SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Endovascular Graft

Device Trade Name: Relay®Pro Thoracic Stent-Graft System

Device Procode: MIH

Applicant's Name and Address: Bolton Medical, Inc.
799 International Parkway
Sunrise, FL 33325 USA

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200045/S002

Date of FDA Notice of Approval: March 7, 2023

The original PMA (P200045) was approved on August 5, 2021 and is intended for endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta (DTA) in patients having appropriate anatomy. The Summary of Safety and Effectiveness Data (SSED) to support the original approval is available on the CDRH website and are incorporated by reference here. Please see the approval order on the CDRH website for the original Indications for Use.

The current supplement was submitted to expand the indication for the Relay®Pro Thoracic Stent-Graft System for the endovascular repair of isolated lesions of the descending thoracic aorta (DTA) to include the treatment of all lesions of the DTA, including Type B dissections and traumatic injuries. The study design and approach is consistent with other endovascular grafts that are currently marketed with these indications.

The current supplement was also submitted to expand the indications for the Relay®Pro Thoracic Stent-Graft System for the distal extension of the Thoraflex™ Hybrid device. The original PMA (P210006) for Thoraflex™ Hybrid was approved on April 19, 2022 and is intended for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection.. The Summary of Safety and Effectiveness Data (SSED) to support the use of the Relay®Pro Thoracic Stent-Graft System with the Thoraflex™ Hybrid is available on the CDRH website and are incorporated by reference here.

The RelayPro device presented in this PMA supplement is the same design as that approved in the original PMA with the addition of the 22mm device configuration.

II. INDICATIONS FOR USE

The Relay®Pro Thoracic Stent-Graft System is indicated for the endovascular repair of all lesions of 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 for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers and dissections
    - 19 – 42 mm for traumatic aortic injuries;
- Proximal landing zone (non-aneurysmal proximal aortic neck lengths for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers or non-dissected length of aorta proximal to the primary entry tear for dissections and length of aorta proximal to the tear for traumatic aortic injuries) of:
    - 15 mm for the 22 – 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 22 – 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 for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers of:
    - 25 mm for the 24 – 38 mm device diameters
    - 30 mm for the 40 – 46 mm device diameters
- Non-aneurysmal distal landing zone of 20 mm for traumatic aortic injuries (22 mm – 46 mm device diameters) and dissections (24 mm – 46 mm device diameters)

The Relay®Pro Thoracic Stent-Graft System (NBS configuration) is indicated for the endovascular distal extension of the Thoraflex Hybrid device.

III. CONTRAINDICATIONS

The Relay®Pro Thoracic Stent-Graft System is contraindicated in the following:

- Patients with a known allergy or intolerance to device materials (Nitinol, polyester, platinum-iridium).
- Patients with a condition that threatens to infect the graft

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Relay®Pro Thoracic Stent-Graft System labeling.

V. DEVICE DESCRIPTION

The Relay®Pro Thoracic Stent-Graft System (referred to as RelayPro hereafter) is designed to treat fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers, Type B dissections and traumatic injuries in the descending thoracic aorta. The RelayPro Stent-Graft System consists of two types of implants, namely the proximal bare stent configuration and the non-bare stent (NBS) configuration.

Each patient receives at least one RelayPro Stent-Graft (**Figure 1**). Each implant configuration is preloaded into its own RelayPro delivery system that is advanced under fluoroscopy to the location of the lesion. Upon deployment the stent-graft creates a blood flow channel, excluding the lesion from blood pressure and flow.

RelayPro Stent-Grafts

All stent-grafts are comprised of self-expanding Nitinol stents sutured to a woven polyester fabric. The stent scaffold is a series of sinusoidal springs stacked in a tubular configuration. These stents are spaced along the length of the graft fabric to provide radial support and allow for the self-expansion of the stent-grafts. A spiraled ("S" shaped) Nitinol strut is sewn to the proximal section of the fabric to provide longitudinal support. The stents and the curved wire are sewn to the graft fabric with polyester surgical grade suture. Radiopaque markers are placed on the stent-graft to aid in visualization and accurate placement.

The RelayPro Stent-Graft is available in two proximal configurations: the proximal bare stent and non-bare stent (NBS). Other than the proximal configuration, the two implants are identical in design as described above.

The proximal bare stent configuration incorporates a bare stent that is mostly uncovered and is made of a slightly larger Nitinol wire than the other stents in the implant. The proximal apexes are designed with larger radii of curvature as compared to all other apexes on all other stents. Additionally, the bare stent has the lowest radial load of all stents on the RelayPro stent-graft. The combination of the large apexes and low radial force of the bare stent is intended to minimize the stress on the aortic wall. There is one bare stent per implant. The proximal stent (just distal to the bare stent) has the highest radial load and is designed to seal with the aortic wall. There are two proximal stents per implant.

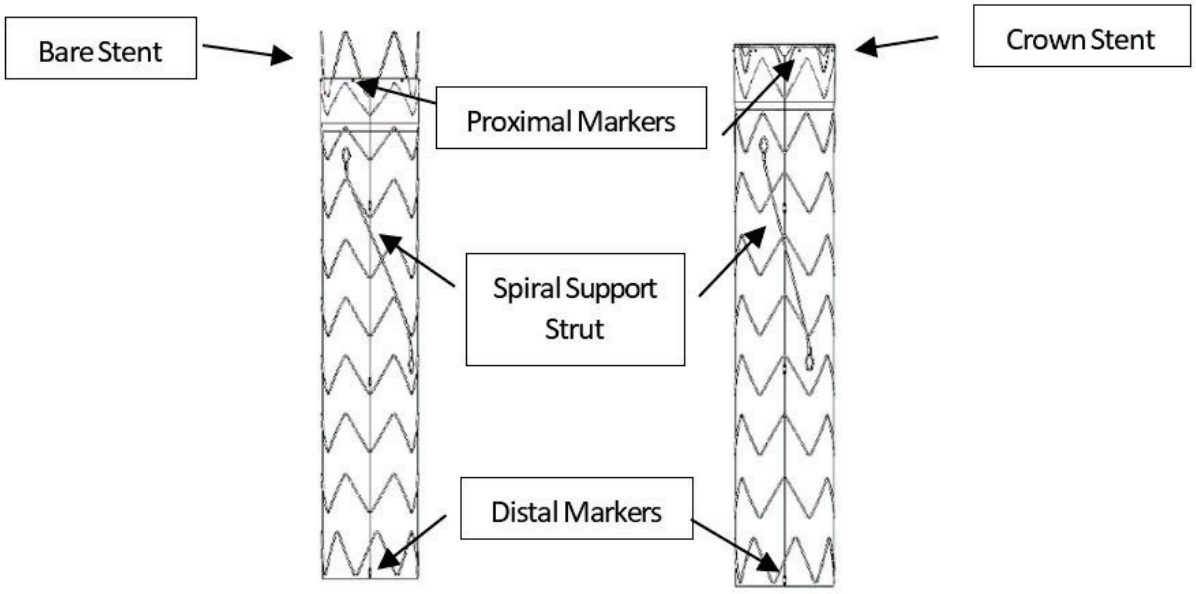
The NBS configuration incorporates a crown stent that consists of a series of apices that are connected by flat sections. The crown stent is designed to support the edge of the graft to appose the vessel wall and to minimize graft infolding. There is one crown stent per implant. The NBS proximal stent (just distal to the crown stent) has the same design intent as proximal stent in the proximal bare stent configuration and has a slightly modified design. There are two NBS proximal stents per implant.

The RelayPro Stent-Graft is available in the following configurations and sizes maximizing device selections available to the physician:

- Two proximal configurations: Proximal Bare Stent & Non-Bare Stent (NBS)

- Covered Lengths (Bare Stent): 100mm (± 10mm depending on graft diameter) to 250 mm
- Covered Lengths (Non-Bare Stent): 109mm (± 10mm depending on graft diameter) to 259mm
- Diameters: 22mm – 46mm in 2 mm increments
- Straight and Tapered Configurations
  - 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)

Figure 1. RelayPro Thoracic Stent-Graft, with bare stent and non-bare stent, illustrating stents and spiral support strut



Delivery System Description

The RelayPro Delivery System consists of a series of coaxially-arranged sheaths and catheters (outer introduction sheath, inner delivery sheath, through lumen), handle and apex release mechanism. The stent-graft is constrained within the inner sheath, which is further constrained within the outer sheath. The tapered tip and introducer sheath have a lubricious hydrophilic coating. The radiopaque, polymeric outer sheath is tracked over a guidewire to facilitate introduction of the device through the femoral and iliac arteries. Once the outer sheath reaches the distal end of the treatment site, the deployment grip of the delivery system is advanced to exit the inner sheath from the outer sheath. The inner sheath is advanced to the proximal landing zone in preparation for deployment. The inner sheath, which is connected to the delivery catheter and the delivery handle, can be retracted to deploy the constrained stent-graft

in a controlled fashion. The apex release mechanism constrains the most proximal stent of the stent-graft. Sliding the outer control tube over the guidewire lumen after the deployment from the inner sheath controls this mechanism. This provides a controlled apposition of the stent to the vessel wall.

The delivery systems used for the RelayPro NBS and Bare Stent configurations are functionally and operationally equivalent. There are minor differences to accommodate the NBS configuration which do not change the mode of operation. **Figure 2** illustrates the delivery system for the Bare Stent and NBS configuration. Item 16 in **Figure 2** (support wires) are not present in the Bare Stent configuration delivery system. The two Nitinol wires, called support wires, control the expansion of the inferior portion of the stent-graft, which helps avoid asymmetrical deployment of the NBS configuration. 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 the figure (apex holder) differs slightly between the configurations. The delivery system is provided in outer diameters ranging from 19 up to 22 French for the Bare Stent Configuration and 23 French for the NBS Configuration, depending on the corresponding stent-graft diameter, with a working length of 90 cm.

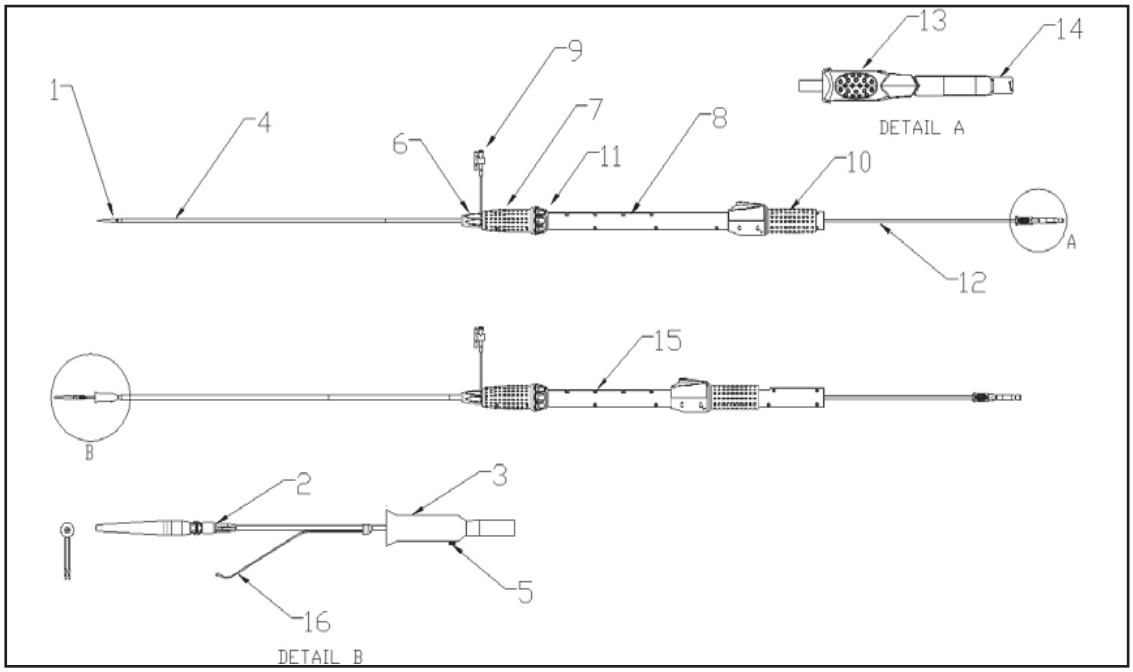


Figure 2. RelayPro Bare and Non-Bare Stent Configuration Delivery System

1. Delivery System Tip
2. Apex Holder
3. Inner Sheath
4. Outer Sheath
5. Radiopaque Marker
9. Flush Port
10. Deployment Grip
11. Controller
12. Stainless Steel Rod
13. Apex Holder Knob

6. Front Nose Cap
7 Gray Grip
8. Handle Body
14. Guidewire Luer
15. Arrow Marker
16. Support Wire (Non-Bare Stent only)

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for the treatment of lesions in the descending thoracic aorta including medical management, open surgical repair, and endovascular repair using other endovascular grafts. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle. For traumatic injuries, surgical or endovascular intervention is required to prevent death.

VII. MARKETING HISTORY

The RelayPro Thoracic Stent-Graft for the treatment of aneurysms and penetrating atherosclerotic ulcers (PAU) was approved August 5, 2021 (P200045). The device is commercially available in countries such as the European Union, Chile, Colombia, Hong Kong, India, Japan, Lebanon, Singapore, South Africa, Thailand, UK and Vietnam since 2018.

The RelayPro Thoracic Stent-Graft has not been withdrawn from the market for any reason related to its safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device:

Table 1. Potential Adverse Events	
Access Failure	Infection / Sepsis
Allergic Reaction (to contrast, antiplatelet therapy, stent-graft materials)	Intercostal pain
Amputation	Intramural Hematoma
Anesthetic reactions/complications (e.g., aspiration)	Ischemia (spinal cord, perfusion pathways)
Aneurysm Sac Enlargement	Limb ischemia
Aneurysm / Lesion Rupture	Lymphocele
Angina	Neuropathy
Aortic vessel damage (perforation, dissection, bleeding, rupture)	Pain

Table 1. Potential Adverse Events	
Arteriovenous fistula / aorto-esophageal fistula	Paralysis/Paresthesia/Paraparesis/Paraplegia/Spinal Cord Shock
Blindness	Perforation
Blood Loss	Peripheral Nerve injury
Bowel complications (e.g., adynamic ileus, transient ischemia, infarction, obstruction, necrosis)	Persistent false lumen flow
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
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
Dissection extension	Stent fracture / break
Dysphagia	Stent-Graft failure (e.g., improper component placement, poor conformability of the graft to the vessel wall, graft material wear or tear, suture break, dilation, erosion, graft twisting or kinking, stent-graft thrombosis / occlusion, puncture, perigraft flow)
Edema	Stent-Graft Infection
Embolism (micro and macro) with transient or permanent ischemia or infarction	Stent-Graft Migration
Endoleak	Tissue Necrosis
Fever and localized inflammation	Transient Ischemic Attack
Fistulas	Unintentional Dissection Septum Rupture
Gastrointestinal complications	Vascular Spasm

Table 1. Potential Adverse Events	
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)
Incision site complications	

For the specific adverse events that occurred in the clinical study, please see **Sections D 1.2 and H 1.2 Secondary Safety Endpoints** below.

IX. SUMMARY OF NONCLINICAL STUDIES

Nonclinical studies were completed to evaluate the RelayPro device, including non-clinical bench testing, biocompatibility, sterilization, packaging, shelf-life (2 years), and animal studies. The SSED containing the Nonclinical studies to support the aneurysm indication (P200045) for the RelayPro device is available on the CDRH website.

Bolton Medical is seeking approval of an expanded indication using the same commercially approved RelayPro Thoracic Stent Graft System. No changes have been made to the product design or specifications, other than the addition of the 22mm configuration. Most pre-clinical studies previously provided in P200045 and P210006 are applicable and were adequate to support the indication expansion (e.g., testing included the full device size matrix; the 22mm configuration has the same migration resistance and radial force acceptance criteria as the 24-28mm device configurations). In addition, new studies were conducted for the following to support the expanded indications:

- Fatigue and Durability – Computational Analyses
- Fatigue and Durability – *in vitro* Testing

A. Laboratory Studies

To support the expanded indications, RelayPro underwent testing for design verification and validation, including long-term durability. Testing was performed in accordance with ISO 25539-1: 2017, "*Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses"* and ISO 25539-1: 2003/A1, "Cardiovascular implants – Endovascular devices – Part 1: Endovascular protheses, Amendment 1: Test Methods." For evaluation of the RelayPro, a subset of device components and sizes were used for each test or alternatively, the worst-case configuration /size was selected. A four-corners approach was utilized for sample selection. This sample selection represented the full size range available for RelayPro. A summary of the new studies is provided in **Table 2**.

Table 2. Non-Clinical Testing: Implant

Test Name	Test Purpose	Acceptance Criteria	Results
Fatigue and Durability – Computational Analyses	Finite element analysis (FEA) was used to compute the maximum strains in all of the RelayPro design's sizes when subjected to catheter loading and maximum alternating strains in an *in-vivo* pulsatile loading environment.	Characterization study. The worst-case component size was identified and used to select the worst-case prosthesis oversizing for *in-vitro* fatigue testing. Worst-case identification also considered differences in vascular compliance between transection and dissection populations. Devices were evaluated in single and overlapped configurations.	Pass
Fatigue and durability – *In-vitro* testing	Pulsatile Fatigue Testing[1]: To evaluate the long-term durability of the stent-graft design following 10 years simulated testing under clinically relevant loading conditions.	The samples must not exhibit physical damage that would represent a failure of their safety or function due to: 1. Component deformation, separation or fractures leading to ineffective proximal or distal seals, migration or severed pieces into the bloodstream 2. Fabric holes larger than 0.5 mm^2 3. Modular disjunctions 4. Compromised luminal integrity due to twisting or component collapse All anomalies must be studied on a case-by-case basis. Anomalies due to test artifacts will not be representative of failure in safety or function of the design.	Pass
	Dynamic Bending Testing[2]: To evaluate the long-term durability of the stent-graft design following 10 years simulated testing under clinically relevant loading conditions.		Pass

Test Name	Test Purpose	Acceptance Criteria	Results
		Devices were evaluated in single and overlapped configurations.	

[1] Pulsatile Fatigue Testing used to support aneurysm, dissection, and transection indications.
[2] Dynamic Bending Testing used to support aneurysm and dissection indications; data collected for aneurysm indication was leveraged to support transection indication.

X. SUMMARY OF PRIMARY CLINICAL STUDIES

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers in the descending thoracic aorta with the RelayPro Thoracic Stent-Graft System in the US and Japan (**P200045**) [shall be referred to as Pro-A]; data from the Pro-A clinical study were the basis for the PMA approval decision. A second primary study was conducted to support the expanded indication to include treatment of blunt traumatic aortic injury (shall be referred to as Pro-T). A third primary study was conducted to support the expanded indication to include treatment of all lesions of the descending thoracic aorta (DTA), including Type B aortic dissections (shall be referred to as Pro-D). A summary of the clinical studies is presented below.

Table 3: Summary of RelayPro Primary Clinical Studies

Pivotal Study	Study Design	Objective	Number of Sites with Enrollment	Number of Subjects
Pro-A: Aneurysm/ PAU	Prospective, multi-center, non-blinded, non-randomized, single-arm multinational (US, Japan)	To evaluate the safety and effectiveness of the RelayPro Thoracic Stent-Grafts in subjects with aneurysms and PAUs within the descending thoracic aorta.	36	110
Pro-T: Blunt Thoracic Aortic Injury (BTAI)	Prospective, non-blinded, non-randomized, single-arm, US multicenter	To evaluate safety and effectiveness of the RelayPro Thoracic Stent-Graft for the treatment of traumatic injury of the descending thoracic aorta.	16	50
Pro-D: Acute, Complicated Type B Dissection	Prospective, non-blinded, non-randomized, single-arm, US multicenter	To evaluate safety and effectiveness of the RelayPro Thoracic Stent-Graft for the treatment of acute, complicated Type B aortic dissections.	22	56

A. Study Design – Pro-D

Patients were treated between September 7, 2017 and September 3, 2021. The database for this panel track supplement reflected data collected through June 3, 2022 and included 56 US patients. There were 22 US investigational sites.

