RELAY® PRO

THORACIC STENT-GRAFT SYSTEM

Bare Stent and Non-Bare Stent Configuration
INSTRUCTIONS FOR USE
(IFU)

TERUMO
Aortic

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1. RELAY®PRO THORACIC STENT-GRAFT SYSTEM DEVICE DESCRIPTION

The **Relay®Pro THORACIC STENT-GRAFT SYSTEM (RelayPro)** is an endovascular device intended to treat fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta. The stent-graft is preloaded into its own delivery system that is advanced under fluoroscopy to the location of the aneurysm. The stent-graft is deployed at the intended location and creates a flow path for blood, excluding the aneurysm from blood pressure and flow.

The **RelayPro Stent-Graft** is available in two proximal configurations: the **proximal bare stent** and **non-bare stent (NBS)**. A description of both proximal configurations is provided below.

1.1. STENT-GRAFT

The **RelayPro Stent-Graft** is constructed of a series of sinusoidal self-expanding Nitinol stents sewn to a tubular woven polyester fabric. These stents are spaced along the entire length of the graft fabric to provide radial support and allow for the self-expansion of the stent-graft. A spiraled ("S" shaped) Nitinol strut, called the Spiral Support Strut, is sewn to the proximal section of the graft fabric to provide longitudinal support. The stents and the Spiral Support Strut are sewn to the graft fabric with surgical suture. Radiopaque markers are placed on the stent-graft to aid visualization and accurate placement **(Figure 1)**. These radiopaque markers are made of platinum iridium alloy and indicate the fabric proximal and distal edges as well as the position of the Spiral Support Strut.

The **bare stent configuration** includes a proximal bare stent that is mainly uncovered. The proximal bare stent is intended to facilitate the alignment of the proximal end of the stent-graft within the aortic lumen. The height of the bare stent varies depending on the graft diameter to optimize the alignment of the stent-graft. The distal end of the stent-graft consists of a stent fully covered with the graft fabric.

The **non-bare stent configuration (NBS)** is similar in design to the bare stent configuration with a few exceptions. Rather than a proximal bare stent, the NBS most proximal stent, called the crown stent, is fully covered with the graft fabric. The crown stent is designed to provide circumferential support to the proximal edge of the graft fabric. The midsection and distal end of the NBS stent-graft is the same as the bare stent configuration. If the lesion requires use of an extension, **only** a RelayPro NBS configuration may be used.

The **RelayPro Stent-Grafts** are available in diameters ranging from 24 – 46 mm and covered lengths from 90 – 259 mm. The implants are also available in straight and tapered size offerings. Refer to **Table 24, Table 25, Table 26** and **Table 27** for stent-graft diameters.

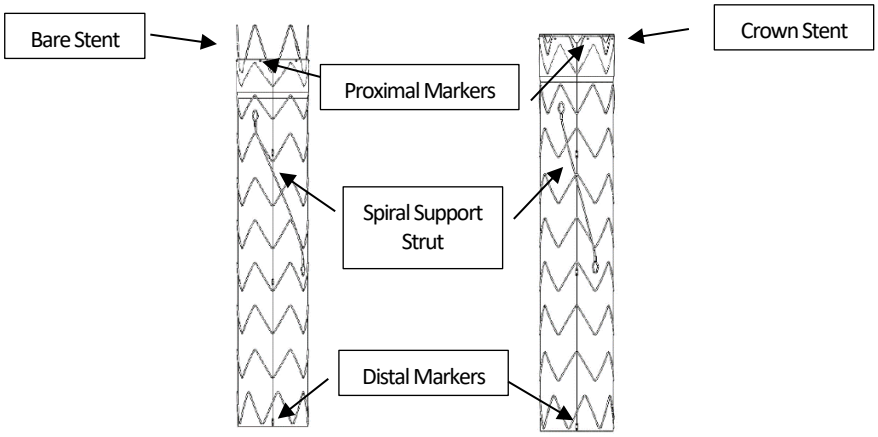


Figure 1: RelayPro Thoracic Stent-Graft (Bare and NBS Configurations)

The **RelayPro Stent-Graft** does not contain any natural rubber latex; however, during the manufacturing process, it may have incidental contact with latex. **Table 1** provides a summary of the materials of the **RelayPro Stent-Grafts.**

Table 1. RelayPro Stent-Graft Materials

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

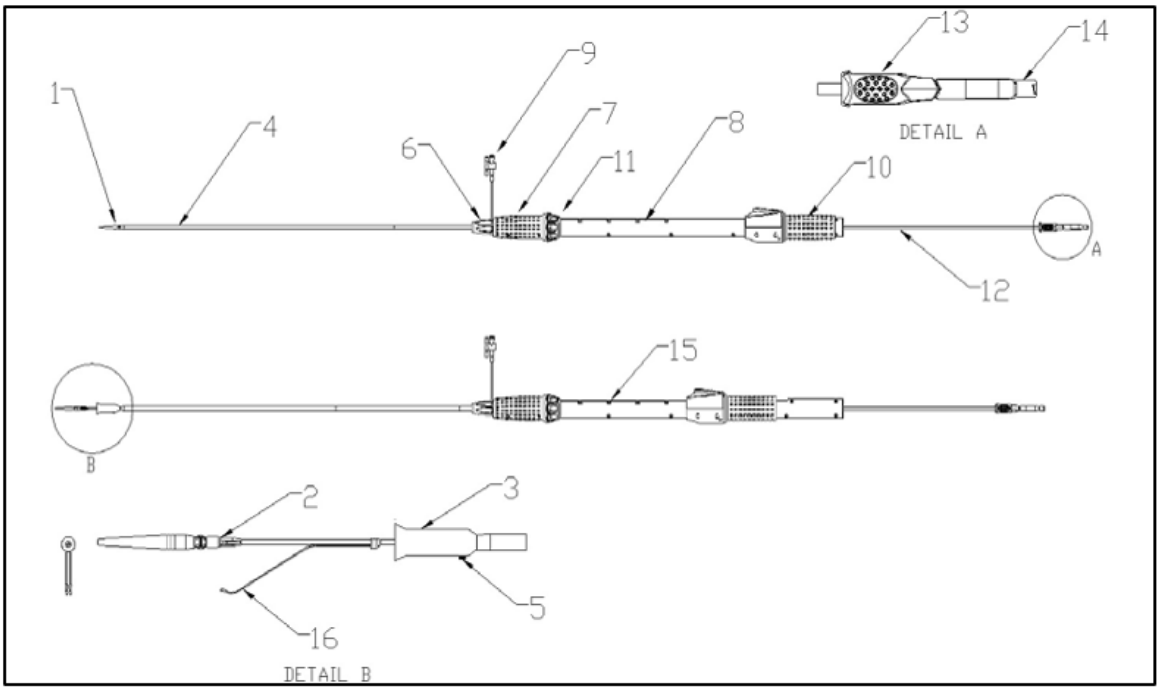
1.2. DELIVERY SYSTEM

The delivery system consists of a series of coaxially-arranged sheaths and catheters attached to a handle body assembly. The delivery system introducer (outer) sheath diameter ranges from 19Fr to 22Fr depending on the stent-graft diameter. The outer sheath and the delivery system tip have a hydrophilic coating. Also, the tip of the outer sheath and the delivery system tip are radiopaque for visibility under fluoroscopy. The delivery system has a working length of 90cm and is designed to track over a 0.035" (0.89 mm) guidewire.

The delivery system uses a combination of two sheaths to deliver the stent-graft to the treatment site. The first sheath, also called the outer sheath, is used to track through the access vessel and is advanced to the distal portion of the treatment site. The second sheath, also called the inner sheath, is made of fabric and has a diameter larger than the outer sheath. The stent-graft is loaded in the inner sheath and the inner sheath with the stent-graft are loaded inside the outer sheath. Once the outer sheath is positioned distal to the treatment site the inner fabric sheath with the stent-graft are advanced to the proximal landing zone. The outer sheath remains stationary while the inner sheath is advanced to the proximal landing zone and during the deployment process. The implant is deployed by pulling back on the inner sheath.

The **RelayPro** delivery system **(Figure 2**) offers a mechanical advantage to aid with the advancement and retraction of the inner sheath. The mechanical advantage can be bypassed and re-engaged anytime during use. The delivery system operates by turning the deployment grip when using the mechanical advantage or by pushing or pulling the deployment grip when the mechanical advantage is disengaged.

The delivery systems used for the **RelayPro bare stent** and **NBS configurations** are functionally and operationally equivalent. There are minor differences to accommodate the NBS configuration which do not change the mode of operation. The two Nitinol wires, called support wires, control the expansion of the inferior portion of the stent-graft. The support wires are attached to the delivery system catheter at one end. The other end of the support wires are atraumatic teardrop-shaped and are tethered to the inferior portion of the graft with loops of suture. The support wires control the expansion of the proximal end of the stent-graft to ensure proper apposition against the anatomical inner curvature and are for NBS graft diameters 32mm to 46mm only. In addition, the design of Item 2 in **Figure 2** (apex holder) differs slightly between the configurations and the NBS delivery system introducer (outer) sheath diameter ranges up to 23Fr depending on the stent-graft diameter.



1. Delivery System Tip
2. Apex Holder
3. Inner Sheath
4. Outer Sheath
5. Radiopaque Marker
6. Front Nose Cap
7 Gray Grip
8. Handle Body
9. Flush Port
10. Deployment Grip
11. Controller
12. Stainless Steel Rod
13. Apex Holder Knob
14. Guidewire Luer
15. Arrow Marker
16. Support Wire (Non-Bare Stent only)

Figure 2. RelayPro Delivery System

2. INDICATIONS FOR USE

The **RelayPro THORACIC STENT-GRAFT SYSTEM** is indicated for the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- Non-aneurysmal aortic neck diameter in the range of 20 – 42 mm;
- Non-aneurysmal proximal aortic neck lengths of:
  - 15 mm for the 24 – 28 mm device diameters (***Bare Stent Configuration***)
  - 20 mm for the 30 – 38 mm device diameters (***Bare Stent Configuration***)
  - 25 mm for the 40 – 46 mm device diameters (***Bare Stent Configuration***)

  - 25 mm for the 24 – 38 mm device diameters (***Non-Bare Stent Configuration)***
  - 30 mm for the 40 – 46 mm device diameters (***Non-Bare Stent Configuration)***
- Non-aneurysmal distal aortic neck lengths of:
  - 25 mm for the 24 – 38 mm device diameters
  - 30 mm for the 40 – 46 mm device diameters

3. CONTRAINDICATIONS OF USE FOR THE RELAYPRO SYSTEM

The **RelayPro THORACIC 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 **RelayPro** requires that physicians be specially trained in endovascular thoracic aortic aneurysm repair techniques, including experience with high resolution fluoroscopy and radiation safety. Terumo Aortic will provide training specific to the **RelayPro** 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.
- Key anatomic criteria that may affect successful exclusion of the aneurysm includes a proximal landing zone with an inner radius of curvature less than 15mm, a proximal landing zone and distal landing zone based on device selection defined in **Section 7.2**. The treatment site should be within the working length of the delivery system (90cm).
- Proximal and distal landing zones need to be considered. They are specified in **Table 23** and **Table 24**.
- **RelayPro** 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.
- **RelayPro** 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.
- Excessive arterial tortuosity and/or disease may result in not being able to reach the treatment site or result in the stent-graft kinking.

- Arterial tortuosity and/or excessive arterial disease may preclude delivery system entrance or passage and result in not being able to reach the treatment site.
- Significant or circumferential calcification or mural thrombus in the landing zones may adversely impact sealing.
- Placement of stent-grafts in the aortic arch often requires proximity to the left subclavian or left common carotid arteries. The distal landing area of the stent-graft may be close to the celiac artery. Care should be taken to not block these critical arteries during device deployment, with the exception of planned coverage of critical arteries. The proximal end of the covered **RelayPro** stent-graft should not be placed beyond the origin of the left common carotid artery.
- If occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition or bypass of the left subclavian artery may be warranted.
- Care should be taken with respect to occlusion of intercostals/spinal cord arteries.
- Coverage of the left subclavian artery (LSA) is at the discretion of the physician as is monitoring of blood flow at the level of the vertebral or cerebral arteries and the retrograde blood flow at the LSA.
- 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 aortic aneurysms and penetrating atherosclerotic ulcers in the descending thoracic aorta 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.**
- **RelayPro** 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 aortic endoprostheses.
- Practitioner must ensure that the access vessel diameter is compatible with the selected delivery system's outer sheath French size and that the aortic inner diameter that can accommodate the expanded inner sheath outer diameter of approximately 10 mm.

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

- are less than 18 years old
- are pregnant
- have a dissection, transection or ruptured aneurysm in the thoracic aorta
- have false aneurysms and diffuse intramural hematomas
- have had a stroke and/or myocardial infarction within 3 months of the planned treatment date
- have coronary artery disease with unstable angina
- have severe congestive heart failure (New York Heart Association functional class IV)
- have anatomic variants which may compromise circulation to the carotid, vertebral or innominate arteries after device placements, and are not amenable to subclavian revascularization
- have a lesion that cannot be crossed by a guide wire
- 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 landing zones
- have significant or circumferential calcification or mural thrombus within the treatment length, which may adversely impact device patency
- have a blood coagulation disorder the treatment for which cannot be suspended pre- and post-repair
- have a creatinine > 2.5 mg/dL
- have had a prior TAA repair (endovascular or surgical) in the descending thoracic aorta
- would require placement of the RelayPro within any prior endovascular or surgical graft
- have concomitant aneurysm/disease of the ascending aorta, aortic arch or abdominal aorta requiring repair

- have had prior abdominal aortic aneurysm repair (endovascular or surgical) that was performed less than 6 months prior to the planned stent implant procedure
- 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 **RelayPro** 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. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death. Also, each single-use device carries specific labeling instructions relative to storage, use, and handling to minimize exposure to conditions that could compromise the product, the patient, or the user. These conditions cannot be assured once the packaging is opened and discarded.
- 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 or emboli may result in renal complications.
- Ensure that the delivery system handle body and outer sheath are parallel with the patient's leg. Excessive angulation where the handle body meets the outer sheath may impair the functionality of the device.
- 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 inner sheath is accidentally withdrawn exposing the prosthesis, the device will prematurely deploy and may be incorrectly positioned.
- Failure to position the prosthesis within healthy tissue (non-aneurysmal and without evidence of circumferential thrombus, intramural hematoma, dissection or ulceration) may result in prosthesis leaks or vessel damage, including perforation.
- Always use fluoroscopy to visually confirm that the stent-graft's distal marker bands can be seen approximately 2 cm outside of the outer sheath. This ensures the inner sheath has completely exited from the outer sheath. Retraction of the inner sheath prior to fully exiting the outer sheath could lead to incomplete deployment of the stent-graft.
- Always use fluoroscopy to verify the prosthesis is completely released from the delivery system. Incomplete retraction of the inner 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.
- An inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent-graft.
- Ensure that the **RelayPro** devices are placed in a landing zone consisting of healthy tissue. Healthy tissue is non-aneurysmal and is without evidence of circumferential thrombus, intramural hematoma, dissection, or ulceration. Failure to place the stent-graft in healthy tissue could lead to inadequate exclusion or vessel damage, including perforation.
- 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.
- If balloon modeling is desired, use a compliant balloon. Balloon inflation should not exceed 1 atm. Inflate the balloon inside the covered portion of the stent-graft. Failure to do so could lead to aortic rupture, atherosclerotic plaque embolization or other complications. Over inflation of a semi or non-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. Ballooning outside the covered portion could cause aortic rupture, atherosclerotic plaque embolization, or other complications.ggest clarifying 'balloon expand'
- ***Bare Stent Configuration****:* Do not balloon expand the bare proximal stent of the stent-graft as expansion of the bare proximal stent may cause vessel injury or rupture and the balloon could snag on the bare proximal stent.
- Be careful not to displace the prostheses upon introducing and retracting the compliant balloon catheter.
- Balloon modeling is not required; however, if it is deemed necessary, excessive arterial blood pressure may lead to dislodging the stent-graft from its intended location.
- 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.
- Placement of stent-graft in the thoracic aorta often requires proximity to the great vessels perfusing the brain, increasing the possibility of thrombus or embolization proximally. Care should be taken to ensure air has been purged from the system.
- Do not bend or kink the delivery system as it may cause damage to not only the delivery system but also the **RelayPro** stent-graft.
- Stop advancing the guidewire or delivery system if resistance is encountered. Assess the source of the resistance before proceeding to avoid vessel or catheter damage.
- Wire fractures are more likely to occur in conditions with an excessively oversized stent-graft, flexion, kinking, or bending during cardiac or respiratory cycles. Fractures of the Spiral Support Strut are more likely to occur if the strut is deployed along the inner radius of curvature. Wire fractures may have clinical consequences including endoleak, migration, or tissue damage.
- Endoleaks detected at the conclusion of the procedure and not corrected should be carefully monitored after implantation.
- Do not attempt to reposition the **RelayPro** stent-graft once it has opposed the vessel wall. Inadvertent partial deployment or migration of the **RelayPro** stent-graft may require surgical removal.
- Inaccurate placement and/or incomplete sealing of the **RelayPro** stent-graft within the vessel may result in increased risk of endoleak, migration, or inadvertent occlusion of the left subclavian, left common carotid, and/or celiac arteries. Surgical intervention may be required.
- Deploying the device in a portion of the aorta with a different diameter than planned when selecting the graft size may potentially result in inadequate sizing and therefore migration, endoleak, aneurysm growth, or increased risk of thrombosis.

4.5. TREATMENT AND FOLLOW UP

- The long-term performance of **RelayPro** 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, or stent-graft migration should prompt further investigation and may indicate the need for additional intervention.

