SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Endovascular Graft and Stent
Device Trade Name:	Zenith® Dissection Endovascular System
Device Procode:	MIH
Applicant's Name and Address:	William Cook Europe ApS Sandet 6, DK 4632 Bjaeverskov, Denmark
Date of Panel Recommendation:	None
Premarket Approval (PMA) Application Number:	P180001
Date of FDA's Notice of Approval:	12/31/2018

The Zenith® Dissection Endovascular System consists of a stent-graft component (Zenith® TX2® Dissection Endovascular Graft with Pro-Form®) and bare stent component (Zenith® Dissection Endovascular Stent). The bare stent component (intended for a subset of the patients covered by the indications for use) is unique to the Zenith Dissection Endovascular System, whereas the stent-graft component (intended for all patients covered by the indications for use) is a line extension to Cook's Zenith® TX2® TAA Endovascular Graft (P070016). The Zenith TX2 TAA Endovascular Graft was approved for the treatment of patients with aneurysms or ulcers of the descending thoracic aorta. The Summary of Safety and Effectiveness Data (SSED) for the Zenith TX2 TAA Endovascular Graft is available on the CDRH website and is incorporated by reference here (http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070016B.pdf).

This PMA builds on the knowledge gained with the Zenith® TX2® TAA Endovascular Graft.

II. INDICATIONS FOR USE

The Zenith® Dissection Endovascular System (Zenith® TX2® Dissection Endovascular Graft with Pro-Form and Zenith® Dissection Endovascular Stent) is indicated for the endovascular treatment of patients with Type B aortic dissection. The Zenith TX2 Dissection Endovascular Graft with Pro-Form is intended to seal entry tears and to exclude aneurysms associated with chronic dissections. The Zenith Dissection Endovascular Stent is intended to be used as a distal component to provide support to delaminated segments of non-aneurysmal aorta with dissection distal to a Zenith TX2

Dissection Endovascular Graft with Pro-Form. The system is indicated for use in patients having vascular anatomy suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with the required introduction systems,
- For the Zenith TX2 Dissection Endovascular Graft with Pro-Form:
  - Non-dissected/aneurysmal aortic segments (fixation sites) distal to the left common carotid artery and proximal to the entry tear with a length of at least 20 mm,
  - Non-dissected/aneurysmal aortic segments (fixation sites) distal to the left common carotid artery and proximal to the entry tear with a diameter (measured outer-wall to outer-wall) of no greater than 38 mm and no less than 20 mm, and
- For the Zenith Dissection Endovascular Stent:
  - Diameter at non-aneurysmal intended implant site (measured outer-wall to outer-wall) of no greater than 38 mm (true lumen) and no less than 20 mm (total aortic diameter).

III. CONTRAINDICATIONS

The Zenith® Dissection Endovascular System is contraindicated in:

- Patients with known sensitivities or allergies to stainless steel, polyester, polypropylene, nitinol or gold.
- Patients with a systemic infection who may be at increased risk of endovascular graft/stent infection.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Zenith® Dissection Endovascular System labeling (Instructions for Use).

V. DEVICE DESCRIPTION

The Zenith® Dissection Endovascular System consists of the Zenith® TX2® Dissection Endovascular Graft with Pro-Form® (stent-graft component) and the Zenith® Dissection Endovascular Stent (bare stent component), as shown in Figure 1.

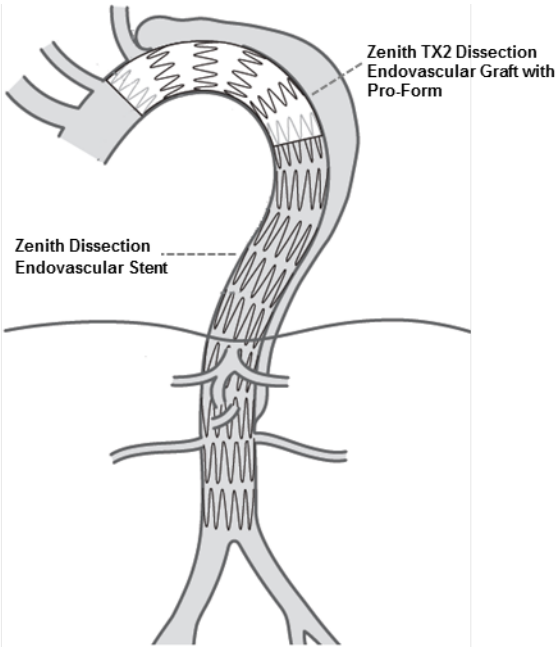


Figure 1. Zenith® Dissection Endovascular System consisting of the Zenith® TX2® Dissection Endovascular Graft with Pro-Form® (stent-graft component) and the Zenith® Dissection Endovascular Stent (bare stent component)

A. Zenith® TX2® Dissection Endovascular Graft with Pro-Form®

The stent-graft component of the Zenith® Dissection Endovascular System is the Zenith® TX2® Dissection Endovascular Graft with Pro-Form® (also referred to as the Dissection Endovascular Graft). It is a one-piece tubular endovascular graft (Figure 2) that is intended to seal entry tears and to exclude aneurysms associated with chronic dissections. The graft is constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook-Z® stents with braided polyester and monofilament polypropylene sutures. The graft is available in a straight or tapered configuration, both of which are fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, the Cook-Z® stents provide the necessary attachment and seal of the graft to the vessel wall without the use of barbs. The proximal and distal ends of the stent-graft have an internal sealing stent. To facilitate fluoroscopic visualization of the stent-graft, four gold radiopaque markers are positioned at each end of the graft. These markers are placed in a circumferential orientation within 1 mm of the most proximal and distal aspects of the graft material. The graft is available in diameters ranging from 22 mm to 42 mm, including non-tapered and tapered (4 mm and 8 mm tapered) configurations. There are multiple lengths available for each graft diameter, ranging from 79 to 218 mm. The Zenith Dissection Endovascular Graft with Pro-Form is loaded onto the Zenith TX2 Dissection Endovascular Graft Z-Trak Plus Introduction System. Pro-Form refers to the attachment with trigger-wires of both ends of the proximal seal stent to the introduction system.