The RelayPro-Dissection (Pro-D) clinical study is a prospective, multicenter, single-arm, non-blinded, non-randomized study of the treatment of patients with acute, complicated Type B aortic dissections with the RelayPro Thoracic Stent-Graft System.

The primary endpoint is the rate of all-cause mortality at 30-days post procedure. The results were tested against a performance goal of 25%, consistent with the performance goal of other endovascular graft pivotal studies for acute, complicated Type B dissections. The hypothesis tested for the primary endpoint was:

Null hypothesis (H_o): $p \geq 0.25$
Alternative Hypothesis (H_A): $p < 0.25$

Interim analyses were planned to be completed when 50, 65, and 80 subjects reached 30 days of post-procedure follow-up. With respect to stopping for success according to the interim analysis plan, a p-value of 0.01317 or less would be required to cross the boundary based on data from the first 50 subjects.

External evaluation groups were used during the course of the Pivotal Study, which are described below:

- *Independent Imaging Core Laboratory:* The Core Laboratory assessed follow-up imaging endpoints, including endoleak, migration, aneurysm sac size increase, patency, stenosis, and stent fracture.

- *Clinical Events Committee and Data Safety Monitoring Board:* An independent Clinical Events Committee (CEC) and a separate, independent Data Safety Monitoring Board (DSMB) were responsible for assuring the study was conducted ethically, and that the health and welfare of each study patient was protected. The CEC adjudicated events, as specified in the CEC Charter, as identified by the Medical Monitor from regular review of all reported adverse events and classified them as related or not related to the device or the procedure. The DSMB met separately to review the safety data in aggregate and assess the overall safety of the study. The DSMB also assessed whether the continuation of enrollment was appropriate, and if not, whether protocol modifications were necessary or whether the study should be halted.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the Pro-D study was limited to patients who met the following inclusion criteria:

- Age ≥18 years.
- Have an acute (symptom onset to diagnosis within 2 weeks), complicated Type B aortic dissection (entire dissection is distal to the left subclavian artery), including those with multiple entry tears, with clinical or imaging evidence of at least one of the following:
    - Malperfusion of the viscera, kidneys, spinal cord, or lower extremities;
    - Aortic rupture.
- Proximal and distal landing zones with diameter between 19 mm and 42 mm.
- Patient's anatomy must meet all of the following anatomical criteria:
    - Proximal landing zone distal to the left common carotid and a distal attachment zone proximal to the origin of the celiac artery.
        - Dissection is permitted in the distal attachment zone but is not permitted in the proximal attachment zone.
    - The length of the proximal landing zone depends on the intended stent-graft diameter, and landing zone should be:
        - 15 mm for 22 – 28 mm RelayPro grafts with bare stent (20 mm for RelayPro grafts with non-bare stent).
        - 20 mm for 30 – 46 mm RelayPro grafts with bare stent (25 mm for RelayPro grafts with non-bare stent).
        - Proximal to non-dissected segment (healthy zone)
    - The distal attachment zone should be 20 mm for all RelayPro grafts.
    - Coverage of the left subclavian artery (LSA) is permitted with mandatory revascularization if patent left internal mammary artery (LIMA) bypass or left upper extremity (LUE) arteriovenous graft or anomalous vertebral artery off the aorta. Revascularization must be performed prior to device placement, and may occur during implant procedure, provided it is before coverage of the LSA by the endograft.
- Proximal landing zone containing a straight segment (non-tapered, non-reverse-tapered, defined by <10% diameter change) with lengths equal to or greater than the required attachment length for the intended device.
- Vascular dimensions (e.g., aortic diameters, length from left subclavian to celiac artery) must be in the range that can be treated with the RelayPro Thoracic Stent-Grafts (able to deliver device to the location of treatment as described in the IFU).
- Adequate iliac or femoral artery access for introduction of the RelayPro Delivery System. Alternative methods to gain proper access may be utilized (e.g., iliac conduit).
- Patient willing to comply with the follow-up evaluation schedule.
- Patient (or Legally Authorized Representative, LAR) agrees to sign an Informed Consent Form prior to treatment.

Patients were not permitted to enroll in the Pro-D study if they met any of the following exclusion criteria:

- Diagnosis of traumatic injury or transection of the descending thoracic aorta.
- Significant stenosis, calcification, thrombus, or tortuosity of intended fixation sites that would compromise fixation or seal of the device.
- Planned coverage of left carotid or celiac arteries; or anatomic variants that 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. Dissection extension into the abdominal aorta is acceptable.
- 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 30 days prior to the planned procedure or is scheduled for a major surgical or medical procedure within 30 days post implantation. This excludes any planned procedures for the prospective stent-graft placement.
- Untreatable allergy or sensitivity to contrast media or device components, including metal stents.
- 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 (not associated with malperfusion due to aortic dissection) or chronic renal insufficiency, and not receiving dialysis.
- Hemodynamically unstable.
- Active systemic infection and/or mycotic aneurysm.
- Bowel necrosis.
- Morbid obesity or other condition that may compromise or prevent the necessary imaging requirements.
- American Society of Anesthesiologists risk classification = V (Moribund patient not expected to live 24 hours with or without operation).
- 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.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 days (± 4 weeks), 6 months (± 8 weeks), 12 months (± 12 weeks) and annually (± 12 weeks) through 5 years postoperatively.

Table 4 summarizes the assessment requirements at each stage include preoperative, at treatment, at discharge and at each post-operative follow-up visit.

Additional assessments that were collected at each follow-up visit included:

- Device-related adverse events
- Aortic rupture
- Stent-graft migration, assessed by an Independent Core Laboratory
- Endoleak, assessed by an Independent Core Laboratory
- Aortic enlargement, assessed by an Independent Core Laboratory
- Stent-graft integrity, assessed by an Independent Core Laboratory
- Loss of stent-graft patency
- Conversion to open surgery
- Secondary interventions
- Aortic-related mortality

Table 4: Schedule of Assessments (Pro-D)

	Screening	Treatment	Discharge	1M ±4 weeks	6M ±8 weeks	12M ±12 weeks	2, 3, 4, 5Y ±12 weeks
Informed Consent	X						
Medical History	X						
Verify Inclusion/Exclusion Criteria	X						
Physical Exam (including neurological assessment)	X						
Pregnancy testing for female patients of childbearing potential	X						
CT Scan with Contrast, or MRA	X						
Angiogram		X					
Clinical Utility Measures		X	X				
Examination of the incision site and assessment of healing			X				

Table 4: Schedule of Assessments (Pro-D)

	Screening	Treatment	Discharge	1M ±4 weeks	6M ±8 weeks	12M ±12 weeks	2, 3, 4, 5Y ±12 weeks
CT scan with/without contrast				X*	X*	X*	X*
Chest X-Ray				X	X	X	X
Adverse Event and device related events assessment		X	X	X	X	X	X

* MRI, combined with unenhanced CT, could be performed at follow-up visits for patients who could not receive contrast.

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

3. Clinical Endpoints

The primary endpoint is the rate of all-cause mortality at 30-days post procedure.

The primary endpoint was compared to a Performance Goal (PG) of 25%.

With regard to success/failure criteria, the Pro-D Study primary endpoint will be considered successful if the primary endpoint performance goal is met.

The following secondary analyses were completed using descriptive statistics:

At the index procedure:

- Technical Success defined as successful device delivery and deployment including withdrawal of the delivery system

Through 1 month

- Treatment success, defined as individual components and as a composite:
    - Absence of major adverse events (MAEs), defined as:
        - Stroke (disabling);
        - Renal failure (excludes pre-existing);
        - Paraplegia;
        - Paraparesis;
    - Absence of perfusion into the false lumen through the primary intimal tear;
    - Absence of retrograde extension of the dissection;

Through 1 month, 6 months, 12 months, and annually through 5 years;

- Dissection treatment success, defined as individual endpoints and a composite:
    - Absence of expansion (> 5mm) in the aorta that has an endograft, compared to the first post-procedural computed tomographic (CT) imaging study;

- Absence of aortic rupture;
- Absence of dissection-related mortality;
- Absence of MAEs including new ischemia due to branch vessel compromise;
- Absence of false lumen perfusion separated by location:
  - Proximal;
  - Distal;
  - Branch;
- Absence of new aortobronchial/tracheal or aortoenteric fistula formation;
- Absence of unintentional rupture of the dissection septum;

- Device imaging assessments, defined as:
  - Endoleaks;
  - Stent graft kinking or twisting;
  - Loss of stent-graft patency;
  - Misalignment;
  - Loss of integrity;
  - RelayPro stent fracture in the attachment zone;
  - Stent migration (> 10mm), compared to the first post-procedural CT;
- Incidence of open or endovascular dissection related secondary interventions to treat malperfusion, rupture, aneurysm formation, or aortic expansion

At 6 months, 12 months, and annually through 5 years, compared to the first post-procedural CT;

- Aortic expansion (> 5mm)
- Stent migration (> 10 mm)

B. <u>Accountability of PMA Cohort – Pro-D</u>

At the time of database freeze, of the 56 patients enrolled in the Pro-D study, all 56 patients were implanted with the RelayPro Stent-Graft System and 56 were seen through discharge. Fifty-three (of 56) eligible patients (94.6%) had a 30-day visit with at least 85.7% of patients with adequate imaging to address endovascular graft parameters. Thirty-seven (of 51) patients had a 6-month visit with at least 58.8% with imaging adequate to address endovascular graft parameters. At the 12-month visit, 34 of 48 eligible patients had a visit performed with at least 62.5% with imaging adequate to address endovascular graft parameters. Additional visits and follow-up assessments have been obtained through 4-years and are provided in **Table 5** below. Two patients are eligible for the 5-year visit; however, they have not yet returned for the visit.

Table 5: Summary of Pro-D Compliance & Core Laboratory Imaging Follow-up

	Patient Follow-Up#				Imaging		Imaging Adequate †				Events Within Window‡				
Visit	Eligible for Visit	Visit Performed	No Visit*	Still in Window	CT Scan	X-Ray	Diameter	Endoleak	Migration	Fracture	Death	Lost to follow-up	Early Withdrawal	Not Yet Due	Patients with ≥1 Element
Index	56	NA	NA	NA	NA	NA	NA	NA	NA	NA	0	0	0	0	0
30D	56	94.6% (53/56)	5.4% (3/56)	0	91.1% (51/56)	87.5% (49/56)	89.3% (50/56)	85.7% (48/56)	91.1% (51/56)	92.9% (52/56)††	5	0	0	0	5
6M	51	72.5% (37/51)	27.5% (14/51)	0	66.7% (34/51)	62.7% (32/51)	66.7% (34/51)	58.8% (30/51)	64.7% (33/51)	66.7% (34/51)	1	2	0	0	3
12M	48	70.8% (34/48)	29.2% (14/48)	14.6% (7/48)	66.7% (32/48)	56.3% (27/48)	66.7% (32/48)	62.5% (30/48)	64.6% (31/48)	64.6% (31/48)	1	1	0	10	12
2Y	36	55.6% (20/36)	44.4% (16/36)	27.8% (10/36)	52.8% (19/36)	50.0% (18/36)	52.8% (19/36)	47.2% (17/36)	50.0% (18/36)	50.0% (18/36)	2	2	0	12	18
3Y	18	50.0% (9/18)	50.0% (9/18)	33.3% (6/18)	38.9% (7/18)	38.9% (7/18)	38.9% (7/18)	33.3% (6/18)	38.9% (7/18)	38.9% (7/18)	0	0	0	10	10
4Y	8	25.0% (2/8)	75.0% (6/8)	75.0% (6/8)	25.0% (2/8)	25.0% (2/8)	25.0% (2/8)	25.0% (2/8)	25.0% (2/8)	12.5% (1/8)	0	0	0	6	6
5Y	2	0	100.0% (2/2)	100.0% (2/2)	0	0	0	0	0	0	0	0	0	2	2

NA – Not Applicable; LTFU, lost to follow-up;

The number of patients eligible for each visit are used for the denominator for the percentages of visits performed, imaging performed, as well as imaging adequate to assess the respective endovascular graft parameters.

Site reported data. No Visit reflects patients who did not have a visit and/or imaging performed within the window. Still in Window reflects patients who have not yet reached the end of the analysis window and have not yet had a visit or imaging performed.

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

‡ These columns reflect patients who had visits within the specified window but were not eligible at the start of the next window due to death, loss to follow-up, conversion to open surgery, or early withdrawal. Please note that 2 patients had a conversion to open surgery and are counted in the Other column.

* One patient was indicated as having voluntarily withdrawn, but the date of withdrawal was not recorded. This patient was not counted as a withdrawal in this table as the patient has subsequently re-consented for participation.

†† There was one patient who had an x-ray but not a CT scan and three patients who had CTs but not an x-ray. Since fractures can be assessed from either imaging modality, the 51 CT scans plus the one x-ray without a CT scan gives a total of 52/56 patients with imaging adequate to assess fracture.

C. Study Population Demographics and Baseline Parameters

Demographics

The pivotal study population is 73.2% male (41/56), 53.6% black (30/56) and predominately younger; two thirds were under 65 with a mean age of 59.5±11.4 years.

Table 6: Patient Demographics (Pro-D)

	Statistics	Pro-D Patients (N=56)
Sex		
Male	% (n/N)	73.2% (41/56)
Female	% (n/N)	26.8% (15/56)
Age (years) at Treatment	Mean ± SD (N)	59.5 ±11.42 (56)
	Median (IQR)	59.5 (51-68)
	Min - Max	36 - 82
Age Group		
18-64 years	% (n/N)	66.1% (37/56)
65-74 years	% (n/N)	25.0% (14/56)
75+ years	% (n/N)	8.9% (5/56)
Ethnic Group		
Not Hispanic/Latino	% (n/N)	89.3% (50/56)
Hispanic/Latino	% (n/N)	1.8% (1/56)
Not Reported	% (n/N)	8.9% (5/56)
Race		
Black	% (n/N)	53.6% (30/56)
White	% (n/N)	42.9% (24/56)
Asian	% (n/N)	1.8% (1/56)
Unknown	% (n/N)	1.8% (1/56)

Site reported data.

Baseline Medical History

The most common comorbidities among patients include hypertension (89.3%, 50/56), history of smoking (82.1%, 46/56), hypercholesterolemia (37.5%, 21/56), documented coronary artery disease (21.4%, 12/56), gastrointestinal complications (19.6%, 11/56), diabetes mellitus (17.9%, 10/56), and renal insufficiency and previous vascular intervention (each reported in 12.5%, 7/56).

Table 7: Patient Comorbidities (Pro-D)

	Pro-D Patients (N=56)
Hypertension (treated or untreated)	89.3% (50/56)
History of Smoking	82.1% (46/56)
Current Smoker	47.8% (22/46)
Hypercholesterolemia	37.5% (21/56)
Current Antiplatelet/Anticoagulant Medication	37.5% (21/56)
Documented Coronary Artery Disease	21.4% (12/56)

Table 7: Patient Comorbidities (Pro-D)

	Pro-D Patients (N=56)
Stable Angina	3.6% (2/56)
Unstable Angina	1.8% (1/56)
Myocardial Infarction	3.6% (2/56)
Arrhythmias	1.8% (1/56)
Congestive Heart Failure	5.4% (3/56)
Other	12.5% (7/56)
History of Gastrointestinal Complications	19.6% (11/56)
Cholecystitis	0
Ischemic Colitis	0
GI Bleed	0
Small Bowel Ischemia	0
GERD	12.5% (7/56)
Other GI condition	7.1% (4/56)
Diabetes Mellitus	17.9% (10/56)
Renal Insufficiency	12.5% (7/56)
History of Vascular Intervention	12.5% (7/56)
History of Limb Ischemia	8.9% (5/56)
History of Peripheral Vascular Disease	7.1% (4/56)
History of Impotence (males only)	2.4% (1/41)

All values expressed as % (n/N). Site reported data.
GERD, gastroesophageal reflux disease; GI, gastrointestinal

Baseline Vessel Measurements

The baseline lesion characteristics for the patients enrolled in the study are presented in **Table 8**. All 56 patients had Type B aortic dissection complicated by either malperfusion or rupture. Based on the site's baseline assessment of the type of dissection, 51.8% (29/56) patients presented with malperfusion of the kidneys, 33.9% (19/56) patients with malperfusion of the viscera, 35.7% (20/56) with malperfusion of the lower extremities, 1.8% (1/56) with malperfusion of the spinal cord, and 10.7% (6/56) with rupture. Sixteen patients (28.6%) had more than one type of malperfusion.

The Core Laboratory reported proximal extent of the dissection in Zone 3 in 78.6% (44/56) of patients, extending distally to the iliac arteries (one or both) in 67.3% (35/52), the abdominal aorta (25.0%, 14/52) or limited to the thoracic aorta (5.4%, 3/52). Mean maximum thoracic aortic diameter is 42.2±6.9 mm (median 40.4 mm, range 27–62.7 mm) and mean aortic diameter at the proximal end of the dissection is 33.8±3.4 mm (median 33.5 mm, range 25—42.1 mm).

Table 8: Core Laboratory-Reported Baseline CT Measurements (Pro-D)

	Pro-D Patients (N=56)
Aortic Diameter at Left Common Carotid (mm)	
n	55
Mean (SD)	33.1 (3.3)
Median (min, max)	32.9 (25.1, 41)
Aortic Diameter at Left Subclavian (mm)	
n	56
Mean (SD)	33.5 (4.2)
Median (min, max)	32.65 (24.3, 45.2)
Aortic Diameter at Proximal End of Dissection (mm)	
n	56
Mean (SD)	33.8 (3.4)
Median (min, max)	33.45 (25, 42.1)
Maximum Thoracic Aortic Diameter (mm)	
n	56
Mean (SD)	42.2 (6.9)
Median (min, max)	40.4 (27, 62.7)
Maximum Thoracic Aortic Diameter - True Lumen (mm)	
n	56
Mean (SD)	18.6 (7.8)
Median (min, max)	17.8 (3.4, 46.7)
Maximum Thoracic Aortic Diameter - False Lumen (mm)	
n	56
Mean (SD)	17.7 (8.9)
Median (min, max)	15.9 (0, 45)
Length from Left Common Carotid to Primary Intimal Tear (mm)	
n	54
Mean (SD)	55.7 (48.4)
Median (min, max)	42.2 (5.7, 222)
Length from Left Subclavian to Primary Intimal Tear (mm)	
n	54
Mean (SD)	39.6 (47.5)
Median (min, max)	24.7 (-8.37, 198.9)
Total Treatment Length (mm)	
n	50
Mean (SD)	207.3 (49.5)
Median (min, max)	214.5 (108, 281)
Dissection Length (mm)	
n	51
Mean (SD)	442.1 (104.9)
Median (min, max)	439 (217, 654)
Proximal End of Dissection	
n	56

Table 8: Core Laboratory-Reported Baseline CT Measurements (Pro-D)

	Pro-D Patients (N=56)
Zone 1	1 (1.8%)
Zone 2	7 (12.5%)
Zone 3	44 (78.6%)
Zone 4 or further distal	4 (7.1%)
Distal End of Dissection	
n	52
Thoracic aorta	3 (5.4%)
Abdominal aorta	14 (25.0%)
Right and left iliacs	14 (25.0%)
Left iliac	11 (19.6%)
Right iliac	10 (17.9%)

Core Laboratory data.