- Patients experiencing reduced blood flow through the stent-graft or due to endoleaks may be required to undergo secondary interventions or surgical procedures.
- Additional treatment including endovascular treatment or surgical procedure should be strongly considered in the following cases:
  - aneurysm growth > 5 mm, with or without endoleak,
  - persistent Type I/III endoleak, with or without aneurysm growth,
  - persistent Type II endoleak with aneurysm growth, and/or
  - stent-graft migration.
- Following thoracic endovascular aneurysm repair (TEVAR), 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 RESONANCE IMAGING (MRI) SAFETY INFORMATION

Nonclinical testing has demonstrated that **RelayPro** 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	
Access Failure	Incision site complications
Allergic Reaction (to contrast, antiplatelet therapy, stent-graft materials)	Infection / Sepsis
Amputation	Intercostal pain
Anesthetic reactions/complications (e.g., aspiration)	Intramural Hematoma
Aneurysm Sac Enlargement	Ischemia (spinal cord, perfusion pathways)
Aneurysm / Lesion Rupture	Limb ischemia
Angina	Lymphocele
Aortic damage (perforation, dissection, bleeding, rupture)	Neuropathy
Arteriovenous fistula / aorto-esophageal fistula	Pain
Blindness	Paralysis/Paresthesia/Paraparesis/Paraplegia
Blood Loss	Perforation
Bowel complications (e.g., adynamic ileus, transient ischemia, infarction, obstruction, necrosis)	Peripheral Nerve injury
Cardiac events (e.g., arrhythmia, tachyarrhythmia, cardiac tamponade, congestive heart failure, myocardial infarction, hypotension, hypertension, tachycardia, bradycardia)	Post Implantation Syndrome
Catheter Breakage	Post-procedural bleeding
Cerebral vascular accident (stroke)	Pseudoaneurysm
Change in mental status	Pulmonary complications
Claudication (e.g., buttock, lower limb)	Pulmonary embolism

Table 2. Potential Adverse Events	
Coagulopathy	Radiation overexposure or reaction
Compartment Syndrome	Reaction to anesthesia
Contrast toxicity / anaphylaxis	Reaction/pain at catheter insertion site
Conversion to Open Repair	Renal failure or Complications
Death	Reoperation
Delivery system failure	Seizure
Deployment failure (partial or inaccurate deployment)	Seroma
Device Dehiscence	Shock
Device Insertion or Removal Difficulty	Stenosis of native vessel
Dysphagia	Stent fracture / break
Edema	Stent-Graft failure (e.g., improper component placement, graft material wear or tear, suture break, dilatation, erosion, graft twisting or kinking, puncture, perigraft flow)
Embolism (micro and macro) with transient or permanent ischemia or infarction	Stent-Graft Infection
Endoleak	Stent-Graft migration
Fever and localized inflammation	Tissue necrosis
Fistulas	Transient Ischemic Attack
Gastrointestinal complications	Vascular Spasm
Genitourinary complications (e.g., ischemia, erosion, femoral-femoral artery thrombosis, fistula, incontinence, hematuria, infection)	Vascular Trauma (perforation / dissection)
Hematoma (surgical)	Vessel Damage
Hemorrhage	Vessel Dissection
Hepatic failure	Vessel Occlusion/Thrombosis
Impotence	Wound complications (dehiscence, infection, hematoma, seroma, cellulitis)

5.2. ADVERSE EVENT REPORTING

Any adverse event or clinical incident involving the **RelayPro THORACIC 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 **RelayPro THORACIC STENT-GRAFT SYSTEM** in subjects with fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta. The study was a multi-center, prospective, single-arm, non-randomized, and non-blinded investigation. One hundred and ten (110) subjects were treated between May 10, 2017 and June 24, 2019 at 36 investigational sites (25 in the United States and 11 in Japan). Subjects are being followed at 1 month, 6 months, 12-months, and annually thereafter for 5-years.

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:

- Death
- Myocardial infarction
- Stroke, excluding transient ischemic attack (TIA)
- Renal failure
- Respiratory failure
- Paralysis, excluding paraparesis
- Bowel ischemia
- Procedural blood loss >1,000 cc

The primary safety endpoint was compared to a performance goal of 20%. The performance goal was based on the Pivotal Study results from the RelayPlus Pivotal Study (P110038).

The hypothesis tested for the primary safety endpoint at a one-sided alpha level of 0.05 was:

Null hypothesis (H_0): $p \geq 0.20$

Alternative Hypothesis (H_A): $p < 0.20$

where p is the proportion of RelayPro subjects with at least one major adverse event through 30-days post implant procedure and 20% was the performance goal for the endpoint.

The primary safety objective will be met if the upper limit of the 95% one-sided exact confidence interval of the 30-day primary safety endpoint rate is below 20%.

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

- Technical success through 24 hours post-procedure, defined as:
  - Successful delivery of the device through the vasculature
  - Successful deployment of the device at the intended location
  - Absence of Type I or III endoleak
  - Patent stent-graft without significant stenosis (>50%)
- Stent-graft patency through 12 months;
- Absence of aneurysm rupture through 12 months;
- Absence of Type I or III endoleak at 12 months;
- Absence of stent fractures in the attachment zone through 12 months;
- Absence of open or endovascular secondary interventions related to the device or treated pathology through 12-months;
- Absence of aneurysm expansion (>5 mm diameter increase) through 12 months, compared to the first post-procedural computed tomographic (CT) imaging study;
- Absence of stent-graft migration (> 10 mm) through 12 months, compared to the first post-procedural CT.

The primary effectiveness endpoint will be compared to a performance goal of 80%. The performance goal was based on the Pivotal Study results from the RelayPlus Pivotal Study (P110038).

The hypotheses that will be tested for the primary effectiveness endpoint at a one-sided level of 0.05 is:

Null hypothesis (H_0): $p \leq 0.80$

Alternative Hypothesis (H_A): $p > 0.80$

where p is the proportion of RelayPro subjects with successful aneurysm treatment at 12-months post-procedure and 80% is the

performance goal.

The primary effectiveness objective will be met if the lower limit of the 95% one-sided exact confidence interval of the 12-month primary effectiveness endpoint rate is above 80%.

6.2.2. Sample Size

The sample size for **RelayPro THORACIC STENT-GRAFT SYSTEM** Pivotal Study was driven by the primary effectiveness endpoint.

Primary Effectiveness Endpoint

Based on the same RelayPlus historical data, the estimated rate for the primary effectiveness endpoint is 92.1%. Using the Exact Binomial Test and assuming a power of 96%, a one-sided alpha of 0.05, and a performance goal of 80%, the sample size needed is 88 subjects. Assumimg 20% attrition, the sample size needed is 110 subjects.

With the assumed attrition rate, a final sample size of 110 subjects satisfied the power requirements for both the primary safety and effectiveness endpoints.

Secondary Endpoints

Secondary endpoints include the following:

- Intervention-Free Technical Success defined as:
  - Successful delivery of the device through the vasculature (i.e. ability to deliver the implant to the intended location without the need for unanticipated corrective intervention related to delivery);
  - Successful and accurate deployment of the device defined as:
    - deployment of the endovascular stent-graft in the planned location;
    - patency of the endovascular stent-graft, absence of device deformations (e.g. kinks, stent eversion, maldeployment, misaligned deployment) requiring unplanned placement of an additional device within the endovascular stent-graft, and;
  - Successful withdrawal (i.e. successful withdrawal of the delivery system, without the need for unanticipated corrective intervention related to withdrawal)
- All-cause mortality and lesion-related mortality through 1-month, 6-months, 12-months and annual through 5 years;
- Loss of stent-graft patency through 1-month, 6-months, 12-months and annual through 5 years;
- Decreased stent-graft lumen diameter through 1-month, 6-months, 12-months and annual through 5 years);
- Aneurysm rupture through 1-month, 6-months, 12-months and annual through 5 years;
- All endoleaks, evaluated individually, at 1 month, 6-months, 12 months and annual through 5 years;
- Stent fractures through 1-month, 6-months, 12-months and annual through 5 years;
- Incidence of open or endovascular secondary interventions related to the device or treated pathology to treat a condition involving the study device and/or the aneurysm treated with the study device through 1-month, 6-months, 12-months and annual through 5 years;
- Aneurysm expansion (> 5 mm diameter increase) at 6-months, 12-months and annual through 5 years compared to the first post- procedural CT;
- Stent migration (> 10 mm) at 6-months, 12-months and annual through 5 years compared to the first post-procedural CT;
- Thromboembolic events attributed to the stent-graft through 1-month, 6-months, 12-months and annual through 5 years;
- Individual outcomes of the composite safety endpoints through 6- months, 12-months and annual through 5 years;
- All adverse events through 6-months and 12-months
- Device-related adverse events through 5 years;
- Vascular access complications at the index procedure;

- Clinical utility measures, including duration of procedure, transfusions required, length of hospital stay, and time in ICU.

6.3. PATIENTS

Patients enrolled in the Pivotal Study met the following criteria:

- Age ≥18 years.
- Subject has any of the following conditions in his/her descending thoracic aorta:
  - Aneurysm ≥ 5.0 cm in diameter;
  - Aneurysm ≥ 4.0 cm in diameter with an increase of ≥0.5 cm within the last 6 months or ≥1.0 cm over the last 12 months;
  - Aneurysm with maximum diameter exceeding two times the diameter of the non-aneurysmal, adjacent aorta;
  - Saccular aneurysm;
  - PAU within the DTA with a depth of 10 mm or more.
- Proximal and distal aortic neck with diameter between 20 mm and 42 mm.
- Proximal landing zone distal to the left common carotid and a distal landing zone proximal to the origin of the celiac artery; the lengths of which are dependent on the diameter and type of the device.
- Proximal and distal landing zones containing a straight segment (non-tapered, non-reverse-tapered, defined by <10% diameter change) with lengths equal to or greater than the required landing length for the intended device.
- Adequate iliac or femoral artery access for introduction of the Relay Delivery System. Alternative methods to gain proper access may be utilized (e.g., iliac conduit).
- Subject willing to comply with the follow-up evaluation schedule.
- Subject (or Legally Authorized Representative, LAR) agrees to sign an Informed Consent Form prior to treatment.

Patients were excluded from enrollment in the Pivotal Study if they had any of the follow anatomic or physiologic characteristics:

- Acute or chronic aortic dissection within the ascending aorta, arch or descending thoracic aorta.
- Diffuse intramural hematoma (current or previous).
- Traumatic aortic injury or transection.
- Aortic false aneurysm.
- Ruptured aneurysm.
- Significant stenosis (>50%), calcification, thrombus, or tortuosity of intended fixation sites that would compromise fixation or seal of the device.
- Anatomic variants which may compromise circulation to the carotid, vertebral, or innominate arteries after device placement, and are not amenable to subclavian revascularization.
- Prior endovascular or surgical repair in the descending thoracic aorta.
- The device may not be placed within any prior endovascular or surgical graft.
- Concomitant aneurysm/disease of the ascending aorta, aortic arch, or abdominal aorta requiring repair.
- Prior abdominal aortic aneurysm repair (endovascular or surgical) that was performed less than 6 months prior to the planned stent implant procedure.
- Major surgical or medical procedure within 45 days prior to the planned procedure, or is scheduled for a major surgical or medical procedure within 45 days post implantation. This excludes any planned procedures for the prospective stent-graft placement.
- Untreatable allergy or sensitivity to contrast media or device components.
- Known or suspected connective tissue disorder.
- Blood coagulation disorder or bleeding diathesis for which the treatment cannot be suspended for one week pre- and/or post-repair.
- Coronary artery disease with unstable angina.
- Severe congestive heart failure (New York Heart Association functional class IV).
- Stroke and/or MI within 3 months of the planned treatment date.
- Pulmonary disease requiring the routine (daily or nightly) need for oxygen therapy outside the hospital setting.

- Acute renal failure or renal insufficiency with a creatinine ≥ 2.5 mg/dL, unless stable on dialysis.
- Active systemic infection and/or mycotic aneurysms.
- Morbid obesity or other condition that may compromise or prevent the necessary imaging requirements.
- Less than two-year life expectancy.
- Current or planned participation in an investigational drug or device study that has not completed primary endpoint evaluation.
- Currently pregnant or planning to become pregnant during the course of the study.
- Medical, social, or psychological issues that Investigator believes may interfere with treatment or follow-up.

All patients enrolled in the Pivotal Study met the selection criteria based on site-reported imaging measurements.

6.4. STUDY RESULTS

6.4.1. Subject Accountability and Follow-Up

Of 110 subjects enrolled in the PMA study, all 110 subjects were implanted with the RelayPro Stent-Graft System and seen through discharge. All but one subject (109/110, 99.1%) completed the 30-day visit (minimum of 96.4% with imaging adequate to assess endovascular graft parameters). Ninety-six subjects (of 108 eligible subjects) completed the 6-month visit with at least 83.3% of imaging adequate to assess endovascular grafts parameters.

At 12-months, 93 of the 105 eligible subjects (88.6%, 93/105) returned for the follow-up visit with at least 81% of imaging adequate to assess aneurysm diameter, endoleak, migration and fracture. At 2-years, 48 of the 91 eligible subjects returned for the follow-up visit with 38 subjects (41.8%, 38/91) still within the follow-up window. At 3-years, 4 subjects of the 19 eligible subjects have completed the follow-up visit. Compliance and imaging follow-up are provided in **Table 3** below.

Table 3. Summary of Compliance and Core Lab Imaging Follow-Up

	Subject Follow-Up				Imaging Performed[d]		Imaging Adequate to Assess the Parameter†				Events Occurring Within Window‡				
Analysis Window	Eligible[a]	Follow-up done[c]	Pending*	Still in Window	CT Scan	X-Ray	Diameter	Endoleak	Migration	Fracture	Death	Lost to follow-up	Early Withdrawal	Other[b]	Not yet due
Procedure	110	NA	NA	NA	NA	NA	NA	NA	NA	NA	0	NA	NA	NA	0
30 Days	110	99.1% (109)	0.9% (1)	0% (0)	99.1% (109)	97.3% (107)	98.2% (108)	96.4% (106)	99.1% (109)	97.3% (107)	2	0	0	0	0
6 Months	108	88.9% (96§)	11.1% (12)	0% (0)	89.8% (97)	85.2% (92)	89.8% (97)	83.3% (90)	89.8% (97)	89.8% (97)	2	1	0	0	0
12 Months	105	88.6% (93)	12.4% (13)	0% (0)	87.6% (92)	88.6% (93)	87.6% (92)	81.0% (85)	87.6% (92)	88.6% (93)	1	2	5	3	3
2 Years	91	52.7% (48)	47.3% (43)	41.8% (38)	50.5% (46)	46.2% (42)	50.5% (46)	45.1% (41)	50.5% (46)	50.5% (46)	3	1	3	0	65
3 Years	19	21.1% (4)	78.9% (15)	78.9% (15)	21.1% (4)	21.1% (4)	21.1% (4)	21.1% (4)	21.1% (4)	21.1% (4)	0	0	0	0	17

	Subject Follow-Up				Imaging Performed[d]		Imaging Adequate to Assess the Parameter†				Events Occurring Within Window‡				
Analysis Window	Eligible[a]	Follow-up done[c]	Pending*	Still in Window	CT Scan	X-Ray	Diameter	Endoleak	Migration	Fracture	Death	Lost to follow-up	Early Withdrawal	Other[b]	Not yet due

NA – Not Applicable

[a] Eligible subjects are all subjects who are enrolled by snapshot date and either have a follow-up visit form or are past due for their follow-up (beyond upper limit of window on study and did not exit the study before the upper limit of the window).

[b] Subjects choose to not reconsent to the study follow up extension.

[c] Subjects with follow-up data according to the investigational site.

[d] Subjects with CT scan data as determined by the Core Lab.

*Subjects who did not have a visit within the window or subjects who did not have a visit but have not yet reached the end of the analysis window. The number of subjects eligible for the visit is used as the denominator when calculating the percentage of visits performed.

† Sac Diameter and Migration assessments use 1 month as baseline. Eligible subjects require valid value at 1 month and at the specified time point.

‡ 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 or early withdrawal.

§ One subject had no site follow-up data but has CT data available; therefore, there are 96 subjects with follow-up completed, and 97 subjects with CT imaging available.

6.4.2. Subject Demographics

The demographics of the study population are typical for a thoracic endovascular graft study performed in the US. In the study, 62.7% of subjects were males (69/110) with 54.5% of the cohort being 75+ (60/110). Additionally, 39.1% (43/110) of the pivotal cohort was Asian and 49.1% (54/110) were white.

Regarding the Japan and US cohorts of the RelayPro Pivotal Study, the Japan cohort was older (mean 78.5 vs. 72.6) and consisted of a higher percentage of male subjects (78.6%, 33/42 vs. 52.9%, 36/68) as compared to the US cohort. The US cohort was predominantly white (79.4%, 54/68).

Table 4. Summary of Subject Demographics

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Sex				
Female	% (n)	47.1% (32)	21.4% (9)	37.3% (41)
Male	% (n)	52.9% (36)	78.6% (33)	62.7% (69)
Age (years) at Treatment	Mean ± SD	72.6 ± 8.5	78.5 ± 6.6	74.9 ± 8.3
	Median (IQR)	73 (67 - 78.5)	81 (73 - 83)	76 (70 - 81)
	Min - Max	45 - 92	65 - 94	45 - 94
Age Group				
18-64	% (n)	14.7% (10)	0% (0)	9.1% (10)
65-74	% (n)	41.2% (28)	28.6% (12)	36.4% (40)
75+	% (n)	44.1% (30)	71.4% (30)	54.5% (60)
Ethnic Group				
Hispanic/Latino	% (n)	4.4% (3)	0% (0)	2.7% (3)

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Not Hispanic/Latino	% (n)	85.3% (58)	100.0% (42)	90.9% (100)
Not Reported	% (n)	10.3% (7)	0% (0)	6.4% (7)
Race				
Asian	% (n)	1.5% (1)	100.0% (42)	39.1% (43)
Black	% (n)	19.1% (13)	0% (0)	11.8% (13)
White	% (n)	79.4% (54)	0% (0)	49.1% (54)

6.4.3. Baseline Medical History

Baseline subject comorbidities are presented in the **Table 5.** The most common comorbidities observed include hypertension and/or treatment for hypertension (86.4%, 95/110), hypercholesterolemia (64.5%, 71/110), history of smoking (81.8%, 90/110), history of peripheral vascular disease (18.2%, 20/110), documented COPD (29.1%, 32/110), history of neurologic disease (20%, 22/110), diabetes mellitus (19.1%, 21/110), and renal insufficiency (19.1%, 21/110).

Regarding the US and Japan cohorts of the RelayPro Pivotal Study, a larger proportion of subjects in the US cohort had history of peripheral vascular disease (26.5% vs. 4.8%), documented myocardial infarction (16.2% vs. 9.5%), documented COPD (33.8% vs. 21.4%), hypercholesterolemia (69.1% vs. 57.1%), and history of GI complications (35.3% vs. 21.4%). A larger proportion of subjects in the Japan cohort had diabetes mellitus (26.2% vs. 14.7%) and renal insufficiency (21.4% vs. 17.6%).