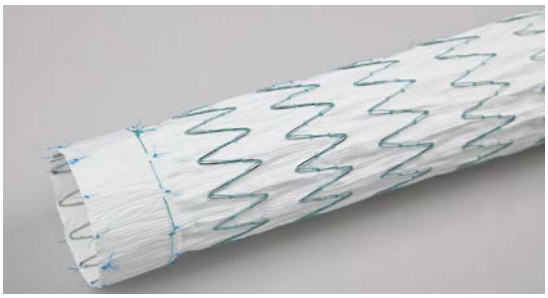


Figure 2. Zenith® TX2® Dissection Endovascular Graft with Pro-Form® shown in a straight configuration

B. Zenith® TX2® Dissection Endovascular Graft Z-Trak Plus® Introduction System

Figure 3 illustrates the Zenith® TX2® Dissection Endovascular Graft Z-Trak Plus® Introduction System (20 Fr or 22 Fr). The Zenith TX2 Dissection Endovascular Graft Z-Trak Plus Introduction System has a single trigger-wire release mechanism to secure the endovascular graft onto the introduction system until released by the user. The introduction system is compatible with a .035 inch wire guide and uses the Captor® Hemostatic Valve and Flexor® introducer sheath. There is a hydrophilic coating on the sheath and tip.

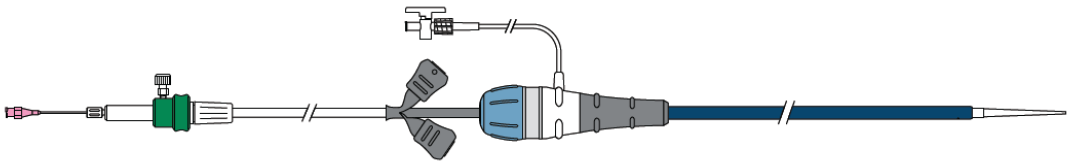


Figure 3. Zenith® TX2® Dissection Endovascular Graft Z-Trak Plus® Introduction System

C. Zenith® Dissection Endovascular Stent

The bare stent component of the Zenith® Dissection Endovascular System is the Zenith® Dissection Endovascular Stent (also referred to as the Dissection Stent). The Dissection Stent is a one-piece tubular device with a slight flare in the stent at its proximal end, constructed from self-expanding nitinol Cook-Z® stent segments sewn together with polyester suture (Figure 4). The Dissection Stent is used as a distal component in combination with the Dissection Endovascular Graft. No graft material is used in this component in order to avoid coverage of spinal and visceral branch vessels. The Dissection Stent is available in 2 diameters (36 mm and 46 mm), which come in multiple lengths. The 36mm diameter Dissection Stent is available in 80mm, 120mm, and 180mm lengths, and the 46mm Dissection Stent is available in 80mm, 120mm, and 185mm

lengths. There are gold radiopaque markers at the proximal and distal ends to facilitate fluoroscopic visualization.

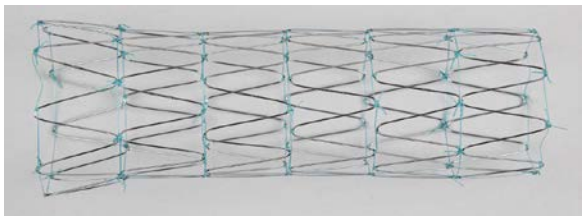


Figure 4. Zenith® Dissection Endovascular Stent

D. Zenith® Dissection Endovascular Stent Z-Trak Plus® Introduction System

The Dissection Stent is shipped preloaded in a 16 Fr Z-Trak Plus® Introduction System (Figure 5), which uses a single trigger-wire release mechanism to secure the endovascular stent onto the introduction system until released by the physician. The introduction system is compatible with a .035 inch wire guide and uses the Captor® Hemostatic Valve and Flexor® introducer sheath. In addition, there is an anti-torque brace at the user interface (adjacent to the valve) to maintain rotational alignment of the sheath relative to the central carrier to which the stent component is attached. There is a hydrophilic coating on the sheath and tip.

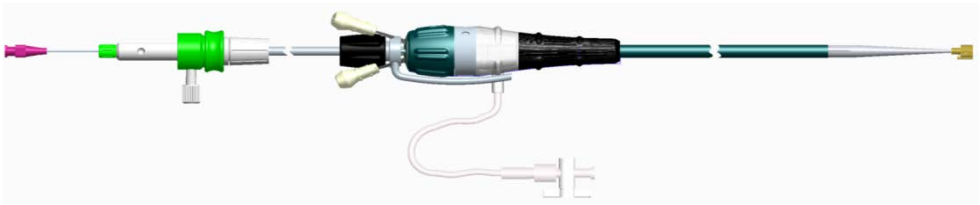


Figure 5. Zenith® Dissection Endovascular Stent 16 Fr Z-Trak Plus® Introduction System

E. Comparison between the Zenith Dissection Endovascular System and Other Endovascular Devices in the Zenith Family

The Zenith Dissection Endovascular System is a line extension to the Zenith family of endovascular devices.

The Dissection Endovascular Graft is nearly identical to the Zenith TX2 TAA Endovascular Graft, which was approved for the treatment of patients with aneurysms or ulcers of the descending thoracic aorta (P070016). The only differences are that the Dissection Endovascular Graft does not have barbs and includes a greater range of stent graft sizes (shorter and longer lengths, smaller diameters, and increased stent graft taper offered).

The Dissection Stent is unique in that it does not include a covering material, but is otherwise very similar to the Zenith Alpha Thoracic Endovascular Graft, which was approved for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta (P140016), utilizing the same materials, vendor, manufacturing processes, and sterilization.

The introduction systems for the Dissection Endovascular Graft and Dissection Stent are based on the Zenith TX2 TAA Endovascular Graft's Z-Trak Plus Introduction System with a few updates to align with more recently approved Zenith Endovascular Grafts and accommodate the Dissection Endovascular Graft and Dissection Stent. The main differences include an increased sheath length for both systems, a smaller sheath size for the bare stent system only, updated ergonomics on the hemostasis valve and knobs on the peel away sheath, the addition of an anti-torque brace for the bare stent system only, and use of a different hydrophilic coating (same as used on the commercially available Zenith Spiral-Z Iliac Leg Graft, approved under P020018/S037).

For additional details on the Zenith Dissection Endovascular System, refer to the Instructions for Use.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several alternatives for treatment of Type B aortic dissection, including: endovascular repair with another stent-graft device, open surgical repair involving implantation of a synthetic graft within the dissected vessel, and medical management. 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.

