study N = 150*
Ipsilateral Leg/Straight Extension Stent-Graft		3/150 (2.0%)
	9	0/150 (0.0%)
	11	1/150 (0.7%)
	13	1/150 (0/7%)
	15	0/150 (0.0%)
	17	0/150 (0.0%)
	20	1/150 (0.7%)
	24	0/150 (0.0%)
Contralateral Leg/Straight Extension Stent-Graft		7**/150 (4.7%)
	9	1/150 (0.7%)
	11	0/150 (0.0%)
	13	0/150 (0.0%)
	15	2/150 (1.3%)
	17	3/150 (2.0%)
	20	3/150 (2.0%)
	24	0/150 (0.0%)

** Denominator included all subjects who received the **TREO** device*
*** Seven subjects received 9 Leg Extensions / Straight Extensions*

6.4.6. Acute Procedural Information

Detailed information and observations about the implantation procedure were documented by physicians on case report forms. **Table 12** summarizes information from the index procedure, including clinical utility endpoints. The majority of subjects underwent general anesthesia, 88.7% (133/150). The mean procedure time was 105.7 minutes, with a mean estimated blood loss of 168 mL. The mean ICU stay was 3.3 hours and the mean length of hospital stay was 2.5 days.

Table 12. Details of the Index Procedure

Characteristic	Statistics	Pivotal
Type of Anesthesia		
General	% (n/N)	88.7% (133/150)
Local	% (n/N)	6.7% (10/150)
Regional/Epidural	% (n/N)	2.0% (3/150)
Other	% (n/N)	2.7% (4/150)
Duration of Procedure (min)	Mean ± SD (N) Median (IQR) Min - Max	105.7 ± 43.6 (150) 93.5 (72.0, 127.0) 35.0 - 284.0
Amount Contrast Administered (cc)	Mean ± SD (N) Median (IQR) Min - Max	100.4 ± 53.7 (149) 88.0 (62.0, 120.0) 30.0 - 330.0
Total Fluoroscopy Time (min)	Mean ± SD (N) Median (IQR) Min - Max	19.8 ± 9.4 (150) 18.0 (14.4, 22.5) 7.3 - 69.3

Table 12. Details of the Index Procedure

Characteristic	Statistics	Pivotal
Estimated Blood Loss (cc)	Mean ± SD (N) Median (IQR) Min - Max	167.5 ± 172.2 (150) 100.0 (50.0, 200.0) 0.0 - 1,000.0
Anticoagulation, Antiplatelet, Antibiotic Given	% (n/N)	98.0% (147/150)
Main Bifurcate Access		
Left Femoral	% (n/N)	13.3% (20/150)
Right Femoral	% (n/N)	86.0% (129/150)
Right Iliac	% (n/N)	0.7% (1/150)
Contralateral Access		
Left Femoral	% (n/N)	86.0% (129/150)
Right Femoral	% (n/N)	13.3% (20/150)
Right Iliac	% (n/N)	0.7% (1/150)
Internal Iliac Artery Covered		
No	% (n/N)	91.3% (137/150)
Yes	% (n/N)	8.7% (13/150)
Left	% (n/N)	46.2% (6/13)
Right	% (n/N)	53.8% (7/13)
Duration of Hospitalization (days)	Mean ± SD (N) Median (IQR) Min - Max	2.5 ± 1.2 (150) 2.0 (2.0, 2.0) 1.0 - 10.0
Duration of ICU Stay (hours)	Mean ± SD (N) Median (IQR) Min - Max	3.3± 13.7 (150) 0.0 (0.0, 0.0) 0.0 – 124.0

6.4.7. Safety Results

6.4.7.1. Primary Safety Endpoint

Safety was assessed by the composite MAE rate at 30 days post-implant and defined when one or more of the following events occurred:

- All-cause mortality
- Myocardial infarction
- Stroke
- Renal failure requiring renal replacement therapy
- Respiratory failure
- Paraplegia
- Bowel ischemia
- Procedural blood loss of 1000 cc or greater

MAEs were adjudicated by the Clinical Events Committee (CEC).

The Pivotal Study composite MAE rate was 0.7% (1/150, 95% CI 0.0% to 3.7%) at 30 days (**Table 13**). The upper bound of the 95% confidence interval of 3.7% is below the 19% performance goal indicating that the primary safety endpoint was met. One subject experienced two MAEs: procedural blood loss of 1000cc during the implant procedure, which required a blood transfusion. The treating investigator reported no complications during the procedure. The CEC adjudicated the procedural blood loss as not related to device but definitely related to the implant procedure. The subject also experienced a myocardial infarction (MI) 12 days post procedure, which the CEC adjudicated as not related to device or procedure and the subject subsequently recovered.

The analysis of safety was based on the Pivotal Cohort of 150 subjects (i.e., all subjects who had the Main Bifurcated Stent-Graft introduced into the body) available for the 30-day (1-month) evaluation.

In addition, the probability of experiencing at least one MAE in the 30 days post procedure was estimated using Kaplan-Meier method. Time to MAE was calculated by determining the number of days between the date of the procedure and the date of the first MAE. Subjects without events (within the first 30 days post procedure) were censored at 30 days (for the primary safety analysis). Subjects who withdrew from the study after device implantation were censored at the time of early discontinuation (if it occurred prior to 30 days).

Table 13. 30-Day Composite Major Adverse Events

Characteristics	Statistics	Pivotal Study
MAE Rate at 30 Days	% (n/N)	0.7% (1/150)
	95% CI	0.0%, 3.7%
	P value	<.0001
Time to MAE Analysis		
Number with Events	n	1
Censored	n	0
At Risk	n	149*
Kaplan-Meier Estimate of MAE within 30 days	% (95% CI)	0.7% (0.1%, 4.6%)

MAE – Major Adverse Events
All MAEs were adjudicated by the Clinical Events Committee (CEC)
**Number of subjects at risk at 30 days (150 – 1 subject with event within 30 days)*

6.4.8. Secondary Safety Endpoints

The following secondary safety endpoints were summarized descriptively and using a similar Kaplan-Meier method as described for primary safety endpoint. The definitions for events and censoring were accounted for at the time point of evaluation.

- The rate of each individual component of the composite MAE, determined at 30 days, 6 months, and 12 months
- The composite MAE rate at 12 months and annually to 5 years
- Procedure-related complications through 30 days, 6 months, 12 months, and annually to 5 years

MAE results are reported below in **Section 6.4.9**. Procedure-related complications are reported in **Table 18**.

6.4.9. Major Adverse Events

The rate of CEC adjudicated MAEs through follow-up and a Kaplan-Meier estimate of the MAE rates from the Pivotal Study are presented in this section. MAEs are defined in **Section 6.4.7.1**

Table 14 summarizes the individual components of the MAE composite endpoint through 30 days. There was one subject with 2 MAEs, specifically myocardial infarction and procedural blood loss of 1,000 cc; no other MAE components (i.e., all-cause mortality, stroke, renal failure requiring renal replacement therapy, respiratory failure, paraplegia, bowel ischemia) were reported through 30 days.

Table 14. Summary of Major Adverse Event Components through 30 Days

MAE Components	Statistics	Pivotal (N=150)
Any MAE	% (n/N)	0.7% (1/150)
All-cause mortality	% (n/N)	0
Myocardial infarction	% (n/N)	0.7% (1/150)*
Stroke	% (n/N)	0
Renal failure requiring renal replacement therapy	% (n/N)	0
Respiratory failure	% (n/N)	0
Paraplegia	% (n/N)	0
Bowel Ischemia	% (n/N)	0
Procedural blood loss of 1000 cc or greater	% (n/N)	0.7% (1/150)*

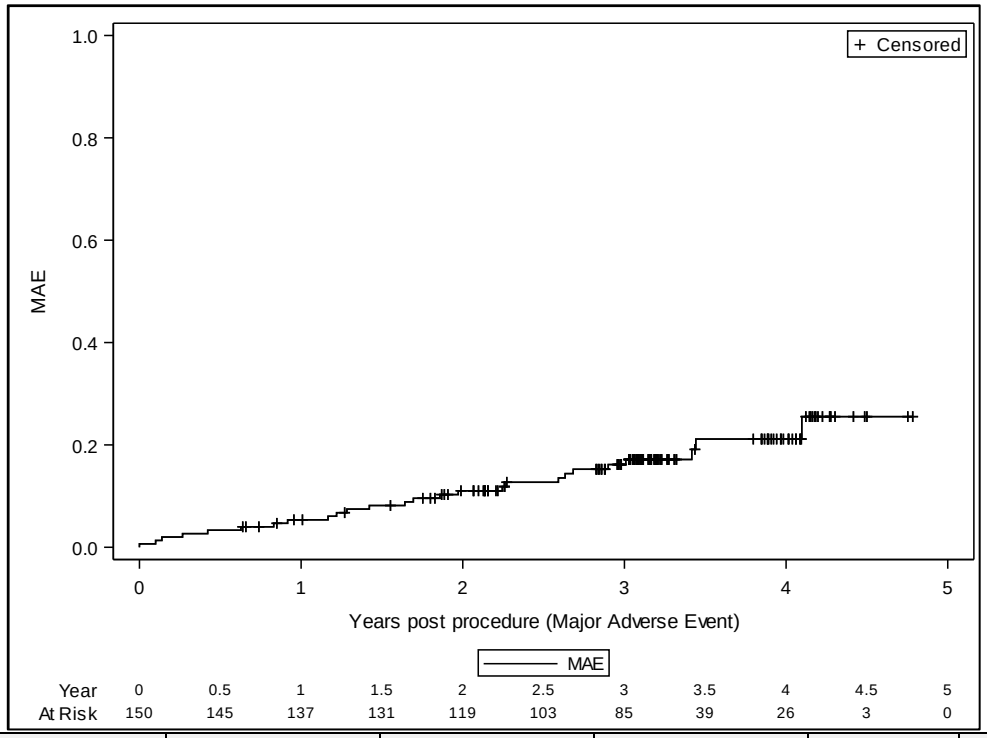
MAE – Major Adverse Events

All MAEs were adjudicated by the Clinical Events Committee (CEC).

** One subject experienced procedural blood loss of 1000cc during the implant procedure, which required a blood transfusion. The treating investigator reported no complications during the procedure. The CEC adjudicated the procedural blood loss as not related to device but definitely related to the implant procedure. The subject also experienced an MI 12 days post procedure, which the CEC adjudicated as not related to device or procedure and the subject subsequently recovered.*

The probability of experiencing at least one MAE in the 30 days post procedure was estimated using Kaplan-Meier method. Time to MAE was calculated by determining the number of days between the date of the procedure and the date of the first MAE. Subjects without events (within the first 30 days post procedure) were censored at 30 days (for the primary safety analysis). Subjects withdrew from the study after device implantation were censored at the time of early discontinuation (if it occurs prior to 30 days).

MAE throughout follow-up is depicted in **Figure 7** as a Kaplan-Meier plot. Kaplan-Meier estimates of the MAE rates were 0.7% at 30 days, 5.4% at 12 months, 11.0% at 2 years, 16.2% at 3 years, and 21.2% at 4 years. The most common event was death unrelated to the device or to the procedure, occurring in 18 subjects through 5 years and accounting for 18 of the 26 reported MAEs (69.2%).



Time	Failure Rate	Lower 95% CI	Upper 95% CI	MAE	At Risk
Procedure	0.67%	0.09%	4.64%	1	149
30 Days	0.67%	0.09%	4.64%	1	149
6 Months	3.33%	1.40%	7.82%	5	145
12 Months	5.37%	2.72%	10.45%	8	137
1.5 Years	8.16%	4.72%	13.93%	12	131
2 Years	11.04%	6.91%	17.40%	16	119
2.5 Years	12.70%	8.18%	19.44%	18	119
3 Years	16.17%	10.91%	23.60%	22	85
3.5 Years	21.15%	14.22%	30.78%	25	26
4 Years	21.15%	14.22%	30.78%	25	26
5 Years	.	.	.	26	0

Figure 7. Kaplan-Meier Plot of Major Adverse Event Rate

Table 15. Summary of Major Adverse Events By Timepoint

Characteristic	Procedure	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years	Overall
Number of Subjects Eligible*	150	150	150	148	141	123	91	28	150
Number of Subjects with any MAE	1 (0.7%)	1 (0.7%)	4 (2.7%)	4 (2.7%)	9 (6.4%)	7 (5.7%)	4 (4.4%)	1 (12.5%)	27 (18.0%)
Death (all-cause)	0	0	2 (1.3%)	2 (1.4%)	8 (5.7%)	4 (3.3%)	2 (2.2%)	0	18 (12.0%)
Stroke	0	0	1 (0.7%)	1 (0.7%)	4 (2.8%)	2 (1.6%)	1 (1.1%)	1 (12.5%)	10 (6.7%)
Myocardial Infarction	0	1 (0.7%)	0	2 (1.4%)	1 (0.7%)	1 (0.8%)	1 (1.1%)	0	5 (3.3%)
Bowel Ischemia	0	0	1 (0.7%)	0	0	0	0	0	1 (0.7%)
Respiratory Failure	0	0	0	1 (0.7%)	0	1 (0.8%)	0	0	2 (1.3%)
Procedural blood loss of 1000cc or more	1 (0.7%)	0	0	0	0	0	0	0	1 (0.7%)
Paraplegia	0	0	0	0	0	0	0	0	0
Renal Failure	0	0	0	0	0	0	0	0	0

**Number of Subjects eligible for each timepoint reflects the number of subjects that were active in the study for a given timepoint, regardless if a visit was completed during that interval.*

6.4.10. All Cause and Aneurysm-Related Mortality

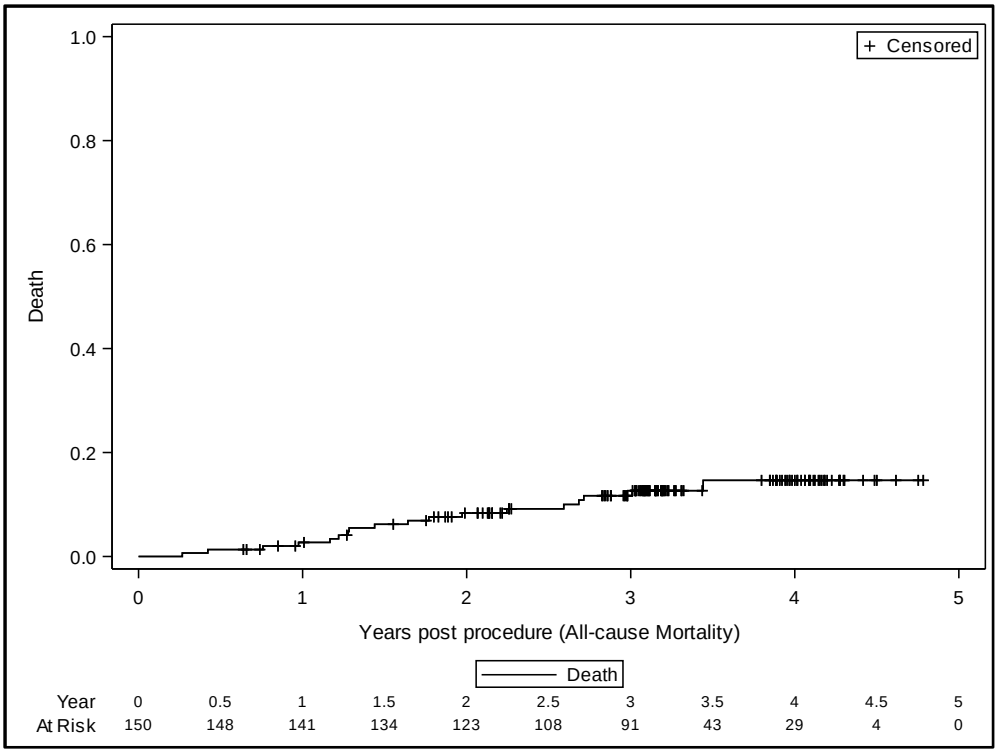
Aneurysm-related mortality (ARM) was defined as any death that occurred within 30 days of aneurysm repair, within 30 days of a secondary procedure performed to address the aneurysm, or from rupture of the aneurysm, infection of the aneurysm, or embolization from the aneurysm. ARM was adjudicated by the CEC. A summary of all-cause mortality and aneurysm-related mortality through follow-up is presented below. There have been 18 deaths in the Pivotal Study, but none were aneurysm related.