Table 5. Summary of Subject Comorbidities

Comorbidity	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
History of Peripheral Vascular Disease	26.5% (18)	4.8% (2)	18.2% (20)
Coronary Artery Disease			
Stable Angina	7.4% (5)	9.5% (4)	8.2% (9)
Unstable Angina	1.5% (1)	0% (0)	0.9% (1)
Myocardial Infarction	16.2% (11)	9.5% (4)	13.6% (15)
Arrhythmias	13.2% (9)	0% (0)	8.2% (9)
Congestive Heart Failure	5.9% (4)	2.4% (1)	4.5% (5)
Other	25.0% (17)	2.4% (1)	16.4% (18)
Chronic Obstructive Pulmonary Disease	33.8% (23)	21.4% (9)	29.1% (32)
Routine (daily/nightly) home oxygen use	0% (0/23)	11.1% (1/9)	3.1% (1/32)
History of Neurologic Disease	20.6% (14)	19.0% (8)	20.0% (22)
Diabetes Mellitus	14.7% (10)	26.2% (11)	19.1% (21)
Hypertension (HTN) and/or Treatment of HTN	88.2% (60)	83.3% (35)	86.4% (95)
Hypercholesterolemia	69.1% (47)	57.1% (24)	64.5% (71)
History of Smoking	83.8% (57)	78.6% (33)	81.8% (90)
Former Smoker	56.1% (32/57)	97.0% (32/33)	71.1% (64/90)
Current Smoker	43.9% (25/57)	3.0% (1/33)	28.9% (26/90)
Renal Insufficiency	17.6% (12)	21.4% (9)	19.1% (21)
Current Antiplatelet/ Anticoagulant Medication	66.2% (45)	40.5% (17)	56.4% (62)
History of Limb Ischemia	7.4% (5)	7.1% (3)	7.3% (8)
History of Vascular Intervention	23.5% (16)	28.6% (12)	25.5% (28)
History of Gastrointestinal Complications	35.3% (24)	21.4% (9)	30.0% (33)

Comorbidity	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Cholecystitis	4.4% (3)	0% (0)	2.7% (3)
Ischemic Colitis	1.5% (1)	0% (0)	0.9% (1)
GI Bleed	2.9% (2)	2.4% (1)	2.7% (3)
Small Bowel Ischemia	0% (0)	0% (0)	0% (0)
History of Impotence (males only)	16.7% (6/36)	3.0% (1/33)	10.1% (7/69)
All values expressed as % (n). Site reported data.			

6.4.4. Baseline Aneurysm Characteristics

Baseline aneurysm and anatomical measurements, as well as access vessel characteristics of the study population, were reported by both the Core Lab and the site. The clinical sites and Core Lab evaluated 100% (110/110) of the baseline contrast CT scans. Baseline aneurysm characteristics are summarized in **Table 6** below**.**

All subjects enrolled in this study met the inclusion criteria based on site-reported CT measurements. Subject eligibility was confirmed by the Core Lab prior to enrollment. There were minor differences observed between the Core Lab and the site measurements. The majority of the measurements including proximal neck inner length, lesion length, diameter of proximal neck, maximum lesion diameter, diameter if distal next (proximal) and access vessels (r/l common iliac, r/l external iliac, r/l femoral) showed minor variance in averages that are likely attributed to measurement technique. Distal neck length and total treatment length showed larger variances between site reported and Core Lab measurements. Sites reported distal neck length as 41.0 ± 21.9mm compared to 78.7 ± 50.1mm from the Core Lab and total treatment length of 197.1 ± 75.3mm verse 284.8 ± 64.5mm. This difference may be attributed to measurement technique and/or site concern for minimized coverage to avoid ischemia.

There were no substantial differences between the US cohort and the Japan cohort related to the baseline aneurysm and anatomical measurements. There were minor differences with proximal neck length and aneurysm length between the two cohorts. The Japan cohort had a longer length from LCC to proximal end of proximal neck (37.0 ± 42.0mm vs. 19.4 ± 17.3mm) and proximal neck length - centerline (75.0 ± 36.8mm vs. 64.9 ± 36.3mm) and inner curve (56.3 ± 30.6mm vs. 47.8 ± 31.4mm). Aneurysm length was longer for the US cohort (104.4 ± 59.0 vs. 85.0 ± 40.3mm). All other measurements were comparable.

Of the 110 subjects enrolled in the study with aneurysms, 76 were fusiform aneurysms (45 US and 31 Japanese patients) and 34 were saccular aneurysms or PAUs, site reported assessment.

Table 6. Core Laboratory – Reported Baseline CT Measurements

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Slice Thickness	Mean ± SD	1.5 ± 0.7	1.7 ± 0.8	1.6 ± 0.8
	Median (IQR)	1.3 (1.0 - 2.0)	1.5 (1.0 - 2.0)	1.3 (1.0 - 2.0)
	Min - Max	0.5 - 3.0	0.5 - 3.0	0.5 - 3.0
Aortic Diameter at LCC (mm)	Mean ± SD	31.8 ± 4.1	34.9 ± 4.7	33.0 ± 4.6
	Median (IQR)	31.5 (29.4 - 33.9)	34.4 (32.0 - 37.1)	32.5 (30.2 - 35.1)
	Min - Max	24.1 - 46.9	27.5 - 49.9	24.1 - 49.9
Aortic Diameter at LSA (mm)	Mean ± SD	30.5 ± 3.7	33.6 ± 4.8	31.7 ± 4.4
	Median (IQR)	30.4 (27.4 - 32.6)	33.6 (30.3 - 36.3)	31.3 (28.7 - 34.6)
	Min - Max	20.6 - 39.8	25.5 - 47.2	20.6 - 47.2
Aortic Diameter at Distal End of Proximal Neck (mm)	Mean ± SD	33.8 ± 4.6	35.3 ± 5.0	34.4 ± 4.8
	Median (IQR)	34.4 (29.9 - 36.8)	36.5 (31.7 - 39.0)	34.7 (30.9 - 37.7)
	Min - Max	23.2 - 44.3	24.7 - 43.8	23.2 - 44.3
Aortic Diameter at Proximal End of Distal Neck (mm)	Mean ± SD	32.2 ± 4.5	31.9 ± 4.4	32.1 ± 4.4

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
	Median (IQR)	32.2 (28.5 - 34.9)	31.0 (28.2 - 34.8)	31.9 (28.3 - 34.8)
	Min - Max	22.4 - 42.1	25.1 - 44.3	22.4 - 44.3
Length from LCC to Proximal End of Proximal Neck (mm)	Mean ± SD	19.4 ± 17.3	37.0 ± 42.0	26.1 ± 30.3
	Median (IQR)	19.3 (0.0 - 28.4)	17.9 (14.4 - 50.2)	18.4 (11.0 - 32.0)
	Min - Max	0.0 - 82.8	0.0 - 156.0	0.0 - 156.0
Proximal Neck Length – Centerline (mm)	Mean ± SD	64.9 ± 36.3	75.0 ± 36.8	68.8 ± 36.7
Centerline distance from the proximal edge of the landing zone to the proximal edge of the aneurysm/lesion	Median (IQR)	54.4 (35.7 - 83.0)	70.3 (42.3 - 106.0)	57.8 (38.6 - 94.0)
	Min - Max	22.6 - 186.0	25.8 - 150.0	22.6 - 186.0
Proximal Neck Length – Inner Curve (mm)	Mean ± SD	47.8 ± 31.4	56.3 ± 30.6	51.0 ± 31.2
Inner curve distance from the proximal edge of the landing zone to the proximal edge of the aneurysm/lesion	Median (IQR)	37.9 (23.3 - 62.4)	46.7 (29.3 - 81.0)	40.9 (25.3 - 74.0)
	Min - Max	13.9 - 158.0	20.0 - 125.0	13.9 - 158.0
Distal Neck Length – Centerline (mm)	Mean ± SD	77.4 ± 47.2	80.7 ± 54.9	78.7 ± 50.1
Centerline distance from the distal edge of the aneurysm/lesion to the proximal edge of the celiac trunk	Median (IQR)	63.0 (40.2 - 95.4)	60.3 (36.3 - 108.0)	63.0 (38.3 - 100.0)
	Min - Max	25.1 - 219.0	25.8 - 204.0	25.1 - 219.0
Distal Neck Length –Inner Curve (mm)	Mean ± SD	71.7 ± 45.3	74.7 ± 51.3	72.8 ± 47.5
Inner curve distance from the distal edge of the aneurysm/lesion to the proximal edge of the celiac trunk	Median (IQR)	57.2 (37.0 - 92.0)	56.8 (34.0 - 107.0)	57.2 (35.4 - 93.3)
	Min - Max	20.0 - 219.0	21.4 - 194.0	20.0 - 219.0
Aneurysm Length (mm)	Mean ± SD	104.4 ± 59.0	85.0 ± 40.3	97.0 ± 53.3
	Median (IQR)	92.0 (54.7 - 142.5)	84.0 (53.1 - 107.0)	89.4 (53.6 - 127.0)
	Min - Max	19.6 - 236.0	18.8 - 172.0	18.8 - 236.0
Right Iliac Tortuosity Index	Mean ± SD	1.3 ± 0.2	1.4 ± 0.2	1.4 ± 0.2
	Median (IQR)	1.3 (1.2 - 1.5)	1.3 (1.2 - 1.5)	1.3 (1.2 - 1.5)
	Min - Max	1.1 - 1.8	1.1 - 2.2	1.1 - 2.2
Left Iliac Tortuosity Index	Mean ± SD	1.3 ± 0.2	1.4 ± 0.2	1.3 ± 0.2
	Median (IQR)	1.3 (1.2 - 1.4)	1.3 (1.2 - 1.5)	1.3 (1.2 - 1.5)
	Min - Max	1.1 - 1.8	1.1 - 2.0	1.1 - 2.0
Proximal Neck Thrombus Max Thickness (mm)	Mean ± SD	0.9 ± 1.6	1.0 ± 2.0	0.9 ± 1.8
	Median (IQR)	0.0 (0.0 - 0.9)	0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
	Min - Max	0.0 - 5.4	0.0 - 8.3	0.0 - 8.3
Proximal Neck Thrombus Degrees >2mm in Thickness (mm)	Mean ± SD	20.1 ± 47.4	19.2 ± 41.7	19.7 ± 45.1
	Median (IQR)	0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
	Min - Max	0.0 - 200.0	0.0 - 151.0	0.0 - 200.0
Proximal Neck Calcium Max Thickness (mm)	Mean ± SD	1.2 ± 1.3	2.1 ± 1.7	1.5 ± 1.5
	Median (IQR)	0.0 (0.0 - 2.2)	2.3 (0.0 - 2.9)	1.8 (0.0 - 2.6)
	Min - Max	0.0 - 4.5	0.0 - 6.0	0.0 - 6.0
Proximal Neck Calcium Degrees	Mean ± SD	24.2 ± 38.3	34.6 ± 38.6	28.2 ± 38.6
	Median (IQR)	0.0 (0.0 - 35.0)	25.0 (0.0 - 45.0)	13.5 (0.0 - 41.0)
	Min - Max	0.0 - 169.0	0.0 - 152.0	0.0 - 169.0
Distal Neck Thrombus Max Thickness (mm)	Mean ± SD	1.5 ± 2.8	1.3 ± 2.1	1.5 ± 2.5

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
	Median (IQR)	0.0 (0.0 - 2.9)	0.0 (0.0 - 2.9)	0.0 (0.0 - 2.9)
	Min - Max	0.0 - 15.5	0.0 - 7.2	0.0 - 15.5
Distal Neck Thrombus Degrees >2mm in Thickness (mm)	Mean ± SD	27.8 ± 48.5	28.6 ± 51.4	28.1 ± 49.4
	Median (IQR)	0.0 (0.0 - 54.0)	0.0 (0.0 - 50.0)	0.0 (0.0 - 51.0)
	Min - Max	0.0 - 211.0	0.0 - 200.0	0.0 - 211.0
Distal Neck Calcium Max Thickness (mm)	Mean ± SD	0.9 ± 1.2	1.4 ± 1.3	1.1 ± 1.3
	Median (IQR)	0.0 (0.0 - 1.9)	1.6 (0.0 - 2.5)	0.0 (0.0 - 2.0)
	Min - Max	0.0 - 4.1	0.0 - 4.5	0.0 - 4.5
Distal Neck Calcium Degrees	Mean ± SD	14.4 ± 29.5	16.0 ± 23.7	15.0 ± 27.3
	Median (IQR)	0.0 (0.0 - 15.5)	11.0 (0.0 - 23.0)	0.0 (0.0 - 19.7)
	Min - Max	0.0 - 173.0	0.0 - 122.0	0.0 - 173.0
Max TAA Diameter (mm)	Mean ± SD	54.6 ± 10.6	58.6 ± 8.0	56.1 ± 9.9
	Median (IQR)	55.2 (48.2 - 61.6)	57.7 (55.6 - 61.0)	56.9 (50.7 - 61.1)
	Min - Max	33.0 - 80.8	34.7 - 81.3	33.0 - 81.3
PAU: Depth (mm)	Mean ± SD (N)	11.0 ± 1.3 (9)	19.7 ± NA (1)	11.8 ± 3.0 (10)
	Median (IQR)	10.2 (10.0 - 11.8)	19.7 (19.7 - 19.7)	10.4 (10.0 - 13.0)
	Min - Max	10.0 - 13.2	19.7 - 19.7	10.0 - 19.7
PAU: Diameter (mm)	Mean ± SD (N)	27.6 ± 7.7 (9)	27.8 ± NA (1)	27.6 ± 7.2 (10)
	Median (IQR)	26.0 (24.0 - 35.6)	27.8 (27.8 - 27.8)	26.9 (24.0 - 35.6)
	Min - Max	14.5 - 36.3	27.8 - 27.8	14.5 - 36.3
Total Treatment Length - Outer Curve (mm)	Mean ± SD (N)	289.6 ± 59.5 (67)	277.1 ± 71.7 (42)	284.8 ± 64.5 (109)
Outer curve distance from the proximal end of the proximal neck to the distal end of the distal neck.	Median (IQR)	293.0 (262.0 - 327.0)	293.5 (242.0 - 320.0)	293.0 (258.0 - 326.0)
	Min - Max	40.6 - 408.0	60.5 - 378.0	40.6 - 408.0
Tortuosity Index	Mean ± SD (N)	1.5 ± 0.2 (64)	1.6 ± 0.2 (42)	1.5 ± 0.2 (106)
	Median (IQR)	1.5 (1.4 - 1.6)	1.6 (1.5 - 1.6)	1.5 (1.4 - 1.6)
	Min - Max	1.2 - 2.0	1.2 - 2.4	1.2 - 2.4
Minimum Right Common Iliac Diameter (mm)	Mean ± SD (N)	9.5 ± 2.5 (66)	9.3 ± 2.7 (42)	9.4 ± 2.5 (108)
	Median (IQR)	9.5 (7.7 - 11.1)	9.0 (7.9 - 10.5)	9.3 (7.8 - 11.0)
	Min - Max	4.6 - 15.9	4.1 - 18.3	4.1 - 18.3
Minimum Right External Iliac Diameter (mm)	Mean ± SD (N)	6.9 ± 1.8 (66)	7.4 ± 1.3 (42)	7.1 ± 1.6 (108)
	Median (IQR)	6.9 (5.5 - 8.2)	7.4 (6.6 - 8.3)	7.2 (5.9 - 8.2)
	Min - Max	3.7 - 11.3	4.5 - 10.9	3.7 - 11.3
Minimum Right Common Femoral Diameter (mm)	Mean ± SD (N)	7.5 ± 1.8 (66)	8.3 ± 1.3 (42)	7.8 ± 1.7 (108)
	Median (IQR)	7.3 (6.2 - 9.0)	8.2 (7.2 - 9.2)	7.6 (6.8 - 9.1)
	Min - Max	4.1 - 12.3	6.0 - 11.3	4.1 - 12.3
Minimum Left Common Iliac Diameter (mm)	Mean ± SD (N)	9.4 ± 2.8 (67)	9.2 ± 2.6 (42)	9.3 ± 2.7 (109)
	Median (IQR)	9.2 (7.0 - 10.8)	8.9 (7.7 - 10.2)	9.2 (7.4 - 10.8)
	Min - Max	3.4 - 18.6	4.7 - 17.5	3.4 - 18.6
Minimum Left External Iliac Diameter (mm)	Mean ± SD (N)	6.7 ± 1.8 (67)	7.4 ± 1.2 (42)	7.0 ± 1.7 (109)
	Median (IQR)	6.8 (5.5 - 8.1)	7.3 (6.6 - 8.0)	6.9 (5.9 - 8.0)
	Min - Max	2.6 - 10.5	5.2 - 10.6	2.6 - 10.6
Minimum Left Common Femoral Diameter (mm)	Mean ± SD (N)	7.5 ± 1.7 (66)	8.0 ± 1.3 (42)	7.7 ± 1.6 (108)

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
	Median (IQR)	7.4 (6.2 - 8.6)	7.8 (7.2 - 8.7)	7.7 (6.5 - 8.7)
	Min - Max	3.8 - 11.6	5.3 - 11.7	3.8 - 11.7
Arch Type				
Type I	% (n)	8.8% (6)	14.3% (6)	10.9% (12)
Type II	% (n)	42.6% (29)	19.0% (8)	33.6% (37)
Type III	% (n)	48.5% (33)	66.7% (28)	55.5% (61)
Arch Type (Normal/Bovine)				
Bovine	% (n)	25.0% (17)	0% (0)	15.5% (17)
Normal	% (n)	75.0% (51)	100.0% (42)	84.5% (93)
Indication				
Aneurysm	% (n)	86.8% (59)	97.6% (41)	90.9% (100)
PAU	% (n)	13.2% (9)	2.4% (1)	9.1% (10)

6.4.5. RelayPro Stent-Grafts Implanted

A total of 168 device components were implanted in the Pivotal Study. The number of devices implanted in the initial procedure are shown in **Table 7.** One RelayPro device was implanted in 51.8% (57/110) of the cohort (43 NBS and 14 Proximal Bare Stent), and two RelayPro devices were implanted in 43.6% (48/110) of the cohort (33 NBS only, 5 Proximal Bare Stent only and 10 received both). Three RelayPro devices were implanted in 5 subjects (4.5%, 5/110) of the cohort (1 NBS only and 4 received both).