VII. MARKETING HISTORY

The Dissection Endovascular Graft and Dissection Stent are commercially available in the following countries and have not been withdrawn from any market for any reason: Afghanistan, Albania, Andorra, Angola, Anguilla, Antarctica, Antigua and Barbuda, Argentina, Armenia, Aruba, Austria, Australia, Azerbaijan, Bahamas, Bahrain, Barbados, Belgium, Belize, Benin, Bermuda, Bhutan, Botswana, Bouvet Island, Brazil, British Indian Ocean, Brunei, Bulgaria, Burkina Faso, Burundi, Cameroon, Canary Island, Cape Verde, Cayman Islands, Central African Republic, Chad, Chile, Christmas Island, Cocos Island, Colombia, Comoros, Congo, Cook Islands, Costa Rica, Côte d'Ivoire, Curacao, Cyprus, Czech Republic, Denmark, Djibouti, Dominica, Dominican Republic, Egypt, El Salvador (graft only), Equatorial Guinea, Eritrea, Falkland Islands, Faroe Islands, Finland, France, French Guiana, French Polynesia, French Southern Territories, Gabon, Gambia, Georgia, Germany, Gibraltar, Grenada, Greece, Greenland, Guadeloupe, Guernsey, Guinea, Guinea Bissau, Guatemala, Guyana, Haiti, Heard Island and McDonald, Hong Kong, Hungary, Iceland, India, Ireland, Iran, Iraq, Israel, Italy, Jamaica, Jersey, Jordan, Kiribati, Kosovo, Lebanon, Lesotho, Liberia, Libya, Liechtenstein, Lithuania, Luxembourg, Macau, Madagascar, Malawi, Maldives, Mali,

Malta, Malaysia, Martinique, Mauritania, Mauritius, Mayotte, Federated states of Micronesia, Monaco, Mongolia, Montserrat, Mozambique, Namibia, Nauru, Nepal, Netherlands, Netherlands Antilles, New Caledonia, New Zealand, Niue, Niger, Nigeria, Norfolk Island, Norway, Oman, Palau, Panama, Paraguay, Peru, Pitcairn, Poland, Portugal, Qatar, Reunion, Romania, Russia, Rwanda, Saint Helena, Saint Kitts and Nevis, Saint Lucia, Saint Pierre and Miquelon, Saint Vincent and the Grenadine, San Marino, Sao Tome and Principe, Senegal, Seychelles, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Georgia and the South Sandwich Islands, South Africa, Southern Territories, Spain, Suriname, Svalbard and Jan Mayen, Sweden, Swaziland, Switzerland, Taiwan, Togo, Tokelau, Tonga, Trinidad and Tobago, Tunisia, Turks and Caicos Islands, Tuvalu, United Arab Emirates, Uganda, United Kingdom, Vanuatu, Vatican City State, Vietnam, Wallis and Futuna, Western Sahara, Zambia, and Zimbabwe.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

- Amputation
- Anesthetic complications and subsequent problems (e.g., aspiration)
- Aortic enlargement
- Aortic rupture and death
- Aortic damage, including perforation, dissection, bleeding, and rupture
- Arterial or venous thrombosis and/or pseudoaneurysm
- Bleeding, hematoma, or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent problems (e.g., arrhythmia, tamponade, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Dissection extension (i.e., either proximal or distal extension)
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Endoprosthesis: improper component placement; incomplete component deployment; poor conformability of the graft to the vessel wall; component migration and/or separation; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture; and perigraft flow;
- Fever and localized inflammation
- Fistula (e.g., aortobronchial, aortoesophageal, arteriovenous)
- Genitourinary complications and subsequent problems (e.g., ischemia, erosion, fistula, urinary incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the dissection, device, or access site, including abscess formation, transient fever, and pain

- Local or systemic neurologic complications and subsequent problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, spinal cord shock, paralysis)
- Lymphatic complications and subsequent problems (e.g., lymph fistula, lymphocele)
- Occlusion of device or native vessel
- Persisting flow in the false lumen
- Pulmonary/respiratory complications and subsequent problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Surgical conversion to open repair
- Unintentional dissection septum rupture
- Vascular access site complications including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)
- Wound complications and subsequent problems (e.g., dehiscence, infection)

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

IX. SUMMARY OF NONCLINICAL STUDIES

The following nonclinical studies were performed on the Zenith Dissection Endovascular System:

A. Biocompatibility Testing

The Zenith Dissection Endovascular System utilizes the same materials, suppliers, and sterilization processes that have been previously accounted for in the biocompatibility testing for other approved Cook products. Specifically, the Zenith Dissection Endovascular System implants are constructed of the same base raw nitinol, stainless steel, polyester, and polypropylene materials as are used in the Zilver® Vascular Stent (P050017), the Zenith Flex® AAA Endovascular Graft (P020018), Zenith® Spiral-Z® AAA Iliac Leg Graft (P020018/S037), the Zenith TX2 TAA Endovascular Graft (P070016), and the Zenith® Alpha Thoracic Endovascular Graft (P140016). These devices have shown acceptable biocompatibility and have a history of safe clinical use in humans. Although there are some differences in manufacturing processes between the currently marketed devices and the subject device, rationale was provided to support that these do not raise any significant biocompatibility concerns. Therefore, additional biocompatibility studies specific to the Zenith Dissection Endovascular System implant were considered unnecessary.

Likewise, the materials and suppliers used in the introduction systems for the Zenith Dissection Endovascular System are also used in the introduction systems for the above

noted Zenith Endovascular Grafts, which have established biocompatibility. Although there are some differences in manufacturing and sterilization processes between the approved devices and the subject device, rationale was provided to support that differences do not raise any significant biocompatibility concerns. Therefore, biocompatibility testing was leveraged from other Zenith Endovascular Grafts devices in support of the Zenith Dissection Endovascular System introduction system.

B. Laboratory Studies

The laboratory studies completed to evaluate each component of the Zenith Dissection Endovascular System, as well as the combination of the Dissection Endovascular Graft with Dissection Stent, are presented separately below. All testing was completed in accordance with international standards, specifically ISO 25539-1 "Cardiovascular implants -- Endovascular devices -- Part 1: Endovascular prostheses." Testing was completed using either all available sizes or a subset of device configurations and sizes to represent the full range available.