RelayPro Devices Implanted

A total of 98 RelayPro devices were implanted in the study: 39.3% (22/56) of patients were treated with a single device; 46.4% (26/56) with two; and 14.3% (8/56) with three.

The RelayPro device can be provided in a straight, tapered, and reversed tapered configurations. A device offered in the straight configuration has the same diameter at the proximal and distal ends. A tapered device has a larger proximal diameter than distal diameter, whereas the reverse tapered device has a larger distal diameter than proximal diameter.

Several patients had their treatment extend proximal to the LSA (14.3%, 8/56 with proximal extent of the dissection <Z3; 33/56, 58.9% covering the LSA). The RelayPro NBS was used most often out of all RelayPro devices implanted (65.3%, 64/98).

Additionally, many patients who were treated with more than one device received a combination of NBS and bare stent configurations.

Table 9: Devices Implanted (Initial Procedure) (Pro-D)

		N=56	NBS*	Bare Stent*
Devices Implanted	1	39.3% (22/56)	34.0% (18/53)	32.1% (17/53)
	2	46.4% (26/56)	37.7% (20/53)	7.5% (4/53)
	3	14.3% (8/56)	3.8% (2/53)	3.8% (2/53)

Table 9: Devices Implanted (Initial Procedure) (Pro-D)

	N=56	NBS*	Bare Stent*
*Total devices implanted**	*98*	*64*	*31*
Straight	91.1% (51/56)	69.8% (37/53)	35.8% (19/53)
Tapered	21.4% (12/56)	11.3% (6/53)	13.2% (7/53)

NBS, non-bare stent.
Site reported data. Denominator includes all patients who received the test device. A patient may have received a single NBS and a single bare stent configuration so it is counted as having two devices implanted in total. Therefore, percentages may total more than 100%. In addition, three patients do not have proximal stent configuration specified. Patients with multiple devices implanted may be counted more than once if more than one device shape was used and therefore percentages may sum greater than 100%.
Many patients in the study who were treated with more than one device received a combination of NBS and bare stent configurations.
**Please note that the device configuration (i.e., NBS or proximal bare stent) for three patients is not known. Therefore, these patients are not included in the denominators for the NBS or bare stent columns.*

The most implanted NBS devices were the 34-mm (22.6%, 12/53), 36-mm (32.1%, 17/53), and 38-mm (17.0%, 9/53) proximal diameters. Regarding the proximal bare stent configuration, the most implanted proximal diameters were the 32-mm (13.2%, 7/53) and 36-mm (18.9%, 10/53) (**Table 10**). The distal end of the RelayPro proximal bare stent configuration and NBS configuration are identical: the most common distal diameters were 34-mm and 36-mm (each 35.8%, 19/53) and 32 mm (30.2%,16/53).

Table 10: Diameter of RelayPro Devices Implanted (Pro-D)

Diameter (mm)		NBS	Proximal Bare Stent
Proximal	24	0	0
	26	1.9% (1/53)	0
	28	7.5% (4/53)	5.7% (3/53)
	30	1.9% (1/53)	0
	32	15.1% (8/53)	13.2% (7/53)
	34	22.6% (12/53)	7.5% (4/53)
	36	32.1% (17/53)	18.9% (10/53)
	38	17.0% (9/53)	7.5% (4/53)
	40	3.8% (2/53)	1.9% (1/53)
	42	1.9% (1/53)	1.9% (1/53)
	44	0	0
	46	0	0
Distal	24	0	
	26	1.9% (1/53)	
	28	11.3% (6/53)	
	30	7.5% (4/53)	
	32	30.2% (16/53)	
	34	35.8% (19/53)	
	36	35.8% (19/53)	

Table 10: Diameter of RelayPro Devices Implanted (Pro-D)

Diameter (mm)	NBS	Proximal Bare Stent
38	15.1% (8/53)	
40	5.7% (3/53)	
42	1.9% (1/53)	
44	0	
46	0	

NBS, non-bare stent.
**Please note that three patients did not have the device configuration listed (i.e., NBS or proximal bare stent. Each patient only received one RelayPro device (straight configuration). These patients are not included in the denominators.*

Procedural Data

Table 11 summarizes information from the index procedure, including clinical utility endpoints. The majority of procedures were percutaneous (85.5%, 47/55). CSF drainage was used in 33.9% (19/56). Median (IQR) total procedure duration was 100 (80-192) min, and the median implantation duration (endovascular part only) was 17 (10-26) min. Postoperatively, patients spent a median 81 (50-142) hours in intensive care. Median overall hospitalization was 7 (5-12) days.

Table 11: Procedural Details (Pro-D)

	Statistics	Pro-D Patients (N=56)
Type of Anesthesia		
General Anesthesia	% (n/N)	100.0% (56/56)
Vascular Access		
Left Femoral	% (n/N)	36.4% (20/55)
Right Femoral	% (n/N)	63.6% (35/55)
Vascular Access Method		
Percutaneous	% (n/N)	85.5% (47/55)
Surgical Cut Down	% (n/N)	14.5% (8/55)
CSF Drainage	% (n/N)	33.9% (19/56)
Duration of Procedure (min)	Mean ± SD (N)	138.4±81.44 (56)
	Median (IQR)	100 (80-192)
	Min - Max	49-429
Duration of Implantation (min)	Mean ± SD (N)	23.9±29.78 (54)
	Median (IQR)	17 (10-26)
	Min - Max	1-180
Estimated Blood Loss (cc)	Mean ± SD (N)	167.2±264.1 (53)
	Median (IQR)	100 (50-150)
	Min - Max	10-1500
Transfusion required	% (n/N)	11.1% (6/54)
Duration of ICU Stay (hours)	Mean ± SD (N)	122.5±201.7 (56)
	Median (IQR)	81 (50-142)
	Min - Max	7-1536
Duration of Hospital Stay (days)	Mean ± SD (N)	8.8±4.74 (56)

Table 11: Procedural Details (Pro-D)

	Statistics	Pro-D Patients (N=56)
	Median (IQR)	7 (5-12)
	Min - Max	2-24

Site reported data.
CSF, cerebrospinal fluid; ICU, intensive care unit.

D. Safety and Effectiveness Results – Pro-D

1. Safety Results

1.1 Primary Endpoint

The primary endpoint is the rate of all-cause mortality at 30-days post procedure and was compared to a performance goal of 25%, which is consistent with other endovascular graft pivotal studies for acute, complicated Type B dissections. The study could stop for success according to the interim analysis plan and based on a sample size of 50 patients (which provides at least 80% power to detect one or more rare adverse events that occur at a population rate of 3.2% or greater) and with a p-value ≤0.01317 to cross the boundary.

The primary endpoint (all-cause mortality at 30-days post procedure) was analyzed with the first 50 patients having completed 30-day follow-up; the result of 2.0% (upper bound of the one-sided 95% CI is 9.1%) was below the 25% performance goal, meaning that the primary endpoint was met (**Table 12**). Further, the calculated p-value met the interim analysis criteria for early stopping for success as the calculated p-value is less than 0.01317.

Table 12: Primary Endpoint Analysis (Pro-D)

Characteristic	Statistics	Pro-D N=50
All-cause mortality at 30 days	% (n/N)	2.0% (1/50)
	Upper 95% CI	--, 9.1%
	p-value*	<.0001

*P-value corresponds to the null hypothesis test that the observed value is less than the Primary Endpoint. Performance Goal of 25% based on exact upper one-sided 95% CI.
CI, confidence interval.

A per-protocol analysis was not performed as there are no patients that would be removed from the intent-to-treat analysis to do a per-protocol analysis.

There was one patient with all-cause mortality at 30-days. This was a 56-year-old male that presented with a complicated Type B aortic dissection, including malperfusion of the kidneys (site reported), extending 65.4 cm in length. The procedure was performed without complications. The estimated blood loss was 10cc. The patient was discharged POD 7. He was found dead (POD 8). No autopsy was performed and the cause of death is unknown.

Supplemental Analysis of Primary Endpoint with full enrollment, N=56

Per study protocol, enrollment continued while 30 day follow-up was being obtained on the initial 50 patients. Six additional patients were treated. A supplemental analysis evaluating the primary analysis using the full study cohort (all 56 patients). The result of 1.8% (upper bound of the one-sided 95% CI is 8.2%) was below the 25% performance goal, also meeting the performance goal (**Table 13**). For this supplemental analysis, per-protocol analysis was not performed as there are no subjects that would be removed from the intent-to-treat analysis to do a per-protocol analysis.

Table 13: Primary Endpoint Analysis (Pro-D) Supplemental Analysis

Characteristic	Statistics	Pro-D N=56
All-cause mortality at 30 days	% (n/N)	1.8% (1/56)
	Upper 95% CI	--, 8.2%
	p-value*	<.0001

*P-value corresponds to the null hypothesis test that the observed value is less than the Primary Endpoint. Performance Goal of 25% based on exact upper one-sided 95% CI.
CI, confidence interval.

1.2 Secondary Safety Endpoints

Mortality (All-Cause & Dissection-Related)
Dissection related mortality is death due to a rupture, death within 30 days or of a reintervention to treat the dissection, or death from a complication from the dissection. Dissection related mortality was adjudicated by the CEC. One patient expired POD 8 and met the definition for dissection-related mortality as adjudicated by the CEC as it occurred within 30 days of the index procedure.

There have been nine all-cause mortalities (16.1%, 9/56) (**Table 14**). There was a single death within 30 days of implant (1.8% dissection-related mortality) and five deaths in total during the total 30-day follow-up window which extends to 90 days (8.9%, 5/56). Subsequently, there was one death in the six-month window (1.9%, 1/52), one in the 12-month window (2.1%, 1/48), two in the 2-year window (5.6%, 2/46), and none thus far in the 3-year or 4-year window.

Table 14: Mortality (Pro-D)

	30 Days	6 Months	12 Months	2 Years	3 Years	Total
Number Eligible	56	52	48	36	18	56
All-Cause Mortality						
	8.9% (5/56)	1.9% (1/52)	2.1% (1/48)	5.6% (2/36)	0	16.1% (9/56)
Dissection-Related Mortality						
	1.8% (1/56)	0	0	0	0	1.8% (1/56)

All deaths are CEC adjudicated for relatedness to the device and/or procedure. Dissection related mortality was also adjudicated by the CEC.

Kaplan Meier analysis estimated a freedom from All-Cause Mortality to be 98.1% at 30 days, 87.5% at six months, 85.0% at 12 months, 80.8% at two years, and 75.4% at three years **(Figure 3**). Kaplan-Meier analysis estimated a freedom from dissection-related mortality of 98.1% at each interval from 30 days to three years (**Figure 4**).

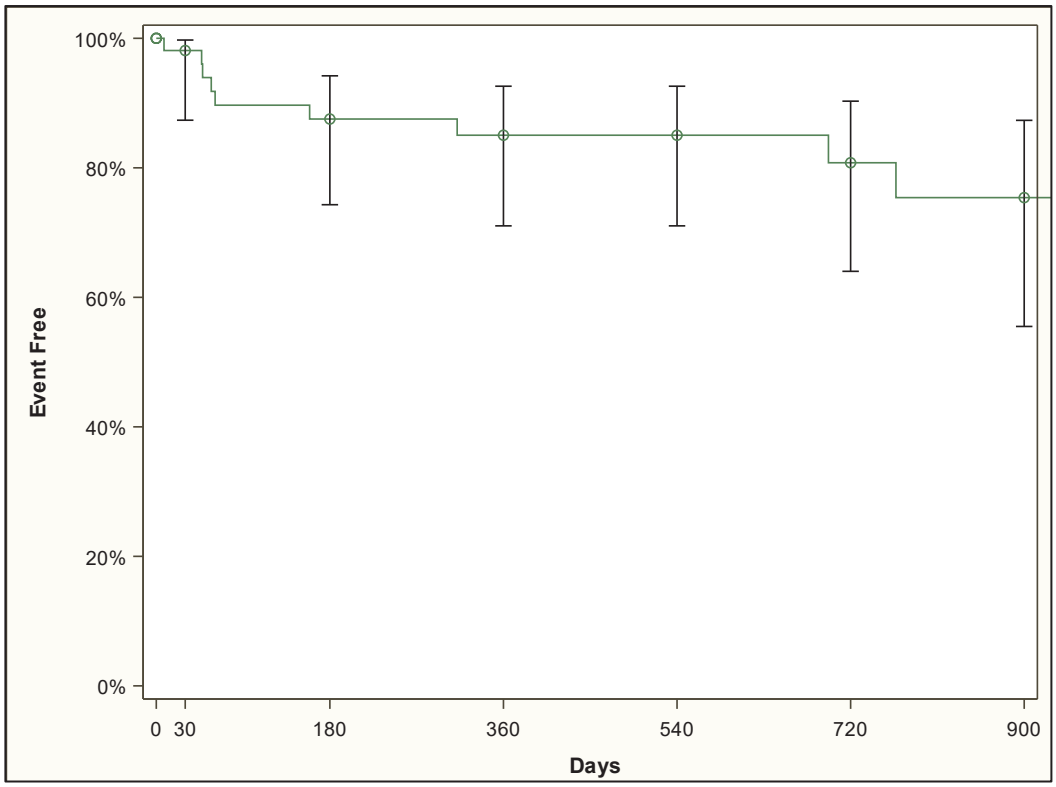


Figure 3: Kaplan Meier Plot for Freedom from All-Cause Mortality

POD	# Entered	# Censored	# Events	Event-free (%)	Greenwood SE (%)	95% CI
0	56	2	0	100.0%	0.0%	-
1-30	54	4	1	98.1%	1.9%	87.4-99.7%
31-180	49	3	5	87.5%	4.8%	74.3-94.2%
181-360	41	8	1	85.0%	5.2%	71.0-92.6%
361-540	32	8	0	85.0%	5.2%	71.0-92.6%
541-720	24	6	1	80.8%	6.5%	64.0-90.3%
721-900	17	10	1	75.4%	8.0%	55.5-87.3%
CI, confidence interval; POD, postoperative day; SE, standard error.						

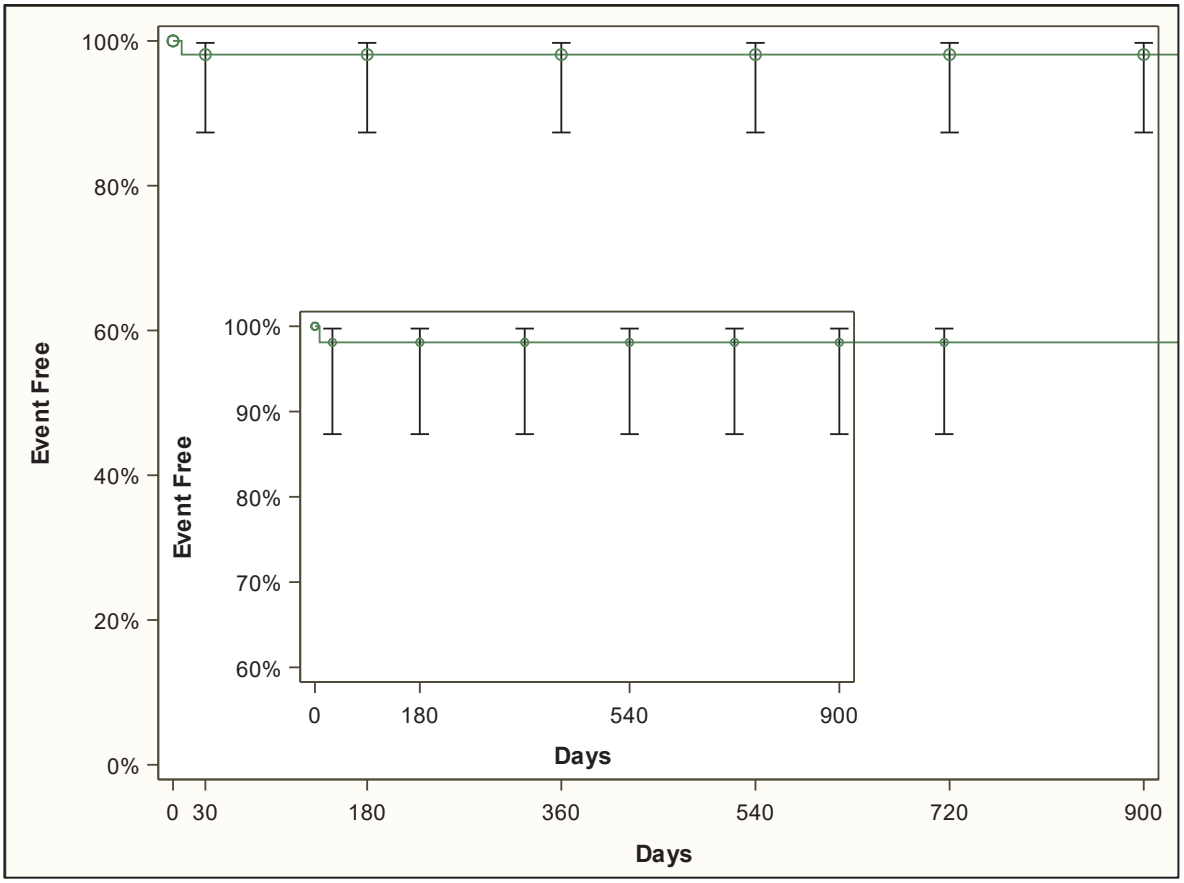


Figure 4: Kaplan-Meier Freedom from Dissection-Related Mortality

POD	# Entered	# Censored	# Events	Event-free (%)	Greenwood SE (%)	95% CI
0	56	2	0	100.0%	0.0%	-
1-30	54	4	1	98.1%	1.9%	87.4-99.7%
31-180	49	7	0	98.1%	1.9%	87.4-99.7%
181-360	42	10	0	98.1%	1.9%	87.4-99.7%
361-540	32	8	0	98.1%	1.9%	87.4-99.7%
541-720	24	7	0	98.1%	1.9%	87.4-99.7%
721-900	17	11	0	98.1%	1.9%	87.4-99.7%

CI, confidence interval; POD, postoperative day; SE, standard error.

Aortic rupture

There have been no Core Laboratory reported aortic or graft ruptures to date. There was one patient with a CEC-adjudicated thoracic aortic rupture in the context of subsequent open surgical thoracoabdominal repair. It is not clear whether the rupture is in the same area that the RelayPro devices were located. Additionally, this observation was not Core Laboratory reported nor was it listed in the clinical notes or imaging studies for this patient.

Major Adverse Events

Major adverse events (MAEs) were CEC adjudicated. Seven MAEs were reported in six patients (10.7%), all within 30-days, including the following: paraplegia (n=3), paraparesis (n=2), disabling stroke (n=1), and renal failure (n=1). One patient had two events (renal failure and paraplegia).