Table 7. Number of RelayPro Devices Implanted During the Initial Procedure

Number of Devices Implanted	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
1	57.4% (39)	42.9% (18)	51.8% (57)
2	36.8% (25)	54.8% (23)	43.6% (48)
3	5.9% (4)	2.4% (1)	4.5% (5)
*Denominator includes all subjects who received the test device. Site reported data			

Table 8. Number of Devices Implanted During the Initial Procedure – Bare Stent

Number of Devices Implanted	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
1	11.8% (8)	14.3% (6)	12.7% (14)
2	13.2% (9)	14.3% (6)	13.6% (15)
3	5.9% (4)	0% (0)	3.6% (4)
*Denominator includes all subjects who received the test device. Site reported data			

Table 9. Number of Devices Implanted During the Initial Procedure - NBS

Number of Devices Implanted	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
1	45.6% (31)	28.6% (12)	39.1% (43)
2	30.9% (21)	52.4% (22)	39.1% (43)
3	5.9% (4)	2.4% (1)	4.5% (5)
*Denominator includes all subjects who received the RelayPro device. Site reported data.			

The diameters of the devices implanted in the Pivotal Study are shown in **Table 10**. The most commonly implanted NBS devices were the 34 mm (19.1%, 21/110), 36 mm (21.8%, 24/110), 38 mm (28.2%, 31/110), and 40 mm (13.6%, 15/110) proximal diameters. The most commonly implanted proximal bare stent configurations were the 36 mm (7.3%, 8/110), 38 mm (10.9%, 12/110), and 40 mm (6.4%, 7/110) proximal diameters.

Table 10. Diameters of RelayPro Devices Implanted During the Initial Procedure

Diameters (mm)	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Proximal (NBS)			
26	0% (0)	4.8% (2)	1.8% (2)
28	1.5% (1)	0% (0)	0.9% (1)
30	4.4% (3)	11.9% (5)	7.3% (8)
32	11.8% (8)	7.1% (3)	10.0% (11)
34	19.1% (13)	19.0% (8)	19.1% (21)
36	22.1% (15)	21.4% (9)	21.8% (24)
38	30.9% (21)	21.4% (9)	27.3% (30)
40	11.8% (8)	16.7% (7)	13.6% (15)
42	5.9% (4)	16.7% (7)	10.0% (11)
44	1.5% (1)	9.5% (4)	4.5% (5)
46	4.4% (3)	0% (0)	2.7% (3)
Proximal (bare stent)			
26	0% (0)	0% (0)	0% (0)
28	0% (0)	0% (0)	0% (0)
30	5.9% (4)	4.8% (2)	5.5% (6)
32	4.4% (3)	2.4% (1)	3.6% (4)
34	5.9% (4)	4.8% (2)	5.5% (6)
36	8.8% (6)	4.8% (2)	7.3% (8)
38	13.2% (9)	7.1% (3)	10.9% (12)
40	5.9% (4)	7.1% (3)	6.4% (7)
42	2.9% (2)	2.4% (1)	2.7% (3)
44	1.5% (1)	2.4% (1)	1.8% (2)
46	2.9% (2)	0% (0)	1.8% (2)
Distal			
26	1.5% (1)	4.8% (2)	2.7% (3)
28	5.9% (4)	2.4% (1)	4.5% (5)
30	5.9% (4)	19.0% (8)	10.9% (12)
32	17.6% (12)	14.3% (6)	16.4% (18)
34	36.8% (25)	31.0% (13)	34.5% (38)
36	25.0% (17)	26.2% (11)	25.5% (28)
38	23.5% (16)	11.9% (5)	19.1% (21)
40	11.8% (8)	19.0% (8)	14.5% (16)
42	5.9% (4)	16.7% (7)	10.0% (11)
44	1.5% (1)	2.4% (1)	1.8% (2)
46	2.9% (2)	0% (0)	1.8% (2)
*Denominator includes all subjects who received the test device. Site reported data.			

6.4.6. Acute Procedural Information

Detailed information and observations regarding the index procedure were documented by the physician on case report forms. **Table 11** summarizes the information from the index procedure, including clinical utility endpoints. The majority of subjects had general anesthesia (93.6%, 103/110). Right femoral access (73.6%, 81/110) was the predominant access location. Mean duration of the procedure was 113.6 ± 79.6 min and the mean implantation duration was 20 ± 16 min.

Vascular access method was different between the US and Japan cohorts, with the Japan cohort using 100% surgical cutdown (42/42) compared to 73.5% of subjects (50/68) in the US cohort having the percutaneous access. In the US cohort, the duration of ICU time (61.4±57.9 hours vs. 21.6±19.4 hours) was lengthier compared to the Japanese cohort, while the duration of hospital stay was lengthier in the Japanese cohort (9.9±6.8 days vs. 4.8±3.8 days).

Table 11. Details of the Initial Procedure

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Type of Anesthesia				
General	% (n)	98.5% (67)	85.7% (36)	93.6% (103)
Local	% (n)	1.5% (1)	14.3% (6)	6.4% (7)
Vascular Access				
Left Femoral	% (n)	25.0% (17)	26.2% (11)	25.5% (28)
Right Femoral	% (n)	73.5% (50)	73.8% (31)	73.6% (81)
Right Iliac	% (n)	1.5% (1)	0% (0)	0.9% (1)
Vascular Access Method				
Conduit	% (n)	2.9% (2)	0% (0)	1.8% (2)
Percutaneous	% (n)	73.5% (50)	0% (0)	45.5% (50)
Surgical Cut Down	% (n)	23.5% (16)	100.0% (42)	52.7% (58)
Procedure time (min)	Mean ± SD	117.2 ± 96.6	107.9 ± 39.3	113.6 ± 79.6
	Median (IQR)	87.5 (53 - 142.5)	96 (85 - 128)	91 (64 - 131)
	Min - Max	27 - 563	53 - 230	27 - 563
Implantation time (min)	Mean ± SD	20 ± 18	20 ± 12	20 ± 16
	Median (IQR)	16 (9.5 - 25.5)	17 (12 - 25)	16 (10 - 25)
	Min - Max	2 - 120	5 - 54	2 - 120
Estimated Blood Loss (cc)	Mean ± SD (N)	195 ± 356 (67)	132 ± 334 (42)	170 ± 348 (109)
	Median (IQR)	100 (50 - 200)	31 (10 - 85)	52 (20 - 150)
	Min - Max	5 - 2500	0 - 1516	0 - 2500
Transfusion Required	% (n)	2.9% (2)	2.4% (1)	2.7% (3)
ICU Stay (hours)	Mean ± SD	61.4 ± 57.9	21.6 ± 19.4)	46.2 ± 50.8
	Median (IQR)	50 (33 - 71.5)	22 (0 - 24)	36 (22 - 57)
	Min - Max	0 - 360	0 - 73	0 - 360
Hospital Stay (days)	Mean ± SD	4.8 ± 3.8	9.9 ± 6.8	6.7 ± 5.7

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
	Median (IQR)	3.8 (3 - 6)	8.5 (7 - 10)	5 (3 - 9)
	Min - Max	1 - 22	3 - 36	1 - 36

6.4.7. Safety Results

6.4.7.1. Primary Safety Endpoint

The analysis of safety was based on the RelayPro Pivotal Study cohort of 110 subjects available for the 30-day (1 month) evaluation. The key safety outcomes for this study are presented below in **Table 12**.

The primary safety endpoint was the MAE rate through 30 days post procedure compared to a performance goal of 20%. Subjects who experienced at least 1 MAE through 30 days were included in the primary safety analysis even if the subject had not completed a 1-month follow-up visit. The composite MAE rate through 30 days was 6.4% (7/110, upper 95% CI 11.6%, P=0.0002). A total of 7 MAEs were observed in 7 subjects. MAEs reported through 30 days include 2 strokes, 2 cases of procedural blood loss >1,000 cc requiring transfusion, 2 paralysis events (excluding paraparesis), and 1 renal failure event.

Since all 110 subjects were available for the primary safety endpoint, there's no missing data and thus no need for sensitivity analysis.

An assessment of poolability was performed by comparing the primary safety endpoint across sites, both Japanese and U.S. sites individually, as well as pooled Japanese sites as compared to pooled U.S. sites. These analyses were based on Fisher's Exact test of binomial proportions. No significant difference between the groups were found.

Table 12. 30-Day Major Adverse Events: Pivotal Study

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
MAE Rate at 30 Days	% (n)			6.4% (7)
	Upper 95% CI			11.6%
	P-Value*			0.0002
Time to MAE Analysis				
Number with Events	n			7
Censored	n			1
At Risk	n			101
Freedom from MAE within 30 days	% (95% CI)			93.6% (87.1%, 96.9%)
MAE individual components				
Death	% (n)	0% (0)	0% (0)	0% (0)
Myocardial Infarction	% (n)	0% (0)	0% (0)	0% (0)
Stroke (excluding TIA)	% (n)	1.5% (1)	2.4% (1)	1.8% (2)
Renal Failure	% (n)	1.5% (1)	0% (0)	0.9% (1)
Respiratory Failure	% (n)	0% (0)	0% (0)	0% (0)
Paralysis (excluding paraparesis)	% (n)	0% (0)	4.8% (2)	1.8% (2)
Bowel Ischemia	% (n)	0% (0)	0% (0)	0% (0)

Characteristic	Statistics	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Procedural blood loss > 1,000 cc requiring transfusion	% (n)	2.9% (2)	0% (0)	1.8% (2)
*P-value corresponds to the null hypothesis test that the observed value is greater than the Primary Safety Endpoint Performance Goal of 20%. MAE – Major Adverse Events, NA – not applicable. All MAEs were adjudicated by the Clinical Events Committee (CEC).				

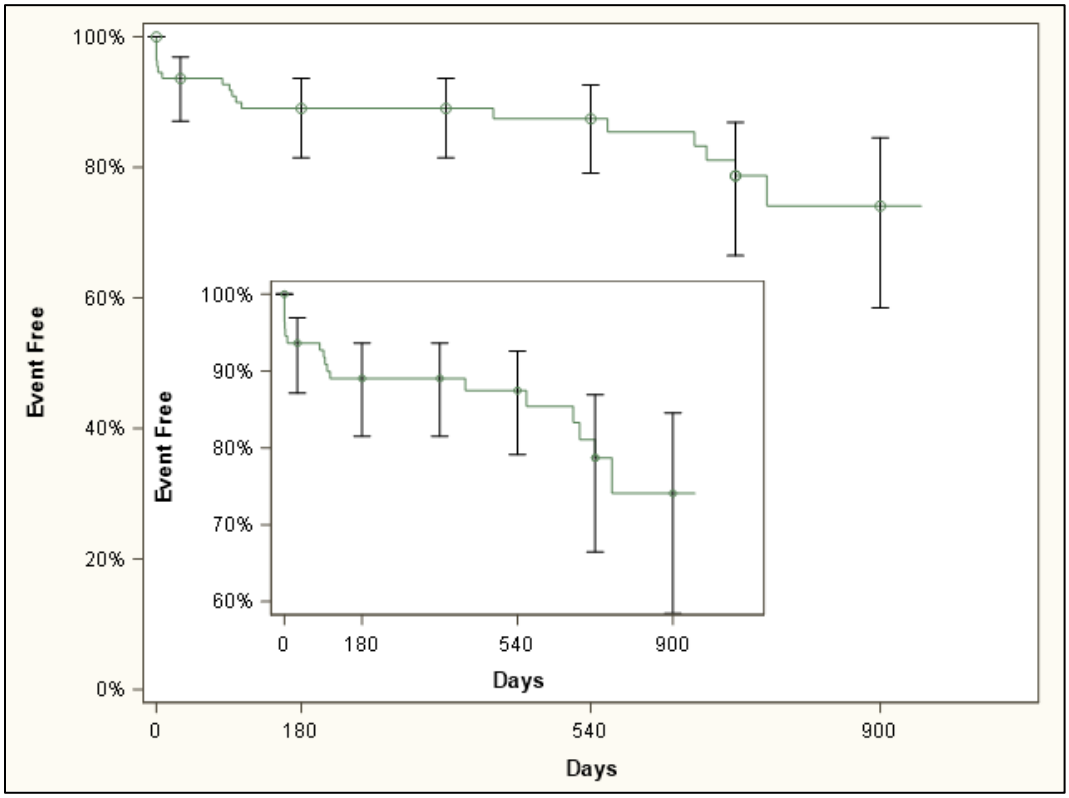
6.4.7.2. Secondary Safety Endpoints

6.4.7.2.1. Major Adverse Events

A secondary safety endpoint includes the individual components of the Major Adverse Events (MAE) endpoint (**Figure 3)**, namely death, myocardial infarction, stroke (excluding transient ischemic attack), renal failure, respiratory failure, paralysis (excluding paraparesis), bowel ischemia, and procedural blood loss > 1000 cc requiring transfusion. All MAEs were adjudicated by the Clinical Events Committee.

MAEs throughout follow-up are depicted in **Figure 3** as a Kaplan-Meier plot and the underlying data. Kaplan-Meier analysis predicts a freedom from MAEs of 93.6% at 1-30 days, 89.0% at 31-180 days, 89% at 181-360 days, 87.4% at 361-540 days, 78.7% at 541-720 days and 74.1% at 721-900 days.

Figure 3. Kaplan-Meier Freedom from Major Adverse Event



From Day X - Day Y	# Entered	# Censored	# Events	Event-free [%]	Greenwood SE [%]	95% Confidence Interval
0	110	0	4	96.4%	1.8%	90.6%-98.6%
1-30	106	2	3	93.6%	2.3%	87.1%-96.9%
31-180	102	0	5	89.0%	3.0%	81.5%-93.6%
181-360	97	11	0	89.0%	3.0%	81.5%-93.6%
361-540	86	42	1	87.4%	3.3%	79.1%-92.6%
541-720	43	7	4	78.7%	5.1%	66.5%-86.9%
721-900	32	29	1	74.1%	6.6%	58.5%-84.6%
901-1080	2	2	0			

The total number of subjects who were eligible for follow-up with MAE(s) was reported as 7.3% (8/110) at 30 days, 3.7% (4/108) at 6 months, 1.9% (2/105) at 12 months, and 5.5% (5/91) at 2-years. Six (6) subjects experienced either a stroke (4 - occuring at 1 day, 7 days, 94 days and 419 days post implant) or paraplegia (2) event during the study. The two subjects in the Japan cohort reporting paraplegia (immobility of the lower limbs) had symptom onset on the day of the procedure. Both were managed with spinal drain placement and the paraplegia improved on the same day; both events were adjucidated by the CEC as procedure relatated, one as also adjudicated as device related.

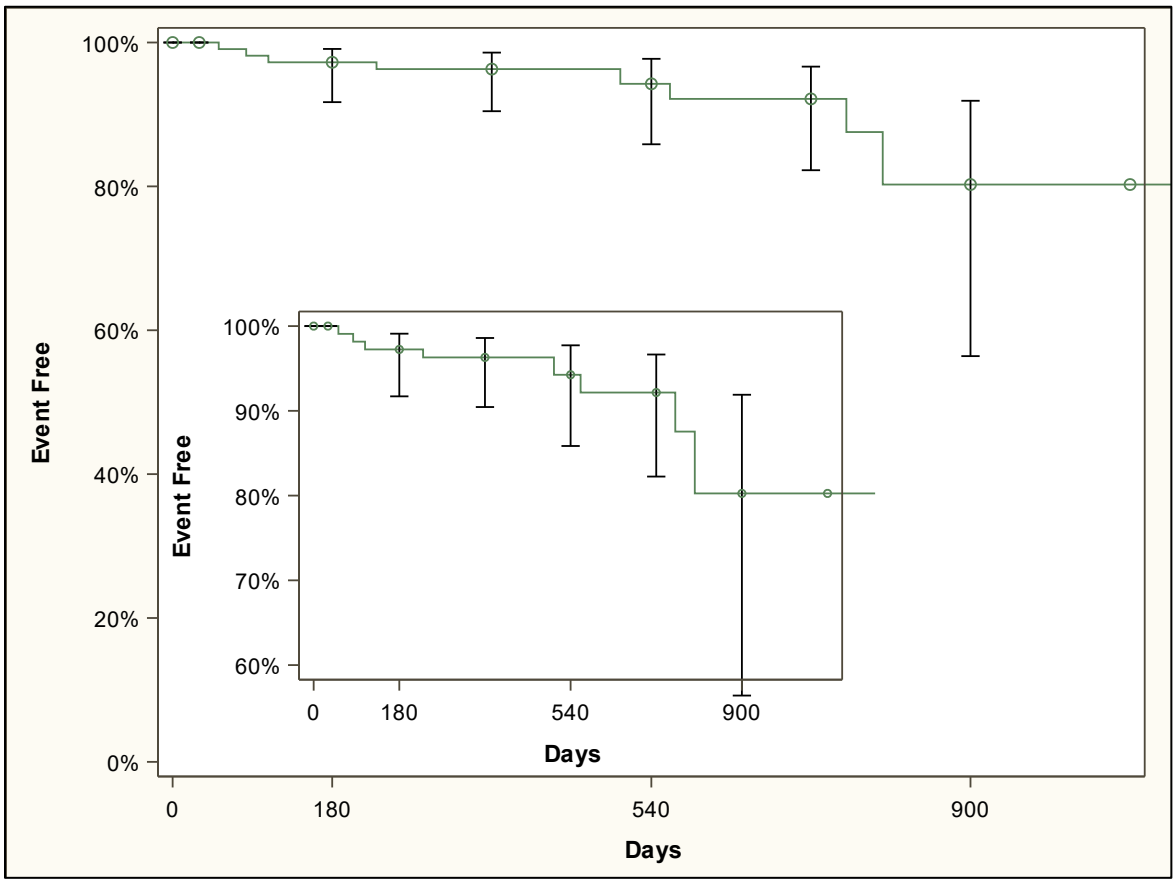
Table 13. Summary of MAEs Reported at Follow-Up

MAE	30 Days	6 Months	12 Months	2 Year
Number Eligible for Follow-Up	110	108	105	91
Subjects with ≥1 MAE (Total)	7.3% (8/110)	3.7% (4/108)	1.9% (2/105)	5.5% (5/91)
MAEs (Total)	9	5	2	5
Death				
New	2	2	1	3
To Date	1.8% (2/110)	3.6% (4/110)	4.6% (5/109)	8.3% (8/96)
Myocardial Infarction				
New	0	1	0	0
To Date	0% (0/110)	0.9% (1/108)	1.0% (1/105)	1.1% (1/91)
Paralysis				
New	2	0	0	0
To Date	1.8% (2/110)	1.9% (2/108)	1.9% (2/105)	2.2% (2/92)
Stroke				
New	2	1	1	0
To Date	1.8% (2/110)	2.8% (3/109)	3.7% (4/107)	4.3% (4/93)
Renal Failure				
New	1	1	0	1
To Date	0.9% (1/110)	1.9% (2/108)	1.9% (2/105)	3.2% (3/93)
Procedural blood loss > 1000 cc requiring transfusion				
New	2	0	0	0
To Date	1.8% (2/110)	1.9% (2/108)	1.9% (2/105)	2.2% (2/91)
Bowel ischemia				
New	0	0	0	1
To Date	0.0% (0/110)	0.0% (0/108)	0.0% (0/105)	1.1% (1/91)

6.4.7.2.2. All Cause and Aneurysm-Related Mortality

There have been 8 reports of death in the Pivotal Study. The Kaplan-Meier analysis estimate for freedom from All-Cause Mortality is shown in **Figure 4**. Kaplan Meier analysis predicts a freedom from All-Cause Mortality to be 100% at 30 days, 97.2% at 31-180 days, , 96.3% at 181-360 days, 94.3% at 361-540 days, 92.2% at 541-720 days and 80.3% at 721-900 days.