Dissection Endovascular Graft

Testing for the Dissection Endovascular Graft was focused on the unique attributes and use conditions as compared to the Zenith TX2 TAA Endovascular Graft and Zenith Flex AAA Endovascular Graft. Because of the similarities between the devices, the only new test that was performed on the Dissection Endovascular Graft implant alone was migration resistance, the results of which are summarized in Table 1. Sufficient rationale was provided to support leveraging all other implant only, delivery system only, and system testing in support of the Dissection Endovascular Graft.

Table 1. Summary of laboratory (in vitro) test results for the Dissection Endovascular Graft (implant only)

Test	Purpose	Acceptance Criteria	Types/Sizes Tested	Results
Migration Resistance	To determine the maximum force required to pull the implant from aortic tissue (i.e., the force to cause migration).	A minimum pull-out force of 8.14 N	Shortest available Dissection Endovascular Graft with lowest radial force stents	Pass

Dissection Endovascular Stent

Testing for the Dissection Stent was focused on the unique attributes and use conditions as compared to the Zenith TX2 TAA Endovascular Graft, Zenith Flex AAA Endovascular Graft, and Zenith Alpha Thoracic Endovascular Graft. Table 2 summarizes the new testing completed on the implant only. Table 3 presents testing completed utilizing the implant and delivery system to further support the Dissection Stent. Sufficient rationale was provided to support leveraging all other implant only, delivery system only, and system testing from other currently marketed Zenith devices.

Table 2. Summary of laboratory (in vitro) test results for the Dissection Stent (implant only)

Test	Purpose	Acceptance Criteria	Types/Sizes Tested	Results
Dimensional Verification	To measure the relaxed length and outside diameter of the implant.	Length ± 10 mm of the label; distal end diameter ± 5% of the label; flared proximal end stent diameter measured for characterization purposes only	Largest diameter and longest length Dissection Stent	Pass
Radial Force/Hoop Strength	To determine the outward radial force exerted by the implant when its diameter is reduced by mechanical constriction.	Minimum/Maximum 1.0 N ≤ x ≤ 7.0 N	All z-stent configurations used in the construction of the Dissection Stent	Pass
Corrosion	To evaluate corrosion resistance (breakdown potential)	The breakdown potential shall be statistically greater than or equivalent to that of a nitinol stent used in an approved endovascular stent-graft	Dissection Stent z-stent configuration under the most strain when compressed to the introducer diameter	Pass
Stress/strain Analysis (FEA)	To evaluate the fatigue behavior of the implant under physiologically relevant loading conditions.	Fatigue safety factor must be > 1.0.	All z-stent configurations used in the construction of the Dissection Stent	Pass

Table 3. Summary of laboratory (in vitro) test results for the Dissection Stent (system)

Test	Purpose	Acceptance Criteria	Types/Sizes Tested	Results
Profile/Diameter	To measure the outer diameter of the loaded system intended for insertion into the vasculature.	Testing was performed for characterization purposes only	All Dissection Stent diameters and lengths	<u>46 mm diameter stent</u> 6.22 ± 0.03 mm 6.21 ± 0.01 mm 6.23 ± 0.02 mm <u>36 mm diameter stent</u> 6.20 ± 0.02 mm 6.23 ± 0.02 mm 6.23 ± 0.01 mm
Simulated Use and Visibility	To examine characteristics related to the geometry and deployment of stent components, and to obtain measurements and/or photographs of the geometry and deployment characteristics of these components.	100% success for all parameters important to proper deployment, including: • flushing • advancement visibility of tapered tips, sheath, and stents • sheath pullback • stent components remain attached to delivery system after sheath pullback • smooth trigger-wire release • devices expand • stents positioned correctly in the anatomic model • sub-assembly and sheath removal	All Dissection Stent diameters and lengths	Pass

Test	Purpose	Acceptance Criteria	Types/Sizes Tested	Results
		• valves remain in place after withdrawal of the grey positioner • no visible debris • stents have no kinks, bends, twisting, component separation, or damage to it or delivery system after deployment		
Force to Deploy	To measure the force required to deploy a stent component inside an anatomical model.	Maximum sheath withdrawal force < 45 N Pull-out force of the release wire < 36 N	Largest diameter and longest length Dissection Stent	Pass

Zenith Dissection Endovascular System

Additional testing of the Dissection Endovascular Graft in combination with the Dissection Stent was also performed, taking into consideration the intended use conditions. Table 4 summarizes the completed testing.

Table 4. Summary of laboratory (in vitro) test results for the Zenith® Dissection Endovascular System (Dissection Endovascular Graft in combination with Dissection Stent).

Test	Purpose	Acceptance Criteria	Types/Sizes Tested	Results
Corrosion	To evaluate the corrosion resistance of the implant.	No acceptance criterion for this test; the assessment of galvanic corrosion behavior of the coupled materials is for characterization purposes only	1. Dissection Stent (Niti) 2. TX2 Stent (304 SS) 3. Gold Markers	Uncoupled corrosion tests I_{corr}: 1. 0.457 ± 0.440 nA/mm^2 2. 0.009 ± 0.004 nA/mm^2 3. 1.112 ± 1.044 nA/mm^2 Uncoupled corrosion tests E_{corr}: 1. -91 ± 89 mV_{SCE} 2. -72 ± 25 mV_{SCE} 3. -217 ± 145 mV_{SCE} Coupled galvanic corrosion testing measured i_{couple}: 2. 0.03 ± 0.02 nA/mm^2 3. 0.01 ± 0.02 nA/mm^2 Coupled galvanic corrosion testing E_{couple}: 2. -95.4 ± 51.2 mV_{SCE} 3. -74.9 ± 27.5 mV_{SCE}

Test	Purpose	Acceptance Criteria	Types/Sizes Tested	Results
Fatigue & Durability	To evaluate the fatigue life of the implant by subjecting it to time-accelerated, physiologically modeled, controlled displacement pulsatile loading for a specified number of cycles.	No through-strut stent fractures shall occur in the stents at any point through the duration of 400 million cycles of simulated pulsatile fatigue	Lowest safety factor Dissection Stent tested while overlapped with a Dissection Endovascular Graft of the same size	No fractures were observed in any of the stents that were subjected to 400 million pulsation cycles.
MRI	To assess magnetic field interactions, RF (radiofrequency) heating, and MRI induced image artifacts for the implant.	Magnetic Field Interactions The measured force and torque at the maximum labeled force product (spatial gradient x magnetic field) shall be less than the forces required to rupture or transect dissected tissue or cause the device to migrate. RF Heating The Cumulative Equivalent Minutes at 43˚C value shall be less than 10 minutes at the labeled Specific Absorption Rate limit. Image Artifact There is no acceptance criterion associated with image artifact.	Largest diameter and longest length Dissection Stent and Dissection Endovascular Graft	Pass Maximum artifact size extended approximately 80 mm relative to the graft overlapped with the stent; the lumen was completely obscured.