A Kaplan-Meier estimate of all-cause mortality is presented for the Pivotal Study. The assessments of all-cause mortality for the Pivotal Study are provided in **Table 16**.

Table 16. All-Cause and Aneurysm-Related Mortality

Deaths	Procedure	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years
All-Cause Deaths							
At Risk	150	150	148	141	123	91	28
Interval	0	0	2	2	8	4	2
Cumulative	0	0	2	4	12	16	18
Aneurysm-Related Deaths*							
Interval	0	0	0	0	0	0	0
Cumulative	0	0	0	0	0	0	0

CEC – Clinical Events Committee
** Aneurysm-related deaths were adjudicated by the CEC.*



Time	Failure Rate	Lower 95% CI	Upper 95% CI	Deaths	At Risk
Procedure	0.00%	.	.	0	150
30 Days	0.00%	.	.	0	150
6 Months	1.33%	0.34%	5.23%	2	148
1 Years	2.70%	1.02%	7.04%	4	141
1.5 Years	6.19%	3.27%	11.57%	9	134
2 Years	8.35%	4.83%	14.24%	12	123
2.5 Years	9.17%	5.42%	15.28%	13	108
3 Years	11.69%	7.31%	18.43%	16	91
3.5 Years	14.65%	9.16%	22.97%	18	43
4 Years	14.65%	9.16%	22.97%	18	28
4.5 Years	14.65%	9.16%	22.97%	18	3
5 Years	.	.	.	18	0

Figure 8. Kaplan-Meier All-Cause Mortality

Table 17. Summary Listing of Deaths

	Procedure Date	Number of Days Post-Procedure that Death Occurred	Cause of Death	Autopsy Performed (Yes/No)	CEC Adjudicated Device Related?	CEC Adjudicated Procedure Related?
1	31-Mar-15	96	Subarachnoid hemorrhage	No	Not Related	Not Related
2	23-Oct-14	152	Creutzfeldt Jakob disease	No	Not Related	Not Related
3	25-Apr-14	273	Respiratory failure	No	Not Related	Not Related
4	27-Aug-15	351	Cerebrovascular accident	No	Not Related	Not Related
5	20-Jul-15	420	Failure to thrive	No	Not Related	Not Related
6	24-Dec-14	439	End state liver disease	No	Not Related	Not Related
7	30-Jun-14	460	Exacerbation of congestive heart failure and non-ST-elevation myocardial infraction	No	Not Related	Not Related
8	25-Aug-14	462	Metastatic esophageal cancer	No	Not Related	Not Related
9	21-Oct-15	518	Intraparenchymal hemorrhage	No	Not Related	Not Related
10	3-Apr-14	591	Cardiopulmonary arrest with a secondary cause of lung cancer	No	Not Related	Not Related
11	9-Jul-15	637	Worsening coronary artery disease and myocardial infraction	No	Not Related	Not Related
12	7-Apr-15	710	Transient ischemic attack and /or cerebrovascular accident	No	Not Related	Not Related
13	27-Nov-13	808	Multisystem organ failure	No	Not Related	Not Related
14	17-Sep-14	933	Cardiopulmonary arrest	No	Not Related	Not Related
15	10-Apr-14	966	Acute cardiac failure	No	Not Related	Not Related
16	31-Aug-15	977	Ischemic cardiomyopathy	No	Not Related	Not Related
17	6-Jan-16	1083	Respiratory failure	No	Not Related	Not Related
18	22-Apr-14	1239	Pancreatic carcinoma	No	Not Related	Not Related

6.4.11. Procedure-Related Adverse Events

Procedure-related AEs were adjudicated by the CEC and are summarized in **Table 18**. There were 34.7% (52/150) of Pivotal subjects with at least one procedure-related AE reported. The majority of procedure-related AEs reported were vascular disorders, 9.3% (14/150) and general disorders and administration site conditions, 8.7% (13/150).

Table 18. Summary of CEC Adjudicated Procedure-Related Adverse Events

MedDRA SOC/Preferred Term	Pivotal Subjects (N=150) n (%)
Subjects with at least one Procedure-Related AE	52 (34.7%)
Blood and Lymphatic System Disorders	1 (0.7%)
Leukocytosis	1 (0.7%)
Cardiac Disorders	2 (1.3%)
Atrial Fibrillation	1 (0.7%)
Myocardial Infarction	1 (0.7%)
Gastrointestinal Disorders	6 (4.0%)
Abdominal Pain	1 (0.7%)
Colitis Ischemic	1 (0.7%)
Constipation	2 (1.3%)
Dyspepsia	1 (0.7%)

Table 18. Summary of CEC Adjudicated Procedure-Related Adverse Events

MedDRA SOC/Preferred Term	Pivotal Subjects (N=150) n (%)
Ileus	1 (0.7%)
General Disorders and Administration Site Conditions	13 (8.7%)
Device Occlusion	1 (0.7%)
Medical Device Site Discharge	1 (0.7%)
Pyrexia	7 (4.7%)
Stent-Graft Endoleak	3 (2.0%)
Vascular Complication Associated with Device	2 (1.3%)
Infections and Infestations	5 (3.3%)
Groin Infection	1 (0.7%)
Pneumonia	1 (0.7%)
Post Procedural Pneumonia	1 (0.7%)
Urinary Tract Infection	2 (1.3%)
Injury, Poisoning and Procedural Complications	9 (6.0%)
Arterial Injury	1 (0.7%)
Incision Site Pain	1 (0.7%)
Procedural Nausea	1 (0.7%)
Procedural Pain	1 (0.7%)
Reocclusion	2 (1.3%)
Seroma	1 (0.7%)
Vascular Graft Occlusion	1 (0.7%)
Wound	1 (0.7%)
Metabolism and nutrition disorders	1 (0.7%)
Hypokalemia	1 (0.7%)
Musculoskeletal and connective tissue disorders	1 (0.7%)
Pain in extremity	1 (0.7%)
Nervous system disorders	2 (1.3%)
Spinal cord ischemia	2 (1.3%)
Renal and urinary disorders	10 (6.7%)
Acute kidney injury	1 (0.7%)
Hematuria	1 (0.7%)
Micturition urgency	1 (0.7%)
Renal artery occlusion	2 (1.3%)
Renal artery stenosis	1 (0.7%)
Renal infarct	2 (1.3%)
Urinary retention	3 (2.0%)
Reproductive system and breast disorders	2 (1.3%)
Genital discomfort	1 (0.7%)
Penile hemorrhage	1 (0.7%)
Respiratory, thoracic and mediastinal disorders	1 (0.7%)
Laryngospasm	1 (0.7%)

Table 18. Summary of CEC Adjudicated Procedure-Related Adverse Events

MedDRA SOC/Preferred Term	Pivotal Subjects (N=150) n (%)
Surgical and medical procedures	2 (1.3%)
Wound drainage	2 (1.3%)
Vascular disorders	14 (9.3%)
Aneurysm	2 (1.3%)
Arterial Stenosis	1 (0.7%)
Arteriovenous Fistula	1 (0.7%)
Hematoma	2 (1.3%)
Hemorrhage	1 (0.7%)
Iliac Artery Rupture	1 (0.7%)
Intermittent claudication	1 (0.7%)
Peripheral artery thrombosis	1 (0.7%)
Peripheral ischemia	4 (2.7%)
All procedure-related AEs were adjudicated by the CEC. The Core Laboratory assessed events evaluated through imaging such as, endoleaks, fractures, and occlusions. *Percentages are based on the number of subjects in the Safe Evaluable Population.* *MedDRA version 18.0 was used for coding adverse events.* *A subject who experienced multiple events within a SOC or PT is counted once for that class and once for the PT.*	

6.4.12. Effectiveness Results

6.4.12.1. Primary Effectiveness

The primary effectiveness endpoint was successful aneurysm treatment through 12-month post implant, defined as a composite of the following:

- Technical success at the conclusion of the index procedure (graft patent with absence of Type I/III endoleak, or treated aneurysm rupture,
- Absence of aneurysm enlargement (> 5 mm compared to 30 day) or stent-graft migration (>10 mm compared to 30 day)
- Absence of fracture, conversion to open surgical repair, treated aneurysm rupture, Type I/III endoleak, or stent-graft occlusion (i.e., loss of patency requiring secondary intervention)

The primary effectiveness endpoint of successful aneurysm treatment was achieved in 93.13% of the Pivotal Study (122/131; 95% CI 87.36% to 96.81%, **Table 19**) through 12 months. The analysis of effectiveness was based on the 131 subjects evaluable for all components of the composite endpoint at the 12 month timepoint. The study did not meet the primary effectiveness endpoint as the lower confidence interval (i.e., 87.36%) was slightly less than the effectiveness performance goal of 88% (P=0.0400). The performance goal for the primary effectiveness endpoint for this pivotal study was more conservative as compared to other endovascular graft pivotal studies evaluating similar intended patient populations.

Table 19. Successful Aneurysm Treatment at 12 Months

Characteristic	Statistics	Pivotal
Successful Aneurysm Treatment at 12 Months	% (n/N)	93.13% (122/131)
	95% CI	87.36%, 96.81%
	P Value	0.0400

Table 20 summarizes the individual components of the primary effectiveness endpoint for the Pivotal Study. Overall, nine subjects did not meet the definition of treatment success. The technical success (intra-procedure) rate was 100%. Stent-grafts were patent at the end of procedure in all subjects. One subject had a Type Ia endoleak noted at the end of the index procedure, but this was not confirmed by the Imaging Core Laboratory and not present on the 30-day CT scan. Type I/III endoleaks were reported by the Core Laboratory in three subjects with evaluable CT imaging through 12 months. No subject had aneurysm enlargement exceeding 5 mm, and there was no stent-graft migration (>10 mm) through 12 months. There were three subjects with endovascular graft occlusions requiring reintervention through 12 months (2.1% of 144 subjects with 12-month follow-up). Stent strut or barb fractures were detected in 4 of 135 (3.0%) subjects with evaluable 12-month x-ray imaging. One of the nine subjects experienced two endpoint events: a Type Ia endoleak at 44 days post index procedure that was treated with endostaples and a non-**TREO** aortic cuff, and a stent fracture which was detected at the 6-month follow-up visit. Additional information regarding these events and observations are discussed in more detail in the proceeding sections.

A total of 19 subjects were excluded from the primary effectiveness endpoint due to a failure to complete the required assessments to evaluate the 8 components of the primary effectiveness endpoint through 12 months. For the analysis, data for all 8 components, as described in **Table 20** below, had to be present and positive to be declared a success and included in the denominator. If a subject experienced an endpoint failure at any time prior to 12 months, even if complete 12-month data was not present, that subject was included as a failure regardless of length of follow-up or complete data availability and included in the denominator. Of the 19 subjects, the reasons for exclusion from analysis were:

- 11 subjects did not complete the 12-month visit: two subjects were Lost To Follow-Up, five subjects were early withdrawals and there were four deaths
    - Reasons for early withdrawal include elective withdrawal by the PI due to non-compliance with recommended follow-up visits (two subjects), withdrawal by subject due to logistical issue related to follow-up requirements (two subjects), and withdrawal by family due to onset of Alzheimer's (one subject).
- Two subjects had incomplete or insufficient baseline imaging at 30 days, resulting in the inability to assess migration in one subject and aneurysm sac change in the other
- Six subjects had incomplete or insufficient 12-month imaging data, resulting in the inability to assess migration in four subjects, and multiple imaging endpoints in two others

Table 20. Individual Components of the Composite Primary Effectiveness Endpoint

Components of Primary Endpoint	Pivotal
Composite of Technical Success at Procedure	100.0% (150/150)
No Type I/III endoleak at Conclusion of Procedure	100.0% (150/150)
Patent Endograft at Procedure	100.0% (150/150)
No Aneurysm Rupture	100.0% (150/150)
Absence of Sac Increase >5 mm through 12 months*	100.0% (138/138)
Absence of Migration >10 mm through 12 months*	100.0% (133/133)
Patency without Reintervention through 12 months	97.9% (141/144) [a,b,c]
Absence of fracture of stent or barb through 12 months*	97.0% (131/135) [d,e,f,g]
No Type I/III endoleaks through 12 months*	97.8% (134/137) [e,h,i]
Absence of Conversion to Open Surgical Repair	100.0% (150/150)

Table 20. Individual Components of the Composite Primary Effectiveness Endpoint

Components of Primary Endpoint	Pivotal
** Core Laboratory assessed components of the primary effectiveness endpoint in subjects with adequate imaging. Adequate imaging was determined by the Core Laboratory. In general, images with contrast were regarded as adequate for interpretation of endograft patency.*	
[a] Subject experienced right Leg Extension occlusion, which was treated 12 days post-implant with right common femoral endarterectomy with patch , right common iliac stent with angioplasty, and right common iliac embolectomy. This treatment did not resolve the occlusion, and 79 days post-index procedure subject was successfully treated with left to right femoral to femoral bypass, right proximal superficial femoral artery stent x 2, and right distal superficial femoral artery stent x 2.	
*[b] Subject experienced right Leg Extension occlusion, which was initially treated 30 days post-implant with lytic therapy, PTA of thrombosis, and angioplasty of right iliac. Subject was then treated the following day (31 days post-implant) with endovascular revascularization and open right iliac with non-**TREO** stent-grafts and angioplasty, which resolved the occlusion.*	
[c] Subject experienced left proximal iliac artery stent occlusion, which was successfully treated 9 days post-implant with angioplasty and embolectomy.	
[d] Subject experienced a wireform fracture in the proximal aspect of the uncovered portion of the Main Bifurcated Stent-Graft that was identified at 24 months. A retrospective analysis of the 12-month imaging showed the presence of the fracture initially at 12 months. There is no evidence of clinical sequelae or migration, and the stent-graft remains patent. The maximum aneurysm diameter also remained stable through 12 months.	
*[e] Subject experienced Type Ia endoleak 44 days post-implantation. This endoleak was sealed with a non-**TREO** device. A Type II endoleak was detected at the 6-month follow-up and confirmed resolved by the Core Laboratory at 12 months. This subject experienced a bare stent strut fracture in the proximal aspect of the uncovered portion of the Main Bifurcated Stent-Graft at 6 months. There is no evidence of clinical sequelae or migration, and the graft remains patent. The maximum aneurysm diameter also remained stable through 12 months.*	
[f] Subject experienced a single barb break on the left side of the anterior aspect of the top stent at 36 months. A retrospective analysis of the 12-month imaging showed presence of the barb initially at 12 months. There have been no reported clinical sequelae through the subject's last visit at 60 months, and no evidence of endoleak, aneurysm sac expansion, patency compromise, or migration.	
[g] Subject experienced a single barb break at the left side of the anterior aspect of the bare proximal stent at 36 months. A retrospective analysis of the 12-month imaging showed presence of the barb initially at 12 months. There have been no reported clinical sequelae through the subject's last visit at 48 months, and no evidence of endoleak, aneurysm sac expansion, patency compromise, or migration.	
[h] Subject experienced Type Ib endoleak at 6 months only. No evidence of endoleak at 30 days, 12 months, 24 months, or 36 months.	
[i] Subject experienced Type II endoleak at 39 days, which was classified as Type Ia at 6 months and 12 months.	

6.4.12.2. Secondary Effectiveness Endpoints

A summary of the secondary effectiveness endpoints is presented in **Table 21** and discussed in the respective sections below in more detail. The data presented in **Table 21** are the number of patients with the event observed during each timepoint.

At 30-days, the technical success rate, defined as a patent endovascular graft, with an absence of Type I/III endoleak, or treated aneurysm sac rupture at 30 days confirmed by an imaging modality, was 98%. There were three device-related events: a Type Ia endoleak and two limb Leg Extension occlusions requiring intervention. There were no instances of aneurysm-related mortality, rupture, stent fracture or conversion to open surgery.

At 6-months, there were two Type 1a endoleaks reported and one Type Ib endoleak. Three additional interventions (two of which were re-interventions) also occurred. One subject experienced a single stent strut fracture. There were no instances of aneurysm-related mortality, migration, aneurysm sac increase, rupture or conversion to open surgery.