Figure 4. Kaplan-Meier Freedom from All-Cause Mortality



From Day X - Day Y	# Entered	# Censored	# Events	Event-free [%]	Greenwood SE [%]	95% Confidence Interval
0	110	0	0	100.0%	0%	
1-30	110	1	0	100.0%	0%	
31-180	109	0	3	97.2%	1.6%	91.7%-99.1%
181-360	106	12	1	96.3%	1.8%	90.4%-98.6%
361-540	93	47	1	94.3%	2.7%	85.9%-97.7%
541-720	45	8	1	92.2%	3.4%	82.2-96.6%
721-900	36	30	2	80.3%	8.6%	56.4%-91.9%
901-1080	4	3	0	80.3%	8.6%	56.4%-91.9%

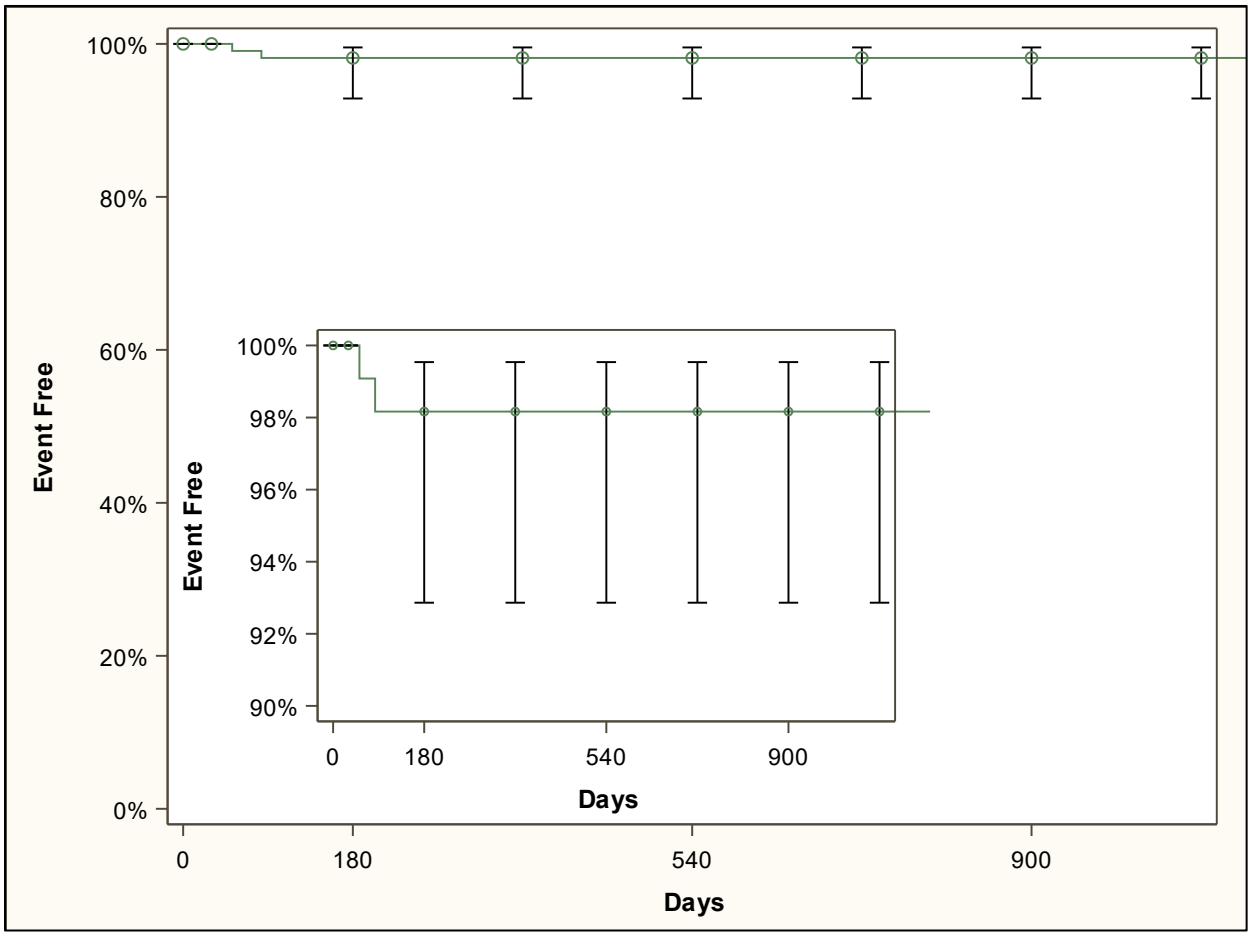
The RelayPro Aneurysm Study (Pro-A) Lesion-Related Mortality is defined as subject death as the result of a serious and device- or procedure-related adverse effect. Two subjects expired on day 52 and 83 post implant, respectively and met the criteria for lesion-related mortality. Kaplan-Meier analysis predicts a freedom from Lesion-Related Mortality at 30 days of 100% and 98.2% through 3 years.

Pro-A Aneurysm-Related Mortality is defined as either death due to a rupture, death within 30 days or prior to hospital discharge from primary procedure, or death within 30 days or prior to hospital discharge for a secondary procedure to

treat the index pathology. There was no aneurysm-related mortality reported.

Please note that there were two definitions for relatedness to mortality for this Pro-A study and were prospectively defined as presented above. The standard aneurysm-related mortality definition used for other thoracic endovascular graft studies includes a combination of both the Pro-A definitions for Lesion-Related and Aneurysm-Related Mortality. As there were no deaths meeting the Pro-A Aneurysm-Related definition, the Pro-A Lesion Related deaths represents the standard aneurysm-related morality definition.

Figure 5. Kaplan-Meier Freedom from Standard Aneurysm-Related Morality (Pro-A Lesion-Related Mortality): Pivotal Study



From Day X - Day Y	# Entered	# Censored	# Events	Event-free [%]	Greenwood SE [%]	95% Confidence Interval
0	110	0	0	100.0%	0.0%	
1-30	110	1	0	100.0%	0.0%	
31-180	109	1	2	98.2%	1.3%	92.9%-99.5%
181-360	106	13	0	98.2%	1.3%	92.9%-99.5%
361-540	93	48	0	98.2%	1.3%	92.9%-99.5%
541-720	45	9	0	98.2%	1.3%	92.9%-99.5%
721-900	36	32	0	98.2%	1.3%	92.9%-99.5%
901-1080	4	3	0	98.2%	1.3%	92.9%-99.5%

6.4.8. Device-Related Adverse Events

Adverse events adjudicated by the CEC as being device-related are summarized in **Table 14** where 11.8% (13/110) of subjects experienced one or more device-related adverse events with the most frequently reported being stent-graft endoleaks (11/110, 10.0%).

Table 14. Summary of CEC Adjudicated Device-Related Adverse Events

MedDRA System-Organ Class/Preferred Term Adverse Event	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Subjects with One or More Device-Related Adverse Events	8 (11.8%)	5 (11.9%)	13 (11.8%)
Gastrointestinal disorders	1 (1.5%)	0 (0%)	1 (0.9%)
Gastrointestinal hemorrhage	1 (1.5%)	0 (0%)	1 (0.9%)
General disorders and administration site conditions	6 (8.8%)	4 (9.5%)	10 (9.1%)
Stent-graft endoleak*	7 (10.3%)	4 (9.5%)	11 (10.0%)
Nervous system disorders	0 (0%)	1 (2.4%)	1 (0.9%)
Paraplegia	0 (0%)	1 (2.4%)	1 (0.9%)
Product issues	1 (1.5%)	1 (2.4%)	2 (1.8%)
Device dislocation	1 (1.5%)**	1 (2.4%)***	2 (1.8%)

Data is presented as n (%). Includes serious and non-serious adverse events.
Percentages are based on the number of subjects in the Safety Evaluable Population. Event verbatim terms are reported by sites. The events listed in this table are coded using MedDRA version 21.0 and then stratified by System-Organ Class (SOC) and Preferred Term. Subjects may be counted in this table more than once by Preferred Term but are only counted once in the SOC summary line.
*Stent-graft endoleak: 3 Subjects with Type Ib endoleaks; 1 Subject with a Type II endoleak; 2 Subjects with a Type Ia endoleak; 2 Subjects with a site-reported Type Ia endoleak (Core Lab reported Type II); 2 Subjects with site reported Type IIIb endoleak (Core Lab reported Type II); 1 Subject with site-reported Type Ia endoleak (Core Lab reported Type II).
**Site-reported proximal migration at the 6-month visit resulting in a secondary intervention where an additional RelayPro was implanted proximally. Secondary intervention was adequate to address the migration as observed during the 12-month and 2-year visits.
***Site-reported Type Ia endoleak and migration at the 2-year follow-up (Core Lab reported Type Ia endoleak with thoracic aorta lengthening, no migration). The secondary intervention was performed to implant competitive devices to successfully exclude the lesion.

6.4.9. Procedure-Related Adverse Events

Adverse events adjudicated by the CEC as being procedure-related are summarized in **Table 15** where 13.6% (15/110) of subjects experienced one or more procedure-related adverse events. The incidences of paraplegia, cereberal infarction and cerebrovascular accident were 1.8% (2/110), 1.8% (2/110) and 0.9 % (1/110), respectively.

Table 15. Summary of CEC Adjudicated Procedure-Related Adverse Events

MedDRA System-Organ Class/Preferred Term Adverse Event	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Subjects with One or More Procedure-Related Adverse Events	10 (14.7%)	5 (11.9%)	15 (13.6%)
Blood and lymphatic system disorders	1 (1.5%)	0 (0%)	1 (0.9%)
Blood loss anemia	1 (1.5%)	0 (0%)	1 (0.9%)
Cardiac disorders	1 (1.5%)	0 (0%)	1 (0.9%)
Chest pain	1 (1.5%)	0 (0%)	1 (0.9%)
General disorders and administration site conditions	2 (2.9%)	1 (2.4%)	3 (2.7%)
Stent-graft endoleak	2 (2.9%)	1 (2.4%)	3 (2.7%)
Injury, poisoning and procedural complications	1 (1.5%)	1 (2.4%)	2 (1.8%)
Arterial injury	1 (1.5%)	0 (0%)	1 (0.9%)
Spinal subdural hematoma	0 (0%)	1 (2.4%)	1 (0.9%)
Investigations	1 (1.5%)	0 (0%)	1 (0.9%)

MedDRA System-Organ Class/Preferred Term Adverse Event	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Blood creatinine increased	1 (1.5%)	0 (0%)	1 (0.9%)
Nervous system disorders	2 (2.9%)	4 (9.5%)	6 (5.5%)
Cerebral infarction	0 (0%)	2 (4.8%)	2 (1.8%)
Cerebrovascular accident	1 (1.5%)	0 (0%)	1 (0.9%)
Intraventricular hemorrhage	1 (1.5%)	0 (0%)	1 (0.9%)
Myelomalacia	1 (1.5%)	0 (0%)	1 (0.9%)
Paraplegia	0 (0%)	2 (4.8%)	2 (1.8%)
Respiratory, thoracic and mediastinal disorders	2 (2.9%)	0 (0%)	2 (1.8%)
Acute respiratory failure	1 (1.5%)	0 (0%)	1 (0.9%)
Pulmonary embolism	1 (1.5%)	0 (0%)	1 (0.9%)
Vascular disorders	2 (2.9%)	0 (0%)	2 (1.8%)
Femoral artery dissection	1 (1.5%)	0 (0%)	1 (0.9%)
Hemorrhage	1 (1.5%)	0 (0%)	1 (0.9%)
Iliac artery rupture	1 (1.5%)	0 (0%)	1 (0.9%)

Data is presented as n (%). Includes serious and non-serious adverse events.
Percentages are based on the number of subjects in the Safety Evaluable Population. Event verbatim terms are reported by sites. The events listed in this table are coded using MedDRA version 21.0 and then stratified by System-Organ Class (SOC) and Preferred Term. Subjects may be counted in this table more than once by Preferred Term but are only counted once in the SOC summary line.

6.4.10. Effectiveness Results

6.4.10.1. Primary Effectiveness

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

- Technical success through 24 hours, defined as:
  - Successful delivery of the device through the vasculature;
  - Successful deployment of the device at the intended location;
  - Absence of Type I or III endoleaks;[1]
  - Patent stent-graft without significant stenosis (>50%);
- Stent-graft patency
- Absence of aneurysm rupture
- Absence of Type I and III endoleak
- Absence of stent fractures in the attachment zone
- Absence of open or endovascular secondary interventions related to the device or treated pathology
- Absence of aneurysm expansion (>5 mm diameter increase, compared to the first post-procedural computed tomographic (CT) imaging study)

[1] *Presumed Type I or III endoleaks observed angiographically at the conclusion of the index procedure shall trigger the performance of a contrast-enhanced computed tomography (CT) or contrast-enhanced magnetic resonance (MR) imaging study prior to discharge. The Primary Effectiveness endpoint will not be triggered without confirmation of the Type I or III endoleak on a pre-discharge contrast CT or contrast MR.

- Absence of stent-graft migration (>10 mm, compared to the first post-procedural CT imaging study)

The primary effectiveness endpoint of treatment success at 12-months was achieved in 89.2% of the Pivotal Study subjects (74/83, lower 95% CI 81.8%, **Table 16**). The analysis of effectiveness was based on the 83 subjects evaluable for all components of the composite endpoint at the 12-month timepoint. The lower bound of the 95% confidence interval of 81.8% is above the 80% performance goal indicating that the primary effectiveness endpoint was met (P=0.0185).

Table 16. Successful Aneurysm Treatment at 12 Months

Primary Effectiveness Endpoint	Statistics	Pivotal (N=110)
Successful Aneurysm Treatment at 12 Months	% (n/N)	89.2% (74/83)
	Lower 95% CI	81.8%
	P-Value	0.0185

A total of 9 subjects did not meet the definition of treatment success (7 subjects in the US and 2 in Japan cohorts). Technical success rate (through 24 hours post-procedure) was 100% (107/107). There was successful delivery of the device through the vasculature, successful deployment of the device at the intended location, absence of Type I or III endoleak and patent stent-graft without significant stenosis.

All subjects had stent-graft patency, absence of aneurysm rupture, absence of stent fractures in the attachment zone and absence of stent-graft migration (> 10 mm) reported through 12 months. Absence of Type I or III endoleak through 12 months was reported in 95.3% (82/86) subjects (92.2%, 47/51 in the US and 100.0%, 35/35 in Japan cohorts). Absence of open or endovascular secondary interventions related to the device or treated pathology through 12 months occurred in 94.1% (95/101), and 98.9% (91/92) of subjects had an absence of aneurysm expansion (>5 mm diameter increase) through 12 months, compared to the first post-procedural computed tomographic (CT) imaging study.

Two of the 9 subjects experienced two endpoint events. One of these subjects experienced a Type Ib endoleak at the 1-month follow-up visit, on post-index procedure day 472 a secondary intervention was performed implanting an additional RelayPro stent-graft, successfully excluding the endoleak. The other subject had a Type Ib endoleak identified at the1-month follow-up visit, a secondary intervention was performed on post-index procedure day 276 implanting an additional RelayPro stent-graft, successfully excluding the endoleak, at the 2-year follow-up visit a Type Ib endoleak was again identified, additional intervention has not occurred to date.

The individual components of the Primary Effectiveness Endpoint is presented in **Table 17**.

A total of 27 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 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 included as a failure regardless of length of follow-up or complete data availability and included in the denominator. Of the 27 subjects, the reasons for exclusion from the analysis were:

- 16 subjects did not complete the 12-month visit: three subjects were Lost To Follow-Up, five subjects withdrew from the study voluntarily, three subjects missed the visit, one subject exited the study for other reason, one subject exited the study for unknown reason and there were three deaths.

- 11 subjects had incomplete or insufficient 12-month imaging data, resulting in the inability to assess graft patency in eight subjects, and endoleaks in three others

While there is information excluded from the primary effectiveness analysis (as described above), there is at least 81% imaging adequate to assess key endovascular graft parameters through 12-months. This compliance information shows that while there is patient information missing that precludes them from being included in the primary effectiveness analysis, there is adequate data available in the RelayPro pivotal study to evaluate important endovascular graft parameters.

A tipping point analysis was conducted imputing missing data over a range of possible scenarios for the treatment effect; for the primary effectiveness analysis, 27 subjects (83/110) did not have a complete data set collected for the analysis. The sensitivity analysis identified the scenario or 'tipping point' where the treatment effect in subjects with missing data overturned the significant treatment effect obtained in the study population at 6 subjects considered failures; at that point, the success rate was 86.4% (95/110, 95% lower CI 79.8%). In other words, when 6 or more subjects out of the 27 missing data were failures, the study would have failed the primary effectiveness endpoint. Based upon the calculated success rate of the available data, it is anticipated that the missing patients would need to have a much lower success rate to fail the primary effectiveness endpoint if they were included in the analysis population. It should be noted that for effectiveness a sample size of 83 subjects provides greater than 90% power for the primary effectiveness endpoint.

A poolability analysis was completed on the primary effectiveness analysis using a Fisher's exact test of binomial proportions to compare the endpoint across sites, both Japanese and U.S. sites individually as well as pooled Japanese sites as compared to pooled U.S. sites. No significant difference between groups was found.