C. Shelf-life Testing

Due to similarities in device design between the Zenith Dissection Endovascular System and other currently marketed Zenith devices, no new non-clinical testing was completed to support a three-year shelf-life claim. The materials used in the Zenith Dissection Endovascular System are the same as those used in the Zenith TX2 TAA Endovascular Graft (P070016 and P070016/S002), except for the hemostatic valve, which is the same as that used for the Zenith Alpha™ Thoracic Endovascular Graft (P140016), and the hydrophilic coating on the sheath, which is the same as for the Zenith Spiral-Z Iliac Leg Graft (P020018/S037). Each of the prior approved devices has an established three-year shelf-life and the information to support the three-year shelf-life for the other products is appropriate to leverage for the Zenith Dissection Endovascular System, thereby supporting a three-year expiration date.

D. Animal Studies

The Zenith Dissection Endovascular System shares the same basic design as the Zenith TX2 TAA Endovascular Graft, a cylindrical endovascular prosthesis with self-expanding z-stents that are bare or are sutured to the internal or external surface of graft material.

Moreover, the Zenith Dissection Endovascular System is constructed of the same base raw nitinol, stainless steel, polyester, and polypropylene materials with similar processing as the Zilver Vascular Stent (P050017), the Zenith Flex AAA Endovascular Graft (P020018), and the Zenith TX2 TAA Endovascular Graft (P070016). These devices underwent previous animal testing and demonstrated acceptable results with respect to patency (freedom from thrombosis) and biological response (histopathology). Additionally, these devices have shown acceptable biocompatibility and have a history of safe clinical use in humans. Therefore, animal studies from prior Cook devices were leveraged in support of the Zenith Dissection Endovascular System.

X. SUMMARY OF THE PRIMARY CLINICAL STUDY

The applicant performed a pivotal clinical study to establish a reasonable assurance of safety and effectiveness of endovascular treatment with the Zenith® Dissection Endovascular System for Type B aortic dissection in the US and Japan under IDE# G070123. Data from this clinical study were the basis for the PMA approval decision.

The Zenith Dissection Endovascular System is a line extension to the Zenith family of endovascular devices. The Dissection Endovascular Graft is similar to other endovascular grafts in the product line, but is designed specifically for the treatment of dissections, having no barbs. Information from previous clinical studies and clinical use of the Zenith endovascular grafts provides a foundation for the expected clinical performance of the Dissection Endovascular Graft, including placement in aneurysmal aortic segments.

The clinical study of the Zenith Dissection Endovascular System enrolled patients with acute, complicated dissections and included implantation of the Dissection Endovascular Graft and the Dissection Stent.

Data from the clinical study performed on use of Zenith Dissection Endovascular System for the treatment of acute, complicated Type B aortic dissection are presented below. Refer to Section XI for supplementary information that supported a broader indication inclusive of chronic dissection.

A. Study Design

Patients were treated between August 4, 2012 and January 15, 2015. The database for this PMA reflected data collected through March 14, 2017 and included 73 patients (67 US, 6 Japan). There were 22 investigational sites (21 US, 1 Japan).

The study was a prospective, non-randomized, single-arm, multi-national / multi-center clinical study based on binomial distribution for hypothesis testing.

Because acute, complicated dissections are life threatening, the primary endpoint for the study was the survival rate at 30 days. The performance goal for this endpoint (79.4%) was an adjusted rate based on the survival rate at 30 days in the Society of Vascular

Surgery (SVS) dataset, which includes pooled data from physician-sponsored studies reported by the SVS Outcomes committee.

Null Hypothesis: The survival rate at 30 days, $\pi_{s(30)}$, does not meet the performance goal (79.4%).

$$H_0: \pi_{s(30)} \leq 79.4\%$$

Alternate Hypothesis: The survival rate at 30 days, $\pi_{s(30)}$, meets the performance goal (79.4%).

$$H_A: \pi_{s(30)} > 79.4\%$$

There was an additional hypothesis-driven safety endpoint of freedom from Major Adverse Events (MAEs) at 30 days. The performance goal for this endpoint (51.2%) was an adjusted rate based on the rate of freedom from MAEs at 30 days in the SVS dataset.

Null Hypothesis: The freedom from MAE at 30 days, $\pi_{s(30)}$, does not meet the performance goal (51.2%).

$$H_0: \pi_{s(30)} \leq 51.2\%$$

Alternate Hypothesis: The freedom from MAE at 30 days, $\pi_{s(30)}$, meets the performance goal (51.2%).

$$H_A: \pi_{s(30)} > 51.2\%$$

Forty patients were necessary to assess the primary hypothesis, under an expected 30-day survival rate of 94.9% (estimated from a feasibility study conducted under G070123 for a previous design of the dissection graft and stent), with a one-sided exact binomial test, at a type I error rate of 0.025 and a power of 0.8.

Sixty patients were necessary to assess the additional hypothesis-driven endpoint, under an expected rate of freedom from 30-day MAE at 69.2% (estimated from a feasibility study conducted under G070123 for a previous design of the dissection graft and stent), with a one-sided exact binomial test, at a type I error rate of 0.025 and a power of 0.8.

A sample size of 67 was initially established to account for possible loss to follow-up. During the course of the study, the sample size was increased to 73 patients in order to account for six previously enrolled US patients who should have been excluded from the study according to additional medical exclusion criteria that were implemented subsequent to enrollment initiation (none of the six had confirmed absence of bowel necrosis at the time of enrollment). While the data from all 73 patients enrolled in the study are reported (enrollment IDs for the six excluded patients are italicized and indicated by footnotes where applicable), the hypotheses were assessed based on the 67 patients enrolled according to the inclusion/exclusion criteria.