Kaplan-Meier analysis estimated a freedom from MAEs of 89.1% at each interval from 30 days to three years (**Figure 5).**

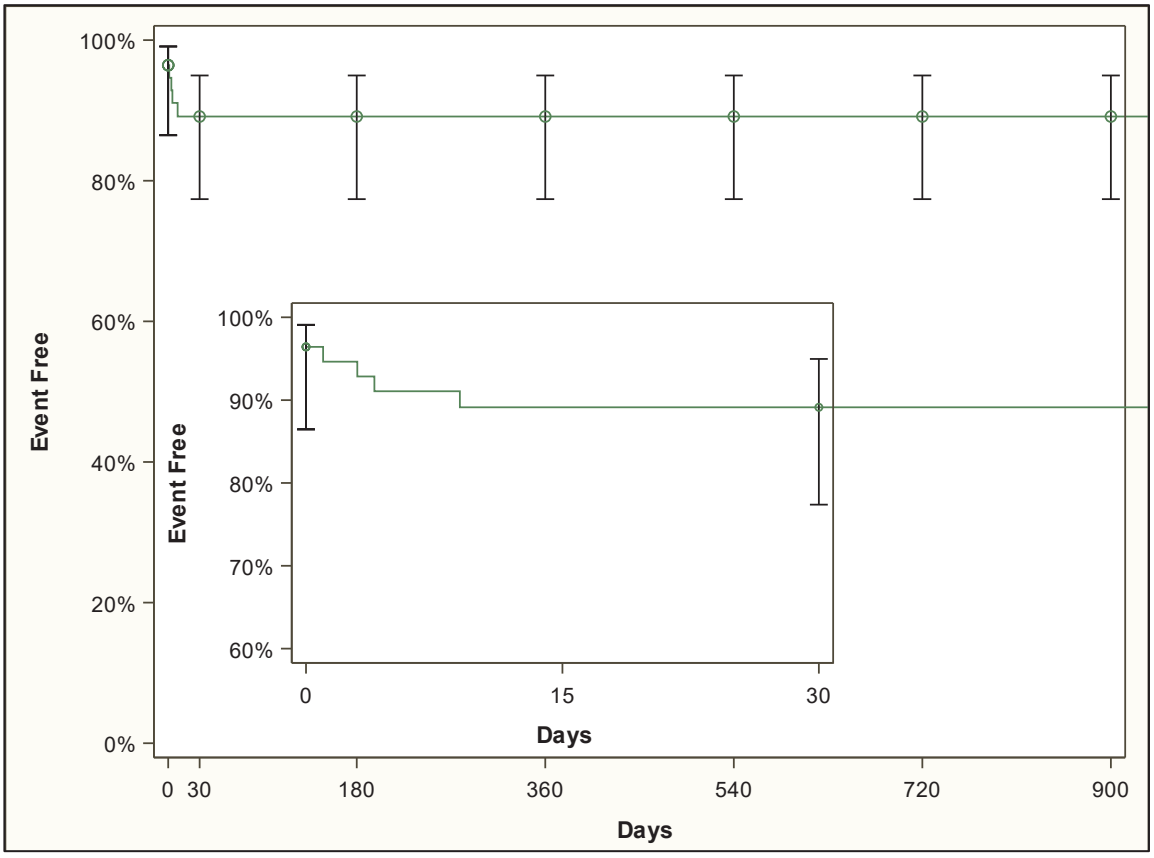


Figure 5: Kaplan-Meier Freedom from Major Adverse Events (MAEs)

POD	# Entered	# Censored	# Events	Event-free (%)	Greenwood SE (%)	95% CI
0	56	0	2	96.4%	2.5%	86.5-99.1%
1-30	54	7	4	89.1%	4.2%	77.4-95.0%
31-180	43	5	0	89.1%	4.2%	77.4-95.0%
181-360	38	10	0	89.1%	4.2%	77.4-95.0%
361-540	28	6	0	89.1%	4.2%	77.4-95.0%
541-720	22	6	0	89.1%	4.2%	77.4-95.0%
721-900	16	11	0	89.1%	4.2%	77.4-95.0%

CI, confidence interval; POD, postoperative day; SE, standard error.

Table 15 presents all MAEs adjudicated by the CEC; once an event is reported it continues to be reported in the "to date" row.

Table 15: Summary of MAEs (CEC adjudicated) (Pro-D)

MAE	30 Days	6 Months	12 Months	2 Years	3 Years	Total
Number Eligible	56	52	48	36	18	-
Patients with ≥1 MAE	10.7% (6/56)	0	0	0	0	6
MAEs (Total)	7	0	0	0	0	7
Stroke (disabling)						
New	1	0	0	0	0	-
To Date	1.8% (1/56)	1.9% (1/53)	2.0% (1/49)	2.7% (1/37)	5.3% (1/19)	1
Renal Failure						
New	1	0	0	0	0	-
To Date	1.8% (1/56)	1.9% (1/52)	2.1% (1/48)	2.8% (1/36)	5.3% (1/19)	1
Paraplegia						
New	3	0	0	0	0	-
To Date	5.4% (3/56)	5.7% (3/53)	6.1% (3/49)	8.1% (3/37)	15.0% (3/20)	3
Paraparesis						
New	2	0	0	0	0	-
To Date	3.6% (2/56)	3.8% (2/52)	4.2% (2/48)	5.4% (2/37)	10.0% (2/20)	2

Note that once an event is reported it continues to show up in the "to date" row in the table.
All MAEs were adjudicated by the CEC using these definitions of the individual MAE components:
- Stroke (disabling): A sudden, non-convulsive loss of neurological function due to an ischemic or hemorrhagic intracranial vascular event defined as focal neurological deficits that impair the patient's day-to-day life as assessed by the CEC members, lasting for 365 days or longer.
- Renal failure: Rise in creatinine >50% above pre-procedure level, resulting in a creatinine level above high normal that does not resolve, and requires prolonged renal replacement therapy
- Paraplegia: Paralysis of both lower extremities and, generally, lower trunk
- Paraparesis: Partial paralysis of lower limbs

CEC, clinical events committee; MAE, major adverse event.

Device-Related Adverse Events

Adverse events adjudicated by the CEC as being device-related are summarized in **Table 16**. This table includes both AEs and SAEs and is sorted by MedDRA SOC and PT: 28.6% (16/56) of patients experienced one or more device-related adverse events with the most frequently reported being stent-graft endoleaks (12 patients; 21.4%) which were coded to the SOC of General Disorders and Administration Site Conditions.

For the 12 patients that have been site-reported as having endoleaks, the Core Laboratory noted false lumen perfusion in 11 patients, namely Type R (7 patients), Type II (2 patients), Type II & Type R (2 patients), and Type Ia & Type R (1 patient). The Case Report Forms (CRFs) for the study did not have a field for reporting false lumen perfusion, resulting in the sites reporting this observation as an endoleak.

The following definitions were utilized for the above Core Laboratory assessment of false lumen perfusion for the 12 patients with a site-reported endoleak:

- Type Ia entry flow is a perigraft leak at the proximal edge of the stent-graft that allows continued antegrade flow into the false lumen through the primary entry tear.
- Type Ib entry flow is a distal perigraft leak caused by a tear in the intimal membrane adjacent to the distal edge of the endograft (distal stent graft-induced new entry [SINE]).
- Type II entry flow is continued retrograde false lumen perfusion through an arch branch (e.g., left subclavian artery) or intercostal or bronchial artery.
- Type R entry flow is antegrade flow from the true lumen to the false lumen through septal, visceral, or distal fenestrations.

Table 16: Summary of CEC Adjudicated Device-Related Adverse Events (Pro-D)

MedDRA System-Organ Class Preferred Term Adverse Event	Pro-D Patients (N=56)
Patients with at least one Device-Related Adverse Event	16 (28.6%)
General disorders and administration site conditions	11 (19.6%)
Complication associated with device	1 (1.8%)
Stent-graft endoleak	12 (21.4%)
Musculoskeletal and connective tissue disorders	1 (1.8%)
Muscular weakness	1 (1.8%)
Nervous system disorders	3 (5.4%)
Paralysis	1 (1.8%)
Paraplegia	1 (1.8%)
Spinal cord ischaemia	1 (1.8%)
Product issues	1 (1.8%)
Device dislocation*	1 (1.8%)
Surgical and medical procedures	1 (1.8%)
Surgery	1 (1.8%)
Vascular disorders	5 (8.9%)
Aortic aneurysm[Ł]	3 (5.4%)
Aortic dilatation[§]	1 (1.8%)
Aortic dissection[Ł]	1 (1.8%)

Data are presented as n (%). Percentages are based on the number of patients in the Safety Evaluable Population.
Event verbatim terms are reported by sites. The events listed in this table are coded using MedDRA version 22.0 and then stratified by System-Organ Class (SOC) and Preferred Term. Patients may be counted in this table more than once by Preferred Term but are only counted once in the SOC summary line. Device Relatedness adjudicated by the CEC.
* One patient had a site reported device dislocation (site reported migration). At the one-year follow-up, the site reported misalignment, migration, and expansion with no endoleak. The Core Laboratory reported Type Ia endoleak and migration due to "dilatation at the proximal end of the device". A secondary intervention (conversion to open surgery) was completed POD 529.
Ł Three patients were reported with device-related aortic aneurysm. One patient had a CEC-adjudicated aortic rupture in the context of subsequent open surgical thoracoabdominal repair. A second patient had an aortic arch aneurysm that was mentioned in the source documentation; however, only in the context of a site reported Type II endoleak and not otherwise detailed. A third patient had aortic lengthening, increased size and opacification of the false lumen that appears to have arisen from a previously coiled LSA, suggestive of a Type II endoleak. This patient was also noted to have aneurysm dilatation of the thoracoabdominal aorta at the diaphragmatic hiatus.
§ Expansion of 5 mm noted by the site at six months. The Core Laboratory reported an increase <5 mm. No intervention was performed. The patient completed four-year follow-up and maximum thoracic aortic diameter has decreased at each follow-up since then the original observation.

Table 16: Summary of CEC Adjudicated Device-Related Adverse Events (Pro-D)

MedDRA System-Organ Class Preferred Term Adverse Event	Pro-D Patients (N=56)
ǁ Patient was noted on POD 40 to have a tear that appears to have begun at the most proximal aspect of the endovascular graft and involved the aortic arch, as well as the ascending aorta. Core Laboratory analysis confirmed a retrograde dissection. She underwent emergency surgery, where a branched open surgical graft was placed to replace the aortic arch and the ascending aorta. Patient was discharged on POD 44.	

Procedure-Related Adverse Events

Adverse events adjudicated by the CEC as being procedure-related are summarized in **Table 17**. This table includes both AEs and SAEs and is sorted by MedDRA SOC and PT. Eighteen patients (32.1%, 18/56) experienced one or more procedure-related adverse events. The most commonly occurring events were within the MedDRA System-Organ Class of nervous system disorders (16.1%, 9/56):

Table 17: Summary of CEC Adjudicated Procedure-Related Adverse Events (Pro-D)

MedDRA System-Organ Class Preferred Term Adverse Event	Pro-D Patients (N=56)
Patients with at least one Procedure-Related Adverse Event	18 (32.1%)
General disorders and administration site conditions	5 (8.9%)
Death	1 (1.8%)
Stent-graft endoleak	4 (7.1%)
Investigations	1 (1.8%)
Pulse absent	1 (1.8%)
Musculoskeletal and connective tissue disorders	2 (3.6%)
Compartment syndrome	1 (1.8%)
Muscular weakness	1 (1.8%)
Nervous system disorders	9 (16.1%)
Cerebellar infarction	1 (1.8%)
Dysarthria	1 (1.8%)
Embolic stroke	1 (1.8%)
Haemorrhagic transformation stroke	1 (1.8%)
Hemiparesis	1 (1.8%)
Ischaemic stroke	1 (1.8%)
Paralysis	1 (1.8%)
Paraplegia	1 (1.8%)
Spinal cord ischaemia	2 (3.6%)
Psychiatric disorders	1 (1.8%)
Delirium	1 (1.8%)
Mental status changes	1 (1.8%)
Renal and urinary disorders	1 (1.8%)
Acute kidney injury	1 (1.8%)
Surgical and medical procedures	1 (1.8%)
Arterial repair	1 (1.8%)
Vascular disorders	2 (3.6%)
Aortic dissection	1 (1.8%)
Poor peripheral circulation	1 (1.8%)

Table 17: Summary of CEC Adjudicated Procedure-Related Adverse Events (Pro-D)

MedDRA System-Organ Class Preferred Term Adverse Event	Pro-D Patients (N=56)

Data are presented as n (%).
Percentages are based on the number of patients in the Safety Evaluable Population.
Event verbatim terms are reported by sites. The events listed in this table are coded using MedDRA version 22.0 and then stratified by System-Organ Class (SOC) and Preferred Term. Patients may be counted in this table more than once by Preferred Term but are only counted once in the SOC summary line.
Procedure Relatedness adjudicated by the CEC.

2. Effectiveness Results

2.1 Summary of Effectiveness Endpoints

A summary of the secondary endpoints are presented in **Table 18**. Details regarding each of these observations and events (along with other captured information) are presented in the subsequent sections.

Table 18: Summary of Secondary Endpoints (Pro-D)

	30 Days	6 Months	12 Months	2 Years	3 Years	Total
Treatment Success[1]	85.7% (48/56)	NA	NA	NA	NA	-
Dissection Treatment Success[2]	84.0% (42/50)	97.0% (32/33)	93.5% (29/31)	88.9% (16/18)	100.0% (7/7)	-
All-Cause Mortality	8.9% (5/56)	1.9% (1/52)	2.1% (1/48)	5.6% (2/36)	0	9
Dissection-Related Mortality	1.8% (1/56)	0	0	0	0	1
Aortic Rupture[3]	0	0	0	0	0	0
Type Ia Endoleaks	0	3.3% (1/30)	3.3% (1/30)	0	0	1
Type Ib Endoleaks	0	0	0	0	0	0
Type III Endoleaks	0	0	0	0	0	0
Loss of Patency	0	0	0	0	0	0
Kinking	0	0	0	0	0	0
Twisting	0	0	0	0	0	0
Misalignment/Birdbeaking	0	0	0	0	0	0
Loss of Integrity	0	0	0	0	0	0
Stent fracture	0	0	0	0	0	0
Migration (>10 mm)	NA	3.0% (1/33)	3.2% (1/31)	11.1% (2/18)	0	3
Aortic Expansion (>5 mm)	NA	2.9% (1/34)	6.3% (2/32)	10.5% (2/19)	0	4
Secondary Intervention[4]	10.7% (6/56)	3.8% (2/52)	8.3% (4/48)	2.8% (1/36)	0	13

1. Treatment success defined as individual components and as a composite:
   a. Absence of major adverse events (stroke, renal failure, paraplegia, paraparesis)
   b. Absence of perfusion into the false lumen through the primary intimal tear;
   c. Absence of retrograde extension of the dissection;
2. Dissection treatment success defined as individual endpoints and as a composite:
   a. Absence of expansion (>5 mm) in the aorta that has an endograft
   b. Absence of aortic rupture;
   c. Absence of dissection-related mortality;
   d. Absence of MAEs including new ischemia due to branch vessel compromise;
   e. Absence of false lumen perfusion separated by location
   f. Absence of new aortobronchial/tracheal or aortoenteric fistula formation;

Table 18: Summary of Secondary Endpoints (Pro-D)

	30 Days	6 Months	12 Months	2 Years	3 Years	Total

g. Absence of unintentional rupture of the dissection septum;
3. Core Laboratory reported rupture
4. Secondary interventions (CEC adjudicated) related to the device or treated pathology.

2.2 RelayPro Dissection: Technical Success

Technical Success was assessed by the site investigator at the time of the index procedure is defined as successful delivery and deployment of the device, including withdrawal of the delivery system. Technical success is 100% (56/56) with all primary entry tears covered (56/56, 100%) (**Table 19**). The stent-graft was reported as accurately deployed and patent, with integrity maintained for all patients. Further, there were no procedures completed related to the inability to withdraw the delivery system.

Although considered a technical success and reported as accurately deployed by the site investigator, one patient had a deployment of the RelayPro device (proximal bare stent configuration) with a twist/kink. During advancement of the inner sheath from the outer sheath, the deployment was noted as stiff and had significant resistance during pullback. The investigator paused the deployment, resulting in the graft falling back approximately 8-10 mm distal of intended landing site (proximal to the LSA as this patient's dissection extended to Z2). The site reported a proximal landing zone of only 13.5 mm, which is possibly why the LSA was covered. There was no patient injury or sequalae as a result of this at time of index procedure nor was there any issues observed on the following day.

Although described as "additional treatment beyond standard of care" (26/56, 46.4%), these procedures were mostly supra-aortic trunk (SAT) revascularizations (33/56, 58.9% of TEVARs were <Z3), which is generally considered standard of care. Also, several patients had LSA coil embolization standardly after SAT revascularization, this was reported as an additional procedure in one patient to correct a Type II endoleak.

Nine patients had additional stents placed during the index procedure (9/56, 16.1%). All additional stents were bare metal stents. Seven patients had stents placed in the visceral or iliac arteries; two patients had stents placed in the aorta. Of the 2 patients with additional stents placed in the aorta, one patient had a bare metal stent overlapping with the distal end of the RelayPro and a second patient had a bare metal stent placed distal to the RelayPro (not overlapping with the RelayPro).

During follow-up, three patients within 30 days; one at two years had a retrograde dissection. Two patients had their observations confirmed by the Core Laboratory.

One patient was reported with vascular access difficulties/complications: this was due to Perclose failure.

There was no conversion to open repair during the index procedure. A data entry error indicated one patient as a conversion to open repair (noted in the below table). The site confirmed by email (18 Jul 2022) that there had been previous open repair (prior to study participation) and no conversion to open repair as part of this study.

Table 19: Summary of Technical Success and Procedure-Related Information [Site-Reported] (Pro-D)

Device Assessment*	Pro-D Patients (N=56)
Technical Success at Index Procedure	56 (100.0%)
Evaluation of RelayPro System	
Stent-Graft Deployed	56 (100.0%)
Deployment Without Stent-Graft Kinking or Twisting[#]	55 (98.2%)
Accuracy of Relay System Deployment Acceptable[#]	56 (100.0%)
Stent-Graft Patent	56 (100.0%)
Stent-Graft Integrity Maintained (no wire fracture)	56 (100.0%)
Performed Without Unplanned Vascular Access Difficulties or Complications	55 (98.2%)
Additional Treatment Required Beyond Standard of Care	26 (46.4%)
LSA Revascularized	15 (26.8%)
Stent Placement[$]	9 (16.1%)
Other †	7 (12.5%)
Corrected Endoleak ††	1 (1.8%)
Balloon Dilation	1 (1.8%)
Vascular Access	
Right Femoral	35 (62.5%)
Left Femoral	20 (35.7%)
Placement of the Proximal End of the Covered Portion of the Device	
Proximal to the LSA	33 (58.9%)
Distal to the LSA	22 (39.3%)
Final Procedure Result	
Primary Tear Covered	56 (100.0%)
Absence of retrograde extension of the dissection	48 (85.7%)
Conversion to Open Repair ‡	1 (1.8%)
Other Outcomes §	3 (5.4%)

Table 19: Summary of Technical Success and Procedure-Related Information [Site-Reported] (Pro-D)

Device Assessment*	Pro-D Patients (N=56)

Site reported data. All values expressed as n (%).
*The device assessment was performed at the time of the procedure. (Site reported data.)
† "Other Additional Treatment" comprises: LSA coiling (4 patients); angioplasty balloon mid-external iliac artery (one patient); excised dissection of left SFA (one patient); right femoral artery repair secondary to Perclose failure (one patient).
†† Type II endoleak.
‡ A data entry error indicated one patient a conversion to open repair. The site confirmed by email (18 Jul 2022) that there had been previous open repair and no conversion.
§ "Other outcomes" comprise LLE fasciotomy, restoration of blood flow to right lower extremity, and misalignment at celiac that did not result in any correction, however.
LSA, left subclavian artery.
See paragraph preceding the table regarding a case that was noted by the site to have accurate deployment; however, the site noted that the device was deployed distally to the intended site.
$ Nine patients had additional stents placed during the index procedure (9/56, 16.1%). All additional stents were bare metal stents. Seven patients had stents placed in the visceral or iliac arteries; two patients had stents placed in the aorta.