Table 17. Individual Components of the Composite Primary Effectiveness Endpoint at 12 Months

Endpoint	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Composite of Technical Success at Procedure	100.0% (66/66)	100.0% (41/41)	100.0% (107/107)
Successful delivery of the device through the vasculature.	100.0% (68/68)	100.0% (42/42)	100.0% (110/110)
Successful deployment of the device at the intended location.	100.0% (68/68)	100.0% (42/42)	100.0% (110/110)
Absence of Type I or III endoleak[a]	100.0% (66/66)	100.0% (41/41)	100.0% (107/107)
Patent stent-graft without significant stenosis	100.0% (68/68)	100.0% (42/42)	100.0% (110/110)
Stent-graft patency through 12 months.*	100.0% (51/51)	100.0% (35/35)	100.0% (86/86)
Absence of aneurysm rupture through 12 months.	100.0% (61/61)	100.0% (40/40)	100.0% (101/101)
Absence of Type I or III endoleak through 12 months.*	92.2% (47/51)	100.0% (35/35)	95.3% (82/86)
Absence of stent fractures in the attachment zone through 12 months.*	100.0% (53/53)	100.0% (40/40)	100.0% (93/93)
Absence of open or endovascular secondary interventions related to the device or treated pathology through 12 months.	93.4% (57/61)	95.0% (38/40)	94.1% (95/101)
Absence of aneurysm expansion (>5 mm	98.1% (52/53)	100.0% (39/39)	98.9% (91/92)

Endpoint	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
diameter increase) through 12 months, compared to the first post-procedural computed tomographic (CT) imaging study.*			
Absence of stent-graft migration (> 10 mm) through 12 months, compared to the first post-procedural CT.*	100.0% (53/53)	100.0% (39/39)	100.0% (92/92)

*Denominators include patients that did not meet the endpoint definition or did not fail the endpoint and had evaluable core lab imaging data available through 1 year.

[a]Presumed Type I or III endoleaks observed angiographically at the conclusion of the index procedure shall trigger the performance of a contrast-enhanced CT or contrast-enhanced magnetic resonance (MR) imaging study prior to discharge. The Primary Effectiveness endpoint will not be triggered without confirmation of the Type I or III endoleak on a pre-discharge contrast CT or contrast MR.

6.4.10.2. Secondary Effectiveness Endpoints

A summary of the secondary effectiveness endpoints is presented in **Table 18.** Secondary effectiveness endpoints**.** The data presented are the number of subjects with the event observed during each timepoint.

Intervention Free Technical Success, based on site-reported data was achieved for all enrolled subjects 100%,. Although 8 subjects experienced Type II endoleak and 2 subjects experienced Type I endoleak at the end of the procedure, in all cases the treating physician did not perform interventions to treat these events during the procedure. They were monitored at the next follow-up visits and none resulted in reintervention.

At 30-days, 1 Type Ia, 2 Type Ib endoleaks, and 15 Type II endoleaks were Core Lab reported. There were 2 lesion-related mortalities. Two secondary interventions related to the device or pathology were performed. There were no instances of rupture or stent fracture. No conversions to open surgery were performed.

At 6-months, two Type Ib endoleaks (both persisting) and 13 Type II endoleaks were reported (11 persisting) by the Core Lab. Two subjects had secondary interventions performed to address the device or pathology. There were no instances of lesion-related mortality, rupture, or stent fracture. No conversions to open surgery were performed.

At 1 year, there was 1 new Type Ia endoleak, 1 persisting Type Ib endoleak, and 14 Type II endoleaks (9 persisting) reported by the Core Lab. The Core Lab reported one new aneurysm enlargement (no persisting). Three secondary interventions related to the device or pathology were performed. There were no instances of lesion-related mortality, rupture, or stent fracture. There were no conversions to open surgery performed.

At 2-years, the Core Lab reported 11 Type II endoleaks (6 persisting), 1 Type Ia (new), and 1 Type Ib (new). There were 4 new aneurysm enlargements (none persisting) and 1 secondary intervention related to device/pathology. There were no instances of lesion-related mortality, rupture, stent fracture or conversion to open surgery performed.

At 3-years, there are 4 subjects with data available. The Core Lab reported 1 new Type Ia endoleak, 1 Type II endoleak (persisting), and 1 new aneurysm enlargement (not persisting) that was addressed with a secondary intervention. There were no instances of lesion-related mortality, rupture, stent fracture or conversion to open surgery.

Table 18. Secondary effectiveness endpoints

Endpoints	30 Days	6 Months	1 Year	2 Years
Intervention-Free Technical Success	100.0% (110/110)	NA	NA	NA
All-cause mortality	1.8% (2/109)	2.0% (2/98)	1.1% (1/92)	7.3% (3/41)
Lesion-related mortality *(Pro-A)*	1.8% (2/109)	0% (0/96)	0% (0/92)	0% (0/38)
Rupture	0% (0/109)	0% (0/96)	0% (0/93)	0% (0/38)
Migration*	NA	0% (0/97)	0% (0/92)	0% (0/46)
All Endoleaks*	17.0% (18/106)	16.7% (15/90)	18.8% (16/85)	31.7% (13/41)
Type Ia	0.9% (1/106)	0% (0/90)	1.2% (1/85)	2.4% (1/41)
Type Ib	1.9% (2/106)	2.2% (2/90)	1.2% (1/85)	2.4% (1/41)
Type II	14.2% (15/106)	14.4% (13/90)	16.5% (14/85)	26.8% (11/41)
Type III	0% (0/106)	0% (0/90)	0% (0/85)	0% (0/41)
Type IV	0% (0/106)	0% (0/90)	0% (0/85)	0% (0/41)
Aneurysm Enlargement*	NA	0% (0/96)	1.1% (1/92)	8.7% (4/46)
Loss of Patency	0% (0/109)	0% (0/96)	0% (0/92)	0% (0/38)
Decreased stent-graft lumen diameter	0% (0/106)	0% (0/90)	0% (0/87)	0% (0/44)
Fractures*	0% (0/107)	0% (0/97)	0% (0/93)	0% (0/46)
Conversion to Open Repair	0% (0/110)	0% (0/96)	0% (0/92)	0% (0/38)
Related Secondary Intervention	1.8% (2/109)	2.1% (2/96)	3.3% (3/92)	2.6% (1/39)
Thromboembolic event attributed to stent-graft	0% (0/108)	0% (0/96)	0% (0/92)	0% (0/38)
Device-Related Adverse Events	11.0% (12/109)	4.2% (4/96)	1.1% (1/92)	15.0% (6/40)
Vascular access complications	5.5% (6/110)	NA	NA	NA

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

Denominators are specified in **Table 3** (Summary of Compliance and Imaging Follow-Up: Pivotal Study). For imaging endpoints (fractures, migration, endoleak, enlargement), the denominator is the number of subjects with imaging adequate to assess the parameter. For clinical endpoints (patency, conversion to open repair, secondary interventions), the denominator is the number of subjects with visits within the window.

Windows for visits are as follows: 30 days (Day 0-90); 6 months (Day 91-270); 1 year (Day 271-540); 2 years (Day 541-900).

*These data represent Core Laboratory assessed endpoints, including any reports of fracture, migration, endoleak, or aneurysm enlargement within each interval, including observations previously identified at earlier intervals that are considered ongoing or persistent and observations identified during an identified that later resolved within the interval.

6.4.11. Technical Success

Technical success is defined as a successful delivery of the device through the vasculature, successful deployment of the device at the intended location, absence of Type I or III endoleak and a patent stent-graft without significant stenosis through 24 hours post-procedure. Technical success, assessed by site Investigator, was achieved by all subjects in the Pivotal Study.

6.4.12. Device Assessment at Index Procedure

Intervention-Free Technical Success is a composite of multiple enquiries of the implanting investigator subsequent to each RelayPro implant procedure regarding the device usability, functionality and expected response of the user. Intervention Free Technical Success is defined as a composite of the following:

- Successful delivery of the device through the vasculature (deliver the implant to the intended location without the need for unanticipated corrective intervention related to delivery);
- Successful and accurate deployment of the device defined as:
  - deployment of the endovascular stent-graft in the planned location;
  - patency of the endovascular stent-graft, absence of device deformations (e.g. kinks, stent eversion, mal-deployment, misaligned deployment) requiring unplanned placement of an additional device within the endovascular stent-graft, and;
- Successful withdrawal (i.e. successful withdrawal of the delivery system, without the need for unanticipated corrective intervention related to withdrawal)

All subjects had an intervention free technically successful procedure. A summary of Investigator-assessed device performance at the index procedure are presented in **Table 19.**

Twenty-six (26) of 110 (23.6%) subjects had additional procedures performed during the RelayPro Stent-Graft procedure. Of the 26 subjects who underwent additional procedures, the majority of the subjects (65.4%, 17/26) had an LSA Revascularization prior to the RelayPro index procedure, 34.6% (9/26) had a Balloon Dilation, 11.5% (3/26) Native Vessel PTA, 3.8% (1/26) had a Stent Placement (right iliac artery and right superficial femoral artery), and 23.1% (6/26) had 'Other' procedures. .

Of the 110 subjects treated with the RelayPro Stent-Graft System, 98.2% (108/110) had a positive Final Procedure Result; the lesion was excluded without a Type I, III or IV Endoleak; Conversion to Surgery; or Procedure Attempted, but Aborted. Two (2) subjects had the Lesion Excluded with a site detected Type IV Endoleak reported as not resolved during the procedure. The Core Lab did not identify the Type IV Endoleaks. The site-reported Type IV Endoleak in one of these subjects was not visualized on the Intra-Procedure Angiogram or any post implant imaging (1 and 6 month). In the second subject the Core Lab classified the site-reported Type IV Endoleak as a Type II Endoleak Intra-Procedure and at 1-month post implant, and not seen on 6 month post implant imaging.

One subject had an overall successful procedure with the Final Procedure Result as Lesion Excluded as reported by the site, with a Core Lab identified Type IV Endoleak that resolved prior to the 1-month follow-up imaging.

Table 19. Summary of Device Assessment by the Investigator

Device Assessment by Investigator*	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Deployment at the Intended Location	100.0% (68)	100.0% (42)	100.0% (110)
Deployment Without Kinking or Twisting	100.0% (68)	100.0% (42)	100.0% (110)
Accuracy of Deployment Acceptable	100.0% (68)	100.0% (42)	100.0% (110)
Stent-Graft Patent	100.0% (68)	100.0% (42)	100.0% (110)
Stent-Graft Integrity (no wire fracture)	100.0% (68)	100.0% (42)	100.0% (110)
Procedure Performed Without Any Unplanned Vascular Access Difficulties	91.2% (62)	100.0% (42)	94.5% (104)
Additional procedures required:	30.9% (21)	11.9% (5)	23.6% (26)[b]
Balloon Dilation	28.6% (6/21)	60.0% (3/5)	34.6% (9/26)
Stent Placement	4.8% (1/21)	0% (0/5)	3.8% (1/26)[a]

Device Assessment by Investigator*	US Cohort (N=68)	Japan Cohort (N=42)	Pivotal (N=110)
Native Vessel PTA	9.5% (2/21)	20.0% (1/5)	11.5% (3/26)
Other[c]	28.6% (6/21)	0% (0/5)	23.1% (6/26)
LSA Revascularized	61.9% (13/21)	80.0% (4/5)	65.4% (17/26)
Pre-implant	100.0% (13/13)	100.0% (4/4)	100.0% (17/17)
Proximal end of the covered portion of the device:			
Distal to the Left Subclavian	73.5% (50)	85.7% (36)	78.2% (86)
Proximal to the Left Subclavian	26.5% (18)	14.3% (6)	21.8% (24)
Final Procedure Result			
Lesion Excluded	89.7% (61)	92.9% (39)	90.9% (100)
Type I, III or IV Endoleak**	0% (0)	4.8% (2)	1.8% (2)
Type II Endoleak	10.3% (7)	2.4% (1)	7.3% (8)

All values expressed as % (n). The denominator is included at the top of the respective column, unless otherwise indicated.
*The device assessment was performed at the time of the procedure.
**Only Type IV endoleaks were observed.
[a] Subject had stent placement at right iliac artery and right superficial femoral artery.
[b] Eight (8) subjects had more than one additional procedure required: 3 subjects had Balloon Dilation at Stent-Graft/LSA Revascularized; 2 subjects had Stent Placement/Native Vessel PTA/LSA Revascularized; 2 subjects had LSA Revascularized/Other and 1 subject had Balloon Dilation at Stent-Graft/Native Vessel PTA/Other.
[c] Six (6) subjects had additional procedures performed classified as 'Other'. These included 1 subject with a LCA/LSA bypass, 1 subject with a right femoral artery repair secondary to Perclose failure, 1 subject with a right femoral cutdown with pericardial patch, 1 subject with a serial dilatation, 1 subject with an LSA embolization and 1 subject with a left CFA patch angioplasty.

6.4.13. Aneurysm Rupture

Aneurysm rupture is defined as rupture of the native aneurysm sac post-implantation of the stent-graft. There have been no reported aneurysm ruptures in this study.

6.4.14. Migration

The protocol defines device migration as a displacement of 10 mm or more relative to the 1-month location, as measured by the Core Lab. There have been no Core Lab reported instances of migration, proximal or distal, or stent-graft component separation in any subject.

There has been one site-reported proximal migration at the 6-month visit in a US subject, resulting in a secondary intervention where an additional RelayPro (proximal bare stent configuration) was implanted proximally. The secondary intervention was adequate to address the migration (as observed on the 12-month and 2-year visit).

6.4.15. Endoleaks

Table 20. Summary of Core Laboratory-Reported Endoleaks presents the Core Lab reported endoleaks observed at each follow-up interval. Six (6) subjects experienced a Type I endoleak during follow-up; 3 endoleaks were Type Ia and 3 Type Ib; all but one Type Ia endoleak were within the US cohort. One Type Ia endoleak was observed at both the 1 month follow-up visit and during an unscheduled follow-up visit (approximately 3 months post index procedure). However, the subject expired from non-aneurysm related pathology before any re-intervention could be performed. The second subject with a Type Ia endoleak had the endoleak observed on 12-month imaging with no aneurysm expansion. On post-index procedure day 538, a secondary intervention was performed to address an aortic ulceration of the arch implanting a TEVAR device in zone zero using the snorkel technique. The aortic ulcer was successfully excluded and subsequent CT imaging has confirmed resolution of the Type Ia endoleak. The third subject with a Type Ia endoleak was observed on 2-year imaging and no aneurysm expansion was observed. On day 791 post-index procedure, the subject had a TEVAR device implanted at the level of the left subclavian artery.

Two subjects experienced a Type Ib endoleak asidentified by the Core Lab at the 30-day follow-up visit and each underwent a secondary intervention where an additional RelayPro device was implanted to successfully resolve the Type Ib endoleak. Subsequent to the secondary intervention, the Core Lab identified a second Type Ib endoleak in one subject at the 2 year follow-up visit. In this same subject, the Core Lab noted secondary procedure after the 6-month follow-up visit and that the Type Ib endoleak resolved. No further intervention has occurred as of the data lock.

Twenty-seven (27) subjects have been identified with a Type II endoleak, 15 were identified by the Core Lab on the 30-day follow-up imaging, 13 on the 6-month follow-up imaging (2 new and 11 persistent); 14 on the 12-month follow-up imaging (5 new and 9 persistent); 11 on the 2-year follow-up imaging (5 new and 6 persistant); and 1 persistant on the 3-year follow-up imaging. Two secondary interventions have been performed to address a Type II endoleak: 1) coil embolization procedure of the proximal left subclavian artery at 9 days post-index procedure and 2) extension of TEVAR into the abdominal aorta with parallel grafts into the SMA and renal arteries and coverage of the celiac artery at 1174 days post-index procedure. For both subjects, the 1-month, 6-month and 12-month follow-up visits were completed. The Core Lab also confirmed continuation of the Type II endoleak proceeding the interventions.

No Type III endoleaks, Type IV endoleaks, or endoleaks of unknown type were reported.

Table 20. Summary of Core Laboratory-Reported Endoleaks

Endoleak	30 Days	6 Months	12 Months	2 Years
Adequate Imaging*	106	90	85	41
Any Endoleaks (Total)	17.0% (18)	16.7% (15)	18.8% (16)	31.7% (13)
Type Ia				
New	1	0	1	1
Persistent	NA	0	0	0
New and Persistent	0.9% (1)	0% (0)	1.2% (1)	2.4% (1)
Type Ib				
New	2	0	0	1
Persistent	NA	2	1	0
New and Persistent	1.9% (2)	2.2% (2)	1.2% (1)	2.4% (1)
Type II				
New	15	2	5	5
Persistent	NA	11	9	6
New and Persistent	14.2% (15)	14.4% (13)	16.5% (14)	26.8% (11)
Type IIIa				
New	0	0	0	0
Persistent	NA	0	0	0
New and Persistent	0% (0)	0% (0)	0% (0)	0% (0)
Type IIIb				
New	0	0	0	0
Persistent	NA	0	0	0
New and Persistent	0% (0)	0% (0)	0% (0)	0% (0)
Type IV				
New	0	0	0	0
Persistent	NA	0	0	0
New and Persistent	0% (0)	0% (0)	0% (0)	0% (0)
Unknown Type				
New	0	0	0	0
Persistent	NA	0	0	0
New and Persistent	0% (0)	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.

6.4.16. Aneurysm Size Change

An increase in aneurysm sac size was defined as a change of 5 mm or more in diameter from the 1-month diameter measurement or the first post implant imaging. These assessments are based on Core Lab measurements. In the Pivotal Study, 97 subjects have images at the 6-month follow-up which have been adequate to assess aneurysm diameter, 92 at the 12-month follow-up, and 46 at the 2-year follow-up and 4 at the 3-year follow-up. Six subjects have been reported to have aneurysm enlargement, 1 newly identified on the 1 year follow-up imaging, 4 newly identified on the 2-year follow-up imaging, and 1 newly identified at 3-year follow-up imaging.

Three US subjects have been reported to have aneurysm enlargement, 1 newly identified on the 1 year follow-up imaging, 1 newly identified on the 2-year follow-up imaging, and 1 newly identified at 3 year follow-up imaging. Two of the three subjects with enlargement had baseline lesions that were fusiform aneurysms, and the third had been treated for a saccular aneurysm at the index procedure. Of these three subjects, 1 enlargement was due to a Type II endoleak, 1 was attributed to worsening of proximal aortic disease requiring a full arch repair, and the third subject (with saccular aneurysm) experienced an enlargement due to unknown cause.

Three Japan subjects have been reported to have aneurysm enlargement, all three newly identified on the 2-year follow-up imaging. Of these three subjects with enlargment, two had baseline lesions that were fusiform aneurysms and the third had been treated for a saccular aneurysm at the index procedure. Two enlargements were due to a Type II endoleak identified by the Core Lab while the site reported Type Ia endoleak and one was attributed to a site reported Type Ia endoleak.