All other endpoints were analyzed descriptively.

Even though the endpoints are at 30-days, data through the 12-month post-procedure was required and has been provided on all surviving patients. This provides information on the ability of the Dissection Endovascular Graft to seal entry tears covered by the device

and the ability of the Dissection Stent to provide support to delaminated segments of aortic dissections distal to the Dissection Endovascular Graft.

An independent core laboratory analyzed all patient imaging. An independent clinical events committee (CEC) adjudicated at a minimum all patient deaths, conversions to open repair, rupture, Type A dissections, and stroke. An independent data safety monitoring board (DSMB) monitored the clinical trial according to an established safety monitoring plan.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the study was limited to patients who had an acute, complicated, Type B aortic dissection with at least one of the following characteristics:

- Aortic rupture; or
- Branch vessel obstruction/compromise resulting in malperfusion

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

General Exclusion Criteria

- Age < 18 years (< 20 years for Japan);
- Other medical condition (e.g., cancer, congestive heart failure) that may cause the patient to be noncompliant with the Clinical Investigation Plan, confound the results, or is associated with limited life expectancy (i.e., less than 2 years);
- Pregnant, breast-feeding, or planning on becoming pregnant within 60 months;
- Unwilling or unable to comply with the follow-up schedule;
- Inability or refusal to give informed consent; or
- Simultaneously participating in another investigative device or drug study. (The patient must have completed the primary endpoint of any previous study at least 30 days prior to enrollment in this study.)

Medical Exclusion Criteria

- Suspicion of bowel necrosis (as determined by the implanting physician based on imaging observations, peritoneal signs, surgical exploration, elevated serum lactate levels, and/or acidosis)
- American Society of Anesthesiologists (ASA) risk class V (i.e., moribund patient not expected to live 24 hours with or without operation)
- Embolic stroke within the last 14 days prior to potential enrollment in the study or hemorrhagic stroke within 30 days prior to potential enrollment in the study;
- Diagnosed or suspected congenital degenerative connective tissue disease (e.g., no Marfan's or Ehler-Danlos syndrome);
- Systemic infection (e.g., sepsis);
- Bleeding diathesis, uncorrectable coagulopathy, or refuses blood transfusion;
- Allergy to stainless steel, polyester, solder (tin, silver), polypropylene, nitinol, or gold;

- Untreatable reaction to contrast, which, in the opinion of the investigator, cannot be adequately pre-medicated;
- Surgical or endovascular abdominal aortic aneurysm (AAA) repair within 30 days before or after dissection repair;
- Previous placement of a thoracic endovascular graft;
- Prior open repair involving descending thoracic aorta including suprarenal aorta and/or arch; or
- Interventional and/or open surgical procedures (unrelated to dissection) within 30 days before or after dissection repair.

Anatomical Exclusion Criteria

- Dissection of aorta proximal to left subclavian artery (either primary entry tear or most proximal extent of dissection);
- Proximal stent-graft component:
    - Aortic arch radius of curvature < 35 mm (if device deployed in the arch);
    - Proximal landing zone length measuring < 20 mm between the left common carotid artery and most proximal extent of dissection (covering left subclavian artery is acceptable, except in patients with a dominant vertebral artery off of the arch in the region of the subclavian or a dominant vertebral off of the subclavian);
    - Proximal landing zone diameter for proximal stent-graft component < 20 mm or > 38 mm, measured outer-wall to outer-wall on a sectional image or multiplanar reconstruction;
    - Distal landing zone diameter for proximal stent-graft component < 20 mm (estimate based on transaortic diameter) or > 38 mm (estimate based on true lumen diameter), measured outer-wall to outer-wall on a sectional image or multiplanar reconstruction;
    - Prohibitive calcification, occlusive disease, or angulation in intended proximal landing zone;
    - Circumferential thrombus in region of intended proximal landing zone;
    - Inability to preserve the native left common carotid artery and celiac artery origins;
- Distal bare stent component:
    - Diameter < 20 mm (estimate based on transaortic diameter) or > 38 mm (estimate based on true lumen diameter) for any segment of vessel into which deployment of bare stent device is intended, measured outer-wall to outer-wall on a sectional image or multiplanar reconstruction;
    - Prohibitive angulation in segments of vessel into which deployment of bare stent device is intended (e.g., radius of curvature < 35 mm, or localized angle > 45 degrees);
- Both iliac arteries having prohibitive tortuosity, calcification, occlusive disease or arterial diameter, measured inner-wall to inner-wall on a sectional image, that are not conducive to placement of the introducer sheath (use of access conduit permitted); or
- Aneurysm or angulation in the distal thoracic aorta that would preclude advancement of the introduction system.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 30 days, 6 months, 12 months, and then annually through 5 years postoperatively.
Preoperatively, patients underwent a clinical exam, blood test, and CT scan, as also shown in Table 5. Postoperatively, the objective parameters measured during the study based on CT included assessment of the total aortic, true lumen, and false lumen diameters at multiple locations, presence of and sources for false lumen flow, extent of false lumen thrombosis, progression of dissection, branch vessel patency, and device position and integrity. Adverse events and complications were recorded at all visits.

The key timepoints are shown below in Table 5 as well as the tables that follow summarizing safety and effectiveness.

Table 5. Study follow-up schedule

	Pre-operative	**Intra-operative**	**Post-procedure**	**30-day** (± 10 days)	**6-month** (± 30 days)	**12-month** (± 45 days)	**2-year to 5-year[e]**
Clinical exam	X		X	X	X	X	X
Blood tests[a]	X		X	X	X	X	X[f]
Contrast CT scan	X		X[c,d]		X[c]	X[c]	X[c]
Angiography	X[b]	X					

[a] Including tests to evaluate kidney and liver function.
[b] Required only to resolve any uncertainties in anatomical measurements necessary for graft sizing.
[c] Transesophageal echocardiography (TEE) or non-contrast CT imaging may be used for those patients experiencing documented renal failure (eGFR< 30) or who are otherwise unable to undergo contrast enhanced CT scan.
[d] CT must be performed prior to hospital discharge. In case of impaired renal function at the time of discharge, CT may be performed at 30 days.
[e] 2 years (730 ± 60 days), 3 years (1095 ± 60 days), 4 years (1460 ± 90 days), and 5 years (1825 ± 90 days).
[f] Required only for patients with malperfusion that has not stabilized.