At 1 year, there were two subjects with one stent strut fracture and there were two subjects with one barb fracture reported (including previously identified subjects) but no clinical sequelae associated with the fractures. One subject experienced a Type 1a endoleak at the 1-month follow-up that was resolved with a non-**TREO** proximal cuff and adjunctive endostapling. No fracture was observed with this subject at the 1-month follow-up where the Type I endoleak was treated. Upon review of the 6-month follow-up imaging, the laser cut bare stent strut fracture was observed, although the Type I endoleak remained resolved. For all subjects, there were no instances of aneurysm-related mortality, migration, aneurysm sac increase, rupture or conversion to open surgery.

At 2 years, there were three subjects reported with one stent strut fracture and two subjects reported with one barb fracture reported (including previously identified subjects) but no clinical sequelae associated with the fractures. There was one Type Ia endoleak observed and was treated with a non-**TREO** proximal cuff. For all subjects, there were no instances of aneurysm-related mortality, rupture, migration, aneurysm expansion, occlusions requiring intervention, or conversion to open surgery.

At 3 years, there were four subjects reported with stent strut fractures, and three subjects reported with one barb fracture reported (including previously identified subjects) but no clinical sequelae associated with the fractures. One subject previously reported with a stent strut fracture at 2 years had a second stent strut fracture reported. There was one Type Ia endoleak observed and is being followed. Five subjects were reported with aneurysm expansion, which was likely attributed to Type II endoleaks. For all subjects, there were no instances of aneurysm-related mortality, rupture, migration, occlusions requiring intervention, or conversion to open surgery.

At 4 years, there were three subjects reported with a single stent strut fracture, and three subjects with a single barb fracture reported (including previously identified subjects) but no clinical sequelae associated with the fractures. There were no Type I or III endoleaks reported. Aneurysm expansion was reported in three subjects: two ongoing from prior timepoints and one new expansion which was likely attributed to Type II endoleak. For all subjects, there were no instances of aneurysm-related mortality, rupture, migration, occlusions requiring intervention, or conversion to open surgery.

Table 21. Summary of Secondary Effectiveness Endpoints

Secondary Effectiveness Endpoints‡	Procedure	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years
Technical Success	NA	98.0% (144/147)	NA	NA	NA	NA	NA
Major Device-Related Events	NA	2.0% (3/150)	3.6% (5/139)	3.6% (5/137)	5.2% (6/116)	14.1% (13/92)	28.1% (9/32)
Stent-Strut Fractures*	NA	0% (0/148)	0.8% (1/133)	1.5% (2/131)	2.7% (3/110)	4.7% (4/86)	10.0%§ (3/30)
Barb Fracture*	NA	0% (0/148)	0% (0/133)	1.5% (2/131)	1.8% (2/110)	3.5% (3/86)	10.0%§ (3/30)
Migration*	NA	NA	0% (0/134)	0% (0/128)	0% (0/111)	0% (0/91)	0% (0/28)
All Endoleaks*	0% (0/150)	24.7% (36/146)	18.7% (25/134)	17.3% (23/133)	13.3% (15/113)	10.6% (10/94)	9.4% (3/31)
Type Ia	0% (0/150)	0.7% (1/146)	1.5% (2/134)	0.8% (1/133)	0.9% (1/113)	1.1% (1/94)	0% (0/31)
Type Ib	0% (0/150)	0% (0/146)	0.7% (1/134)	0% (0/133)	0% (0/113)	0% (0/94)	0% (0/31)
Type II	0% (0/150)	23.3% (34/146)	17.2% (23/134)	15.0% (20/133)	11.5% (13/113)	9.6% (9/94)	9.4% (3/31)
Type III	0% (0/150)	0% (0/146)	0% (0/134)	0% (0/133)	0% (0/113)	0% (0/94)	0% (0/31)
Type IV	0% (0/150)	0% (0/146)	0% (0/134)	0% (0/133)	0% (0/113)	0% (0/94)	0% (0/31)
Unknown	0% (0/150)	0.7% (1/146)	0% (0/134)	1.5% (2/133)	0.9% (1/113)	0% (0/94)	0% (0/31)

Table 21. Summary of Secondary Effectiveness Endpoints

Secondary Effectiveness Endpoints‡	Procedure	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years
Aneurysm Enlargement*	NA	NA	0% (0/137)	0% (0/136)	0% (0/116)	5.3% (5/94)	3.30% (3/30)
Occlusion Requiring Intervention	0% (0/150)	1.3% (2/148)	6.9% (1/145)	0% (0/138)	0% (0/122)	0% (0/91)	0% (0/28)
Conversion to Open Repair	0% (0/150)	0% (0/150)	0% (0/149)	0% (0/144)	0% (0/132)	0% (0/120)	0% (0/69)
Any Secondary Intervention	NA	4.7% (7/150)	2.0% (3/149)	0.7% (1/144)	2.3% (3/132)	1.7% (2/120)	0% (0/69)

All values expressed as % (n/N) for endpoints reported within the specified window.

*Denominators are specified in **Table 4** (Summary of Compliance and Imaging Follow-Up: Pivotal Study). For imaging endpoints (fractures, migration, endoleak, aneurysm enlargement), the denominator is the number of subjects with imaging adequate to assess the parameter. For clinical endpoints (occlusion requiring intervention, conversion to open repair, secondary interventions), the denominator is the number of subjects with visits within the window).*

Major device-related events are defined as those events comprising the primary effectiveness endpoint (fracture, migration, Type I/III endoleaks, aneurysm enlargement, occlusion requiring intervention, conversion to open repair).

**This data represents Core Laboratory assessed endpoint for any reports of fracture, migration, endoleak or aneurysm enlargement at each interval, including events previously identified at earlier intervals that are considered ongoing or persistent.*

‡For consistency, the cutoff for all data presented in this table is February 14, 2019, the initial PMA datacut. Information on events occurring after this datacut are presented in subsequent sections as appropriate.

§Section 6.4.19 Stent Graft Integrity includes additional longer-term data on barb and strut fractures. The stent-strut fracture rate at 4 years based on these data are 5.1% (3/59) and the barb break rate at 4 years was 6.8% (4/59). Please note that not all subjects with previously identified fracture had reached the 4-year interval at the time of data lock.

6.4.13. Technical Success

Technical success was defined as a patent endovascular graft, with an absence of Type I/III endoleak, or treated aneurysm sac rupture at 30 days confirmed by an imaging modality.

While Technical Success at the index procedure is a component of the primary effectiveness endpoint, Technical Success at 30 days is a prespecified secondary endpoint. The rate of 30-day Technical Success is shown in **Table 22.** Technical success was 98.0% (144/147) in the Pivotal Study. There were 2 endovascular graft occlusions with reinterventions within 30 days and one Type Ib endoleak. A subject with deployment from the introducer was classified as not acceptable by the Investigator but did not trigger the 30-day Technical Success endpoint since this was not confirmed on imaging studies. For additional details on this subject, see the footnote in **Table 23**.

Table 22. Technical Success Through 30 Days

Endpoints	Pivotal
Technical Success at 30 days	98.0% (144/147)
Endograft Occlusion within 30-days*	1.3% (2/150)
Endoleak at 30 days†	
Type Ia	0.7% (1/146)
Type Ib	0% (0/146)
Type II	23.3% (34/146)
Type III	0% (0/146)
Type I or III	0.7% (1/146)
None	75.3% (110/146)
Unknown	0.7% (1/146)

Table 22. Technical Success Through 30 Days

Endpoints	Pivotal
All values expressed as % (n/N) ** Subjects that had freedom from occlusions (site-reported) and freedom from an intervention to treat the occlusion.* *† Core Laboratory assessed endpoint of 146 subjects with evaluable imaging to assess endoleak.*	

6.4.14. Device Assessment at Index Procedure

A summary of Investigator-assessed device performance at the index procedure is presented in **Table 23**. Among the 150 subjects in the Pivotal Study, the Investigator judged device delivery, deployment, patency, and integrity acceptable in all but one subject (149/150, 99.3%). This subject had unsatisfactory stent-graft deployment from the introducer.

The protocol did not define specific criteria of acceptability for consideration when answering yes/no to each Investigator Device Assessment question. The assessments are intended to capture investigator impressions of acceptability for vascular access and device deployment during implant of the **TREO** Stent-Graft System versus access failures and deployment system failures defined in the protocol as follows:

Access Failure - Failure to reach the intended site with the implant due to mechanical failure or patient anatomy. Whether or not successful implant deployment was achieved should be documented.

Deployment System Failure - Inability to deploy the device at the intended site due to mechanical failure or patient anatomy. Whether or not successful implant deployment was achieved should be documented.

Table 23. Summary of Device Assessments by the Investigators

Device Assessment by Investigator*	Pivotal
Was AAA Device Introduction into Entry Site Acceptable?	100.0% (150/150)
Was Advancement of AAA Device to Lesion Site Acceptable?	100.0% (150/150)
Was AAA Device Fluoroscopic Visualization Acceptable?	100.0% (150/150)
Was AAA Stent-Graft Deployment from Introducer Acceptable?	99.3% (149†/150)
Was Accuracy of AAA Device System Deployment Acceptable?	100.0% (150/150)
Was AAA Stent-Graft Patent?	100.0% (150/150)
Was AAA Device Integrity Maintained?	100.0% (150/150)
Did AAA Stent-Graft Deploy without Kinking or Twisting?	100.0% (150/150)

All values are % (n/N)

** The device assessment was performed at the time of the procedure.*

† For one subject, the investigator indicated "No" for "Was AAA Stent-Graft Deployment from Introducer Acceptable?" This response did not impact procedural technical success, a component of the primary effectiveness endpoint. The non-acceptable deployment was not confirmed by an imaging modality (as the Statistical Analysis Plan requires for the secondary endpoint of 30-day Technical Success). No adjunctive procedures were performed, and no additional device components were deployed at the index procedure. Through available 3-year follow-up, subject has experienced no clinical sequelae, and no endoleaks, patency events, secondary procedures, or migrations have been reported for this subject.

The treating investigator reported that the Main Bifurcated Stent-Graft and contralateral (left) Leg Extension Stent-Graft were deployed with no issues or complications. They were then unable to remove the subassembly of the device from the sheath, so the entire subassembly and sheath were removed as a unit and exchanged for a 20-French Check Flow Sheath. Deployment of the ipsilateral (right) Leg Extension Stent-Graft was completed and the delivery device removed. The ipsilateral Leg Extension Stent-Graft was then deployed without complication. At the conclusion of the procedure, the investigator reported excellent apposition of the graft, without evidence of endoleak.

6.4.15. Aneurysm Sac Rupture

There have been no aneurysm ruptures reported in the Pivotal Study.

6.4.16. Migration

Migration in the pivotal study was defined as movement greater than 10 mm compared to the 1-month imaging. Through 4 years, no stent-graft migration greater than 10 mm has been observed in the study (**Table 24)**. In addition, one subject completed 5-year follow-up and no migration was observed. Clinically significant migration is defined as when a secondary intervention is completed to address migration whether or not the migration reached the > 10 mm threshold. No clinically significant migration has been observed in the study.

Table 24. Summary of Core Laboratory Assessed Stent-Graft Migration (> 10 mm)

	6 Months	1 Year	2 Years	3 Years	4 Years
# of subjects eligible	134	128	111	91	28
Stent-Graft Migration (> 10 mm)	0	0	0	0	0
Clinically Significant Migration	0	0	0	0	0

6.4.17. Endoleaks

Endoleaks in the pivotal study were defined as the persistence of blood flow outside the lumen of stent-graft but within a native aorta or adjacent vascular segment being treated by the stent-graft. Endoleaks are categorized as follows:

- Type I endoleak is periprosthetic and occurs at the proximal or the distal attachment zone
- Type II endoleak is caused by retrograde flow from patent branch arteries, for example, lumbar vessels or inferior mesenteric artery
- Type III endoleak arises from a defect in the graft material or from an inadequate seal between modular graft components
- Type IV endoleak is due to graft permeability

A summary of post-procedure endoleaks is provided in **Table 25**. Endoleaks were assessed by the Core Laboratory through follow-up. The majority were classified by the Imaging Core Laboratory as Type II. At the 30-day visit, 34 subjects had confirmed Type II endoleaks, with half persisting through the 6-month visit.

Four subjects (2.7%) developed a Type Ia endoleak over follow-up to date. One subject developed a Type Ia endoleak 44 days post implant, which was excluded with a non-**TREO** device. This subject did experience a bare stent fracture in the proximal aspect of the uncovered portion of the main body stent at 6 months. There was no evidence of clinical sequelae or migration, and the graft remained patent. The maximum aneurysm diameter remained stable through 12 months, after which the subject withdrew from study participation. One subject had a Type Ia at 6 months which the investigator elected not to treat. Two subjects experienced Type Ia endoleaks during later follow-up: one at 2 years, which was treated with a non-**TREO** proximal cuff, and one at 3-year follow-up that is currently being followed.

One subject developed a Type Ib endoleak at 6 months which resolved without additional intervention by 12-months.

There were no Type III or Type IV endoleaks observed by the Imaging Core Laboratory. Endoleaks that were determined by the Imaging Core Laboratory to have continued from one study visit to the next were captured as persistent.

One subject has completed 5-year follow-up and no endoleaks of any type were observed.

Table 25. Summary of Core Laboratory Reported Endoleaks

Endoleak	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years
Adequate Imaging*	146	134	133	113	94	31
Endoleaks (Total)**	36 (24.7%)	25 (18.7%)	23 (17.3%)	15 (13.3%)	10 (10.6%)	3 (9.4%)
Type Ia						
New	1[a]	1[b]	0	1[c]	1[d]	0
Persistent	0	1	1	0	0	0
New and Persistent	1 (0.7%)	2 (1.5%)	1 (0.8%)	1 (0.9%)	1 (1.1%)	0 (0.0%)
Type Ib						
New	0	1[e]	0	0	0	0
Persistent	0	0	0	0	0	0
New and Persistent	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II						
New	34	6	4	1	2	1
Persistent	0	17	16	12	7	2
New and Persistent	34 (23.3%)	23 (17.2%)	20 (15.0%)	13 (11.5%)	9 (9.6%)	3 (9.4%)
Type III						
New	0	0	0	0	0	0
Persistent	0	0	0	0	0	0
New and Persistent	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type IV						
New	0	0	0	0	0	0
Persistent	0	0	0	0	0	0
New and Persistent	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unknown Type						
New	1	0	2	0	0	0
Persistent	0	0	0	1	0	0
New and Persistent	1 (0.7%)	0 (0.0%)	2 (1.5%)	1 (0.9%)	0 (0.0%)	0 (0.0%)

** Adequate imaging was determined by the Core Laboratory. In general, images with contrast and non-contrast series were regarded as adequate for interpretation of endoleaks.*

*** Endoleaks (Total) reflects the number of subjects experiencing at least one endoleak of any type at the timepoint. One subject experienced two endoleaks at 6 months.*

[a] Subject experienced Type Ia endoleak at 30 days. Classified as Type II at 6 months and resolved at 12-month follow-up visit.

[b] Subject experienced Type II endoleak at 39 days but classified as Type Ia at 6 months and 12 months.

[c] Subject experienced Type Ia endoleak at 2-year follow-up, which was then reported as a Type II at 3 years.

[d] Subject experienced Type Ia endoleak at 3-year follow-up, which is currently being followed. Subject had Type II lumbar endoleak reported at 30 days, which has persisted through 3 years.

[e] Subject experienced Type Ib endoleak at 6 months only (resolved without intervention by 12 months), and a Type II at 12 months. No evidence of endoleak at 30 days, 2 years or 3 years.

6.4.18. Aneurysm Size Change

Aneurysm enlargement is defined as an increase in aneurysm sac diameter greater than 5 mm compared to the diameter determined at the 1-month baseline. Aneurysm size changes are summarized in **Table 26**. Aneurysm size changes were assessed by the Core Laboratory. In the Pivotal Study, 46.3% (63/136) of subjects had >5 mm of sac regression at 12 months. At 2 and 4 years, 54.3% and 53.3% had regression. Sac expansion was observed in 5/94 Pivotal subjects (5.3%) followed to 3 years, and 3/30 (10%) followed to 4 years (1 new expansion and 2 persisting expansions at 4 years). One subject completed 5-year follow-up and a stable aneurysm diameter was observed. All subjects with reported aneurysm sac expansion had previously reported Type II endoleaks, which may have contributed to the expansion. No other contributing factors were identified.