The incidence of subjects with decrease in aneurysm sac diameter was 16.7% (16/96), 33.7% (31/92), 34.8% (16/46) and 0.0% (0/4) at 6 months, 12 months, 2 years, and 3 years, respectively, when compared to the first post implant imaging.

Table 21. Summary of Core Laboratory Assessed Changes in Aneurysm Sac Diameter: Pivotal Study

Changes in Aneurysm Size	6 Months	12 months	2 Years
Imaging Adequate to Assess Diameter Change (N)	97	92	46
Increase > 5mm			
New	0% (0)	1.1% (1)	8.7% (4)
Persistent	0% (0)	0.0% (0)	0.0% (0)
Total	0% (0)	1.1% (1)	8.7% (4)
Decrease	16.7% (16)	33.7% (31)	34.8% (16)
No Change	83.3% (80)	65.2% (60)	56.5% (26)

All values expressed as % (n), where n = Subjects with evaluable images at 30 days (based on first procedure measurement made within 30 day follow up analytical window) and at time point (e.g. 6 or 12 months) and N = Subjects evaluable at time point.

6.4.17. Stent-Graft Integrity

Stent fracture was defined as fracture or breakage of any portion of the stent. Fractures are assessed by the Core Lab with x-ray and CT imaging, or may be reported by the site. For the Pivotal Study cohort, 107 subjects had adequate imaging to assess for fracture at 30-days, 97 subjects at 6-months, 93 subjects at 1 year, 46 subjects at 2-years, and 4 subject at 3-years. No fractures (site reported or Core Lab reported) have been reported in any subject at any follow-up visit.

6.4.18. Stent-Graft Patency-Related Events

Loss of patency is defined within the study protocol as the unintentional obstruction of 100% of the stent-graft lumen. There have been no Core Lab or site-reported stent-graft occlusions reported in any subject at any timepoint.

6.4.19. Conversion to Open Surgery

There were no open surgical conversions in the study.

6.4.20. Secondary Interventions

A summary of the reasons for secondary interventions are shown in **Table 22.** There have been a total of 11 secondary interventions performed in 9 subjects. In summary, 3 interventions were performed to address site reported Type Ia endoleaks (Core Lab reported Type II), 2 to address site and Core Lab identified Type Ib endoleaks, 1 to address a site and Core Lab reported Type II endoleak, 1 to address site-reported migration, 1 to address a site and Core Lab reported Type I endoleak with site reported migration (Core Lab reported thoracic aorta lengthening, no migration) and 3 interventions within the same subject to address arch disease, Type Ib endoleak and a Type II endoleak.

Table 22. Summary of Reasons for Secondary Intervention

	30 Days	6 Months	1 Year	2 Years
Subjects at Risk (N)	109	96	92	38
Interventions (n)	2	2	3	1
Any Secondary Intervention	1.8% (2)	2.1% (2)	3.3% (3)	2.6% (1)
Type Ia Endoleak	0.9% (1)	1.0% (1)	1.1% (1)	2.6% (1)
Extension	1	1	1	1
Type Ib Endoleak	0% (0)	0% (0)	2.2% (2)	0% (0)
Extension	0	0	2	0
Type II Endoleak	0.9% (1)	0% (0)	0% (0)	0% (0)
Coil Embolization	1	0	0	0
Migration	0% (0)	1.0% (1)	0% (0)	2.6% (1)
Extension	0	1	0	0

Where % (n), % is the percentage of subjects with an event, n is number of subjects with an event and N is the number of subjects with visits in the specified window.
Windows for visits are as follows: 30 days (Day 0-90); 6 months (Day 91-270); 1 year (Day 271-540); 2 years (Day 541-900)

6.4.21. Thromboembolic Events

All intra-vascular implants have the potential for triggering the coagulation cascade, and therefore pose the risk for serving as a nidus for thrombus formation. A multitude of mechanical and physiologic factors contribute to this risk: while high velocity and high volume of blood flow and the large vessel diameter decrease the risk of thrombus formation within aortic endografts as compared to more peripheral stent-grafts, thromboembolic events are a known potential complication of TEVAR. Three subjects with possible thromboembolic events were identified to have occurred within 30 days of RelayPro implant.

The Medical Monitor and Clinical Events Committee (CEC) assessed all three events to be procedure-related but not device-related. There was no evidence of the possible thromboembolic event being related to the delivery system in any of these cases. In the case of the earliest event, only one device was used (therefore, only one delivery system), and the procedure was not considered prolonged, with no additional procedures.

6.4.22. Vascular access complications at the index procedure

Vascular access complications are injuries to vessels as a result of the endovascular procedure, including dissections, perforations, iliac thromboses, common femoral artery injuries not related to pre-existing disease, false or true aneurysms. Six of the 110 subjects (5.5%) experienced vascular access complications at the index procedure as reported by the sites. These vascular access complications included 1 subject with a neck hematoma that was addressed with a LSA/LCA by-pass, 1 subject with a right femoral artery dissection secondary to Perclose failure that was repaired, 1 subject with a right femoral artery laceration secondary to Perclose failure that was addressed by right femoral cutdown and pericardial patch, 1 subject with right femoral and left common femoral artery injury that was addressed with serial dilatation, 1 subject with a left CFA patch angioplasty, and 1 subject with a right iliac artery rupture and 1 dissection of the right SFA.

6.5. SUB-GROUP ANALYSES

The following preoperative characteristics were evaluated for potential association with outcomes: gender, race, baseline lesion type

(i.e., fusiform, non-fusiform aneurysm), and geography of enrollment (i.e., US, Japan). There were no statistically significant differences in the primary endpoints for any subgroup analyses.

In the pivotal study, 68 US patients and 42 Japanese patients were enrolled. The demographics, comorbidities, and baseline lesion characteristics, as well as outcomes reported in each cohort are presented in detail in each of the respective sections above. Regarding primary safety and effectiveness outcomes, the following were reported:

- A total of 6.4% (7/110) patients experienced an MAE through 30 days; 5.9% (4/68) in the US and 7.1% (3/42) in Japan. A total of 7 MAEs were observed in these 7 patients. The MAEs reported include: 2 strokes, 1 renal failure, 2 paralysis, and 2 procedural blood loss > 1,000 cc requiring transfusion. The two paralysis events and one stroke event occurred in 3 patients within the Japan cohort. All other events occurred in the US cohort.
- The primary effectiveness endpoint of treatment success at 12-months was achieved in 89.2% of the Pivotal Study patients (74/83, lower 95% CI 81.8%) and varied slightly between geography (85.7%, 42/49 in US cohort, 94.1%, 32/34 in Japanese cohort).

6.6. ADDITIONAL FOLLOW-UP DATA

Between 7 December 2020 and 10 March 2021, 17 subjects have returned for follow-up visits; 13 subjects have completed the 2-year follow-up, 3 subjects have completed 3-year follow-up and 1 subject has completed 4-year follow-up. Since 7 December 2020, there have been no deaths, no secondary interventions, no open surgical conversion, no aneurysm rupture as well as no Core Lab reports of endoleak, migration, fracture, occlusion or aneurysm expansion.

7. PATIENT SELECTION AND TREATMENT

7.1. PATIENT SELECTION

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

- Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- Non-aneurysmal aortic neck diameter in the range of 20 – 42 mm;
- Non-aneurysmal proximal aortic neck lengths of:
  - 15 mm for the 24 – 28 mm device diameters (***Bare Stent Configuration***)
  - 20 mm for the 30 – 38 mm device diameters (***Bare Stent Configuration***)
  - 25 mm for the 40 – 46 mm device diameters (***Bare Stent Configuration***)
  - 25 mm for the 24 – 38 mm device diameters (***Non-Bare Stent Configuration)***
  - 30 mm for the 40 – 46 mm device diameters (***Non-Bare Stent Configuration)***
- Non-aneurysmal distal aortic neck lengths of:
  - 25 mm for the 24 – 38 mm device diameters
  - 30 mm for the 40 – 46 mm device diameters

Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications. Additional anatomic considerations for patient selection include the following:

- Key anatomic criteria that may affect successful exclusion of the aneurysm includes a proximal landing zone with an inner radius of curvature less than 15mm (**Figure 6**), a proximal landing zone and a distal landing zone based on device selection defined in **Section 7.2**. The treatment site should be within the working length of the delivery system (90cm).

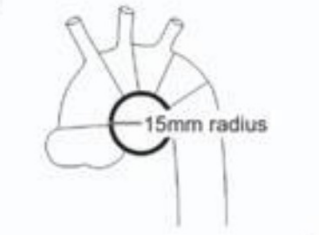


Figure 6. Inner Radius of Curvature

- Wire fractures are more likely to occur in conditions with an excessively oversized stent-graft, flexion, kinking, or bending during cardiac or respiratory cycles. Fractures of the Spiral Support Strut are more likely to occur if the strut is deployed along the inner radius of curvature. Wire fractures may have clinical consequences including endoleak, migration, or tissue damage.
- Practitioner must ensure that the access vessel diameter is compatible with the selected delivery system's outer sheath French size and that the aortic inner diameter that can accommodate the expanded inner sheath outer diameter of approximately 10 mm.

Additional considerations for patient selection when considering TEVAR 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. RELAYPRO STENT-GRAFT SIZING

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

- Refer to the recommended device sizing for the proximal and distal aortic landing zone lengths recommended for stent-graft diameters in **Table 23** for the ***Bare Stent Configuration*** and **Table 24** for the ***Non-Bare Stent Configuration***. Seal zones outside these recommendations could result in migration, endoleak, or other complications.
- 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. **Table 25** and **Table 26** address the selection of the appropriate stent-graft diameter based on vessel size for the Straight and Tapered stent-grafts, respectively for the ***Bare Stent Configuration***. **Table 27** and **Table 28** address the selection of the appropriate stent-graft diameter based on vessel size for the Straight and Tapered stent-grafts, respectively for the ***Non-Bare Stent Configuration***. For Tapered devices, the delivery system sheath size is driven by the largest diameter of the stent-graft.

Note:	The Straight and Tapered Configurations consist of: • Straight: Consistent diameter through the implant length • Standard Taper: Diameter of device decreases proximal to distal (typical 4mm transition; availability from 2mm and up to 18mm transition) • Reverse Taper: Diameter of device increases proximal to distal (availability from 2mm and up to 18mm transition)

- Sizing should be based on relatively recent imaging (within 6 months) and reconfirmation at the index procedure.
- All aortic diameter measurements should be adventitia to adventitia. The final treatment decision is at the discretion of the physician and patient.

- Deploying the device in a portion of the aorta with a different diameter than planned when selecting the graft size may potentially result in inadequate sizing and therefore migration, endoleak, aneurysm growth, or increased risk of thrombosis.
- Length of the stent-grafts should take into account tortuosity of vessels and minimum overlap requirements.
- As part of prudent preoperative case planning, an inventory of device lengths and diameters necessary to complete the procedure should be available to the physician.
- Practitioner must ensure that the access vessel diameter is compatible with the selected delivery system's outer sheath French size.

Table 23. TARGET LANDING ZONE – *BARE STENT CONFIGURATION*

Stent-Graft Diameter	Proximal Length		Stent-Graft Diameter	Distal Length
24 – 28 mm	15 mm		24 – 38 mm	25 mm
30 – 38 mm	20 mm		40 – 46 mm	30 mm
40 – 46 mm	25 mm			

Table 24. TARGET LANDING ZONE – *NON-BARE STENT CONFIGURATION*

Stent-Graft Diameter	Proximal Length		Stent-Graft Diameter	Distal Length
24 – 38 mm	25 mm		24 – 38 mm	25 mm
40 – 46 mm	30 mm		40 – 46 mm	30 mm

Table 25. STRAIGHT STENT-GRAFTS - *BARE STENT CONFIGURATION*

Stent- Graft Size (mm)	Thoracic Proximal Vessel Size (mm)	Graft Covered Length* (mm)				Graft Total Length (mm)				Delivery System French Size (O.D.)			
		100 mm	150 mm	200 mm	250 mm	100 mm	150 mm	200 mm	250 mm	100 mm	150 mm	200 mm	250 mm
24	20-21	90	150	190	250	104	164	204	264	19	19	19	19
26	22-23	95	155	195	250	109	169	209	264	19	19	19	19
28	24-25	95	155	195	250	110	170	210	265	19	19	19	19
30	26-27	95	155	200	250	111	171	216	266	19	19	19	19
32	28-29	95	155	200	250	112	172	217	267	20	20	20	20
34	30-31	100	145	200	250	117	162	217	267	20	20	20	20
36	32-33	100	145	190	250	118	163	208	268	20	20	20	20
38	34	100	145	190	250	119	164	209	269	21	21	21	21
40	35-36	105	145	195	250	125	165	215	270	21	21	21	21
42	37-38	105	150	195	250	125	170	215	270	22	22	22	22
44	39-40	105	155	200	250	126	176	221	271	22	22	22	22
46	41-42	105	155	200	250	126	176	221	271	22	22	22	22

**Graft covered lengths are available from 100 – 250 mm. Please note that interim lengths are available within that range in 10 – 20 mm increments.*

TERUMO Aortic

Table 26. 4 MM TAPERED STENT-GRAFTS* - *BARE STENT CONFIGURATION*

Tapered Stent-Graft Size (mm)	Thoracic Vessel Size (mm)		Graft Covered Length** (mm)			Graft Total Length (mm)			Delivery System French Size (O.D.)		
	Proximal	Distal	150 mm	200 mm	250 mm	150 mm	200 mm	250 mm	150 mm	200 mm	250 mm
28x24	24-25	20-21	155	195	250	170	210	265	19	19	19
30x26	26-27	22-23	155	200	250	171	216	266	19	19	19
32x28	28-29	24-25	155	200	250	172	217	267	20	20	20
34x30	30-31	26-27	145	200	250	162	217	267	20	20	20
36x32	32-33	28-29	145	190	250	163	208	268	20	20	20
38x34	34	30-31	145	190	250	164	209	269	21	21	21
40x36	35-36	32-33	145	195	250	165	215	270	21	21	21
42x38	37-38	34	150	195	250	170	215	270	22	22	22
44x40	39-40	35-36	155	200	250	176	221	271	22	22	22
46x42	41-42	37-38	155	200	250	176	221	271	22	22	22

**The degree of tapering can range from 2-18 mm.*

*** Graft covered lengths are available from 100 – 250 mm. Please note that interim lengths are available within that range in 10 – 20 mm increments.*

Table 27. STRAIGHT STENT-GRAFTS - *NON-BARE STENT CONFIGURATION*

Stent- Graft Size (mm)	Thoracic Proximal Vessel Size (mm)	Graft Covered Length* (mm)				Delivery System French Size (O.D.)			
		100 mm	150 mm	200 mm	250 mm	100 mm	150 mm	200 mm	250 mm
24	20-21	99	159	199	259	19	19	19	19
26	22-23	104	164	204	259	19	19	19	19
28	24-25	104	164	204	259	20	20	20	20
30	26-27	104	164	209	259	20	20	20	20
32	28-29	104	164	209	259	21	21	21	21
34	30-31	109	154	209	259	21	21	21	21
36	32-33	109	154	199	259	22	22	22	22
38	34	109	154	199	259	22	22	22	22
40	35-36	114	154	204	259	22	22	22	22
42	37-38	114	159	204	259	23	23	23	23
44	39-40	114	164	209	259	23	23	23	23
46	41-42	114	164	209	259	23	23	23	23

**Graft covered lengths are available from 100 – 250 mm. Please note that interim lengths are available within that range in 10 – 20 mm increments.*

Table 28. 4 MM TAPERED STENT-GRAFTS* - *NON-BARE STENT CONFIGURATION*

Tapered Stent-Graft Size (mm)	Thoracic Vessel Size (mm)		Graft Covered Length** (mm)			Delivery System French Size (O.D.)		
	Proximal	Distal	150 mm	200 mm	250 mm	150 mm	200 mm	250 mm
28x24	24-25	20-21	164	204	259	20	20	20
30x26	26-27	22-23	164	209	259	20	20	20
32x28	28-29	24-25	164	209	259	21	21	21
34x30	30-31	26-27	154	209	259	21	21	21
36x32	32-33	28-29	154	199	259	22	22	22
38x34	34	30-31	154	199	259	22	22	22
40x36	35-36	32-33	154	204	259	22	22	22

Tapered Stent-Graft Size (mm)	Thoracic Vessel Size (mm)		Graft Covered Length** (mm)			Delivery System French Size (O.D.)		
	Proximal	Distal	150 mm	200 mm	250 mm	150 mm	200 mm	250 mm
42x38	37-38	34	159	204	259	23	23	23
44x40	39-40	35-36	164	209	259	23	23	23
46x42	41-42	37-38	164	209	259	23	23	23

**The degree of tapering can range from 2-18 mm.*

*** Graft covered lengths are available from 100 – 250 mm. Please note that interim lengths are available within that range in 10 – 20 mm increments.*

The minimum recommended amount of overlap between devices is three overlapping covered stents (approximately 50 mm). Less than this amount of overlap may result in endoleak (with or without component separation). For modular, unsupported junctions, a 2 mm oversizing is recommended. Sizing outside these guidelines could result in endoleak, migration, stent-graft separation, infolding, or device damage.

Note:	Given the indications for use and the device configurations, if the lesion requires use of an extension, **only** a RelayPro Non-Bare Stent (NBS) configuration may be used. Refer to Section 1.1 for a description of the NBS configuration stent-graft which is fully detailed in its own Instructions for Use.

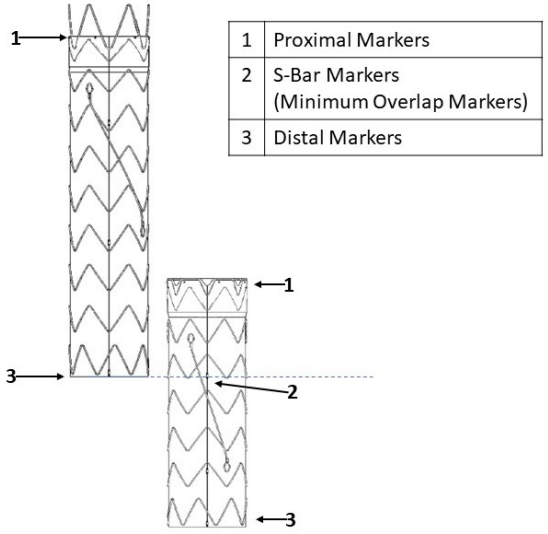


Figure 7. Marker Band Placement in Overlap Configuration

8. PATIENT COUNSELING INFORMATION

The benefits and risks of the endovascular procedure using **RelayPro** 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 **RelayPro** 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 **RelayPro** 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 **RelayPro** have been sterilized by gamma irradiation. **RelayPro** 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 **RelayPro** in a cool, dry place 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 29.**

Table 29. Product Designation

Internal Code	Identifier	Proximal Diameter (mm)	Family Length* (mm)	Distal Diameter (mm)	Device Designation	French Size**
28	**M4**: Bare Stent Configuration **N4**: Non-Bare Stent Configuration	XX	XXX	XX	**U**: Standard Catalog Product for US	(XX Fr)
*Family lengths listed. Final lengths to be listed on product labeling (Tolerance of ±10 mm). **Identified on label but not part of model designation.						