2.3 Treatment Success at 30 Days

Treatment success through one month, defined as a composite of the following:

- Absence of major adverse events (MAEs), defined as:
  - Stroke (disabling)
  - Renal failure (excludes pre-existing)
  - Paraplegia
  - Paraparesis
- Absence of perfusion into the false lumen through the primary intimal tear
- Absence of retrograde extension of the dissection.

Two patients had two events/observations each as summarized in **Table 20**: one patient had renal failure and paraplegia; a second patient had paraparesis and false lumen perfusion through the primary intimal tear.

Table 20: Treatment Success at 30-Days (Pro-D)

	Pro-D Patients (N=56)
Treatment Success at 30 days	85.7% (48/56)
Freedom from MAEs at 30 days	89.3% (50/56)
Stroke (disabling)	1.8% (1/56)
Paraplegia	5.4% (3/56)
Paraparesis	3.6% (2/56)
Renal Failure (excluding pre-existing)	1.8% (1/56)
Absence of false lumen perfusion through the primary intimal tear	95.7% (45/47)
Absence of retrograde extension of the dissection	97.9% (46/47)

CEC and Core Laboratory reported data.
Core Laboratory reported data (e.g., false lumen perfusion through the primary intimal tear) is based on patients with adequate imaging for that parameter.

2.4 Dissection Treatment Success by Timepoint

Dissection treatment success is a composite of the following:

- Absence of expansion (>5 mm) in the aorta that has an endograft, compared to the first post-procedural computed tomographic (CT) imaging study
- Absence of aortic rupture
- Absence of dissection-related mortality
- Absence of MAEs including new ischemia due to branch vessel compromise
- Absence of false lumen perfusion
- Absence of new aortobronchial/tracheal or aortoenteric fistula formation
- Absence of unintentional rupture of the dissection septum.

Dissection treatment success is summarized in **Table 21**. The specific components of dissection treatment success are discussed in more detail in the corresponding event/observation sections.

There was one patient with a CEC-adjudicated aortic rupture. However, this rupture was not Core Laboratory reported and so is not presented in the definition of dissection treatment success.

Table 21: Dissection Treatment Success by Timepoint (Pro-D)

	30 Days	6 Months	12 Months	2 Years	3 Years
Dissection treatment success					
	84.0% (42/50)	97.0% (32/33)	93.5% (29/31)	88.9% (16/18)	100.0% (7/7)
Absence of aortic expansion (>5 mm)					
	NA	97.1% (33/34)	93.8% (30/32)	89.5% (17/19)	100.0% (7/7)
Absence of aortic rupture*					
	100.0% (50/50)	100.0% (34/34)	100.0% (32/32)	100.0% (19/19)	100.0% (7/7)
Absence of dissection-related mortality					
	98.2% (55/56)	100.0% (52/52)	100.0% (48/48)	100.0% (36/36)	100.0% (19/19)
Absence of MAE					
	89.3% (50/56)	100.0% (52/52)	100.0% (48/48)	100.0% (36/36)	100.0% (19/19)
Absence of ischemia due to vessel branch compromise					
	100.0% (56/56)	100.0% (52/52)	100.0% (48/48)	100.0% (36/36)	100.0% (19/19)
Absence of false lumen perfusion from primary intimal tear					
	95.7% (45/47)	100.0% (30/30)	100.0% (30/30)	100.0% (17/17)	100.0% (6/6)
Absence of new aortic fistula formation					
	100.0% (48/48)	100.0% (32/32)	100.0% (31/31)	100.0% (18/18)	100.0% (7/7)
Absence of unintentional rupture of dissection septum					
	100.0% (49/49)	100.0% (34/34)	100.0% (31/31)	100.0% (19/19)	100.0% (7/7)

Table 21: Dissection Treatment Success by Timepoint (Pro-D)

	30 Days	6 Months	12 Months	2 Years	3 Years

Core Laboratory and CEC reported data.
Treatment success is a composite endpoint: the first row presents the component percentage with the individual components listed in the subsequent rows.
Denominators vary by row and timepoint based on the number of patients eligible or those with imaging adequate to assess that parameter.
MAE, major adverse event; NA, not applicable.
* There have been no Core Laboratory reported thoracic aortic or graft ruptures to date. There was one patient with a CEC-adjudicated aortic rupture in the context of subsequent open surgical thoracoabdominal repair. This observation was not Core Laboratory reported nor was it listed in the clinical notes or imaging studies. No additional information is currently available beyond it was in the thoracic aorta.

2.5 Migration

The protocol defines device migration as the longitudinal movement of all or part of a stent or attachment system for a distance >10 mm relative to anatomical landmarks that were determined at the first post-procedural imaging study, as measured by the Core Laboratory. There have been three patients with migrations reported, specifically in one patient at six and 12 months and two patients at two years. All patients were also noted by the Core Laboratory to have aortic lengthening in addition to the migration observed.

A brief overview of these cases are described below:

- One patient had proximal migration (distal direction) and aortic lengthening of the treated segment identified by the Core Laboratory on the 2-year imaging. At all timepoints, the length of aorta covered by the implants, including the amount of device overlap was maintained. Additionally, review of the imaging shows that there is aortic elongation between the LSA and Celiac Artery. The observed migration is likely due to aortic lengthening. No perfusion through the primary entry tear was observed at any follow-up timepoint. The patient has not had any intervention to address this observation.
- One patient had Core Laboratory reported Type Ia endoleak, aortic lengthening of the treated segment, and distal migration of the proximal end of the stent-graft on the 6-month and 12-month imaging; no aortic expansion was noted at either timepoint by the Core Laboratory. Review of the imaging shows that there was aortic remodeling proximally, as well as aortic elongation and dilatation, and the device adapted to the change in the aorta. The length of aorta covered by the implant did not change over the 6-months and no distal movement (of the distal end of the device) was noted by the Core Laboratory. After presenting with radiating chest pain and hypertension, patient was hospitalized to address the observations. The Type Ia endoleak was treated unsuccessfully with a proximal extension, and the patient ultimately underwent ascending and total arch replacement with a frozen elephant trunk with reimplantation of the innominate artery and LCCA using a surgical graft (POD 529).
- At 19-months post operatively, the Core Laboratory reported the following: the proximal end of the device had migrated distally on the 2-year imaging, aortic lengthening in the treated segment, an increase in aortic diameter, and

also confirmed the new dissection proximal to the LSA. This patient had a CEC adjudicated aortic rupture; however, this observation was not Core Laboratory reported nor was it listed in the clinical notes or imaging studies. Review of the imaging suggests that disease progression (development of new dissection and focal aneurysm) and also aortic elongation contributed to the migration observation reported. Additionally, the length of aorta covered by the implant did not change over time. Patient underwent a Type II TAAA open surgical repair with a surgical graft.

Table 22: Core Laboratory Assessed Stent-Graft Migration (Pro-D)

	1 Month	6 Months	12 Months	2 Years	3 Years	Total
Adequate Imaging	51	33	31	18	7	-
Migration (>10 mm)	Baseline*	3.0% (1/33)	3.2% (1/31)	11.1% (2/18)	0	3

Core Laboratory reported data. Migration observed in 3 patients: 1 patient at 6-months and 12-months; 2 patients at 24 months

* First post-procedure measurement (within the 30-day follow-up analytical window) is used for baseline measurement.

2.6 All Endoleaks

There is adequate imaging to assess endoleaks in 48 patients at 30 days, 30 at 6 and 12 months, 17 at 2 years, 6 at 3 years, and 2 at 4 years. There was one Core Laboratory reported Type Ia endoleak observed at the 6-month visit that persisted to the 12-month visit. This patient also had Core Laboratory reported migration and expansion. A secondary intervention was completed on POD 529 to address the observations (discussed in the stent-graft migration section above).

No Type Ib, Type II, Type III, Type IV, or endoleaks of unknown types have been reported by the Core Laboratory at any timepoint.

In this study, the sites reported endoleaks as adverse events. Additionally, the case report forms (CRFs) for the study did not have a field for reporting false lumen perfusion; therefore, this was also reported as an endoleak. In summary, the following endoleaks were site-reported: 4 patients with a Type Ib endoleak, 3 patients with a Type Ia endoleak, 2 patients with a Type II endoleak, and 3 patients with multiple endoleaks (one with Type Ia and Ib endoleak, one with Type I and III endoleak, and one with Type II, Ib, and III endoleak). For the 12 patients that have been site-reported as endoleaks, the Core Laboratory noted false lumen perfusion in 11 patients. Reinterventions were performed to address some of the site reported endoleaks. Please refer to the device-related adverse event section above.

2.7 Component Separation

Component separation is defined as complete separation of any stent-graft components and is assessed by the Core Laboratory. There have been no component separations noted by the Core Laboratory in any patient at any timepoint to date.

2.8 Aortic Expansion

The protocol defines aortic expansion as a change >5 mm in total aortic diameter from the first post procedural imaging. These assessments are based on Core Laboratory measurements. Four patients were noted by the Core Laboratory to have aortic expansion through available follow-up **(Table 23)**.

Table 23: Changes in Aortic Diameter (Core Laboratory) (Pro-D)

	6 Months	12 Months	2 Years	3 Years	Total
Adequate Imaging	34	32	19	7	-
Increase >5 mm					
New	2.9% (1/34)	3.1% (1/32)	10.5% (2/19)	0	4
Persistent	0	3.1% (1/32)	00	0	-
Total	2.9% (1/34)	6.3% (2/32)	10.5% (2/19)	0	-
Decrease	20.6% (7/34)	18.8% (6/32)	31.6% (6/19)	14.3% (1/7)	-
No Change	76.5% (26/34)	75.0% (24/32)	57.9% (11/19)	85.7% (6/7)	-

Core Laboratory reported data. All values expressed as % (n/N).
Patients with aortic expansion: 1 patient at 6-months that persisted to 12-months; 1 patient at 12 months; 2 patients at 2-years
Baseline based on first post-procedure measurement made within the 30-day follow-up analytical window.

2.9 Patency Related Events/Observations

The following patency-related definitions are applied by the Core Laboratory:

- **Patency:** Contrast flow throughout entire length of the device(s)
- **Stenosis:** Stenosis (>50% narrowing) throughout length of stent-graft
- **Kink:** Bending deformation of the stent graft resulting in an unintentional obstruction (>50%) of blood flow through the vascular lumen and not caused by anatomy of the vessel wall
- **Twisting:** Torsional deformation of the stent graft resulting in an unintentional obstruction (>50%) of blood flow through the vascular lumen and not caused by anatomy of the vessel wall.
- **Misalignment/Bird Beak:** Misalignment of stent (centerline of device doesn't follow centerline of lumen) or bird beak (incomplete apposition of stent a proximal end of device) that restricts blood flow greater than 50%.

All devices have been reported as patent at all timepoints by the Core Laboratory. There have been no observations of stenosis, kinking, twisting, misalignment or bird beak in any patient at any timepoint as of the data cut. As described above in Section D2.2, one patient had a deployment of the RelayPro device with a twist/kink. There was no injury or sequalae as a result of this at time of index procedure nor were there any issues observed on the following day.

2.10 Device Integrity (including RelayPro Stent Fracture in the Attachment Zone)

The secondary endpoints for this study include both loss of device integrity, as well as stent fracture in the attachment zone. The clinical protocol defines stent fracture as "fracture or breakage of any portion of the RelayPro stent in the attachment zone,

including metallic fracture." These secondary endpoints are assessed by the Core Laboratory with x-ray and CT imaging or may be reported by the site.

No suture breaks or fractures (site reported or Core Laboratory reported) have been reported in any patient at any follow-up visit.

2.11 Device- or Lesion-Related Events/Observations

Device or lesion-related events and observations include retrograde dissection beyond the LSA, false lumen perfusion, rupture of the dissection septum, fistula formation (aortobronchial, aortoenteric, tracheal), stent graft stenosis, device kink, device twist, suture break visualized, misalignment/bird beak, as well as extrusion/erosion (**Table 24**). These events and observations were reported by the Core Laboratory. Please note that false lumen status was not captured in the clinical study.

False lumen perfusion through the primary intimal tear was reported by the Core Laboratory in two patients at 30-days (2/51,3.9%), no secondary intervention was required and no false lumen perfusion was found at subsequent visits. All other false lumen perfusion (expect for one patient reported at the LSA/Type II false lumen perfusion and also a Type R false lumen perfusion) was reported below the level of the celiac and, therefore, beyond the treatment zone.

At the time of the data freeze, there were no Core Laboratory reported ruptures; however, there was one patient with a CEC-adjudicated aortic rupture.

Table 24: Device or Lesion-Related Secondary Endpoint Events by Follow-up Visit (Pro-D)

	1 Month	6 Months	1 Year	2 Year	3 Years	Total
Number with Adequate Imaging	51	34	32	19	7	-
Retrograde Dissection (beyond LSA)	1 (2.1%)	0	0	1 (5.6%)	0	2
New	1	-	-	1	-	-
Persistent	0	-	-	0	-	-
False Lumen Perfusion	44 (91.7%)	27 (87.1%)	25 (83.3%)	15 (83.3%)	6 (100.0%)	-
New	44	3	3	2	2	-
Persistent	0	24	22	13	4	-
Source of False Lumen Perfusion						
Primary Intimal Tear[a]	2 (4.3%)	0	0	0	0	2
Celiac Artery	13 (72.2%)	5 (55.6%)	5 (50.0%)	1 (25.0%)	1 (100.0%)	-
Endoleak	0	0	0	0	0	-
Innominate	0	0	0	0	0	-
Left Common Carotid	0	0	0	0	0	-
Left Iliac	25 (83.3%)	14 (77.8%)	8 (61.5%)	5 (55.6%)	2 (66.7%)	-
Left Renal	19 (76.0%)	9 (64.3%)	6 (46.2%)	5 (62.5%)	2 (100.0%)	-

Table 24: Device or Lesion-Related Secondary Endpoint Events by Follow-up Visit (Pro-D)

	1 Month	6 Months	1 Year	2 Year	3 Years	Total
Left Subclavian Artery	0	0	1 (16.7%)	0	0	-
Lumbar Arteries	41 (91.1%)	24 (85.7%)	24 (80.0%)	14 (82.4%)	4 (100.0%)	-
Right Iliac	24 (82.8%)	16 (80.0%)	14 (73.7%)	8 (72.7%)	2 (66.7%)	-
Right Renal	11 (64.7%)	7 (63.6%)	5 (45.5%)	4 (50.0%)	0	-
Superior Mesenteric Artery	11 (64.7%)	1 (16.7%)	3 (37.5%)	1 (25.0%)	0	-
Undetermined	2 (28.6%)	3 (42.9%)	1 (14.3%)	0	3 (100.0%)	-
Rupture of Dissection Septum	0	0	0	0	0	0
Aortic Rupture*	0	0	0	0	0	0
Fistula Formation Aortobronchial	0	0	0	0	0	0
Tracheal	0	0	0	0	0	0
Aortoenteric	0	0	0	0	0	0
Stent-Graft Stenosis (>50%)	0	0	0	0	0	0
Device Kink (Compression)	0	0	0	0	0	0
Device Twist	0	0	0	0	0	0
Suture Break Visualized	0	0	0	0	0	0
Misalignment / Bird beak	0	0	0	0	0	0
Extrusion / Erosion	0	0	0	0	0	0
Patients with No Device or Lesion-Related Events[a] Ongoing in Window	46 (90.2%)	30 (88.2%)	29 (90.6%)	16 (84.2%)	7 (100.0%)	-

Core-Laboratory reported data. All n (%)

[a] Any Core-Laboratory observed false lumen perfusion is reported. However, only false lumen perfusion from the primary intimal tear is considered a secondary endpoint event.

2.12 Secondary Interventions, including Open Surgical Conversions

The incidence of open or endovascular dissection related secondary interventions to treat malperfusion, rupture, aneurysm formation, or aortic expansion are captured and reported as part of the secondary endpoints.

For this pivotal study, secondary interventions, including conversions to open surgery could be site reported and/or CEC adjudicated. Regarding CEC adjudication, if a site reported event meets the adjudication trigger for secondary intervention, these events are sent to the CEC for adjudication. The CEC then decides if this event was indeed a secondary intervention or if it meets some other trigger. If an event led to a surgery or procedure related to the device or treated pathology, these events are then adjudicated by the CEC as secondary interventions.

A summary of the reasons for secondary interventions (CEC adjudicated secondary interventions), including conversions to open surgery is provided in **Table 25**. Please note that the following windows are used for the presentation of the secondary interventions through follow-up: 30 days (Day 0 – 90), 6-months (Day

91-270), 1-year (Day 271-540), 2-years (Day 541 – 900), and 3-years (Day 901-1260).

As of the data freeze, 56 patients were eligible for 30-day follow-up, 52 patients for 6-months, 48 patients for 1-year, 36 patients for 2-years, 18 patients for 3-years, and 2 patients for the 4-year follow-up. Fifteen (15) secondary interventions (CEC adjudicated) were performed in 13 patients through available follow-up. Two of these interventions were open surgical conversions: one at one-year (POD 528); a second at two-years (POD 585). No secondary interventions were reported for the 2 patients with 4-year follow-up.

The reasons for intervention are based on site information and include the following: Type Ia endoleak (3), persistent Type I endoleak (distal aspect of stent) with retrograde filling of false lumen (1), Type II endoleak (2), aortic expansion (1), site reported Type III endoleak (1), site reported thoracoabdominal aneurysm rupture (1), spinal cord ischemia (1), lower extremity malperfusion (1), Type A dissection (2), stenosis of stent (1), and thrombosis of renal artery (1). Please note that one patient had multiple reasons for the same intervention, namely this patient had one intervention completed to address site reported Type III endoleak and persistent site reported Type I endoleak at the distal most aspect of the stent with retrograde filling of the false lumen.

Table 25: Reasons for CEC Adjudicated Secondary Intervention (Pro-D)

	30 Days (Day 0-90)	6 Months (Day 91-270)	1 Year (Day 271-540)	2 Years (Day 541-900)	3 Years (Day 901-1260)	Total
Patients at Risk (N)	56	52	48	36	18	-
Interventions (n)	7	3	4	1	0	15
Patients with Any Secondary Intervention	10.7% (6/56)	3.8% (2/52)	8.3% (4/48)	2.8% (1/36)	0	13
Type Ia Endoleak	1.8% (1/56)	0	4.2% (2/48)	0	0	-
Extension	1	-	2	-	-	-
Type II Endoleak	1.8% (1/56)	1.9% (1/52)	0	0	0	-
Embolization	1	1	-	-	-	-
Type III Endoleak	0	0	2.1% (1/48)	0	0	-
Extension	-	-	1	-	-	-
Other	0	1.9% (1/52)	4.2% (2/48)	0	0	-
Thrombectomy & EVAR cuff/ballooning	-	1	-	-	-	-
Extension	-	-	1	-	-	-
Embolization & Physician-Modified TEVAR extension	-	-	1	-	-	-
Uncategorized*	7.1% (4/56)	0	0	2.8% (1/36)	0	-
Clot removal & LSA-LCCA bypass	1	-	-	-	-	-

Table 25: Reasons for CEC Adjudicated Secondary Intervention (Pro-D)

	30 Days (Day 0-90)	6 Months (Day 91-270)	1 Year (Day 271-540)	2 Years (Day 541-900)	3 Years (Day 901-1260)	Total
Total Arch Repair (Open)	1	-	-	-	-	-
Right Common & Superficial Femoral Artery suture angioplasty	1	-	-	-	-	-
Proximal extension, debranching and ascending repair	1	-	-	-	-	-
Extent II TAAA Open Surgical Repair	-	-	-	1	-	-

CEC data.