Table 26. Summary of Core Laboratory Assessed Changes in Aneurysm Sac Diameter

Changes in Aneurysm Size	6 Months	1 Year	2 Years	3 Years	4 Years
Imaging Adequate to Assess Diameter Change	100% (137/137)	100% (136/136)	100% (116/116)	100% (94/94)	100% (30/30)
Increase > 5mm					
New	0% (0/137)	0% (0/136)	0% (0/116)	5.3% (5/94)	3.3% (1/30)
Persistent	0% (0/137)	0% (0/136)	0% (0/116)	0% (0/94)	6.7% (2/30)
Total (New and Persistent)	0% (0/137)	0% (0/136)	0% (0/116)	5.3% (5/94)	10.0% (3/30)
No Change Total	68.6% (94/137)	53.7% (73/136)	45.7% (53/116)	40.4% (38/94)	36.7% (11/30)
Decrease (>5 mm)	31.4%(43/137)	46.3% (63/136)	54.3% (63/116)	54.3% (51/94)	53.3% (16/30)
All values expressed as % (n/N)					

6.4.19. Stent-Graft Integrity

Fracture is defined as any breakage of a metallic component of the Stent-Graft. The **TREO® ABDOMINAL STENT-GRAFT SYSTEM** is comprised of metallic components that are manufactured from either laser cut tubing or shape set wire. No shape set wire components exhibited fractures. The only fractures reported were located in the bare stent component that is manufactured from laser cut tubing. Therefore, no fractures were identified in areas where the stents were connected to the fabric. Fractures of the bare stent were located in one of three areas: a suprarenal barb, the proximal end of a transrenal strut or the distal end of transrenal strut. In all cases of fracture, all portions of the metallic component were accounted for.

Incidence of the barb and stent strut fractures observed in 10 subjects from the initial datacut for the PMA are presented in **Table 21**. A comprehensive summary of observed fracture through 5 years is presented in **Table 27** and includes available data on fractures observed in 13 subjects through January 2020, inclusive of outcomes of Core Laboratory re-review.

Stent fractures were reported by the Core Laboratory based on the images received from each site. Upon review of subject images by the Core Laboratory, 4 subjects have been identified with 1 fracture each in a suprarenal barb. Two subjects with a barb fracture were first observed with fracture at 1 year, 1 subject at 2 years, and 1 subject at 3 years.

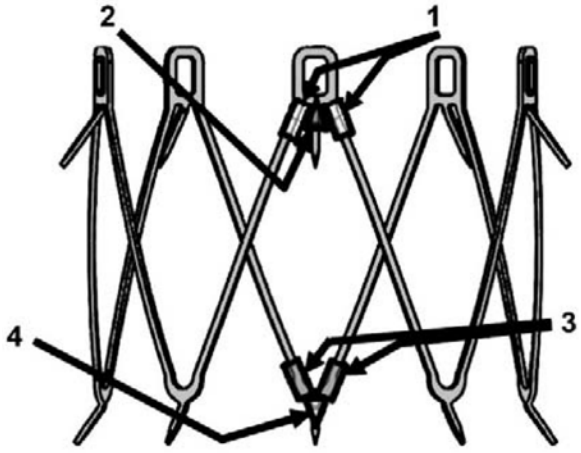
Nine different subjects have been identified with a total of 13 stent strut fractures in the bare proximal stent (8 subjects with fracture in the Main Bifurcated Stent-Graft, 1 subject with fracture in the Proximal Cuff Stent-Graft). One subject with stent strut fracture was reported at 6 months, 1 subject was reported with a new fracture at 1 year, 2 subjects at 2 years, 1 subject at 3 years, 3 subjects at 4 years, and 1 subject at 5 years. Only two of these 9 subjects with stent strut fracture(s) have been observed with multiple fractures (1 subject with 2 stent strut fractures and one subject with 4 stent strut fractures), as presented in **Table 28**.

Table 27. Fracture Incidence and Prevalence Summary

	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years
Strut Fracture							
# of Subjects Newly Identified with at Least 1 Strut Fracture[a]	0 /148	1/133	1/131	2/111	1/94	3/59	1/22
Cumulative # of Subjects with a Strut Fracture[b]	0	1	2	4	5	8	9
Cumulative # of Strut Fractures[c]	0	1	2	4	8	11	13
Barb Fracture							
# of Subjects Newly Identified with at Least 1 Barb Fracture[a]	0/148	0/133	2/131	1/111	1/94	0/59	0/22
Cumulative # of Subjects with a Barb Fracture[b]	0	0	2	3	4	4	4
Cumulative # of Barb Fractures[c]	0	0	2	3	4	4	4

[a]Newly identified subjects with fracture at identified timpoint / number subjects at timepoint with imaging adequate to assess fracture through January 2020.
[b]Subjects with fracture continue to be reported for later timepoints, regardless if they have reached the follow-up window.
[c]Number of fractures continue to be reported for later timepoints.

All fractures that have been reported in the **TREO** Pivotal Study have been observed in the bare proximal stent. For eight of the subjects with stent strut fracture, the fracture was located on the bare proximal stent of the Main Bifurcated Stent-Graft. For one of the subjects with stent strut fracture, the fracture was located on the bare proximal stent of the Proximal Cuff Stent-Graft. Please note that the proximal end of the Main Bifurcated Stent-Graft and the Proximal Cuff Stent-Graft (i.e., bare proximal stents) are identical. For the subjects with stent strut fracture(s), the fracture(s) have been observed near the eyelet (9 fractures in 7 subjects) and the distal strut (4 fractures in 3 subjects). For the subjects with a single barb fracture, the fracture has been observed in the suprarenal barbs of the bare proximal stent of the Main Bifurcated Stent-Graft. No fractures have been observed in the infrarenal barbs. Please note that a single subject has been reported with both a fracture in the eyelet and also in the distal strut. No subject has been reported with both a barb fracture and a stent strut fracture. Please see **Figure 9** below for depiction of these fracture locations.



Fracture Location Description / Summary		
1	Proximal Strut	7 Subjects 9 Fractures[1]
2	Proximal Barb	4 Subjects 4 Fractures
3	Distal Strut	3 Subjects[1] 4 Fractures
4	Distal Barb	0 Fractures

[1]One subject had both a proximal and distal strut fracture and is counted at each location.

Figure 9. TREO Proximal Bare Stent Fracture Locations

Two subjects have been reported with multiple stent strut fractures. Subject #1 was observed with 3 fractures at 3-years and 1 additional fracture reported at 5-years. Subject #2 was observed with 1 fracture at 2-years and 1 additional fracture at 3-years. All fractures have occurred in the bare proximal stent. **Table 28** below presents the fractures newly identified for these two subjects at each follow-up visit.

Table 28. Subjects with Multiple Stent Fractures at Follow-Up

Subject	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years	5 Years
Subject #1	0	0	0	0	3	0	1
Subject #2	0	0	0	1	1	0	0

None of the subjects with fracture have had clinical sequelae associated with fracture. This includes no observations of implant migration, Type Ia endoleaks, aneurysm enlargement, embolization of stent strut or barb segments, vessel perforation, aortic rupture, secondary interventions required as a result of the fractures or death attributed to stent strut or barb fracture.

A root cause investigation was conducted regarding the observation of fracture. This investigation included subject anatomical data analysis, bench top testing of acute performance characteristics in observed and beyond observed fault conditions, in-vivo deformation analysis, computational strain simulations, and experimental fatigue testing. High axial drag forces and minimal barb penetration were identified as potential contributing causes of fracture. The information from the root cause investigation could not be extrapolated to any subject anatomical, demographic, or procedural related factors that may contribute to an increased risk of fracture.

6.4.20. Stent-Graft Patency-Related Events

Loss of stent-graft patency was defined as an occlusion where complete luminal obstruction of the Main Bifurcated Stent-Graft or one or both limbs of the stent-graft, leading to the absence of flow (i.e., loss of patency) across the involved segment/s was observed by the Core Laboratory **(Table 29)**. There were no Core Laboratory reports of patency issues involving full occlusion of the Main Bifurcated Stent-Graft and/or Leg Extension Stent-Grafts in the study, beyond events which were recognized clinically. Site-reported patency issues are described in **Table 30**

As reported by the investigational sites, occlusion of a single Leg Extension Stent-Graft requiring intervention occurred in 3/150 (2%) subjects. Among these, 2/150 occurred within 30 days, both of which were treated with secondary interventions. There was one additional occlusion requiring an intervention which occurred during the 6 months timepoint. All occlusions were of the Leg Extensions; there were no occlusions of the Main Bifurcated Stent-Graft.

The Kaplan-Meier estimate of site-reported patency related events (thromboses, stenosis, occlusions) is shown in **Figure 10.** The rate of patency related events was 2.0% at 1 month, 2.7% at 1 year, and 3.5% at 4 years.

Table 29. Core-Laboratory Reported Endograft Patency

Patency	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years
Pivotal	100% (147/147)	100% (134/134)	100% (134/134)	100% (113/113)	100% (66/66)	100.0% (12/12)
Core Laboratory reported. These data may differ from the site reported data if an occlusion was treated such that the endograft was patent later, on the imaging submitted to the Core Laboratory.						

Table 30. Summary of Site Reported Endograft Occlusions

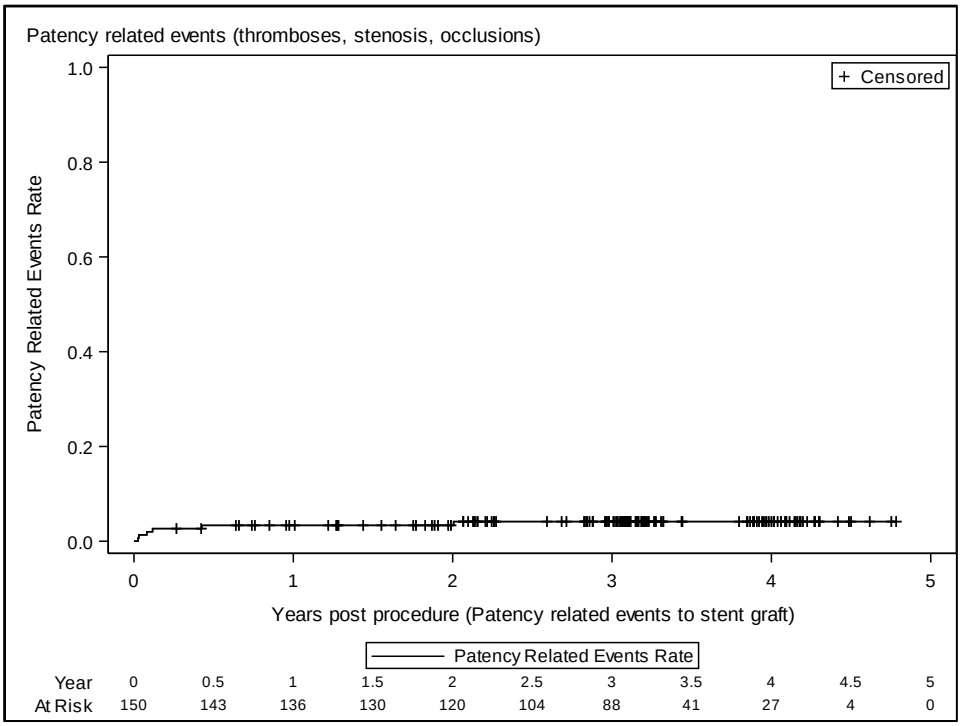
Interval	Eligible Subjects	New Occlusions	Persistent Occlusions	Cumulative Secondary Procedures*
Procedure	150	0	0	0
30 Days	148	2[a,b]	0	2
6 Months	145	1[c]	0	3
1 Year	138	0	0	3
2 Years	122	0	0	3
3 Years	91	0	0	3
4 Years	28	0	0	3
5 Years	0	0	0	3

** Secondary Procedures that successfully restored patency. There were no unsuccessful secondary procedures in the study.*

[a] One subject experienced stent occlusion of the left proximal iliac artery, which was successfully treated 9 days post-implant with angioplasty and embolectomy. Subject's medical history was significant for peripheral vascular disease and extensive atherosclerotic vascular disease, with a narrow distal aortic neck. There were no other site-reported contributing factors related to this thrombosis event.

*[b] One subject experienced occlusion of the right iliac Leg Extension, which was initially treated 30 days post-implant with lytic therapy, PTA of thrombosis, and angioplasty of right iliac. Subject was then treated the following day (31 days post-implant) with endovascular revascularization and open right iliac with non-**TREO** stents and angioplasty, which resolved the occlusion. There were no site-reported contributing factors related to this thrombosis event.*

[c] One subject experienced occlusion of the right iliac Leg Extension, which was treated 12 days post-implant with right common femoral endarterectomy with patch arthroplasty, right common iliac stent with angioplasty, and right common iliac embolectomy. This treatment did not resolve the occlusion, and 79 days post-index procedure subject was successfully treated with left to right femoral to femoral bypass, right proximal superficial femoral artery stent x 2, and right distal superficial femoral artery stent x 2. Subject's medical history was significant for aneurysmal right and left common iliac arteries, left lower extremity peripheral vascular disease status post thrombectomy, and PTA and SFA stenting in 2004. Per the Operative Report, the subject's pre-implant imaging was significant for right hypogastric artery coiling, and subject had moderate to severe disease distal to the external iliac artery. There were no other site-reported contributing factors related to this thrombosis event.



Time	Failure Rate	Lower 95% CI	Upper 95% CI	Patency Related Events (with intervention)	At Risk
Procedure	0.00%	NA	NA	NA	150
30 Days	2.00%	0.65%	6.07%	3	147
6 Months	2.68%	1.01%	6.97%	4	144
1 Year	2.68%	1.01%	6.97%	4	137
1.5 Years	2.68%	1.01%	6.97%	4	131
2 Years	2.68%	1.01%	6.97%	4	121
2.5 Years	3.48%	1.46%	8.18%	5	105
3 Years	3.48%	1.46%	8.18%	5	89
3.5 Years	3.48%	1.46%	8.18%	5	42
4 Years	3.48%	1.46%	8.18%	5	27
4.5 Years	3.48%	1.46%	8.18%	5	3
5 Years	NA	NA	NA	5	0

Figure 10. Kaplan-Meier Analysis of Site Reported Patency Related Event Rate

6.4.21. Conversion to Open Surgery

There have been no open surgical conversions in the Pivotal Study.

6.4.22. Secondary Interventions

There have been a total of 18 secondary interventions performed in 16 subjects through 4 years in the Pivotal Study. The majority of interventions were performed to address patency-related events and endoleaks. Three subjects were treated for implant occlusion, and an additional five subjects received treatment for thrombus, ischemia, stenoses and one was treated for AV fistula. One subject who experienced aneurysm sac expansion underwent embolization due to a persistent Type II endoleak. One subject followed through 5 years has no reported secondary interventions.

Table 31. Summary of Reasons for Secondary Intervention

	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years
Number of Subjects Eligible (at Risk)	150	149	144	132	120	69
Subjects with Any Intervention	7 4.7% (7/150)	3 2.0% (3/149)	1 0.7% (1/144)	3 2.3% (3/132)	2 1.7% (2/120)	0 0% (0/69)
Number of Interventions	8	4	1	3	2	0
Secondary Intervention for Type I Endoleak	1 (1) 0.7% (1/150)	3 (3) 2.0% (3/149)	1 (1) 0.7% (1/144)	1 (1) 0.8% (1/132)	0 (0) 0% (0/120)	0 (0) 0% (0/69)
Extension	1[a]	3[b, c, d]	0[d]	1[e]	0	0
Secondary Intervention for Type II Endoleak	0 (0) 0% (0/150)	0 (0) 0% (0/149)	0 (0) 0% (0/144)	1 (1) 0.8% (1/132)	1 (1) 0.8% (1/120)	0 (0) 0% (0/69)
Coil Embolization	0	0	0	1[f]	1[g]	0
Secondary Intervention for Implant Occlusion	3 (3) 2.0% (3/150)	0 (0) 0% (0/149)	0 (0) 0% (0/144)	0 (0) 0% (0/132)	0 (0) 0% (0/120)	0 (0) 0% (0/69)
Endarterectomy, Arthroplasty, and Embolectomy	1[h]	0	0	0	0	0
Angioplasty, Embolectomy and Stenting	2[i, j]	0	0	0	0	0
Secondary Intervention for Aneurysm Sac Expansion	0 (0) 0% (0/150)	0 (0) 0% (0/149)	0 (0) 0% (0/144)	1 (1) 0.8% (1/132)	0 (0) 0% (0/120)	0 (0) 0% (0/69)
Embolization	0	0	0	1[k]	0	0
Secondary Intervention for Thrombus	1 (1) 0.7% (1/150)	0 (0) 0% (0/149)	0 (0) 0% (0/144)	1 (1) 0.8% (1/132)	1 (1) 0.8% (1/120)	0 (0) 0% (0/69)
Embolectomy	1[l]	0	0	0	1[n]	0
Embolectomy and Extension	0	0	0	1[m]	0	0
Secondary Intervention for Ischemia	1 (1) 0.7% (1/150)	1 (1) 0.7% (1/149)	0 (0) 0% (0/144)	0 (0) 0% (0/132)	0 (0) 0% (0/120)	0 (0) 0% (0/69)
Extension	1[o]	1[c]	0	0	0	0
Secondary Intervention for AV Fistula	1 (1) 0.7% (1/150)	0 (0) 0% (0/149)	0 (0) 0% (0/144)	0 (0) 0% (0/132)	0 (0) 0% (0/120)	0 (0) 0% (0/69)
Extension	1[p]	0	0	0	0	0

Where n(n) is number of subjects with an event (number of events) and N is the number of subjects with visits in the specified window.