3. Clinical Endpoints

With regards to safety and effectiveness, the primary endpoint is the survival rate at 30 days.

With regards to safety, an additional hypothesis-driven endpoint for the study was freedom from major adverse events (MAEs) at 30 days. MAEs were defined as the following: myocardial infarction, chronic renal insufficiency/chronic renal failure requiring dialysis, bowel ischemia, stroke, paraplegia or paraparesis, and prolonged (> 72 hours) ventilatory support.

With regards to success/failure criteria, the study would be considered successful if both performance goals were met.

Additional (secondary) endpoints that were evaluated, not for the purpose of statistical inference, included changes in total aortic, true and false lumen size, presence of and sources for false lumen flow, extent of false lumen thrombosis, progression of dissection,

branch vessel patency, secondary interventions, and device migration and integrity.

B. Accountability of PMA Cohort

At the time of the database lock, of 73 patients enrolled in the PMA study, 94.5% (69) were available for 30-day follow-up and 78.1% (57) were available for 12-month follow-up, as there were 4 deaths within 30 days and 9 deaths as well as 3 patients who withdrew from the study or became lost to follow-up between the 30-day and 12-month visits. Table 6 reports the follow-up availability through 12 months.

Of the 73 patients enrolled in the study, 79.5% (58) received at least one Dissection Endovascular Graft and one Dissection Stent during the index procedure, while the remaining 20.5% (15) received only a Dissection Endovascular Graft, not a Dissection Stent. Although the study was not powered to assess for differences in outcomes based on the different component combinations (namely the presence vs. absence of a Dissection Stent), the results were analyzed and reported separately for the following groups where appropriate: total patient population, cohort with a Dissection Stent, and cohort without a Dissection Stent.

Table 6. Follow-up availability

Follow-up Visit[c]	Patients Eligible for Follow-up	Percent of Data Available (Site)		Adequate Imaging to Assess the Parameter (Core Lab)						Events Occurring Before Next Interval			
		Clinical Assessment	CT[a]	Size Increase in Stent-graft	Size Increase in Dissection Stent[b]	Entry-flow in Thoracic Aorta	Entry-flow in Abdominal Aorta	Migration	Device Integrity	Death	Conversion	LTF/ WTHD	Not Due for Next Visit
Postoperative	73	100.0% (73/73)	53.4% (39/73)	NA	NA	45.2% (33/73)	45.2% (33/73)	NA	49.3% (36/73)	4	0	0	0
30-day	69	97.1% (67/69)	76.8% (53/69)	NA	NA	71.0% (49/69)	68.1% (47/69)	NA	75.4% (52/69)	1	0	1	0
6-month	67	77.6% (52/67)	83.6% (56/67)	98.2% (55/67)	84.6% (44/52)	76.1% (51/67)	70.1% (47/67)	74.6% (50/67)	83.6% (56/67)	8	0	2	0
12-month	57	86.0% (49/57)	89.5% (51/57)	92.2% (47/57)	84.8% (39/46)	82.5% (47/57)	78.9% (45/57)	80.7% (46/57)	86.0% (49/57)	2	0	4	1

LTF: lost-to-follow-up; WTHD: withdrawal.

[a] Per clinical investigation plan amendment 11-007-04, a patient is required to have a CT scan prior to discharge unless the patient has renal issues; in this case, the patient will have the CT scan completed at the 1-month visit.

[b] Size increase in Dissection Stent assessment only applies to patients who received a Dissection Stent.

[c] Follow-up visit windows as follows: 30 days (± 10 days), 6 months (180 ± 30 days), 12 months (365 ± 45 days).

C. Study Population Demographics and Baseline Parameters

The demographics and baseline parameters of the study population are typical for an acute, complicated Type B aortic dissection study performed in the US.
The demographics, pre-existing comorbid medical conditions, and presenting complications were compared between this study and SVS dataset to support the use of the performance goals based on the SVS dataset. Comparisons were also made between two patient groups within the study; patients who received and patients who did not receive a Dissection Stent.

Partially due to the small number of patients, few statistically significant differences were found when comparing populations, despite numerical differences. None of the differences were found to be clinically meaningful with respect to supporting the performance goals. Some of the differences in the patient groups within the study population are likely associated with the greater percentage of patients who did not receive the Dissection Stent having been treated for rupture rather than malperfusion. Comparisons are not presented between the US and Japanese patients as only 6 patients were treated in Japan. Four patients presented with rupture, one patient presented with rupture and malperfusion, and one patient presented with malperfusion alone; none received the Dissection Stent.

Demographics

The demographics and patient characteristics are presented in Table 7. Of the demographic and patient data in the present study compared with that of the SVS dataset, only the ethnicity/race distribution was significantly different ($p = 0.046$), which is not expected to be clinically significant with respect to evaluating the safety and effectiveness endpoints. Similarly, with the exception of the ethnicity distribution, the demographics appeared comparable between patients who either received or did not receive a Dissection Stent.

Table 7. Demographics and patient characteristics

Demographic	Mean ± SD (N, range) or Percent Patients (number/total number)			
	Without Dissection Stent	**With Dissection Stent**	**All Pivotal Patients**	**SVS Acute Patients**
Age (years)				
All patients	65.1 ± 13.1 (15, 42 - 81)	59.5 ± 10.1 (58, 34 - 77)	60.7 ± 10.9 (73, 34 - 81)	58.8 ± 15.4 (85, 25.9 - 88.6)
Gender				
Male	53.3% (8/15)	69.0% (40/58)	65.8% (48/73)	72.9% (62/85)
Female	46.7% (7/15)	31.0% (18/58)	34.2% (25/73)	27.1% (23/85)

Ethnicity/Race[a]				
White	33.3% (5/15)	67.2% (39/58)	60.3% (44/73)	52.9% (45/85)
Hispanic or Latino	0%	5.2% (3/58)	4.1% (3/73)	14.1% (12/85)
Black or African American	20.0% (3/15)	25.9% (15/58)	24.7% (18/73)	27.1% (23/85)
First Nations[b]	0%	0%	0%	2.4% (2/85)
Asian	46.7% (7/15)	1.7% (1/58)	11.0% (8/73)	3.5% (3/85)
Height (in)	64.4 ± 3.6 (15, 59.8 - 72.0)	68.5 ± 4.4 (58, 59 - 76)	67.7 ± 4.5 (73, 59 - 76)	NC
Weight (lbs)	168.1 ± 39 (15, 116.0 - 255.7)	202.5 ± 56.0 (58, 101.4 - 357.1)	195.4 ± 54.5 (73, 101.4 - 357.1)	NC
Body mass index (BMI)	28.4 ± 5.5 (15, 21.4 - 40.0)	30.0 ± 7.2 (57, 16.3 - 50.6)	29.7 ± 6.9 (72, 16.3 - 50.6)	NC

NC: not collected.