Totals were included for the number of interventions and also the patients with any intervention. The total was not included for the reasons for a secondary intervention as a patient may have more than one reason for a given intervention. Additionally, the specific rows with interventions may not add up to the total number of interventions completed as a patient may have more than one reason for a given intervention.

Please note that the following windows are used for the presentation of the secondary interventions through follow-up: 30 days (Day 0 – 90), 6-months (Day 91-270), 1-year (Day 271-540), 2-years (Day 541 – 900), and 3-years (Day 901-1260).

Data presented as % (n/N) in a specified window, where n is the number of patients with the characteristic and N is the number of patients at risk.

*Uncategorized:

- One patient: 1 intervention due to right lower extremity malperfusion treated successfully by clot removal and 1 intervention due to spinal cord ischemia treated successfully with LSA-LCCA bypass, 30-days,
- One patient: Site reported Type A aortic dissection treated successfully with total arch repair, 30-days,
- One patient: Site reported postoperative intermittent loss of right pedal pulses treated successfully with right common and superficial femoral artery suture angioplasty of the dissection flap, 30-days,
- One patient: Site reported Type A aortic dissection treated successfully with proximal extension, debranching and ascending repair, 30-days, and
- One patient: Site reported ruptured thoracoabdominal aortic aneurysm successfully treated by Extent II TAAA open surgical repair, 2-years. The Core Laboratory also reported the following in this patient: the proximal end of the device migrated distally on the 2-year imaging, aortic lengthening in the treated segment, an increase in aortic diameter, and also confirmed the new dissection proximal to the LSA.

Other:

- One patient: 1 intervention due to site reported acute thrombosis of left renal artery successfully treated with thrombectomy and mid-abdominal aortic stenosis of dissection stent treated successfully with EVAR cuff and ballooning (6 months),
- One patient: Persistent Type Ib endoleak with retrograde filling of the false lumen treated successfully with distal extension (1 year), and
- One patient: Aortic expansion treated successfully with embolization with physician-modified TEVAR extension (1 year).

Type Ia Endoleak:

- One patient: Type Ia endoleaks treated successfully with: proximal extension (30 days),
- One patient: Patient was also noted to have Core Laboratory reported migration and aortic lengthening. After presenting with radiating chest pain and hypertension, patient was hospitalized to address the observations. The Type Ia endoleak was treated unsuccessfully with a proximal extension, and the patient ultimately underwent ascending and total arch replacement with a frozen elephant trunk with reimplantation of the innominate artery and LCCA using a surgical graft (1 year), and
- One patient: Proximal extension with LSA-LCCA bypass (1 year).

Type II Endoleak:

Table 25: Reasons for CEC Adjudicated Secondary Intervention (Pro-D)

	30 Days (Day 0-90)	6 Months (Day 91-270)	1 Year (Day 271-540)	2 Years (Day 541-900)	3 Years (Day 901-1260)	Total

- One patient: Type II endoleaks treated successfully with LSA embolization (30 days),
- One patient: Type II endoleaks treated successfully with LSA embolization (6 months).

Type III Endoleak: One patient with site reported Type III endoleak repaired successfully with distal extension (1 year). This is the same patient noted above with persistent site reported Type Ib endoleak with retrograde filling of the false lumen reasons for the intervention at 1-year.

3. Subgroup Analyses

In the RelayPro Dissection study, 41 patients (73.2%, 41/56) were male and 15 (26.8%, 15/56) were female. Mean age at treatment was similar between groups (female, 60.5 ± 12.28 years; males: 59.1 ± 11.23 years). Both groups were mostly black (female, 60%; male, 51.2%).

Comorbidities in the male group were comparable but with greater prevalence of hypertension (95.1%, 39/41), hypercholesterolemia (41.5%, 17/41), and renal insufficiency (17.1%, 7/41) and less CAD (17.1%, 7/41) and diabetes mellitus (14.6%, 6/41). Most also had a history of smoking (80.5%, 33/41) with half current smokers (48.5%, 16/33). Sixteen (39.0%, 16/41) were currently on antiplatelet/anticoagulant medications. The female subgroup had a lower history of vascular intervention than the male subgroup (-8.0%, 95%CI -24.6%, 8.7%).
Regarding all-cause mortality, there was no significant difference between males (2.4%, 1/41) and females (0%, 0/15). Treatment success at 30-days was also similar: 86.7% (13/15) in female patients and 85.4% (35/41) in male. All MAEs were in the male subgroup.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

E. Study Design – Pro-T

Patients were treated between November 3, 2017 and June 13, 2021. The database for this panel track supplement reflected data collected through September 23, 2022 and included 50 US patients. There were 16 US investigational sites.

The RelayPro-Transection (Pro-T) clinical study is a single-arm, prospective, multicenter, non-blinded, non-randomized study of the treatment of patients with traumatic injury of the DTA with the RelayPro Thoracic Stent-Graft System.

The primary endpoint is the rate of all-cause mortality at 30-days post procedure. This is not a hypothesis driven study. The primary analysis was performed on all enrolled patients and is summarized with a two-sided 95% CI and compared to an expected rate of 8%.

The sample size is 50 subjects, which is based upon the desire to obtain a specific level of precision around the estimated 30-day all-cause mortality rate, where precision is defined as the half-width of a 95% confidence interval. Based on an expected incidence rate of 8% for all-cause mortality, the exact two-sided 95% confidence interval for a sample of 50 subjects spans from 2.2% to 19.2%. Based on the calculated bounds of 2.2% to 19.2%, the width is 17%; so the precision (confidence interval half-width) is 8.5%.

External evaluation groups were used during the course of the Pivotal Study, which are described below:

- *Independent Imaging Core Laboratory:* The Core Laboratory assessed follow-up imaging endpoints, including endoleak, migration, aneurysm sac size increase, patency, stenosis, and stent fracture.

- *Clinical Events Committee and Data Safety Monitoring Board:* An independent Clinical Events Committee (CEC) and a separate, independent Data Safety Monitoring Board (DSMB) were responsible for assuring the study was conducted ethically, and that the health and welfare of each study patient was protected. The CEC adjudicated events, as specified in the CEC Charter, as identified by the Medical Monitor from regular review of all reported adverse events and classified them as related or not related to the device or the procedure. The DSMB met separately to review the safety data in aggregate and assess the overall safety of the study. The DSMB also assessed whether the continuation of enrollment was appropriate, and if not, whether protocol modifications were necessary or whether the study should be halted.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the Pro-T study was limited to patients who met the following inclusion criteria:

   - Age ≥18 years.
   - Traumatic injury of the descending thoracic aorta (confirmed by CTA or MRA) that occurred no more than 30 days prior to the planned stent implant procedure.
   - Proximal and distal landing zones with diameter between 19 mm and 42 mm.
   - Anatomy meeting all of the following anatomical criteria:
     - Proximal landing zone distal to the left common carotid and a distal landing zone proximal to the origin of the celiac artery; the length of the landing zones will depend on the intended stent graft diameter.
     - The length of the proximal landing zone depends on the intended stent graft diameter and should be:
       - 15 mm for 22–28 mm grafts with bare stent (20 mm for RelayPro NBS).
       - 20 mm for 30–46 mm grafts with bare stent (25 mm for RelayPro NBS).

    - The distal landing zone should be 20 mm for all RelayPro grafts.
    - Coverage of the left subclavian artery was permitted with mandatory revascularization if patent left internal mammary artery (LIMA) bypass or left upper extremity (LUE) AV graft or anomalous vertebral artery off the aorta.
- 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 attachment length for the intended device.
- Adequate iliac or femoral artery access for introduction of the RelayPro delivery system. Alternative methods to gain proper access may be utilized (e.g., iliac conduit).
- Willingness to comply with the follow-up evaluation schedule.
- Informed Consent Form prior to treatment.

Patients were not permitted to enroll in the Pro-T study if they met any of the following exclusion criteria:

- Significant stenosis, calcification, thrombus, or tortuosity of intended fixation sites that would compromise fixation or seal of the device.
- Planned coverage of left carotid or celiac arteries; or anatomic variants that 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 DTA. 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.
- 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 (not associated with the aortic traumatic injury) or chronic renal insufficiency, and not receiving dialysis.
- Hemodynamically unstable.
- Active systemic infection and/or mycotic aneurysm.
- Morbid obesity or other condition that may compromise or prevent the necessary imaging requirements.
- Injury Severity Score of 75.

- Less than two-year life expectancy.
- Current or planned participation in an investigational drug or device study that had 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 believed could interfere with treatment or follow-up.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 days (± 4 weeks), 6 months (± 8 weeks), 12 months (± 12 weeks) and annually (± 12 weeks) through 5 years postoperatively.

Table 26 summarizes the assessment requirements at each stage include preoperative, at treatment, at discharge and at each post-operative follow-up visit.

Additional assessments that were collected at each follow-up visit included:

- Device-related adverse events
- Aortic rupture
- Stent-graft migration, assessed by an Independent Core Laboratory
- Endoleak, assessed by an Independent Core Laboratory
- Aortic enlargement
- Stent-graft integrity, assessed by an Independent Core Laboratory
- Loss of stent-graft patency
- Conversion to open surgery
- Secondary interventions
- Aortic-related mortality

Table 26: Schedule of Assessments (Pro-T)

	Screening	Treatment	Discharge	1M ±4 weeks	6M ±8 weeks	12M ±12 weeks	2, 3, 4, 5Y ±12 weeks
Informed Consent	X						
Medical History	X						
Verify Inclusion/Exclusion Criteria	X						
Physical Exam (including neurological assessment)	X						
Pregnancy testing for female patients of childbearing potential	X						
Mechanism, location, extent of aortic and associated injuries (ISS)	X						

Table 26: Schedule of Assessments (Pro-T)

	Screening	Treatment	Discharge	1M ±4 weeks	6M ±8 weeks	12M ±12 weeks	2, 3, 4, 5Y ±12 weeks
CT Scan with Contrast, or MRA	X						
Angiogram		X					
Clinical Utility Measures		X	X				
Examination of the incision site and assessment of healing			X				
CT scan with/without contrast				X*	X*	X*	X*
Chest X-Ray				X	X	X	X
Adverse Event and device related events assessment		X	X	X	X	X	X

* MR, combined with unenhanced CT, could be performed at follow-up visits for patients who could not receive contrast.
ISS, injury severity score; M, month; MR, magnetic resonance (imaging); Y, year

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

3. Clinical Endpoints

The primary endpoint is the rate of all-cause mortality at 30-days post procedure.

This is not a hypothesis driven study. The primary endpoint is reported as the proportion and exact 95% confidence interval.

With regard to success/failure criteria, the Pro-T Study primary endpoint was compared to an expected incidence of 8% all-cause mortality at 30 days.

The following secondary analyses were completed using descriptive statistics:

At the index procedure:

- Successful device delivery, deployment including withdrawal of the delivery system
- Vascular access complications

Through 1 month, 6 months, 12 months, and annually through 5 years;

- Aortic-related death
- Major adverse events (stroke and paralysis)
- Aortic rupture
- Secondary interventions (open or endovascular) to treat malperfusion, rupture, aneurysm formation, or aortic expansion

- Endoleaks (evaluated individually)
- Loss of stent-graft patency
- Stent fractures in the attachment zone
- Compression
- Erosion
- Extrusion
- Endograft infection

At 6 months, 12 months, and annually through 5 years, compared to the first post-procedural CT;

- Aortic dilation (> 5mm)
- Stent migration (> 10 mm)

Through 6 months, 12 months, and annually through 5 years;

- All adverse events
- All-cause mortality

F. <u>Accountability of PMA Cohort – Pro-T</u>

Fifty patients were enrolled and treated in the Pro-T study with the RelayPro Stent-Graft System. Forty-eight (of 49) eligible patients (98%) had a 30-day visit with at least 98% of patients with adequate imaging to address endovascular parameters. Additional follow-up was collected through 4-years. Compliance and imaging follow-up through available follow-up are provided in **Table 27** below. Three patients are eligible for the 5-year visit; however, these visits have not yet been performed as of the data freeze.

Table 27: Summary of Pro-T Compliance & Core Laboratory Imaging Follow-up

	Patient Follow-Up				Imaging		Imaging Adequate †				Events Within Window‡				
Visit	**Eligible for Visit****	**Visit Performed**	**No Visit***	**Still in Window**	**CT Scan**	**X-Ray**	**Diameter**	**Endoleak**	**Migration**	**Fracture**	**Death**	**Lost to follow-up**	**Early Withdrawal**	**Not Yet Due**	**Patients with ≥1 Element**
Index	50	NA	NA	NA	NA	NA	NA	NA	NA	NA	1	0	0	0	1
30D	49	98% (48/49)	2% (1/49)	0	98% (48/49)	95.9% (47/49)	98% (48/49)	98% (48/49)	98% (48/49)	98% (48/49)	0	0	0	0	0
6M	49	79.6% (39/49)	20.4% (10/49)	0	73.5% (36/49)	65.3% (32/49)	71.4% (35/49)	69.4% (34/49)	73.5% (36/49)	73.5% (36/49)	0	0	0	0	0
12M	49	81.6% (40/49)	18.4% (9/49)	0	75.5% (37/49)	69.4% (34/49)	75.5% (37/49)	73.5% (36/49)	75.5% (37/49)	75.5% (37/49)	0	2	0	0	2
2Y	47	61.7% (29/47)	38.3% (18/47)	19.1% (9/47)	55.3% (26/47)	51.1% (24/47)	55.3% (26/47)	55.3% (26/47)	55.3% (26/47)	57.4% (27/47)#	0	0	1	14	15
3Y	32	34.4% (11/32)	65.6% (21/32)	50.0% (16/32)	31.3% (10/32)	31.3% (10/32)	31.3% (10/32)	31.3% (10/32)	31.3% (10/32)	31.3% (10/32)	0	2	0	17	19
4Y	13	15.4% (2/13)	84.6% (11/13)	76.9% (10/13)	15.4% (2/13)	15.4% (2/13)	15.4% (2/13)	15.4% (2/13)	15.4% (2/13)	15.4% (2/13)	0	0	0	10	10

Note: Patients may have a visit completed and/or imaging completed; they are independent fields.

NA, Not Applicable

* Patients who did not have a visit within the window or patients who did not have a visit but have not yet reached the end of the analysis window.

** This value is used for the denominator for calculating the percentage of visits performed and the imaging adequate to assess each endovascular graft parameter.

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

‡ These columns reflect patients 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.

The number of patients with imaging adequate to assess fracture is higher than the number of CT Scans or x-rays performed because one patient had an X-ray available but no CT Scan. This imaging was determined by the Core Laboratory to be adequate to assess fracture.

G. Study Population Demographics and Baseline Parameters (Pro-T)

Demographics

As is typical in a BTAI population, patients were mostly male (74.0%, 37/50) and young (mean age of 42.4 ± 17.2 years); most patients were white (66%, 33/50) and non-Hispanic (86.0%, 43/50).

Table 28: Patient Demographics (Pro-T)

Characteristic		Pro-T N=50
Male		37 (74.0%)
Female		13 (26.0%)
Age (years)	Mean (±SD)	42.4 (±17.2)
	Median (IQR)	39 (30)
	Min - Max	19 – 76
Age Group (years)		
	18—64	43 (86.0%)
	65—74	6 (12.0%)
	≥75	1 (2.0%)
Ethnic Group		
Not Hispanic/Latino		43 (86.0%)
Hispanic/Latino		4 (8.0%)
Unknown		2 (4.0%)
Not Reported		1 (2.0%)
Race		
White		33 (66.0%)
Black		14 (28.0%)
Unknown		2 (4.0%)
Other		1 (2.0%)

Data are n (%) unless specified otherwise.
IQR, interquartile range; SD, standard deviation.
Site reported data.

Baseline Medical History

Due to the relatively young age of the majority of the patients, few have significant medical history, but comorbidities include hypertension (26.0%, 13/50) and a history of smoking (36.0%, 18/50).

Table 29: Patient Comorbidities (Pro-T)

Comorbidity or Medical History	Pro-T N=50
History of Smoking	18 (36.0%)
Current smoker	11 (22.0%)
Hypertension (treated or untreated)	13 (26.0%)
Coronary artery disease	7 (14.0%)
Myocardial infarction	4 (8.0%)

Table 29: Patient Comorbidities (Pro-T)

Comorbidity or Medical History	Pro-T N=50
Arrhythmias	3 (6.0%)
Congestive heart failure	2 (4.0%)
Angina (stable or unstable)	0
Gastrointestinal complications	6 (12.0%)
Gastroesophageal reflux disease (GERD)	4 (8.0%)
Adynamic ileus	1 (2.0%)
Other	1 (2.0%)
Current antiplatelet/anticoagulant medication	6 (12.0%)
Hypercholesterolemia	5 (10.0%)
Diabetes mellitus	4 (8.0%)
Renal insufficiency	1 (2.0%)
Impotence (males only, n=37)	1 (2.7%)
Peripheral vascular disease	0
Limb ischemia	0
Vascular intervention	0

All values expressed as n (%). Site reported data.

Baseline Vessel Measurements

The baseline lesion characteristics for the patients enrolled in the study are presented in **Table 30**.

Table 30: Baseline Lesion Characteristics (Pro-T)

Characteristic	Site reported	Core Laboratory reported
Mechanism of injury		
Automobile accident	33 (66.0%)	
Motorcycle accident	7 (14.0%)	
Fall	5 (10.0%)	
Other traumatic mechanism	4 (8.0%)	
Pedestrian injury from a motor vehicle	1 (2.0%)	
Location of the aortic injury*		
Aortic isthmus (distal to LSA)	41 (82.0%)	
Distal DTA	9 (18.0%)	
Extent of aortic injury		
Grade 1	2 (4.0%)	4 (8.0%)
Grade 2	4 (8.0%)	9 (18.0%)
Grade 3	38 (76.0%)	30 (60.0%)
Grade 4	6 (12.0%)	7 (14.0%)
Injury severity score (ISS)		
Mean (±SD)	30.3 (±16.3)	
Median (Min, Max)	29 (2, 66)	

Table 30: Baseline Lesion Characteristics (Pro-T)

Characteristic	Site reported	Core Laboratory reported
Common origin BCT/LCCA (Bovine arch)		13 (26.0%)
Intimal tear		
Associated with aortic false aneurysm	28 (56.0%)	
Associated with intramural hematoma	12 (24.0%)	
Alone	6 (12.0%)	
Associated with free rupture	3 (6.0%)	
Length measurements		
From LCCA to intimal tear (mm)		
Mean (±SD)		41.0 (±39.3)
Median (Min, Max)		31.8 (3.1, 218.0)
Proximal aortic neck (mm)		
Mean (±SD)	26.8 (±26.6)	
Median (Min, Max)	22.3 (13.0, 208.0)	
Distal aortic neck (mm)		
Mean (±SD)	41.1 (±25.9)	
Median (Min, Max)	39.5 (0, 150.0)	
Treatment total (mm)		(n=48)
Mean (±SD)	44.0 (±39.6)	83.2 (±28.0)
Median (Min, Max)	26.0 (10.0, 200.0)	73.0 (62.8, 209.0)
Diameter measurements		
Aorta at LCCA (mm)		
Mean (±SD)		26.5 (±3.6)
Median (Min, Max)		26.9 (19.1, 33.4)
Aorta at LSA (mm)		
Mean (±SD)		25.0 (±3.9)
Median (Min, Max)		24.7 (18.1, 35.0)
Maximum thoracic aorta (mm)		
Mean (±SD)		30.0 (±5.9)
Median (Min, Max)		28.6 (20.3, 54.3)
Superior proximal neck (mm)		
Mean (±SD)	24.7 (±3.6)	
Median (Min, Max)	24.45 (17.4, 33.0)	
Inferior proximal neck (mm)		
Mean (±SD)	24.0 (±3.5)	
Median (Min, Max)	23.7 (18.1, 33.0)	
Superior distal neck (mm)		
Mean (±SD)	22.8 (±4.1)	
Median (Min, Max)	22.0 (17.0, 35.0)	
Inferior distal neck (mm)		
Mean (±SD)	22.3 (±4.0)	
Median (Min, Max)	21.7 (14.3, 34.0)	

Data are n (%) or mean (±SD) and median (min, max). N=50 unless indicated otherwise. Shaded fields were not assessed.