[a] *One subject presented with a Type I endoleak 44 days post-implantation, which was treated with a non-**TREO** aortic cuff. A Type II endoleak was detected at the 6-month follow-up but confirmed resolved by the Core Laboratory at 12 months. This subject experienced a wireform fracture in the proximal aspect of the uncovered portion of the Main Bifurcated Stent-Graft at 6 months. There is no evidence of clinical sequelae or migration, and the graft remains patent. The maximum aneurysm diameter remained stable through 12 months.*

[b] *One subject was reported by the site to have a Type Ia endoleak; however, this was not confirmed by the Imaging Core Laboratory and is therefore not reported as such elsewhere in this report. Per the Imaging Core Laboratory, there was no evidence of endoleak of any type upon completion angiogram for this subject. At the 30-day follow-up, a Type II endoleak was detected by the Imaging Core Lab (as opposed to a Type Ia). This endoleak was confirmed by the Imaging Core Laboratory to persist at the 6-month and 12-month follow-up visits, and had resolved by the 2-year follow-up visit. The endoleak and non-occlusive thrombus in the right limb was treated with the implantation of another **TREO** device during a secondary intervention at 169 days post-implant procedure. This subject also had an embolectomy at 1141 days post-implant for recurrence of non-occlusive thrombus.*

[c] *One subject underwent a secondary intervention 231 days post-implant to address a Type Ib endoleak by placement of an extension. Shortly thereafter, on day 265 post-implant, the subject developed severe right leg ischemia and underwent an additional procedure the following day to address the ischemia. A non-**TREO** stent was placed in the right iliac, resolving the ischemia.*

[d] *One subject experienced a Type II endoleak at 39 days, which was not present on the completion angiogram. The subject then experienced a Type Ia endoleak at 6 months and 12 months, which was treated with a competitor's device placed within the **TREO** stent-graft on day 265 post-implant, and later a coil embolization on day 390 post-implant.*

[e] *One subject experienced a Type Ia endoleak at the 2-year follow-up. On day 870 post-implant, the subject had a competitor extension implanted.*

[f] *One subject had a Core Laboratory-determined maximum aneurysm diameter of 59.7mm at 1-month follow-up, which was stable at 60.9mm through 24 months. The site-reported 1-month aneurysm diameter was 55mm; smaller than the Core Lab. At 24 months, the site-reported aneurysm diameter increased to 63mm; an 8mm increase compared to the 1-month site measurement. A Type II endoleak, first noted at 1 month, was embolized. Following embolization (27 months), maximum aneurysm diameter was 73mm (+13.3mm compared to 1-month image, Core Lab measurements). The maximum diameter of the aneurysm decreased to 69.2mm (+9.5mm) at 36 months, without a detectable endoleak reported at that time. The aneurysm continued to decrease to 67.1 (+7.4) at 48 months.*

[g] *One subject experienced a Type II endoleak that had persisted since implant and was treated with embolization on days 1141 and 1148 post-implant. This subject had a maximum aneurysm diameter of 58.2mm at 1 month, which was stable through 24 months but increased to 63.9mm (+5.7mm) at 36 months, meeting the criteria for aneurysm sac increase. The diameter increased further to 68.8mm (+10.6mm) at 48 months.*

[h] *One subject experienced an occlusion of the right Leg Extension, which was treated 12 days post-implant with right common femoral endarterectomy with patch arthroplasty, right common iliac stent with angioplasty, and right common iliac embolectomy. This treatment did not resolve the occlusion, and 79 days post-index procedure subject was successfully treated with left to right femoral to femoral bypass, right proximal superficial femoral artery stent x 2, and right distal superficial femoral artery stent x 2.*

[i] *One subject experienced stent occlusion of the left proximal iliac artery, which was successfully treated 9 days post-implant with angioplasty and embolectomy.*

[j] *One subject experienced an occlusion of the right Leg Extension, which was initially treated 30 days post-implant with lytic therapy, PTA of thrombosis, and angioplasty of right iliac. Subject was then treated the following day (31 days post-implant) with endovascular revascularization and open right iliac with non-**TREO** stents and angioplasty, which resolved the occlusion.*

[k] *One subject had a Core Laboratory-determined maximum aneurysm diameter of 59.7mm at 1-month follow-up, which was stable at 60.9mm through 24 months. The site-reported 1-month aneurysm diameter was 55mm; smaller than the Core Laboratory. At 24 months, the site-reported aneurysm diameter increased to 63mm; an 8mm increase compared to the 1-month site measurement. A Type II endoleak, first noted at 1 month, was embolized. Following embolization (27 months), maximum aneurysm diameter was 73mm (+13.3mm compared to 1-month image, Core Lab measurements). The maximum diameter of the aneurysm decreased to 69.2mm (+9.5mm) at 36 months, without a detectable endoleak reported at that time. The aneurysm continued to decrease to 67.1 (+7.4) at 48 months.*

[l] *One subject experienced thrombosis in the right iliac one-day post-implant, which was corrected via embolectomy.*

[m] *One subject experienced thrombus in the left Leg Extension iliac limb 723 days post-implant. A non-**TREO** left iliac limb was deployed with successful results.*

[n] *One subject was reported by the site to have a Type Ia endoleak; however, this was not confirmed by the Imaging Core Laboratory and is therefore not reported as such elsewhere in this report. Per the Imaging Core Laboratory, there was no evidence of endoleak*

*of any type upon completion angiogram for this subject. At the 30-day follow-up, a Type II endoleak was detected by the Imaging Core Laboratory (as opposed to a Type Ia). This endoleak was confirmed by the Imaging Core Laboratory to persist at the 6-month and 12-month follow-up visits, and had resolved by the 2-year follow-up visit. The endoleak and non-occlusive thrombus in the right limb was treated with the implantation of another **TREO** device during a secondary intervention at 169 days post-implant procedure. This subject also had an embolectomy at 1141 days post-implant for recurrence of non-occlusive thrombus.*

[o] One subject experienced right iliofemoral ischemia 11 days post-implant, which was successfully treated with a right iliofemoral embolectomy, PTA of bilateral iliac limbs, and stenting of the right CIA.

*[p] One subject experienced a left groin av fistula 74 days post-implant, which was treated with a non-**TREO** covered stent, overlapping with the Leg Extension of the **TREO** device.*

6.5. ADDITIONAL FOLLOW-UP DATA

As of January 2020, 26 subjects have completed five-year follow-up visits, of which 25 had CT imaging assessed by the imaging Core Laboratory, and 22 had x-ray imaging assessed. In addition, 74 subjects have completed 4-year follow-up and 107 subjects have completed 3-year follow-up. Among the subjects returning for follow-up since the initial PMA datacut on February 14, 2019, there have been four deaths (one secondary to metastatic squamous cell carcinoma and three resulting from MI). Two subjects have undergone secondary interventions (one for renal artery stenosis and the other to address a previously identified Type Ia endoleak that was contributing to aneurysm sac expansion at 4 years). Aneurysm sac increase was reported in three subjects at 4 years and two subjects through 5 years, all related to persistent Type II endoleaks. There have been no reports of migration, open surgical conversion, aneurysm rupture or aneurysm related mortality.

7. PATIENT SELECTION AND TREATMENT

7.1. PATIENT SELECTION

Physicians should evaluate each patient to determine if the **TREO® ABDOMINAL STENT-GRAFT SYSTEM** would be appropriate to treat their aneurysm according to the criteria as specified in the Indications For Use, including:

- Adequate iliac or femoral access compatible with the required delivery systems and accessories
- Proximal aortic landing zone with:
  - Infrarenal landing neck length of ≥ 15mm
  - Aortic neck diameters ≥ 17 mm and ≤ 32 mm
  - Suprarenal neck angle of ≤ 45 degrees
  - Infrarenal neck angle of ≤ 60 degrees
- Distal iliac landing zone with:
  - an inside diameter of 8 mm – 13 mm and a length of ≥ 10 mm or
  - an inside diameter of > 13 mm – 20 mm and a length of ≥ 15 mm
- Minimum overall AAA treatment length (proximal landing location to distal landing location) of 13 cm
- Minimum overall length from the lowest renal artery to the aortic bifurcation of 9 cm

Additional anatomic considerations for patient selection include the following:

- A total length of less than 49 cm length from infrarenal landing location to introducer vessel access site. Infrarenal landing neck having non-significant calcification or thrombus formation and having an outer diameter specified for the corresponding devices and neck anatomy listed in **Table 32a**.
- Infrarenal landing neck length of 15 mm or greater and an angle of ≤ 60 degrees relative to the long axis of the aneurysm (**Figure 11, Angle 1**) and a suprarenal neck angle of ≤ 45 degrees relative to the infrarenal neck axis (**Figure 11, Angle 2**) and an outer diameter specified for the corresponding devices and neck anatomy listed in **Tables 32a and 32b**.
- Distal iliac landing neck having non-significant calcification or thrombus formation, having a length and an outer diameter meeting the vessel size requirements specified for the corresponding devices in **Tables 33a** and **33b**.
- Distal aorta with sufficient diameter to accommodate Leg Extension Stent-Grafts. Diameter recommended to be >70% of the sum of the two diameters anticipated passing through the native aortic bifurcation zone.

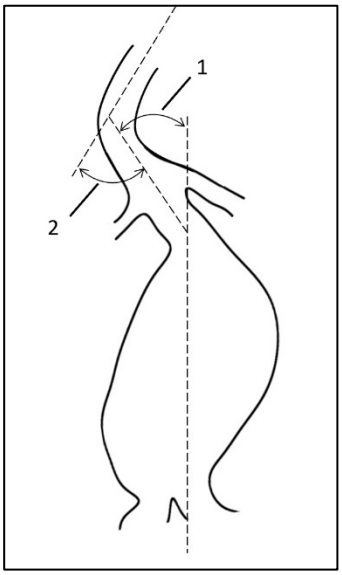


Figure 11. Proximal Neck Angle Definition

Additional considerations for patient selection when considering EVAR may include the following:

- Age and life expectancy
- Comorbidities such as cardiac, pulmonary, renal insufficiency, morbid obesity)
- Patient's suitability for endovascular repair
- Patient's suitability for open surgical repair
- Ability to tolerate general, regional, or local anesthesia.
- The device should not be used in patients unwilling or unable to comply with the recommended post procedure follow-up imaging.

7.2. TREO STENT-GRAFT SIZING

For patient specific device selection, the following criteria shall be followed:

- Select the appropriate device size based on artery outer diameter measurement taken from CT images. Diameters of the proximal and distal landing zones are needed.
- Length of the stent-grafts should take into account tortuosity of vessels and minimum overlap requirements.

Table 32a. Main Bifurcated Stent-Graft and Proximal Cuff Stent-Graft Diameters

Stent-Graft Proximal Diameter (mm)	Indicated Vessel Outer Diameter (Landing Zone)	Seal Zone Neck Length Requirement (Landing Zone)	Delivery System French Size (OD)	Delivery System Usable Length
20	17-18	15 mm	18 Fr	49 cm
22	18-19	15 mm		
24	19-21	15 mm		
26	21-23	15 mm		
28	23-25	15 mm		
30	25-27	15 mm	19 F	49 cm
33	27-30	15 mm		
36	30-32	15 mm		

Table 32b. Main Bifurcated Stent-Graft Lengths

Main Bifurcate Contralateral Length (mm)	Minimum Renal-Aortic Bifurcation Length Requirement (mm)	Main Body Length (mm)	Maximum Treatable Infrarenal Neck Length (mm)*
80	90	40	40
100	110	60	60
120	130	80	80

*Maximum infrarenal neck length restrictions do not apply if outer diameter of proximal neck is > 28mm.

Table 33a. Leg Extension Stent-Graft Sizes

Prox Graft Size (mm)	Distal Graft Size (mm)	Distal Vessel OD Size (mm) (Landing Zone)	Seal Zone Neck Length Requirement (Landing Zone)	Delivery System French Size (OD)					Delivery System Usable Length
				80mm Graft Length	100mm Graft Length	120mm Graft Length	140mm Graft Length	160mm Graft Length	
15	9	8	10 mm	13 Fr					80 cm
	11	9	10 mm						
	13	10-11	10 mm						
	15	12-13	10 mm						
	17	14-15	15 mm	14 Fr					
	20	16-17	15 mm						
	24	18-20	15 mm						

Table 33b. Straight Extension Stent-Graft Sizes

Proximal Graft Size (mm)	Distal Graft Size (mm)	Seal Zone Neck Length Requirement	Graft Length	Delivery System French Size (OD)	Delivery System Usable Length
9	9	10 mm	80mm	13 Fr	80 cm
11	11	10 mm			
13	13	10 mm			

Note: Straight Extension Stent-Grafts are only for use with previously placed Leg Extension Stent-Grafts with identical distal diameters.

8. PATIENT COUNSELING INFORMATION

The benefits and risks of the endovascular procedure using **TREO** should be discussed with patients, including the following:

- Patient age and life expectancy
- Risks and benefits related to open surgical repair
- Risks and benefits related to endovascular repair
- Risks and benefits related to **TREO** as compared to other marketed endovascular devices
- Risks related to non-interventional treatment or medical management
- Risks of aneurysm rupture compared to endovascular repair
- Possibility that subsequent endovascular or open surgical repair of the aneurysm may be required.
- The long-term safety and effectiveness of **TREO** has not been established
- Long-term, regular follow-up by a vascular specialist with periodic imaging is needed to assess patient health status and stent-graft performance
- Patients with specific clinical findings (e.g. endoleaks, enlarging aneurysms) should be monitored closely.
- Symptoms of aneurysm rupture

9. HOW PRODUCT IS SUPPLIED:

9.1. PACKAGE CONTENTS

- Each Stent-Graft is pre-loaded in its individual delivery system and packaged using a double pouch system with peel-open end seals.
- Each package contains a label describing the device details such as catalog number, diameter, length, delivery system size, etc.

9.2. STERILIZATION, STORAGE AND HANDLING

- The package contents of **TREO** have been sterilized by gamma irradiation. **TREO** is provided sterile for single use only. Do not re-sterilize any components of the system.
- Use prior to the "Use By" date specified on the package.
- Store the packaged **TREO** to avoid exposure to extreme temperatures and humidity.

The product is supplied with the following model designation identified on the label as shown in **Table 34**.

Table 34. Product Designation

Internal Code	Identifier	Internal Code	Stent Diameter*	Stent Length**	Device Designation
28	**B**: Main **B**ifurcated **C**: Proximal **C**uff **L**: **L**eg Extension **S: S**traight Extension	X	XX	XXX	**U**: Standard Catalog Product for US
** Stent diameter is for proximal diameter for Main Bifurcated Stent-Grafts. Stent diameter is for distal diameter for Leg Extension Stent-Grafts. Stent diameter is for both the proximal and distal diameters for Proximal Cuff Stent-Grafts and Straight Extension Stent-Grafts.* *** Stent length is for covered contralateral length on Main Body Bifurcated Stent-Grafts. Stent length is for total covered length on Proximal Cuff, Leg Extension and Straight Extension Stent-Grafts.*					

10. CLINICAL USE INFORMATION

10.1. PHYSICIAN TRAINING REQUIREMENTS

All physicians should be trained in the use of **TREO** before using it.