10. CLINICAL USE INFORMATION

10.1. PHYSICIAN TRAINING REQUIREMENTS

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

Caution:	**RelayPro** 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 **RelayPro**:

- Knowledge of radiographic, fluoroscopic and angiographic image interpretation
- Knowledge of natural history and associated comorbidities of TAA, fusiform and saccular aneurysms or PAU
- A multi-disciplinary team that has combined procedural experience with:
  - Appropriate use of radiographic contrast material
  - Appropriate use of anticoagulants
  - 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 **RelayPro THORACIC STENT-GRAFT SYSTEM** should have a thorough understanding of endovascular procedures and techniques. In particular, the **RelayPro THORACIC 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 **RelayPro THORACIC 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 pouch has any punctures, tears or opening as this may have affected system sterility.

10.4. DEVICES, SUPPLIES AND EQUIPMENT REQUIRED

- **RelayPro** 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
- Surgical suite in the event that emergency open conversion surgery is necessary

10.5. SUPPORTIVE/SUPPLEMENTARY EQUIPMENT

- Inflation device with pressure gauge
- Guidewire torque devices
- Vascular Balloon-Catheters of the appropriate size
- Gooseneck snare (10-15mm diameter)
- Assortment of vascular stents

10.6. MAGNETIC RESONANCE (MR) IMAGING SAFETY INFORMATION

MRI SAFETY INFORMATION

MR Conditional

A person with the RelayPro Thoracic Stent-Graft may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	RelayPro Thoracic Stent-Graft
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole-body transmit coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of the RelayPro Thoracic Stent-Graft may produce an image artifact at 5mm. Some manipulation of scan parameters may be needed to compensate for the artifact.

11. DIRECTIONS FOR USE

11.1. PATIENT AND DEVICE PREPARATION: (STEPS 1 THROUGH 10)

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 **RelayPro** delivery system into the aorta, do not disturb the thrombus mass within the aneurysm. Doing so may dislodge emboli, which can cause embolization. If 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.
- Stop advancing the guidewire or delivery system if resistance is encountered. Assess the source of the resistance before proceeding to avoid vessel or catheter damage.
- 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.

Note:	Do not bend or kink the delivery system as it may cause damage to not only the delivery system but also the **RelayPro** stent-graft.

4. Perform a vascular access at the common femoral artery that will be used to track the device. Place a .035" [0.89mm], 260 or 300cm long, super stiff guidewire up to the aortic arch. The second femoral artery can be accessed for angiographic catheter placement.

Note:	Angiography is performed at the discretion of the physician.

5. Ensure that the controller is in the "1" position, if it is not change it to the "1" position to prevent premature deployment of the stent-graft.
6. Verify that the delivery system tip is properly seated in the outer sheath and that the tip side hole is not covered. If not, correct by rotating the deployment grip until the delivery system tip is properly seated.
7. Flush the guidewire flush port with minimum of 5 cc of heparinized saline. Flush the delivery system with minimum of 20 cc of heparinized saline through the flush port to purge air from the inside of the sheath and the coaxially situated sheaths. Ensure that saline can be seen exiting from the tip area. Visually inspect the system for remaining air and repeat if necessary. It may be necessary to elevate the distal end of the system to different positions to bring air to the highest point for purging.

Warning:	Placement of stent-graft in the thoracic aorta often requires proximity to the great vessels perfusing the brain, increasing the possibility of thrombus or embolization proximally. Care should be taken to ensure air has been purged from the system.

8. Verify that the apex holder knob [ITEM 13] is securely engaged in the V-shaped notch of the guidewire luer [ITEM 14] (see **Figure 2**).

Cautions:	• DO NOT USE the system if the apex holder knob is not engaged in the V-shaped notch provided by the guidewire luer. • Do not attempt to re-engage the apex holder knob with the guidewire luer.

9. Flush the delivery system with heparinized saline through the gray guidewire luer.

Note:	Attention should be paid to not rotate the apex holder knob during this step.

Figure 8. Guidewire lumen flush port

10. Activate the hydrophilic coating by wetting the tip and outer sheath with sterile saline.

11.2. INTRODUCTION/ADVANCEMENT OF THE OUTER SHEATH (STEPS 11 THROUGH 12)

11. Advance the outer sheath into the artery over the guidewire.

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

12. Under fluoroscopic control, advance the outer sheath until the delivery system tip is just below the intended distal landing zone. If the descending aorta presents tight tortuosity, the tip should be advanced past the tight curvature(s) to facilitate navigation of the inner sheath.

Caution:	Do not advance the outer sheath into the thoracic arch.

Note:	If the outer sheath cannot be advanced beyond the region of tight curvatures, the delivery system should be removed from the patient and an alternate procedure be considered.

11.3. ADVANCEMENT OF THE INNER SHEATH (STEPS 13 THROUGH 18)

Cautions:	• Once the inner sheath is advanced, the user will be committed to implant the graft. • The controller must be in the "1" position.

Note:	The handle body can be rotated to position the top of the device facing the user. The handle body should not be rotated more than half a turn.

13. While holding the gray grip so that the main body remains stationary, rotate the deployment grip clockwise to advance the inner sheath. Ensure that while the deployment grip is being turned, it is being pushed toward the gray stationary grip.

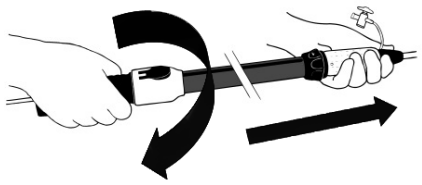


Figure 9. Actuating the device using mechanical advantage

If preferred, the mechanical advantage can be bypassed by pressing on the "disengagement button" while advancing the deployment grip.

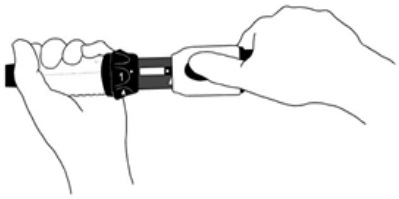


Figure 10. Disengagement button

14. Advance the inner sheath until the stent-graft proximal markers reach the proximal landing zone. Upon reaching the intended proximal landing zone, visually confirm that the stent-graft's distal markers bands can be seen approximately 2 cm outside of the outer sheath. If the stent-graft's distal marker bands do not appear to have exited the outer sheath, while in Position 1, press the disengagement button and hold the deployment grip stationary while pulling back on the gray stationary grip until the stent-graft's distal marker bands have exited the outer sheath by approximately 2 cm. Verify that the white arrow marker has been covered by the deployment grip assembly.

Caution:	Do NOT advance the delivery system tip or guidewire across the aortic valve.

15. As the inner sheath is advanced out of the outer sheath, note the alignment of the Spiral Support Strut by locating the Spiral Support Strut markers under fluoroscopy.

16. If the device is to be implanted in a curved section of the aorta, verify that the D-shaped marker on the inner sheath and the Spiral Support Strut marker(s) face the greatest curvature.

    If radial adjustment is needed, retract the deployment grip (disengage mechanical advantage by pressing on disengagement button) to bring the stent-graft to a straight portion of the vessel. When retracting the deployment grip, ensure that the distal end of the stent-graft is not pulled into the outer sheath (the white arrow marker can be used as a reference). If the Spiral Support Strut is not facing the outer curvature of the aorta, it may be necessary to retract the whole device a few centimeters to bring the stent-graft to a straight position. After the stent-graft is in the straight position, while holding the front nose cap, rotate the whole handle body to manually align the Spiral Support Strut markers toward the greatest curvature of the aorta. The D-shaped marker can be used to aid in this placement. If the round portion of the D-shaped marker is facing the greater curvature, the handle body should be turned clockwise. If the round portion is facing the lesser curvature, the turn should be counterclockwise. One to three handle revolutions maybe required before the stent-graft begins rotating. Once alignment is confirmed, re-advance the stent-graft into the desired position.

Figure 11. Device rotation while holding nose cap

17. Perform an angiogram of the area of interest to confirm proper position of the device in preparation for deployment.

Cautions:	• Once the proximal position of the 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 proximal landing zone to avoid parallax or other source of visualization error that could impact proper positioning. • Ensure the inner sheath and stent-graft have fully exited the outer sheath before deployment.

18. Finalize the longitudinal placement of the stent-graft in relation to the proximal landing zone by adjusting the deployment grip as necessary. Confirm the position of the proximal and distal marker bands as well as the Spiral Support Strut markers.

11.4. STENT-GRAFT DEPLOYMENT (STEPS 19 THROUGH 23)

19. With the stent-graft in the desired deployment position, turn the controller to the "2" position.

Figure 12. Turn controller to Position 2

20. While holding the gray grip fixed, rotate the deployment grip counterclockwise to pull down the inner sheath until the first covered stent begins to expand.

Notes:	• The inner sheath has the D-Shaped radiopaque marker located between the stent-graft proximal marker and the most proximal Spiral Support Strut marker. This marker can be used to visualize the inner sheath's movement under fluoroscopy. • ***NBS Configuration****:* The D-shaped marker should not be retracted past the proximal Spiral Support Strut marker to allow linear re-adjustments. If the D-marker is moved beyond the proximal Spiral Support Strut marker, the proximal end of the graft is expanded too much to allow repositioning.

21. Make any final linear position adjustments (proximally or distally), if necessary.

Warnings:	• Do not attempt to reposition the **RelayPro** stent-graft once it has opposed the vessel wall. Inadvertent partial deployment or migration of the **RelayPro** stent-graft may require surgical removal. • Inaccurate placement and/or incomplete sealing of the **RelayPro** stent-graft within the vessel may result in increased risk of endoleak, migration, or inadvertent occlusion of the left subclavian, left common carotid, and/or celiac arteries. Surgical intervention may be required.

22. Deploy the stent-graft by holding the gray stationary grip fixed and, while pressing the disengagement button down, retract the deployment grip with one continuous motion without stopping until the stent-graft is fully deployed and the inner sheath completely retracted.

Cautions:	• Failure to promptly deploy the stent-graft will cause blood pressure to increase and may result in distal migration of the device during deployment. • Attachment of the proximal end of the stent-graft is maintained by the apex holder. As such, the handle body should not be moved until the apex holder is released.

23. Under fluoroscopic control, release the stent-graft from the apex holder by rotating the black apex holder knob and sliding it toward the gray guidewire luer. The stent-graft is now fully released.

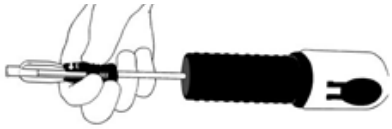


Figure 13. Clasp release

11.5. SYSTEM REMOVAL (STEPS 24 THROUGH 30)

24. Place the controller in the "4" position.

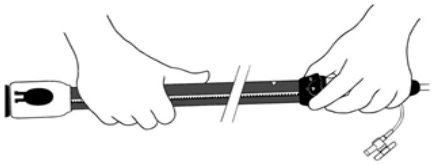


Figure 14. Turn controller to Position 4

25. Under fluoroscopic control, retract the stainless steel rod allowing the tip to rejoin the outer sheath. Monitor the travel of the delivery system tip through the deployed stent- graft so that stent-graft's position is not affected. If the tip does not rejoin easily, apply slightly greater force until the tip rejoins with the outer sheath.

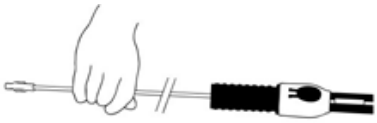


Figure 15. Retraction of stainless steel rod

Notes:	• Anatomy and graft position may change during the withdrawal of the delivery system and/or guidewire; therefore, constant monitoring of the graft position is important. Use angiography as necessary. • Ensure there is no gap between the tip and outer sheath prior to withdrawing the system from the patient.

26. Withdraw the entire system from the patient.

Warnings:	• Balloon modeling is not required but if it is deemed necessary, it is recommended that balloon modeling be done with a compliant balloon. Balloon inflation should not exceed 1 atm. • Over inflation of semi or non-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. ***For the Bare Stent Configuration***, ballooning outside the covered portion could cause aortic rupture, atherosclerotic plaque embolization, or other complications. • ***Bare Stent Configuration****:* Do not expand the bare proximal stent as expansion of the bare proximal stent may cause vessel injury or rupture and the balloon could snag onto the bare proximal stent.

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.

27. Perform a final angiogram to assess for endoleaks, migration and aneurysm/lesion exclusion.
28. If a Type I endoleak is detected, consider balloon modeling to correct the endoleak. A proximal extension device may also be considered to treat Type I endoleaks. Endoleaks detected at the conclusion of the procedure and not corrected should be carefully monitored after implantation.
29. Straighten the angiographic pigtail catheter and remove all catheters and sheaths from the access sites and perform standard surgical closure of the arteriotomy sites.
30. Assess blood flow to the distal extremities.

12. BAIL OUT TECHNIQUE

In the unlikely event the mechanical advantage does not function as intended, the following technique may be used:

- The mechanical advantage can be bypassed by pressing the "disengagement button" and the delivery system can be operated by manually pushing or pulling the deployment grip as needed.

In the unlikely event the stent-graft cannot be deployed because the stainless steel rod fails to remain stationary in relation to the handle body during the deployment phase (controller to the "2" position), the following technique may be used:

- The stainless steel rod and the handle body can be manually held together to complete the deployment of the stent-graft.

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 13**. 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 stent.

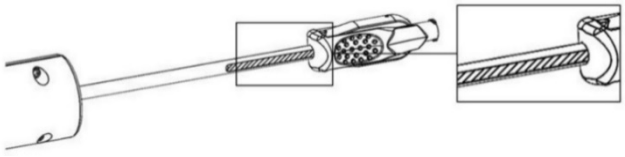


Figure 16. Identification of Slot in Delivery System

13. FOLLOW UP PROCEDURE

13.1. GENERAL

All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (such as, endoleaks, enlarging aneurysms, enlarging false lumens, or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be informed that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of thoracic aortic lesions. This includes aneurysms, saccular aneurysms and penetrating atherosclerotic ulcers. Physicians should evaluate patients on an individual basis and prescribe follow-up relative to the needs and circumstances of each individual patient.

Current recommended imaging of stent-graft patients includes single or multislice CT scans 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 that cannot be adequately premedicated. 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 enlargement 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:

- Thoracic radiographs to examine device integrity (stent fracture, separation between the prostheses, 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 contrast media, alternative imaging modalities should be considered (see proceeding sections).

13.2. X-RAY

Thoracic X-rays should be used to assess the presence of stent fracture and component separation. 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, TAA size, and endoleak (including source and type if present). A pre-contrast scan of 3 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 CT scans with ≤ 3 mm slice thickness with coverage from the sino-tubular junction to the origin of the superior mesenteric artery beyond the end of the prosthesis are recommended.

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 regressing by more than 5 mm within the first year, volume measurements may be obtained as a more sensitive indicator of TAA size using 3-dimensional software.

13.4. NON-CONTRAST CT

For patients with impaired renal function or those who are allergic to contrast medium and cannot be adequately premedicated, a 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 and size of the TAA diameter and volume measurements.

13.5. TRANSESOPHAGEAL ECHOCARDIOGRAPHY

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

13.6. MRI OR MRA

Patients with impaired renal function 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 TAA size. Volume measurement may be helpful if the aneurysm is not clearly regressing in size. 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 thoracic X-rays, a CT should be performed to assess aneurysm size and the presence or absence of an endoleak.
- If a new endoleak or increase in TAA size is observed by 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.
- 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 TAA size of more than 5mm or evidence of sub-optimal fixation, proximal endoleak, distal endoleak, junction endoleak, or unknown origin of peri-graft flow.

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's comorbidities, life expectancy, and the patient's personal choices. Patients should be counseled that subsequent reintervention may become necessary following an endovascular graft procedure.

15. DEVICE TRACKING INFORMATION

The **RelayPro THORACIC STENT-GRAFT SYSTEM** is packaged with the following:

- **Implant Information Form.** This form must be completed by the hospital staff and sent to Bolton Medical for the purposes of tracking all patients who receive the RelayPro Thoracic Stent-Graft (as required by U.S. Federal Regulation).
- **Device Identification Card**. This card must be completed by the hospital staff and provided to the patient. Patients should be instructed by their physician to keep this card with them at all times. Patients should refer to the card when visiting other healthcare practitioners, and especially when visiting MR imaging facilities since the card provides specific information on the safe imaging of the **RelayPro** stent-graft via MR.

16. DISCLAIMER OF WARRANTY

ALTHOUGH THE **RELAYPRO THORACIC STENT-GRAFT SYSTEM** HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, BOLTON MEDICAL, INC., AND ANY ASSOCIATED AFFILIATES, HAVE NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. BOLTON MEDICAL, INC., THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BOLTON MEDICAL, INC. SHALL NO BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSE OR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT WHETHER A CLAIM FOR SUCH DAMAGES IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE. NO PERSON AHS ANY AUTHORITY TO BIND BOLTON MEDICAL, TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT. BOLTON MEDICAL, INC. (d/b/a Terumo Aortic) IS THE LEGAL MANUFACTURER OF THE **RELAYPRO THORACIC STENT-GRAFT SYSTEM**.

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17. PATENTS

http://www.boltonmedical.com/patents.html

18. 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
	Keep away from sunlight
	Keep Dry

18. DEFINITIONS

	Temperature Limit
	Do not use if package is damaged
Rx Only	Caution: Federal (USA) law restricts this device for sale by or on the order of a physician.
NBS	Non-Bare Stent Configuration

 MANUFACTURER:

BOLTON MEDICAL, INC
799 INTERNATIONAL PARKWAY
SUNRISE, FLORIDA 33325 USA
TELEPHONE: 954 838-9699
terumoaortic.com

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