Site report & Core Laboratory reported data.
* Nine patients (18.0%) were reported as 'Other location' but the description indicated distal to LSA/proximal DTA/Z3 and mid-DTA and so have been counted within the options 'Aortic isthmus' and 'Distal DTA'.
DTA, descending thoracic aorta; ISS, injury severity score; LCCA, left common carotid artery; LSA, left subclavian artery.

RelayPro Devices Implanted

A summary of the RelayPro devices implanted during the study is presented in **Table 31**.

Table 31: Devices Implanted (Initial Procedure) (Pro-T)

		Pro-T N=50	NBS	Bare stent
Devices Implanted	1	90.0% (45/50)	85.7% (30/35)	93.8% (15/16)
	2	8.0% (4/50)	11.4% (4/35)*	6.3% (1/16)*
	3	2.0% (1/50)	2.9% (1/35)	-
	Straight	98.0% (49/50)	100.0% (35/35)	93.8% (15/16)
	Tapered	2.0% (1/50)	0	6.3% (1/16)*
	Reverse tapered	0	0	0

Denominator includes patients who received the test device. Site reported data.
* One patient had one NBS and one bare stent device and so it is counted in both columns.
NBS, non-bare stent.

Device diameters were relatively evenly distributed in the range 22—32 mm proximally (**Table 32)**. The distal end of the RelayPro proximal bare stent configuration and non-bare stent (NBS) configuration are identical. Therefore, **Table 32** presents the distal diameter of all implanted RelayPro configurations (both RelayPro Proximal Bare Stent and NBS). Distal device diameters were also relatively evenly distributed in the range of 22—32 mm.

Table 32: Diameter of RelayPro Devices Implanted (Pro-T)

Diameter (mm)		NBS	Proximal Bare Stent
Proximal	22	16.0% (8/50)	6.0% (3/50)
	24	14.0% (7/50)	4.0% (2/50)
	26	14.0% (7/50)	0
	28	14.0% (7/50)	10.0% (5/50)
	30	10.0% (5/50)	4.0% (2/50)
	32	8.0% (4/50)	4.0% (2/50)
	34	2.0% (1/50)	0
	36	2.0% (1/50)	4.0% (2/50)
	38	0	0
	40	0	0
	42	0	0
	44	0	0
	46	0	0
Distal	22	20.0% (10/50)	
	24	20.0% (10/50)	
	26	14.0% (7/50)	
	28	22.0% (11/50)	

Table 32: Diameter of RelayPro Devices Implanted (Pro-T)

Diameter (mm)	NBS	Proximal Bare Stent
30	14.0% (7/50)	
32	12.0% (6/50)	
34	2.0% (1/50)	
36	6.0% (3/50)	
38	0	
40	0	
42	0	
44	0	
46	0	

*Denominator includes all patients who received the test device. Site reported data.
NBS, non-bare stent.

Procedural Data

Table 33 summarizes information from the index procedure, including clinical utility endpoints.

One patient had significantly longer intensive care stays and hospitalization (818 h and 181 days). He was a 35-year-old with a complicated clinical course after polytrauma that included chronic hypoxemic respiratory failure/tracheostomy collar, anoxic brain injury, bilateral deep vein thrombosis (DVT) recurrent sepsis/septic shock, hypertension, and pneumonia.

Table 33: Procedural Details (Pro-T)

Characteristic		Pro-T N=50
General anesthesia		50 (100.0%)
Percutaneous access		40 (80.0%)
Surgical cut down		10 (20.0%)
Vascular access		
Left femoral		13 (26.0%)
Right femoral		37 (74.0%)
Proximal landing zone		
Distal to the LSA		29 (58.0%)
Proximal to the LSA		21 (42.0%)
Duration of procedure (min)	Mean (±SD)	73.5 (±39.6)
	Median (IQR)	63 (30)
	Min - Max	23 – 240
Duration of implantation (min)	Mean (±SD)	10.9 (±6.2)
	Median (IQR)	9 (9)
	Min - Max	3 - 30
Estimated blood loss (cc)	Mean (±SD)	48.3 (±51.5)
	Median (IQR)	27.5 (30)
	Min - Max	0 – 300

Table 33: Procedural Details (Pro-T)

Characteristic		Pro-T N=50
Transfusion required		6 (12.0%)
Intensive care (hours)	Mean (±SD)	124.6 (±148.0)
	Median (IQR)	70 (132.5)
	Min - Max	0 - 818
Hospitalization (days)	Mean (±SD)	16.8 (±25.8)
	Median (IQR)	10 (13)
	Min - Max	1 - 181

Date are n (%) unless specified otherwise. Site reported data.
IQR, interquartile range; LSA, left subclavian artery; SD, standard deviation.

H. Safety and Effectiveness Results – Pro-T

1. Safety Results

1.1 Primary Endpoint

The primary endpoint (all-cause mortality at 30-days post procedure) was analyzed with all patients having completed 30-day follow-up; the result of 2.0% (exact two-sided 95% CI, 0.1%, 10.6%) was below the expected incidence (8%) (**Table 34**).

Table 34: Primary Endpoint Analysis (Pro-T)

Characteristic	Statistics	Pro-T N=50
All-cause mortality at 30 Days	% (n/N)	2.0% (1/50)
	Exact two-sided 95% CI	0.1%, 10.6%

CI, confidence interval

A per-protocol analysis was not performed as there are no patients that would be removed from the intent-to-treat analysis to do a per-protocol analysis.

There was one patient with all-cause mortality at 30-days. This was a 61-year-old female that who presented with a grade 4 aortic injury of the distal DTA. She underwent immediate aortic injury repair with a RelayPro NBS (24 mm proximal diameter × 100 mm length ×24 mm distal diameter). The proximal end of the covered portion of the device was placed in the appropriate position distal to the LSA, without kinking or twisting and covering the primary tear. Post-completion angiogram showed retrograde flow into the LSA. The patient was transferred to critical care and kept on life-support until withdrawal of support and comfort care on POD 11. The patient was pronounced dead on POD 12. The CEC adjudicated the death as procedure-related cardiopulmonary arrest but not device-related.

1.2 Secondary Safety Endpoints

1.2.1 Mortality (All-Cause & Aortic-Related)

Aortic-related morality is death due to a rupture, death within 30 days or prior to hospital discharge from the primary procedure, or death within 30 days or prior to hospital discharge for a secondary procedure designed to treat the original lesion. One patient expired on POD 12 and met the definition for aortic-related mortality. As it happened within 30 days of the index procedure, it is considered aortic-related; it was adjudicated by the CEC as not device-related but procedure-related. There has been no other mortality (**Table 35**).

There has only been one death in the study to date. Therefore, both aortic-related and all-cause mortality are the same for the study.

Table 35: Mortality (Pro-T)

	30 Days	6 Months	12 Months	2 Years	3 Years	4 Years	Total
Number Eligible	50	49	49	47	32	14	50
All-Cause Mortality	2.0% (1/50)	0	0	0	0	0	2.0% (1/50)
Aortic-Related Mortality	2.0% (1/50)	0	0	0	0	0	2.0% (1/50)

Site reported data. Relatedness to the device and/or procedure was adjudicated by the CEC.

Kaplan Meier analysis estimated a freedom from All-Cause Mortality and Aortic-Related Mortality **)**, respectively, to be 98% at 30 days through to four years (95% CI, 86.6—99.7%). Kaplan-Meier analysis estimated a freedom from aortic-related mortality of 98% at each interval from 30 days to four years (95% CI, 86.6—99.7%).

1.2.2 Major Adverse Events

Major Adverse Events for the Pro-T study included one case each of all-cause mortality and paralysis. The MAE rate at 30 days is 2% (1/50), 2% (1/50) at 6 months and 0% at 1, 2, 3 and 4 years. At 30 days, one patient expired (described in the preceding section), and at 6 months, one patient reported new onset paralysis. There has been no incidence of stroke reported to date. The CEC adjudicated the paralysis as related to the device and not related to the procedure.

The Kaplan-Meier analysis estimate of freedom from MAEs is 98.0% from 1-180 days and 95.6% from 181-1260 days.

Table 36 presents all MAEs adjudicated by the CEC.

Table 36: Summary of MAEs (CEC adjudicated) (Pro-T)

	30 Days	6 Months	12 Months	2 Years	3 Years	4 Years	Total
	n=49	n=49	n=49	n=47	n=32	N=14	-
Patients with ≥1 MAE (Total)	2% (1/49)	2% (1/49)	0	0	0	0	2
MAEs (Total)	1	1	0	0	0	0	2
Death (all-cause)	1	0	0	0	0	0	1
Paralysis	0	1	0	0	0	0	1
Stroke	0	0	0	0	0	0	0

Data are % (n/N), where n is the number of patients with that event, N is the number of eligible patients.
MAEs are CEC adjudicated.
Paralysis was defined as loss of power or voluntary movement in a muscle through injury to or disease of its nerve supply.
Stroke was defined as a sudden, non-convulsive loss of neurological function due to an ischemic or hemorrhagic intracranial vascular event.

1.2.3 Endograft Infection

Endograft infections are site reported and the CEC adjudicated. There was no endograft infection reported in any patient at any follow-up timepoints.

1.2.4 Device-Related Adverse Events

Adverse events adjudicated by the CEC as being device-related are summarized in **Table 37**. This table includes both AEs and SAEs and is sorted by MedDRA SOC and PT. 6.0% (3/50) of patients experienced one or more device-related adverse events. One patient was reported with paraplegia and a Type II endoleak that required secondary intervention. One patient was reported thrombosis, and a separate patient reported with a Type I endoleak. Core Laboratory reported endoleaks are discussed in detail in a subsequent section.

Table 37: Summary of CEC Adjudicated Device-Related Adverse Events (Pro-T)

MedDRA System Organ Class Preferred Term Adverse Event	Pro-T N=50
Patients with at least one Device-Related Adverse Event	3 (6.0%)
General disorders and administration site conditions	3 (6.0%)
Stent-graft endoleak	2 (4.0%)
Vascular stent thrombosis	1 (2.0%)
Nervous system disorders	1 (2.0%)
Paraplegia	1 (2.0%)
Vascular disorders	1 (2.0%)
Artery dissection	1 (2.0%)

CEC data. Data is presented as n (%), where n is the number of patients reported with the event and % is the percentage of patients with the event. Includes serious and non-serious adverse events. Percentages are based on the number of patients in enrolled in the study. Event verbatim terms are reported by sites. The events listed in this table are coded using MedDRA version 22.0 and then stratified by System-Organ Class (SOC) and Preferred Term. Patients may be counted in this table more than once by Preferred Term but are only counted once in the SOC summary line.

1.2.5 Procedure-Related Adverse Events

Adverse events adjudicated by the CEC as being procedure-related are summarized in **Table 38**. This table includes both AEs and SAEs and is sorted by MedDRA SOC and PT. Four patients (8.0%) were reported with 4 procedure-related adverse events. One patient was reported with a Type II endoleak that required secondary intervention. One patient was reported with a Type I endoleak. Both endoleaks were adjudicated by the CEC as device-related and presented above; the other events included peripheral artery thrombosis and cardiorespiratory arrest that resulted in death.

Table 38: Summary of CEC Adjudicated Procedure-Related Adverse Events (Pro-T)

MedDRA System-Organ Class Preferred Term Adverse Event	Pro-T N=50
Patients with at least one Procedure-Related Adverse Event	4 (8.0%)
General disorders and administration site conditions	2 (4.0%)
Stent-graft endoleak	2 (4.0%)
Cardiac disorders	1 (2.0%)
Cardio-respiratory arrest	1 (2.0%)
Vascular disorders	1 (2.0%)
Peripheral artery thrombosis	1 (2.0%)

CEC data. Data is presented as n (%), where n is the number of patients reported with the event and % is the percentage of patients with the event. Includes serious and non-serious adverse events. Percentages are based on the number of patients in enrolled in the study. Event verbatim terms are reported by sites. The events listed in this table are coded using MedDRA version 22.0 and then stratified by System-Organ Class (SOC) and Preferred Term. Patients may be counted in this table more than once by Preferred Term but are only counted once in the SOC summary line.

2. Effectiveness Results – Pro-T

2.1 Summary of Effectiveness Endpoints

A summary of the secondary effectiveness endpoints are presented in **Table 39** and briefly described below. Details regarding each of these observations and events (along with other captured information) are presented in the subsequent sections.

For the 30-day follow-up window, there were three secondary interventions in three subjects to address Type Ia endoleak (n=1), Type II endoleak (n=1), and uncategorized (n=1, same day as the index procedure to address popliteal thrombus in distal left leg).

For the 6-month follow-up window, there was one loss of patency and one secondary intervention to address thrombosis in the same subject. For the 2-year follow-up window, there was one secondary intervention to address narrowing distal to the stent graft. For the 3-year follow-up window, there was one secondary intervention to address a remaining dissection intimal flap and no other reported events or observations.

Table 39: Summary of Secondary Effectiveness Endpoints

	30 Days	6 Months	12 Months	2 Years	3 Years	4 Years	Total
Aortic rupture	0	0	0	0	0	0	0
Aortic dilation	NA	0	0	0	0	0	0
Secondary intervention	6.1% (3/49)	2% (1/49)	0	2.1% (1/47)	3.1% (1/32)	0	6
Type Ia endoleak	2.1% (1/48)	0	0	0	0	0	1
Type Ib endoleak	0	0	0	0	0	0	0
Type III endoleak	0	0	0	0	0	0	0
Loss of patency	0	2.8% (1/36)	0	0	0	0	1
Compression (kinking)	0	0	0	0	0	0	0
Twisting	0	0	0	0	0	0	0
Extrusion/erosion	0	0	0	0	0	0	0
Stent fracture	0	0	0	0	0	0	0
Suture break	0	0	0	0	0	0	0
Migration	NA	0	0	0	0	0	0

MAE, major adverse event; NA, not applicable.
All values expressed as % (n/N) for endpoints reported within the specified window. Denominators are specified in **Table 27** (Summary of Compliance and Imaging Follow-Up). For imaging endpoints (fractures, migration, endoleak, dilation), the denominator is the number of patients with imaging adequate to assess the parameter. For clinical endpoints (e.g., secondary interventions), the denominator is the number of patients 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); 3 years (Day 901-1260); 4 years (Day 1261-1620).

2.2 Technical Success & Access Complications

Technical success at the time of the index procedure (defined as successful delivery and deployment of the device, including withdrawal of the delivery system) was 98%. One patient had an early Type Ia endoleak that the site associated with retroflex (nonparallel to the aortic wall) upon deployment (captured as kinking in **Table 40**). This was corrected in a secondary intervention on POD 3, specifically ballooning and a RelayPro proximal extension.

There was one (2.0%) vascular access complication unrelated to the device: the procedure was being performed percutaneously (with Perclose access device) when the patient's sutures broke at the Perclose device's access point and surgical cut-down was then required. The procedure was nevertheless a technical success.

Four patients (8%) required additional procedures. One patient is described above regarding the Type Ia endoleak. One patient had coil embolization to address a Type II endoleak. One patient required additional ballooning to improve aortic wall apposition after a Bentson guidewire interacted with the stent-graft. Another had popliteal thrombus that required embolectomy catheters and returned a large amount of thrombus (platelet not fresh) which likely embolized from the aortic injury.

Table 40: Summary of Technical Success (Pro-T)

	Pro-T N=50
Evaluation of RelayPro System (index procedure)	
Deployment without kinking or twisting	49 (98.0%)
Accuracy of deployment acceptable	50 (100.0%)
Stent-graft deployed	50 (100.0%)
Stent-graft patent	50 (100.0%)
Stent-graft integrity (no wire fracture)	50 (100.0%)
Procedure performed without unplanned vascular access difficulties or complications	49 (98.0%)
Additional treatment required	4 (8.0%)
Primary tear covered	50 (100.0%)
Absence of retrograde extension of the dissection	
N/A	9 (18.0%)
Yes	40 (81.6%)*

Site reported data.
N/A: When there was no retrograde extension of the dissection prior to treatment and none after treatment, this was indicated as not applicable.
* Please note that these fields reflect data collected after the data freeze. Total is 49 because of missing data.

2.3 Aortic rupture

There have been no reported aortic or graft ruptures to date.

2.4 Aortic Dilation (>5 mm)

Aortic dilation is defined as an increase of 5 mm or more in diameter from the first postprocedural imaging. These assessments are based on Core Laboratory measurements. Thirty-five (35) patients had imaging adequate to assess aortic diameter at 6-months, 37 at 12-months, 26 at 2-years, 10 at 3-years, and 2 at 4-years. No patient had aortic dilation >5 mm at any timepoint. One patient (1/37) had a decrease in aortic diameter at 12 months.

2.5 Secondary Interventions

All secondary interventions were site reported and/or CEC adjudicated as a secondary intervention. The reasons noted for secondary intervention are based on site reported information. As of the data freeze, 6 secondary interventions were reported in 5 patients to address Type Ia endoleak (1 patient), Type II endoleak (1 patient), stent graft patency (1 patient), stenosis (narrowing distal to the RelayPro device) (1 patient), and uncategorized (1 patient). One patient underwent two interventions; the patient noted with the Type II endoleak intervention (embolization) received an additional RelayPro device to address the remaining dissection intimal flap at 3-years.

There were no reinterventions related to Type Ib endoleaks, migration, aortic dilation or rupture.

There was no conversion to open surgery at any timepoint.

Table 41: Reasons for Secondary Intervention (Pro-T)

	30 Days	6 Months	12 Months	2 Years	3 Years	4 Years	Total
N at risk	*49*	*49*	*49*	*47*	*32*	*13*	-
n secondary interventions	*3*	*1*	*0*	*1*	*1*	*0*	*6*
Patients with any secondary intervention	6.1% (3/49)	2.0% (1/49)	0	2.1% (1/47)	3.1% (0/32)	0	5
Type Ia endoleak	2.0% (1/49)	0	0	0	0	0	1
Extension	1	0	0	0	0	0	1
Type II endoleak	2.0% (1/49)	0	0	0	0	0	1
Embolization	1	0	0	0	0	0	1
Other*	0	2.0% (1/49)	0	2.1% (1/47)	3.1% (1/32)	0	3
Extension	0	1	0	1	1	0	3
Uncategorized**	2.0% (1/49)	0	0	0	0	0	1
Embolectomy	1	0	0	0	0	0	1

Data presented as % (n/N), where N is the number of patients at risk.
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); 3 years (Day 901-1260); 4 years (Day 1261-1620).
*Other includes thrombus (6-months), stenosis post stent-graft (2 years), intimal flap (3 years) reported by site.

- One patient had thrombosis addressed successfully by relining with a RelayPlus device.
- One patient had stenosis post-implant of patient with coarctation physiology treated successfully (POD645) via distal extension of the RelayPro using a competitor 22x100mm device.
- One patient had an Intimal flap successfully treated (POD955) with additional RelayPro (24x99 NBS).