Caution:	• **TREO** should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.

A team trained in vascular surgery should be available while the implant procedure is in progress in case conversion to open surgery is required. In addition, the following are the knowledge and skill requirements for physicians using **TREO**:

- Knowledge of the natural history of abdominal aortic aneurysms (AAA), aortoiliac aneurysms, and comorbidities associated with AAA repair
- Knowledge of radiographic, fluoroscopic and angiographic image interpretation
- A multi-disciplinary team that has combined procedural experience with:
  - Appropriate use of radiographic contrast material
  - General arterial cut down, arteriotomy, and repair or percutaneous access and closure techniques
  - Nonselective and selective guidewire and catheter techniques
  - Embolization
  - Angioplasty
  - Endovascular stent placement/ Snare techniques
  - Techniques to minimize radiation exposure
  - Device selection and sizing
  - Expertise in necessary patient follow-up modalities.

10.2. CASE PRE-PLANNING AND INDIVIDUALIZATION OF TREATMENT

Practitioners using the **TREO® ABDOMINAL STENT-GRAFT SYSTEM** should have a thorough understanding of endovascular procedures and techniques. In particular, the **TREO® ABDOMINAL STENT-GRAFT SYSTEM** should only be used by physicians and teams with experience and training in vascular interventional techniques, including, but not limited to, training on the use of the **TREO® ABDOMINAL STENT-GRAFT SYSTEM**, as described in the preceding section. Selecting the proper graft with the appropriate length and diameter is paramount to the successful exclusion of the aneurysm/lesion and to minimize endoleaks and migration. Measure all parameters needed for proper sizing of the stent-graft carefully. Terumo Aortic recommends evaluation of all imaging studies available, i.e., angiograms, CT scans, MRI scans, MRA scans and plain radiographs. Each imaging modality offers additional information to the sizing process. The physical characteristics of the vessel should be evaluated in addition to its size. Factors such as stenosis, atherosclerotic disease, ectasia and tortuosity may affect Stent-Graft selection and placement strategy. The final Stent-Graft selection will be the responsibility of the physician.

10.3. DEVICE INSPECTION PRIOR TO USE

- Inspect the system packaging pouches for tears, punctures, breaks, or opening that would compromise the system sterility.

Warning:	• Do not use the system if the outer pouch has any punctures, tears or opening as this may have affected system sterility.

10.4. DEVICES, SUPPLIES AND EQUIPMENT REQUIRED

- **TREO** implants of appropriate sizes, including redundant components
- Fluoroscopic DSA equipment (ceiling/pedestal mounted or portable image intensifier on a freely angled C-arm). It is desirable if the image intensifier has a complete range of motion.
- Minimum 260cm Guidewire/0.035" [0.89mm] (Super Stiff)
- Arterial puncture needles 18G or 19G

- Assorted vascular introducers and angiographic catheters
- Contrast media
- Syringes
- Heparinized saline solution
- Sterile gauze pads

10.5. SUPPORTIVE/SUPPLEMENTARY EQUIPMENT:

- Inflation device with pressure gauge
- Guidewire torque devices
- Vascular Balloon-Catheters of the appropriate size
- PTA Balloons with diameters equivalent to the anatomical iliac diameters
- Gooseneck snare
- Extra Leg Extension Stent-Graft products allowing for different length options

10.6. MAGNETIC RESONANCE (MR) IMAGING SAFETY INFORMATION

MRI SAFETY INFORMATION

MR Conditional

Non-clinical testing demonstrated that the **TREO® ABDOMINAL STENT-GRAFT** is MR Conditional. A person with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the **TREO® ABDOMINAL STENT-GRAFT** is expected to produce a maximum temperature rise of less than 4ºC after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the **TREO® ABDOMINAL STENT-GRAFT** when imaged with a gradient echo pulse sequence and a 3 T MRI system. This artifact does not obscure the device lumen.

11. DIRECTIONS FOR USE

11.1. PATIENT AND DEVICE PREPARATION: (STEPS 1 THROUGH 4)

Warnings:	• Exercise care during handling and delivery to help prevent vessel rupture. • Excessive use of contrast agents, emboli or a misplaced stent-graft may result in renal complications. • When advancing the guidewires, catheters, and the **TREO** delivery system into the abdominal aorta, do not disturb the thrombus mass within the aneurysm. Doing so may dislodge emboli, which can cause distal embolization. If distal embolization should occur, use conventional treatment methods.

Cautions:	• Failure to use a 0.035" (0.89 mm) stiff guidewire may result in vessel trauma and compromise deliverability and/or performance of the delivery system. • Do not use power/pressure injections through the delivery systems.

Notes:	• Anticoagulation and anti-platelet therapies are used at the discretion of the physician. Similarly, arterial blood pressure adjustment and spinal cord protection measures are also at the discretion of the physician. • Position the patient on the surgical table where standard aseptic preparation of the surgical site is conducted. • Drape the patient with sterile surgical drapes leaving exposed the bilateral groin access sites.

1. Verify devices are correct for the patient.
2. Open the end of the product box and remove the system in its packaging pouches from the box.
3. Take the delivery systems out from the sterile packaging and bring them to the surgical table. Examine the delivery systems for structural integrity. DO NOT USE the system if defects are noted. It is recommended that the delivery system is analyzed under fluoroscopy to ensure that the physician understands the orientation of the prosthesis and configuration of the marker bands.
4. Perform a vascular access at the common femoral arteries. Introduce a .035" [0.89mm] stiff guidewire into each artery and advance them to the descending thoracic aorta.

11.2. MAIN BIFURCATED STENT – GRAFT DEPLOYMENT (STEPS 5 THROUGH 7)

The Main Bifurcated Stent-Graft is implanted first. It is recommended that the contralateral Leg Extension Stent-Graft is implanted second, and the ipsilateral Leg Extension Stent-Graft is implanted last.

5. Check the proximal end of the Main Bifurcated Stent-Graft Delivery System to ensure that the Main Bifurcated Stent-Graft Delivery System tip is properly aligned with the Outer Sheath. If the Main Bifurcated Stent-Graft Delivery System tip and sheath are not properly aligned as shown in **Figure 12**, the device should not be used.

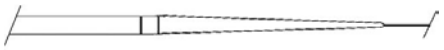


Figure 12. Sheath and Tip Alignment

6. Flush the guidewire flush port (**Figure 13**) with minimum of 5 cc of heparinized saline. Flush the Main Bifurcated Stent-Graft Delivery System with minimum of 20 cc of heparinized saline through the two-way flush port (**Figure 14**) to purge air from the inside of the sheath. Ensure that saline can be seen exiting from the tip area. Visually inspect the system for remaining air and repeat if necessary.

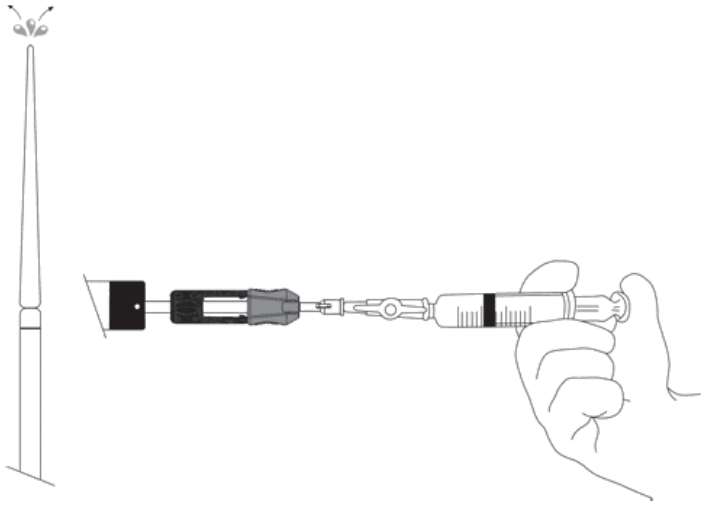


Figure 13. Flushing the Guidewire Lumen

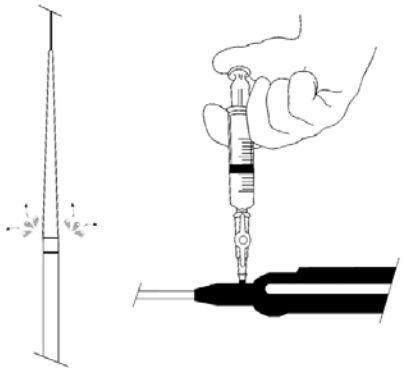


Figure 14. Flushing the Sheath

7. Activate the hydrophilic coating by wetting the Tip and Introducer Sheath with sterile saline.

11.3. INTRODUCTION/ADVANCEMENT OF MAIN BIFURCATED STENT-GRAFT (STEPS 8 THROUGH 10)

8. Advance the introducer sheath into the artery over the guidewire.

Note:	• The guidewire should always remain in the Main Bifurcated Stent-Graft Delivery System while inside the patient.

9. Under fluoroscopic monitoring, advance the Main Bifurcated Stent-Graft Delivery System until the sheath tip is near the deployment site in the aorta. Continue advancing while observing the radiopaque markers at the proximal end of the stent-graft. Advance until the proximal end of the stent-graft is at the deployment site. (**Figure 15**)

Cautions:	• Once the proximal position of the Main Bifurcated Stent-Graft has been identified, do not move the patient or imaging equipment, as it may compromise accuracy of prosthesis placement. • When aligning the position of prosthesis, be sure the fluoroscope is angled perpendicularly to the center line of the infrarenal aorta to avoid parallax or other source of visualization error that could impact proper positioning. Some proximal-distal angulation of the image intensifier tube may be necessary to achieve this, especially if there is anterior angulation of the aneurysm neck.

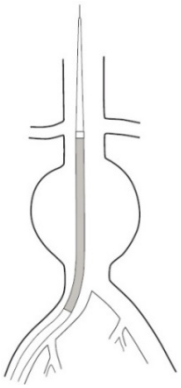


Figure 15. Main Bifurcated Stent-Graft Delivery System Advancement

10. The radial orientation of the stent-graft can be adjusted if desired. The system can be rotated using the Black Stationary Grip. The maximum and minimum radiopaque markers on the contralateral side of the Main Bifurcated Stent-Graft identify the location of the contralateral gate within the delivery sheath. It may be necessary to move the sheath to a straight area of the aorta to facilitate rotation. **(Figure 16**)

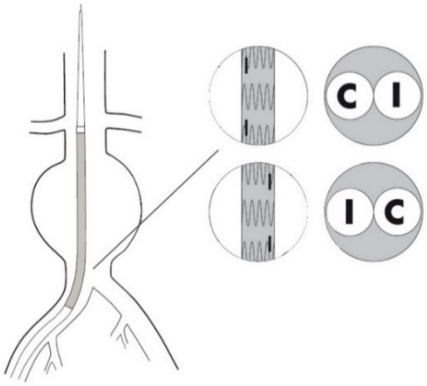


Figure 16. Identification of Ipsilateral and Contralateral Sides of Implant

11.4. DEPLOYMENT OF MAIN BIFURCATED STENT-GRAFT (STEPS 11 THROUGH 15)

Warnings:	• Prosthesis components cannot be re-sheathed or drawn back into the delivery system without compromising the system, even if the prosthesis component is only partially deployed. • Use fluoroscopic guidance to advance the delivery system and to detect kinking or alignment problems with the stent-graft system. Do not use excessive force to advance or withdraw the delivery system when resistance is encountered. If the delivery system kinks during insertion, do not attempt to deploy the stent-graft component. Carefully remove the device and insert a new delivery system. • Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification or tortuosity, or where excessive resistance is experienced, as vessel or catheter damage could occur. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system. Also exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity and/or angulation which can affect successful initial treatment of the aneurysm

Caution:	• Ensure that the delivery system handle and delivery system sheath are parallel with the patient's leg. Excessive angulation where the white handle meets the delivery system sheath may prevent delivery system sheath retraction.

Notes:	• Stent-Graft deployment should be done while observing the proximal end of the stent-graft under fluoroscopy. • Turn the gray turn knob in the direction of the arrow on the gray turn knob. Turning the gray turn knob in the wrong direction will not result in sheath retraction, although no damage will occur to the system. • Do not torque the Main Bifurcated Stent-Graft Delivery System more than 90° without confirming rotational response of the maximum and contralateral minimum overlap markers. • Before deployment ensure that the delivery system is straight and without any slack. • Be aware that the delivery system should not be bent without an appropriate guidewire inserted into the guidewire lumen. • Do not start deployment until the delivery system is accurately placed within the vasculature and ready for deployment. • When positioning the loaded delivery system, hold only the black stationary grip. • When deploying the prosthesis, be sure to hold the black stationary grip of the delivery system firmly against a stationary object (such as the patient's leg).

11. Holding the Black Stationary Grip so that the stent-graft does not move, rotate the Gray Turn Knob in the direction of the arrow to start the deployment of the stent-graft (**Figure 17**). Observe the proximal end of the stent-graft as it starts to expand, noting any longitudinal or radial movement that may require adjustment.

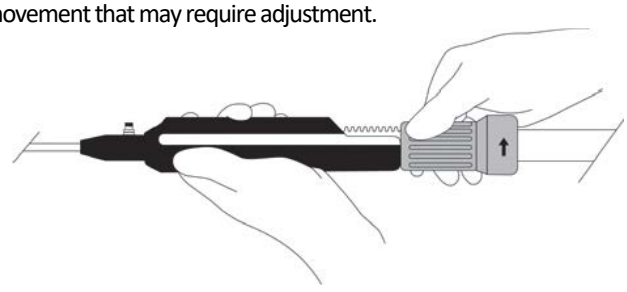


Figure 17. Main Bifurcated Stent-Graft Deployment Technique

12. Continue turning the Gray Turn Knob until the proximal stent is expanded. (**Figure 18**) At this time, if needed, adjust the longitudinal location of the stent-graft by moving the Black Stationary Grip as required.

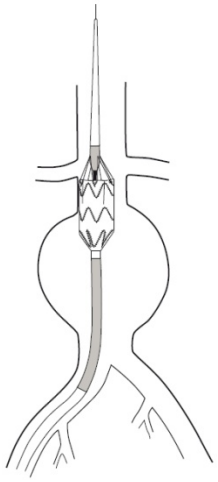


Figure 18. Initial Deployment of Main Bifurcated Stent-Graft

Warnings:	• Failure to position the bifurcate proximal edge markers within the healthy infrarenal aortic neck may result in prosthesis leaks or require a further procedure such as the placement of a Proximal Cuff. • Failure to position the proximal edge markers below the lowest renal ostium may result in occlusion of the renal arteries. • An inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent-graft. • Prosthesis migration or incorrect prosthesis deployment may require surgical intervention.

Caution:	• Prosthesis components cannot be re-sheathed or drawn back into the delivery system without compromising the system, even if the prosthesis component is only partially deployed.

13. Continue to deploy the stent-graft until the contralateral gate is exposed, leaving the sheath over the remaining stents on the ipsilateral side. (**Figure 19**). This secures the distal end of the Main Bifurcated Stent-Graft by still capturing the end of the ipsilateral gate.

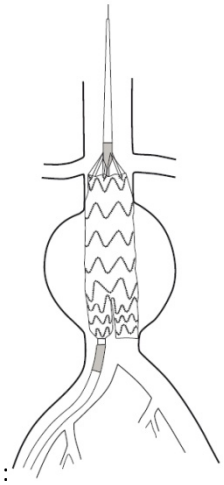


Figure 19. Deployment of Main Bifurcated Stent-Graft till Contralateral Gate is Exposed

Warnings:	• Do not rotate the black stationary grip once position has been confirmed and the stent-graft final deployment is started. • High pressure injections of contrast media made at the edges of the stent-graft immediately after implantation can cause endoleaks.

14. At this time, make any final longitudinal adjustments to the stent-graft by moving the Black Stationary Grip as required.
15. Release the bare stent using the clasp release mechanism. To do this, first push the grey thumb grip towards the handle body. This allows actuation of the clasp release mechanism (See **Figure 20-1 Step 1**). While the Gray Thumb Grip is pushed towards the handle body, turn the gray thumb grip in either direction approximately 90 degrees (See **Figure 20-1 Step 2**). At this point the Clasp Release mechanism should look like **Figure 20 -2**. At this time the bare stent has not yet been released from the clasp. In order to fully release the bare sent from the clasp, while holding the Main Bifurcated Stent-Graft Delivery System stationary, pull the Black Release Grip back over the Gray Thumb Grip until it is fully seated as shown in **Figure 21**.

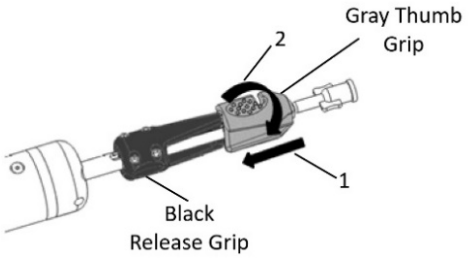


Figure 20-1. Steps 1 and 2 for Bare Stent Release

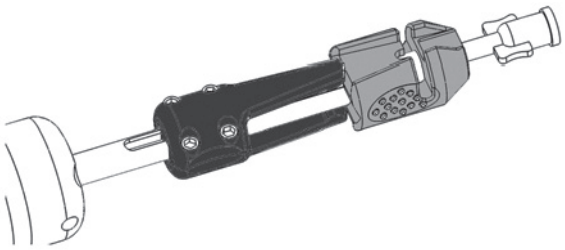


Figure 20-2. Position of Clasp Release Mechanism After Step 2 (*Note that the Bare Stent is STILL in Clasp*)

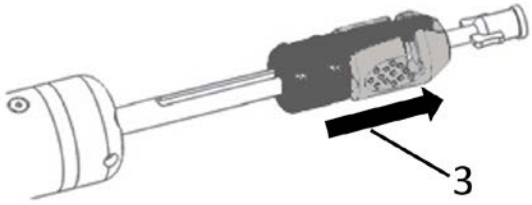


Figure 21. Fully Retracted Clasp Release

Warnings:	• Always use fluoroscopy to verify the prosthesis is completely released from the delivery system. Incomplete retraction of the delivery system sheath or incomplete retraction of the clasp release mechanism could lead to dislodgement of the prosthesis when the delivery system is removed from the patient. • Do not re-advance the clasp. Re-advancement of the clasp may cause capture of a bare stent strut resulting in an unintended movement of the stent-graft during system withdrawal. The device is designed to withdraw with the clasp fully open. The black release grip is locked in place when fully retracted over the gray thumb grips.

11.5. CONTRALATERAL LEG EXTENSION STENT-GRAFT DEPLOYMENT

11.5.1. Preparation of the Contralateral Leg Extension Stent-Graft Delivery System (steps 16 through 20)

16. Cannulate the contralateral gate of the Main Bifurcated Stent-Graft with a guidewire. Advance the guidewire and a catheter through the bifurcated stent-graft into the descending thoracic aorta.

17. Exchange the guidewire for a .035" super stiff wire, then remove the catheter while ensuring the super stiff wire remains in the descending thoracic aorta.

Note:	• Care should be taken to ensure the guidewire and catheter do not pass between the struts of the proximal bare stent.

18. Check the proximal end of the Leg Extension Stent-Graft Delivery System to ensure that the Leg Extension Stent-Graft Delivery System tip is properly seated in the outer sheath. If it is not seated properly as shown in **Figure 12**, the device should not be used.
19. Flush the guidewire flush port (**Figure 13**) with minimum of 5 cc of heparinized saline. Flush the Leg Extension Stent-Graft Delivery System with minimum of 20 cc of heparinized saline through the two-way flush port (**Figure 14**) to purge air from the inside of the sheath. Ensure that saline can be seen exiting from the tip area. Visually inspect the system for remaining air and repeat if necessary.
20. Activate the hydrophilic coating by wetting the tip and introducer sheath with saline.

11.5.2. Introduction/Advancement of the Contralateral Leg Extension Stent-Graft (steps 21 through 24)

Warning:	• Ensure the contralateral gate has been cannulated before contralateral iliac limb prosthesis deployment. Oblique imaging may be helpful in determining actual guidewire position relative to the gate opening. In the event that the contralateral gate is cannulated prior to placing the ipsilateral limb, ensure that the appropriate limb is cannulated prior to deployment.

21. Advance the introducer sheath into the artery over the super stiff guidewire.

Note:	• The guidewire should always remain in the delivery system while inside the patient.

22. Advance the Leg Extension Stent-Graft Delivery System through the contralateral gate of the Main Bifurcated Stent-Graft. Pay close attention as the tip of the Leg Extension Stent-Graft Delivery System advances into the contralateral gate to ensure that the Main Bifurcated Stent-Graft is not moved proximally. (**Figure 22**)

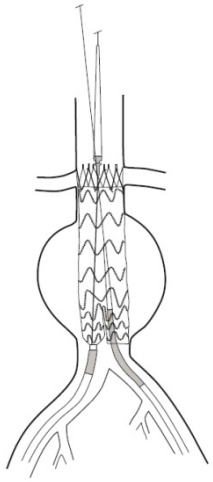


Figure 22. Advancement of Contralateral Leg Extension Stent-Graft Delivery System

23. Continue to advance the Leg Extension Stent-Graft Delivery System noting the markers on the proximal end of the Leg Extension Stent-Graft. The contralateral side of the Main Bifurcated Stent-Graft has two markers that indicate the overlap region. The radiopaque markers on the proximal end of the Leg Extension Stent-Graft must be advanced so that they are within these two markers. (**Figure 22**)
24. Once the proximal end markers of the Leg Extension Stent-Graft are past the minimum overlap marker on the contralateral side of the Main Bifurcated Stent-Graft, confirm that the distal markers of the Leg Extension Stent-Graft are aligned with the target distal landing location. Confirm the proximal markers of the Leg Extension Stent-Graft remain within the overlap zone. (**Figure 22**).

Warnings:	• Failure to position the Leg Extension Stent-Graft distal edge marker proximal to the internal iliac artery origin may result in occlusion of the internal iliac artery. • Failure to position the proximal markers of the Leg Extension Stent-Graft at or distal to the maximum overlap marker on the Main Bifurcated Stent-Graft could lead to blockage of the opposite gate. • Failure to position the proximal markers of the Leg Extension Stent-Graft at or proximal to the minimum overlap marker on the Main Bifurcated Stent-Graft could lead to modular dis-junction.

11.5.3. Deployment of the Contralateral Leg Extension Stent-Graft (steps 25 and 26)

Notes:	• Deployment of the Leg Extension Stent-Graft must be monitored under fluoroscopy at all times. • Once the first stent of the Leg Extension Stent-Graft is exposed, the Leg Extension Stent-Graft Delivery System should not be moved proximally.

25. Begin deployment of the Contralateral Leg Extension by turning the Gray Turn Knob (clockwise with the arrow – **Figure 17**). Closely monitor the expansion of the Leg Extension Stent-Graft under fluoroscopy to ensure proper location and adjust as necessary.
26. Continue the deployment of the Leg Extension Stent-Graft until the Leg Extension Stent-Graft is fully deployed. Confirm that the sheath tip is distal to the marker bands on the distal end of the stent-graft (**Figure 23**).

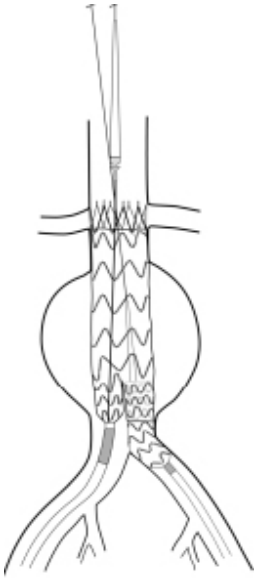


Figure 23. Deployment of Contralateral Leg Extension Stent-Graft

11.5.4. Contralateral Leg Extension Stent-Graft Delivery System Removal (Steps 27 through 36)

27. The Leg Extension Stent-Graft Delivery System may be removed completely or may be disassembled, allowing for the sheath to remain behind as a working catheter.
28. To remove the system completely, the tip may be reseated onto the introducer sheath using **steps 29-31**.
29. Once the stent-graft is completely out of the delivery sheath, rotate the Gray Turn Knob in the opposite direction of the arrow until it is completely seated against the end of the Lead Screw.
30. Holding the Gray Turn Knob stationary, bring the Black Stationary Grip back to the Gray Turn Knob.
31. At this point, the Leg Extension Stent-Graft Delivery System tip is now seated properly with the Leg Extension Stent-Graft Delivery System introducer sheath tip, and the entire delivery system can be removed.
32. To detach the introducer sheath of the Leg Extension Stent-Graft Delivery System, follow **steps 33 – 36**.
33. Ensure the Lead Screw is fully retracted by pulling the Gray Turn Knob all the way to the back end of the Leg Extension Stent-Graft Delivery System, such that the Lead Screw is against the end of the slot on the handle. It is not critical where the Gray Turn Knob is relative to the Lead Screw. (**Figure 24-1**)

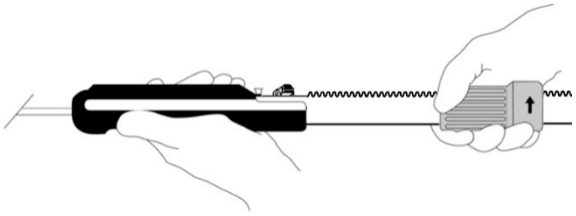


Figure 24-1. Full Retraction of Gray Turn Knob of Stent-Graft Delivery System

34. Flip over the sheath release lever, which is now exposed at the back end of the black stationary grip. The sheath release lever is fully flipped over when it clicks into place. (**Figure 24-2**)

Caution:	• Sheath release lever must be clicked into place prior to detaching delivery system from introducer sheath.

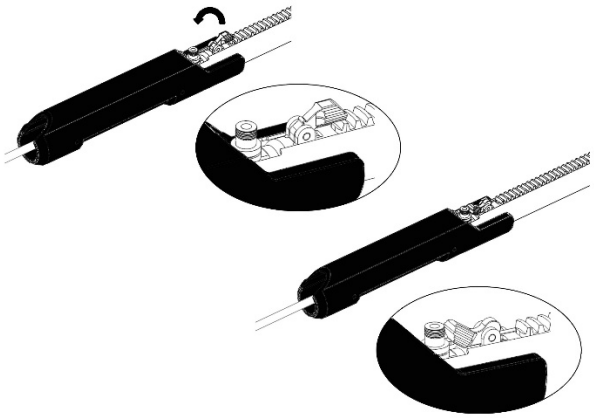


Figure 24-2. Sheath Detachment Mechanism. Ensure Sheath Release Lever is Fully Flipped Over

35. While holding the sheath with one hand, retract the Black Stationary Grip until the tip of the Leg Extension Stent-Graft Delivery System is seen at the hemostasis valve. It is advised that this be done under fluoroscopy to watch the tip of the Leg Extension Stent-Graft Delivery System as it is withdrawn through the Leg Extension Stent-Graft. A dry gauze pad may be helpful to hold the sheath and keep it from moving. (**Figure 25**)

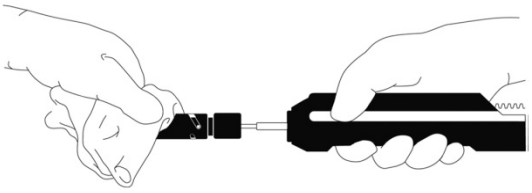


Figure 25. Removal of Stent-Graft Delivery System Leaving Introducer Sheath Behind

Caution:	• For cases involving the detachment of the sheath, ensure that the tip of the leave behind sheath remains within the access artery at all times.

Notes:	• If excessive force is needed, or if tip snags on any of the devices, stop and evaluate the situation before proceeding. • Non-straight catheters should be straightened with a guidewire prior to removal.

36. While continuing to remove the delivery system, be sure to maintain control of the guidewire. Once the tip of the delivery system has cleared the hemostasis valve, the valve may be turned clockwise to maintain hemostasis if necessary.

11.6. MAIN BIFURCATED STENT-GRAFT DEPLOYMENT COMPLETION

11.6.1. Main Bifurcated Stent-Graft Delivery System Handle Retraction (Step 37)

37. Release the ipsilateral side of the Bifurcated Stent-Graft by moving the Gray Turn Knob back until the Lead Screw is seated against the back end of the slot on the handle. (**Figure 24-1**)

11.6.2. Main Bifurcated Stent-Graft Delivery System Removal (Steps 38 through 47)

38. The Main Bifurcated Stent-Graft delivery system may be removed completely or may be disassembled, allowing for the introducer sheath to remain behind as a working catheter.
39. To remove the system completely, the tip may be reseated onto the introducer sheath using **steps 40-42**.
40. Once the Stent-Graft is completely out of the delivery sheath, rotate the Gray Turn Knob in the opposite direction of the arrow until it is completely seated against the end of the Lead Screw. Check to confirm that the bare stent clasp is still fully open.
41. Holding the Gray Turn Knob stationary, bring the Black Stationary Grip back to the Gray Turn Knob.
42. At this point, the Main Bifurcated Stent-Graft Delivery System tip is now seated properly with the Main Bifurcated Stent-Graft Delivery System introducer sheath tip, and the entire delivery system can be removed.
43. To detach the introducer sheath of the Main Bifurcated Stent-Graft Delivery System, follow **steps 44 – 47**.
44. Ensure the Lead Screw is fully retracted by pulling the Gray Turn Knob all the way to the back end of the delivery system, such that the Lead Screw is against the end of the slot on the handle. It is not critical where the Gray Turn Knob is relative to the Lead Screw. (**Figure 24-1**)
45. Flip over the sheath release lever, which is now exposed at the back end of the black stationary grip. The sheath release lever is fully flipped over when it clicks into place. (**Figure 24-2**)

Caution:	• Sheath release lever must be clicked into place prior to detaching delivery system from introducer sheath.

46. While holding the sheath with one hand, retract the Black Stationary Grip until the tip of the delivery system is seen at the hemostasis valve. It is advised that this be done under fluoroscopy to watch the tip of the delivery system as it is withdrawn through the Main Bifurcated Stent-Graft. A dry gauze pad may be helpful to hold the sheath and keep it from moving. (**Figure 25**)

Caution:	• For cases involving the detachment of the sheath, ensure that the tip of the leave behind sheath remains within the access artery at all times.

47. While continuing to remove the delivery system, be sure to maintain control of the guidewire. Once the tip of the delivery system has cleared the hemostasis valve, the valve may be turned clockwise to maintain hemostasis if necessary.

11.7. IPSILATERAL LEG EXTENSION STENT-GRAFT DEPLOYMENT

11.7.1. Preparation of the Ipsilateral Leg Extension Delivery System

48. The ipsilateral Leg Extension Stent-Graft is prepared and flushed in the same way as the Contralateral Leg Extension Stent-Graft (**steps 18 through 20**).

11.7.2. Introduction and Advancement of the Ipsilateral Leg Extension Delivery System Through Main Bifurcated Stent-Graft Delivery System Introducer Sheath (steps 49 through 52)

49. While holding the hemostasis valve with one hand, advance the Leg Extension Stent-Graft Delivery System over the wire until the tip of the Delivery System touches the hemostasis valve.
50. If closed, open the hemostasis valve by turning the knob counterclockwise. Insert the Leg Extension Delivery System through the hemostasis valve.
51. Continue to advance the Leg Extension Delivery System past the end of the introducer sheath while monitoring under fluoroscopy.
52. Advance the tip into the ipsilateral gate and into the Main Bifurcated Stent-Graft. Pay close attention as the tip of the Leg Extension Delivery System enters and advances into the Main Bifurcated Stent-Graft to ensure that the Main Bifurcated Stent-Graft is not moved proximally. (**Figure 26**)

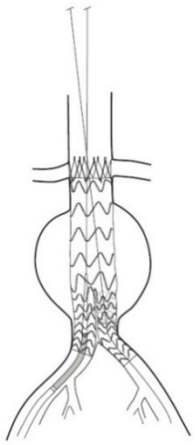


Figure 26. Advancement of Ipsilateral Leg Extension Delivery System into Main Bifurcated Stent-Graft

Note:	• The guidewire should always remain in the delivery system while inside the patient.