**Uncategorized includes events reported by CEC without further categorization available:

- One patient had popliteal thrombus in the distal left leg (30 days). Upon completion of index procedure, popliteal thrombus noted and embolectomy catheters were passed and thrombus removed successfully.

Interventions Completed by Reason for the Intervention:

- One patient had a Type Ia endoleak treated successfully (POD3) with a third RelayPro bare stent deployed distal to the LCCA and ballooning of the proximal end.

One patient had Type II endoleak treated successfully (POD9) with coil embolization in the proximal subclavian.

2.6 All Endoleaks

Core Laboratory Reported

Table 42 shows the six patients that the Core Laboratory reported with endoleak: one Type Ia, four Type II, and one undetermined. There was one undetermined intraoperative endoleak that persisted to 30-days. No Type Ib or Type III endoleaks have been reported by the Core Laboratory.

The one Type Ia endoleak was observed at 30-day follow-up and did not persist at any follow-up visits.

None of the three observed Type II endoleaks were associated with aortic dilatation.

Site Reported

Please note that site reported endoleaks were reported as adverse events and adjudicated by the CEC for relatedness to the device and/or procedure. There were two patients with a site reported endoleak: One Type II endoleak and one Type I endoleak.

Table 42: Summary of Core Laboratory Reported Endoleaks (Pro-T)

Endoleak	30 Days	6 Months	12 Months	2 Years	3 Years	4 Years	Total
Adequate Imaging	*48*	*34*	*36*	*26*	*10*	*2*	-
Any endoleak	**10.4% (5/48)**	**5.9% (2/34)**	**2.8% (1/36)**	**3.8% (1/26)**	**10% (1/10)**	**0**	**10**
Type Ia							
New	1	0	0	0	0	0	1
Persistent	NA	0	0	0	0	0	-
New & Persistent	2.1% (1/48)	0	0	0	0	0	-
Type Ib	0	0	0	0	0	0	0
Type II							
New	3	1	0	0	0	0	4
Persistent	NA	1	1	0	0	0	-
New & Persistent	6.3% (3/48)	5.9% (2/34)	2.8% (1/36)	0	0	0	-
Type IIIa	0	0	0	0	0	0	0
Type IIIb	0	0	0	0	0	0	0
Type IV	0	0	0	0	0	0	0
Undetermined Type	1	0	0	0	0	0	1
New & Persistent	2.1% (1/48)	0	0	0	0	0	-

NA, not applicable.

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.

2.7 Additional Secondary Endpoints (Integrity, Patency, Migration, Compression, Erosion, Extrusion)

No suture breaks or fractures (site reported or Core Laboratory reported) or device migration have been reported in any patient at any follow-up visit. There were no Core Laboratory observations of kinking, twisting, extrusion or erosion, fistula formation, misalignment or bird-beak in any patient at any timepoint as of the data freeze.

There was one Core Laboratory reported occurrence of loss of patency at 6 months which was stent-graft stenosis >50% (thrombosis). A review of this case for potential contributing causes of the observation included device design, thrombus characteristics, procedural considerations, medications, as well as anatomical and

patient characteristics. No device-specific factors were identified that may have contributed to this observation. The patient had some factors (obesity, DVT, enoxaparin treatment, COVID-19, hormonal contraception, pneumonia) that could influence coagulability; however, it was not possible to definitively identify the root cause of the thrombus in this patient.

In one patient, the site reported thrombus around the distal stent (32-months post procedure) and renal infarct noted as likely embolic from the aortic thrombus around the distal stent. The Core Laboratory did not identify stenosis (> 50%) or occlusion; the imaging did not show any renal infarcts (22-months post procedure). The 32-month imaging had not yet been reviewed by the Core Laboratory as of the date freeze. Patient began anticoagulation starting with intravenous heparin and was discharged on apixaban four days after hospitalization with the instruction not to continue her hormonal contraceptive. The site-reported thrombus and acute kidney injury was reported as resolved.

A site-reported event at two years, specifically narrowing not inside but distal to the stent-graft (treated originally with a single RelayPro NBS 22×100×22) was related to aortic coarctation and was not identified by the Core Laboratory. The CEC adjudicated this site-reported event as not related to the device and not related to the procedure. This observation was addressed with a distal extension with post-operative resolution of the intramural hematoma and all symptoms.

There was a kink later clarified by the site investigator to be retroflex (with associated Type Ia endoleak) and resolved with ballooning POD 3; this kink was not reported by the Core Laboratory. The CEC adjudicated as related to both the device and procedure.

Table 43: Device Performance (Core Laboratory Reported) (Pro-T)

Parameter	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years	Total
Subject with Adequate Imaging	*48*	*36*	*37*	*27*	*10*	*2*	-
Fractures	0	0	0	0	0	0	0
Subject with Adequate Imaging	*47*	*36*	*37*	*26*	*10*	*2*	-
Loss of patency	0	1 (2.8%)	0	0	0	0	1
Subject with Adequate Imaging	*48*	*36*	*37*	*26*	*10*	*2*	-
Migration (> 10 mm)	NA	0	0	0	0	0	0
Subject with Adequate Imaging	*48*	*36*	*37*	*26*	*10*	*2*	-
Extrusion / erosion	0	0	0	0	0	0	0
Fistula formation Aortobronchial	0	0	0	0	0	0	0
Tracheal	0	0	0	0	0	0	0
Aortoenteric	0	0	0	0	0	0	0
Device kink (compression)	0	0	0	0	0	0	0
Misalignment / bird-beak	0	0	0	0	0	0	0
Stent-graft stenosis (>50%)	0	1 (2.9%)	0	0	0	0	1

Table 43: Device Performance (Core Laboratory Reported) (Pro-T)

Parameter	1 Month	6 Months	1 Year	2 Years	3 Years	4 Years	Total
New	-	1	-	-	-	-	1
Persistent	-	0	-	-	-	-	-
Suture break	0	0	0	0	0	0	0
Device twist	0	0	0	0	0	0	0

One patient had stent graft occlusion (stenosis >50%) at 6 months.

NA, not applicable.

Results are presented on a per patient basis; a single patient may be reported with more than one of the same event/observations (e.g., fracture).

Regarding performance-related events and observations, the following definitions are applied by the Core Laboratory:

• Patency: Contrast flow throughout entire length of the device(s).

• Stenosis: Stenosis (>50% narrowing) throughout length of stent-graft.

• Kink: Bending deformation of the stent graft resulting in an unintentional obstruction (>50%) of blood flow through the vascular lumen and not caused by anatomy of the vessel wall.

• Twisting: Torsional deformation of the stent graft resulting in an unintentional obstruction (>50%) of blood flow through the vascular lumen and not caused by anatomy of the vessel wall.

• Misalignment/Bird-beak: Misalignment of stent (centerline of device doesn't follow centerline of lumen) or bird-beak (incomplete apposition of stent a proximal end of device) that restricts blood flow greater than 50%.

• Loss of device integrity (stent fracture in the attachment zone) is any fracture or breakage of any portion of the RelayPro stent in the attachment zone, including metallic fracture.

• Device migration is longitudinal movement of all or part of a stent or attachment system for a distance >10 mm relative to anatomical landmarks that were determined at the first post-procedural imaging study, as measured by the Core Laboratory.

3. Subgroup Analyses

   There were 13 women (26%) and 37 men (64%) treated as part of the study. There was one failure of the primary endpoint (one early mortality) and that was in a woman. It is not possible to interpret the differences as a result of the single event and the exact two-sided 95% confidence interval is wide (-6.8%, 22.2%).

4. Pediatric Extrapolation

   In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

I. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical studies included 161 investigators. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

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

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA supplement was not referred to the Circulatory

Systems Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA supplement substantially duplicates information previously reviewed by this panel.

XII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

The RelayPro Thoracic Stent-Graft System was initially approved to treat aneurysms and PAUs. In this supplement, the indications for use was expanded to include treatment of traumatic injuries and dissections of the descending thoracic aorta, as well as distal extension of the Thoraflex™ Hybrid. Safety and effectiveness were not assessed using the Pro-T and Pro-D clinical study alone but on all available data including nonclinical laboratory and animal studies as well as clinical data from the Pro-A clinical study, reviewed under PMA **P200045,** and the nonclinical studies reviewed under **P210006**.

A. Effectiveness Conclusions

Pro-D

For the RelayPro-D study, technical success at the time of the index procedure was 100%. Treatment success at 30 days was 85.7%.

There have been three patients with migrations reported, specifically in one patient at six and 12 months (associated with Type Ia endoleak as well as aortic lengthening and causing radiating chest pain and hypertension and treated unsuccessfully with a proximal extension that subsequently required total arch repair) and two patients at two years. Of the two patients at two years, one had no clinical consequences and no secondary interventions. The second presented with back and abdominal pain and retrograde dissection with aneurysmal degeneration in the descending thoracic aorta that was successfully treated Extent II TAAA open surgical repair. All three cases were associated with aortic disease progression.

There was one Type Ia endoleak (mentioned in the previous paragraph) observed at six months that persisted to 12 months visit. There were no other endoleaks and no component separations, no losses of stent-graft patency, stenosis, kinking, twisting, misalignment or bird beak, loss of device integrity, suture break or stent fracture.

There were two retrograde dissections reported by the Core Laboratory: one within 30 days (successfully treated with total arch repair) and one at two years (the same patient had migration which is described above). There were no ruptures of the dissection septum or fistula formation.

There have been no Core Laboratory reported thoracic aortic or graft ruptures. There was one patient with a CEC-adjudicated aortic rupture in the context of subsequent open surgical thoracoabdominal repair. It is not clear if this rupture was in the RelayPro treated segment.

There have been 15 secondary interventions in 13 patients through available follow-up, including two open surgical conversions.

Pro-T

For the RelayPro-T study, technical success at the time of the index procedure was 98%. There was one early Type Ia endoleak that the site associated with retroflex upon deployment (captured as kinking). This was corrected in a secondary intervention on POD 3, specifically ballooning and a RelayPro proximal extension.

One Type Ia endoleak observed at 30-day follow-up did not persist at any follow-up visits. At 6 months, there was one loss of patency, which was stent-graft stenosis > 50% (thrombosis). A review of this case for potential contributing causes of the observation included device design, thrombus characteristics, procedural considerations, medications, as well as anatomical and patient characteristics. No device-specific factors were identified that may have contributed to this observation. The patient had some factors that could influence coagulability (obesity, DVT, enoxaparin treatment, COVID-19, hormonal contraception, pneumonia); however, it was not possible to definitively identify the root cause of the thrombus in this patient.

In one patient, the site reported thrombus around the distal stent (32-months post procedure) and renal infarct that the site noted likely embolic from the aortic thrombus around the distal stent. Subject began anticoagulation starting with intravenous heparin and was discharged on apixaban four days after hospitalization with the instruction not to continue her hormonal contraceptive. The site-reported thrombus and acute kidney injury was resolved.

Three secondary interventions were completed post-index procedure through one year to address Type Ia endoleak (treated successfully with proximal extension) and II endoleak (treated successfuly with coil embolization) and stent-graft patency (thrombosis addressed successfully with TEVAR relining). A fourth secondary intervention (embolectomy) was the same days as the index procedure to address popliteal thrombus in the distal left leg;) thrombus was successfully removed and likely to have embolized from the aortic injury.

As of the data freeze, there were no aortic ruptures, endograft infections, aortic dilation, migration, compression (kinking), twisting, extrusion/erosion, fracture, suture breaks, Type Ib endoleaks, or Type III endoleaks at any timepoint. There were also no conversions to open surgery reported at any timepoint.

Conclusion

Based on the effectiveness-related outcomes presented above, there is a reasonable assurance of effectiveness of the RelayPro Thoracic Stent-Graft for the proposed intended use.

B. Safety Conclusions

Pro-D

For the RelayPro-D study, the primary endpoint is the rate of all-cause mortality at 30-days post procedure. All-cause mortality at 30-days was 2.0% (1/50, upper 95% CI 9.1%, $p<0.0001$) and the primary endpoint performance goal is met as the upper bound of the one-sided 95% confidence interval is 8.2%, which is below the performance goal of 25%. Further, the calculated p-value met the interim analysis criteria for early stopping for success.

There have been nine all-cause mortalities reported . No deaths were adjudicated by the CEC as device-related, and one death was adjudicated by the CEC as procedure-related. Kaplan Meier analysis estimated a freedom from all-cause mortality to be 98.1% at 30 days, 87.5% at six months, 85.0% at 12 months, 80.8% at two years, and 75.4% at three years. There was one dissection-related mortality that occurred 8 days post-procedure.

A total of 7 MAEs were reported in 6 (10.7%) patients: paraplegia (n=3), paraparesis (n=2), disabling stroke (n=1), renal failure (n=1). Kaplan-Meier analysis estimated a freedom from MAEs of 89.1% at each interval from 30 days to 3 years. All MAEs were within 30 days of treatment.

The above events support the safety of the RelayPro Thoracic Stent-Graft in patients with Type B aortic dissections.

Pro-T

For the RelayPro-T study, the primary endpoint (all-cause mortality at 30-days post procedure) was analyzed with all 50 patients having completed 30-day follow-up; the result of 2.0% (exact two-sided 95% CI, 0.1%, 10.6%) was below the expected incidence (8%). There was no formal hypothesis testing.

Major Adverse Events included: all-cause mortality and paralysis. The MAE rate at 30 days is 2%, 2% at 6 months and 0% at 1, 2, 3 and 4 years. At 30 days, one patient expired (due to cardiopulmonary arrest), and at 6 months, one patient reported new onset paralysis. The CEC adjudicated the death as procedure-related and not device-related and the paralysis as related to the device and not related to the procedure.

The above events support the safety of the RelayPro Thoracic Stent-Graft in patients with traumatic aortic injuries.

Conclusion

The risks of the device are based on data collected on nonclinical information, as well as data collected in a clinical study conducted to support PMA panel track approval as described above.

The outcomes presented above are comparable to previous studies of this type and demonstrate a reasonable assurance of safety of the RelayPro Thoracic Stent-Graft for the proposed intended use.

C. Benefit-Risk Determination

The probable benefits and risks of the device are also based on data collected in a clinical study conducted to support the indication expansion of this PMA-approved device **(P200045)** as described above.

The RelayPro-D study, data demonstrate the benefit to patients when receiving endovascular treatment of their acute, complicated Type B aortic dissections using the RelayPro Stent-Graft System.

The RelayPro-T study data demonstrate the benefit to patients when receiving endovascular treatment of their blunt traumatic injuries of the descending thoracic aorta.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA panel track approval as described above. The MAEs reported under this study are consistent with other studies of endovascular grafts intended for the repair of dissections and blunt traumatic injuries of the descending thoracic aorta. Device-related risks include Type Ia endoleaks, patency observations, migration, increase in aortic diameter, retrograde dissection, and the need for secondary intervention as described above.

In conclusion, given the available information above, the data support that for the endovascular treatment of patients with dissections and blunt traumatic aortic injury in the descending thoracic aorta, the probable benefits outweigh the probable risks.

1. Patient Perspectives
   This submission did not include specific information on patient perspectives for this device.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The pre-clinical testing performed in accordance with applicable guidance documents and national and internal standards confirmed that the RelayPro met its performance and design specifications. The primary endpoints were met. Available longer-term clinical data supports continued favorable safety and effectiveness-related outcomes. Patients are likely to benefit from the use of the RelayPro in the endovascular repair of dissections and blunt traumatic injuries in the descending thoracic aorta. Overall, the clinical and non-clinical information provided and reviewed in this submission, in combination with that previously reviewed for the original PMA for the aneurysm indication (P200045) support the indications for use of the endovascular repair of all lesions of the descending thoracic aorta. Additionally, the

data previously reviewed for the Thoraflex™ Hybrid original PMA (P210006) in conjunction with that from P200045 support the indications for distal extension of the Thoraflex™ Hybrid device.

XIII. CDRH DECISION

CDRH issued an approval order on March 7, 2023. The final conditions of approval cited in the approval order are described below.

1. *Clinical Update:* The sponsor has agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include, for the IDE and Post-Approval studies, respectively, a summary of the number of patients for whom data are available, with the rates of major adverse events, all-cause mortality, lesion-related mortality, false lumen perfusion, retrograde extension, aortic expansion, fistula formation, stent graft kinking or twisting, secondary endovascular procedures, conversions to surgical repair, endoleaks, aortic rupture, compression, erosion, extrusion, stent-graft infection, stent-graft thrombosis, intra-graft thrombus formation, prosthesis migration, occlusions, stenoses, losses of device integrity, and other procedure or device-related events. Reasons for secondary interventions and conversion to open surgery as well as causes of lesion-related death and rupture are to be described. Additional relevant information from commercial experience within and outside the United States is also to be included. A summary of any explant analysis findings is to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.

2. *Post-Approval Study Reporting:* In addition to the Annual Report requirements, the sponsor must provide the following data in post-approval study (PAS) reports for each study listed below.

    a. *Continued Follow-up of the RelayPro Thoracic Stent Graft System Dissection Study Subjects:*
    This is a prospective, single-arm, multi-center study that consists of continued follow-up of all available subjects from the IDE Dissection Study. A total of 56 subjects were enrolled in study and the remaining subjects will be followed for 5 years. Clinical outcomes will include all-cause mortality, lesion-related mortality, major adverse events, false lumen perfusion, retrograde extension, fistula formation, stent graft kinking or twisting, patency, device misalignment, stent fracture, secondary interventions, conversion to open repair, occlusions, stenosis, all types of endoleaks, stent graft migration (>10 mm), aortic expansion (>5 mm), aortic rupture, loss of device integrity, and other device-related events. These endpoints will be analyzed descriptively, and PAS reports submitted on a yearly basis.

    b. *Continued Follow-up of the RelayPro Thoracic Stent Graft System Transection Study Subjects:*

This is a prospective, single-arm, multi-center study that consists of continued follow-up of all available subjects from the IDE Transection Study. A total of 50 subjects were enrolled in study and the remaining subjects will be followed for 5 years, with a minimum of 25 subjects with evaluable 5 year data. Clinical outcomes will include all-cause mortality, lesion-related mortality, major adverse events, secondary interventions, conversion to open repair, occlusions, stenosis or kink, all types of endoleaks, stent graft migration (>10 mm), aortic dilatation (>5 mm), aortic rupture, compression, erosion, extrusion, stent-graft infection, stent-graft thrombosis, intra-graft thrombus formation, loss of device integrity, and other device-related events. These endpoints will be analyzed descriptively, and PAS reports submitted on a yearly basis.

c. *Registry Data Collection for Dissection:*
The sponsor has also agreed to support and actively participate as a stakeholder in the Society for Vascular Surgery Patient Safety Organization governed Vascular Quality Initiative and/or establish a specific study arm for Dissection within the **T**erumo Aor**t**i**c** **G**lobal **E**ndovascular **R**egistry (TiGER) and undertake such activities to ensure that surveillance occurs for the Bolton RelayPro Thoracic Stent Graft System when used to repair Type B dissections in the descending thoracic aorta in 60 patients with acute dissections in 60 patients with chronic dissections. If collected via TiGER, a minimum of 50% of each indication will be from the US. This surveillance should monitor false lumen characteristics and freedom from dissection-related mortality, additional dissection-related intervention, dissection treatment success, the individual elements of the composite endpoint dissection treatment success, all-cause mortality, endovascular device penetration of the aortic wall, loss of device integrity, stent graft migration (>10 mm), device technical success at the time of the procedure, and device procedural success. The reports will include data at the following timepoints: preoperative, 30-day, 1-year, and yearly thereafter through 5 years. These endpoints will be analyzed descriptively, and PAS reports submitted every 6 months for the first 2 years and then annually thereafter.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XIV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

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

Post-approval Requirements and Restrictions: See approval order.