53. Continue to advance the Leg Extension Delivery System noting the radiographic markers on the proximal end. The Main Bifurcated Stent-Graft has two markers that indicate the overlap region for the ipsilateral Leg Extension Stent-Graft. The minimum overlap marker is located on the ipsilateral side of the Main Bifurcated Stent-Graft, while the maximum overlap marker is the same maximum overlap marker as used on the contralateral side. Once the proximal end markers of the Leg Extension Stent-Graft are past the minimum overlap marker on the ipsilateral side of the Main Bifurcated Stent-Graft, confirm that the distal markers of the Leg Extension Stent-Graft are aligned with the target distal landing location. Confirm the proximal markers of the Leg Extension Stent-Graft remain within the overlap zone.

Warnings:	• Failure to position the Leg Extension Stent-Graft distal edge marker proximal to the internal iliac artery origin may result in occlusion of the internal iliac artery. • Failure to position the proximal markers of the Leg Extension Stent-Graft at or distal to the maximum overlap marker on the Main Bifurcated Stent-Graft could lead to blockage of the opposite gate. • Failure to position the proximal markers of the Leg Extension Stent-Graft at or proximal to the minimum overlap marker on the Main Bifurcated Stent-Graft could lead to modular dis-junction.

Note:	• The distal radiographic markers on the Leg Extension Stent-Graft must be beyond the end of the Main Bifurcated Introducer Sheath. If not, retract the Main Introducer Sheath while holding the Leg Extension Delivery System so that it does not move until the Main Introducer Sheath clears the distal markers of the Leg Extension Stent-Graft.

11.7.3. Deployment of the Ipsilateral Leg Extension Stent-Graft (steps 54 and 55)

Note:	• Deployment of the Leg Extension Stent-Graft must be monitored under fluoroscopy at all times.

54. Begin deployment of the Ipsilateral Leg Extension Stent-Graft by turning the Gray Turn Knob (clockwise with the arrow – (**Figure 17**). Closely monitor the expansion of the Leg Extension Stent-Graft under fluoroscopy to ensure proper location and adjust slowly as necessary. (**Figure 27**)

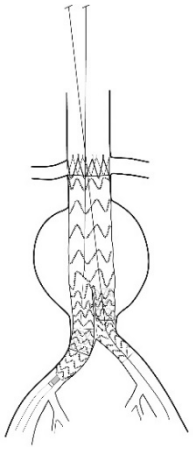


Figure 27. Full Deployment of Ipsilateral Leg Extension Stent-Graft

Note:	• Once the first stent of the Leg Extension Stent-Graft is exposed, the Leg Extension Delivery System should not be moved proximally.

55. Continue the deployment of the Leg Extension Stent-Graft while observing the distal markers on the Leg Extension Stent-Graft to ensure the sheath clears both. (**Figure 27**)

11.7.4. Ipsilateral Leg Extension Delivery System Removal (steps 56 through 58)

56. Once the stent-graft is completely out of the delivery sheath, rotate the Gray Turn Knob in the opposite direction of the arrow until it is completely seated against the end of the Lead Screw.
57. Holding the Gray Turn Knob stationary, bring the Black Stationary Grip back to the Gray Turn Knob.

58. At this point, the delivery system tip is now seated properly with the sheath tip, and the entire delivery system can be removed, and the system is fully deployed. (**Figure 28**)

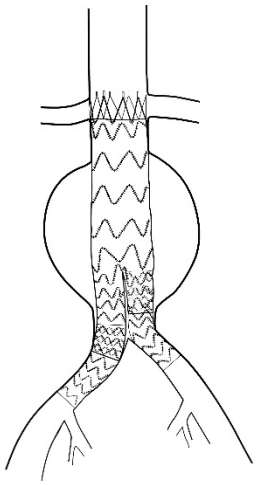


Figure 28. Fully Deployed TREO System

11.8. POST IMPLANT PROCEDURE (STEPS 59 THROUGH 64)

59. Balloon molding of the proximal and distal seal zones, as well as along the length of the limb extensions including the modular overlap, is recommended.
60. Kissing balloon technique should be considered in the areas of the prosthesis flow divider as well as in the area of the native aortic bifurcation.

Warnings:	• Endovascular techniques such as kissing balloons should be considered in the graft flow divider and native aortic bifurcation zone as the anatomy warrants. • It is recommended that balloon modeling be done with a compliant balloon. Balloon inflation should not exceed 1 atm. • Over inflation of compliant balloon can cause graft tears and/or vessel dissection or rupture. • When expanding the prostheses, there is an increased risk of vessel injury and/or rupture, and possible patient death, if the compliant balloon's proximal and distal radiopaque markers are not completely within the covered (graft fabric) portion of the prosthesis. • Do not expand the bare proximal stent of the Main Bifurcated Stent-Graft as expansion of the bare proximal stent may cause vessel injury or rupture and the balloon could snag onto the bare proximal stent of the Main Bifurcated Stent-Graft.

Cautions:	• Be careful not to displace the prostheses upon introducing and retracting the compliant balloon catheter. • Always recheck position of stent-graft following ballooning. • Care should be taken when inflating the compliant balloon, especially with calcified, tortuous, stenotic, or otherwise diseased vessels. • Inflate the compliant balloon slowly. It is recommended that a backup compliant balloon be available.

61. Perform a final angiogram to assess for endoleaks, migration and aneurysm/lesion exclusion.
62. If a Type I endoleak is detected, consider balloon modeling to correct the endoleak. A Proximal Cuff device may also be considered to treat Type I endoleaks. For Proximal Cuff deployment see **steps 65 through 72**.
63. Remove all catheters and sheaths from the access sites and perform standard surgical closure of the arteriotomy sites.
64. Assess blood flow to the distal extremities.

11.9. PROXIMAL CUFF STENT-GRAFT DEPLOYMENT

The **TREO** system includes a Proximal Cuff Stent-Graft that can be used to extend the system proximally. It also may help to resolve Type I endoleaks. The stent-graft uses the same type of delivery system as the Main Bifurcated Stent-Graft, and is implanted in the same way as the Main Bifurcated Stent-Graft. The proximal extension is available in the same diameters as the Main Bifurcated Stent-Graft and in three lengths, 40 mm, 55 mm and 70 mm.

11.9.1. Proximal Cuff Stent-Graft Delivery System Preparation

65. The Proximal Cuff Stent-Graft Delivery System is prepared in the same way as the Main Bifurcated Stent-Graft Delivery System (**steps 5 through 7**).

11.9.2. Introduction and Advancement of Proximal Cuff Stent-Graft Delivery System (Steps 66 and 67)

Note:	• The Main Bifurcated Stent-Graft Delivery System sheath must be removed prior to introducing the Proximal Cuff.

66. While holding and directing the tip and introducer sheath with one hand and holding the Black Stationary Grip with the other hand, advance the introducer sheath into the artery over the guidewire.

Caution:	• Advancing the Proximal Cuff must be fluoroscopically monitored to ensure that the deployed stent-grafts are not moved by the Proximal Cuff Stent-Graft Delivery System.

Note:	• The guidewire should always remain in the delivery system while inside the patient.

67. Under fluoroscopic monitoring, advance the sheath until the delivery system tip is near the deployment site in the aorta. Continue advancing while observing the markers at the proximal end of the stent-graft. Advance until the proximal end of the stent-graft is at the deployment site.

Note:	• Ensure that there is enough overlap between the Proximal Cuff and Main Bifurcated Stent-Graft by ensuring that the distal marker on the Proximal Cuff is at least 3 cm distal to the Main Bifurcated Stent-Graft's proximal markers.

11.9.3. Deployment of Proximal Cuff Stent-Graft (Steps 68 through 72)

Caution:	• Stent-graft deployment should be done while observing the proximal end of the stent-graft under fluoroscopy.

Note:	• The Proximal Cuff is deployed in the same way as the Main Bifurcated Stent-Graft.

68. Holding the Black Stationary Grip, rotate the Gray Turn Knob clockwise (in direction of arrow on the Turn Knob) to start the deployment of the Proximal Cuff. Observe the proximal end of the Proximal Cuff as it starts to expand, noting any movement of the Proximal Cuff that may have occurred.
69. Once the Proximal Cuff's position is confirmed, continue to deploy the stent-graft until the sheath tip is distal to the end of the Proximal Cuff and allowing full expansion of the Proximal Cuff. This part of the deployment can be done by continuing to turn the Gray Turn Knob or pinning the Black Stationary Grip and pulling the Gray Turn Knob, without turning, as would be done in a typical "pin and pull" system.
70. Release the bare stent using the clasp release mechanism as described in **step 15** using **Figures 20-1**, **20-2** and **21**.
71. Rotate the Gray Turn Knob counterclockwise (opposite direction of arrow) as far as it will go. Then, pull back the Black Stationary Grip while holding the Gray Turn Knob stationary. The tip will move through the stent-grafts and must be monitored under fluoroscopy to ensure that the stent-grafts are not moved.
72. Continue pulling on the Black Stationary Grip until the tip is re-seated on the sheath and pull the Proximal Cuff Stent-Graft Delivery System out from the patient.

11.10. DEPLOYMENT OF ADDITIONAL LEG EXTENSION OR STRAIGHT EXTENSION STENT-GRAFTS

Warnings:	• When extending Leg Extension Stent-Grafts that have distal diameters of 9, 11 or 13mm, only Straight Extension Stent-Grafts of the same diameter may be used. (**Table 33b**). • Using a Leg Extension Stent-Graft device from **Table 33a** when extending a 9, 11 or 13mm Leg Extension may lead to limb thrombosis. • When extending Leg Extension Stent-Grafts of 15, 17, 20 or 24mm, Leg Extension Stent-Grafts with the same distal diameter may be used. (**Table 33a**).

Notes:	• Stent-graft deployment should be done while observing the proximal end of the stent-graft under fluoroscopy. • In cases where the physician wishes to extend the seal zone in the iliac artery additional Leg Extension or Straight Extension Stent-Grafts may be used.

73. The Leg Extension and Straight Extension Stent-Graft Delivery Systems are identical. Therefore, deployment of either a Leg Extension or Straight Extension Delivery Stent-Graft to extend the seal zone in the iliac artery should be done following **steps 54 thru 57**.

Note:	• After use, all components used, and packaging materials may be a potential biohazard. Handle and dispose of in accordance with the accepted medical practice and with applicable local, state and federal laws and regulations.

12. BAIL OUT TECHNIQUE

In the unlikely event of an inability to release the proximal bare stent the following bail out technique may be used:

- There is a slot open near the clasp release grip identified by the hash marks below in **Figure 29**. Inside this slot there is a green tube that can be accessed by a pair of forceps. This green tube is directly attached to the clasp release mechanism and can be pulled directly in the event that the full retraction of the clasp release mechanism does not fully release the bare stent.

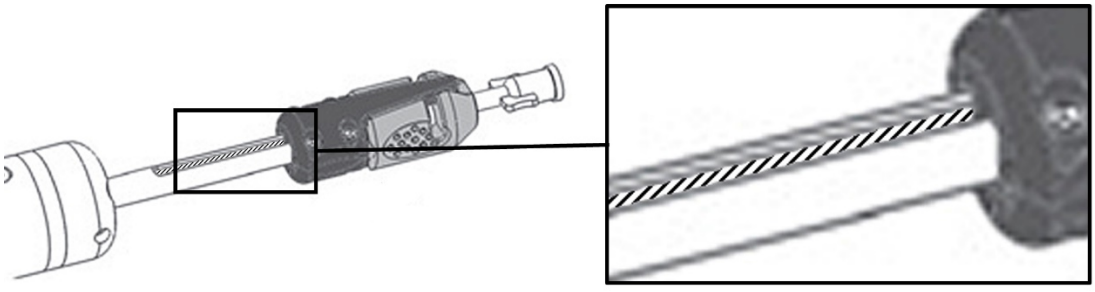


Figure 29. Identification of Slot in Main Bifurcated or Proximal Cuff Stent-Graft Delivery System

13. FOLLOW UP PROCEDURE

13.1. GENERAL

Current recommended imaging of stent-graft patients includes abdominal X-ray and CT, with and without contrast medium. Alternative imaging modalities such as magnetic resonance imaging should be used in patients with impaired renal function or intolerance to contrast media. Imaging should be decided based upon the physician's clinical assessment of the patient pre- and post-implantation of the stent-graft. After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. At a minimum, baseline post-procedure imaging within 30 days following implant along with annual imaging is recommended, including:

- Abdominal radiographs to examine device integrity (stent fracture, separation between the Main Bifurcated Stent-Graft, Proximal Cuff Stent-Graft or Leg Extension Stent-Grafts, if applicable), and
- Contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide alternative means of providing some of this information.

13.2. X-RAY

Abdominal X-rays should be used to assess the presence of stent fracture. Four-view kidney, ureter, bladder (KUB) X-rays should be taken. Posterior/anterior (PA) and lateral images are recommended for visualization of the stent-graft. Ensure the entire device is captured on images for device assessment.

13.3. CT WITH CONTRAST

Contrast-enhanced CT should be used to assess stent-graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent-graft migration, stent-graft patency, AAA size, occlusion of branch vessels, and endoleak (including source and type if present). A pre-contrast scan of 5 mm thick slices is suggested to determine if there are calcifications or areas where metal artifacts may be misinterpreted as endoleak. Arterial and venous phase spiral CT scans with <3 mm slice thickness and overlapping images with coverage from the celiac artery to the common femoral artery beyond the end of the prosthesis are recommended. The venous phase scan may also be performed with thicker collimation (5 mm).

It is recommended that the source data set be archived in case specialized evaluation is needed later (volume measurements, 3-dimensional reconstruction, or computer-aided measurement software). If the aneurysm is not shrinking by more than 5 mm within the first year, volume measurements may be obtained as a more sensitive indicator of AAA size using 3-dimensional software. Patients who are allergic to contrast should be pre-medicated 12-24 hours prior to receiving the drug.

13.4. NON-CONTRAST CT

For patients with impaired renal function or those who are allergic to contrast medium, a spiral CT without contrast may be considered to assess stent-graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent-graft migration, occlusion of vessels, and size of the AAA diameter and volume measurements.

13.5. DUPLEX ULTRASOUND

For patients with impaired renal function or those who are allergic to contrast medium, a color- duplex ultrasound may be considered to assess size of AAA diameter, endoleaks, and stent-graft occlusion and stenosis.

13.6. MRI OR MRA

Patients with impaired renal function, i.e., renal insufficiency, may also be considered for magnetic resonance imaging or angiography (MRI, MRA) in facilities that have expertise in this area. Artifact may occur related to the stent, and care should be used to ensure adequate imaging of the outer aneurysm wall to assess AAA size. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed.

13.7. SUPPLEMENTAL IMAGING

Note: Additional radiological imaging may be necessary to further evaluate the stent-graft *in-situ* based on findings revealed by one of the surveillance programs. The following recommendations may be considered.

- If there is evidence of poor or irregular position of the stent-graft, severe angulation, kinking or migration of the stent-graft on abdominal X-rays, a spiral CT should be performed to assess aneurysm size and the presence or absence of an endoleak.
- If a new endoleak or increase in AAA size is observed by spiral CT, adjunctive studies such as 3-D reconstruction or angiographic assessment of the stent-graft and native vasculature may be helpful in further evaluating any changes of the stent-graft or aneurysm.
- Spiral CT without contrast, MRI or MRA may be considered in select patients who cannot tolerate contrast media or who have renal function impairment. For centers with appropriate expertise, gadolinium or CO2 angiography may be considered in patients with renal function impairment requiring angiographic assessment.

14. ADDITIONAL SURVEILLANCE AND TREATMENT

Additional endovascular repair or open surgical aneurysm repair should be considered for patients with an increase in AAA size of more than 5mm or evidence of sub-optimal fixation, proximal endoleak, distal endoleak, junction endoleak, or unknown origin of peri-graft flow.

15. DISCLAIMER OF WARANTY

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16. PATENTS

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17. DEFINITIONS

	Manufacturer
	Date of Manufacture
	Use By
	Model/Catalogue Number
	Lot Number
	MR Conditional
	Sterilized by Irradiation
	Do not Re-Sterilize
	Do not Re-use
	Caution: Consult Accompanying Documents
	Consult Instructions for use
	Store in a cool, dry place
	Do not use if package is damaged

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