[a] Ethnicity/race distribution difference was significant between the pivotal study and SVS dataset (p = 0.046).

[b] First Nations includes American Indian/Alaskan Native, and Native Hawaiian/Pacific Islander.

Medical History and Comorbidities

Medical history and comorbid conditions are presented in Table 8. None of the differences in the medical histories of patients enrolled in the present study and those recorded in the SVS dataset are statistically significant. A history of aneurysm or dissection is the biggest difference in patient groups within the study, being more prevalent in patients that did not receive a Dissection Stent.

Table 8. Medical history and comorbid conditions

Medical History	Percent Patients (number/total number)			
	Without Dissection Stent	**With Dissection Stent**	**All Pivotal Patients**	**SVS Acute Patients**
Cardiovascular				
Previous myocardial infarction	13.3% (2/15)	3.4% (2/58)	5.5% (4/73)	11.8% (10/85)
Previous symptomatic congestive heart failure	0% (0/15)	3.4% (2/58)	2.7% (2/73)	10.6% (9/85)
Coronary artery disease	20.0% (3/15)	15.5% (9/58)	16.4% (12/73)	NC
Cardiac arrhythmia	20.0% (3/15)	13.8% (8/58)	15.1% (11/73)	11.8% (10/85)
Vascular				
Thromboembolic event	0%	8.6% (5/58)	6.8% (5/73)	NC
Peripheral vascular disease	6.7% (1/15)	3.4% (2/58)	4.1% (3/73)	2.4% (2/85)
Family history of aneurysm or dissection	0%	6.9% (4/58)	5.5% (4/73)	NC
Patient history of aneurysm or dissection	60.0% (9/15)	22.4% (13/58)	30.1% (22/73)	NC
Hypertension	100.0% (15/15)	82.8% (48/58)	86.3% (63/73)	83.5% (71/85)
Previous thoracic surgery or thoracic trauma	26.7% (4/15)	10.3% (6/58)	13.7% (10/73)	NC
Aortobronchial fistula				
Aortoesophageal fistula	0%	0%	0%	NC
Bleeding diathesis or uncorrectable coagulopathy	0%	0%	0%	NC
	0%	0%	0%	NC

Medical History	Percent Patients (number/total number)			
	Without Dissection Stent	With Dissection Stent	All Pivotal Patients	SVS Acute Patients
Carotid endarterectomy	0%	0%	0%	NC
Diagnosed or suspected congenital degenerative collagen disease	0%	0%	0%	NC
Pulmonary				
Chronic obstructive pulmonary disease	40.0% (6/15)	15.5% (9/58)	20.5% (15/73)	10.6% (9/85)
Renal				
Chronic renal insufficiency or dialysis	6.7% (1/15)	8.6% (5/58)	8.2% (6/73)	7.1% (6/85)
Endocrine				
Diabetes	0%	5.2% (3/58)	4.1% (3/73)	12.9%(11/85)
Infectious disease				
Previous diagnosis of sepsis	0%	0%	0%	NC
Hepatobiliary				
Liver disease	6.7% (1/15)	1.7% (1/58)	2.7% (2/73)	0% (0/85)
Neoplasms				
Cancer	20.0% (3/15)	8.6% (5/58)	11.0% (8/73)	9.4% (8/85)
Neurologic				
Stroke	13.3% (2/15)	5.2% (3/58)	6.8% (5/73)	NC
Paraparesis	6.7% (1/15)	5.2% (3/58)	5.5% (4/73)	1.2% (1/85)
Paralysis	0% 6.7% (1/15)	3.4% (2/58)	2.7% (2/73)	2.4% (2/85)
Transient ischemic attack		3.4% (2/58)	4.1% (3/73)	0% (0/85)
Smoking				
Past	13.3% (2/15)	31.0% (18/58)	27.4% (20/73)	37.3% (31/83)
Current	40.0% (6/15)	50.0% (29/58)	47.9% (35/73)	31.8% (27/83)
Never	46.7% (7/15)	19.0% (11/58)	24.7% (18/73)	30.1% (25/83)

NC: not collected.

ASA Classification

Table 9 reports the ASA classification. The distribution of ASA physical status classifications in the present study was statistically different from that in the SVS dataset, with the SVS patients having more severe disease. However, due to the subjective nature of the ASA classification, and considering the similarities between the present study and the SVS dataset for most other variables, the difference is not considered clinically significant with respect to establishing the performance goals. The majority of patients were class 4 in both the group with a Dissection Stent and group without a Dissection Stent.

Table 9. ASA physical status classification

ASA Classification[a]	Percent Patients (number/total number)			
	Without Dissection Stent	With Dissection Stent	Total	SVS
Healthy patient (1)	0%	0%	0%	0%

Mild systemic disease (2)	20.0% (3/15)	5.2% (3/58)	8.2% (6/73)	2.4% (2/85)
Severe systemic disease (3)	20.0% (3/15)	29.3% (17/58)	27.4% (20/73)	22.4% (19/85)
Incapacitating systemic disease (4)	60.0% (9/15)	65.5% (38/58)	64.4% (47/73)	64.7% (55/85)
Moribund patient (5)	0%	0%	0%	10.6% (9/85)

[a] ASA classification distribution difference was significant between the present study and the SVS dataset ($p = 0.008$).

SVS-ISCVS Risk Score

Table 10 reports the Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS-ISCVS) risk score. The SVS-ISCVS risk scores were consistent with the preexisting comorbid conditions for the patient population in the present study. Of the distribution of risk scores, patients who received a Dissection Stent were more likely to present with higher smoking risk scores and higher renal status risk scores, leading to higher total risk scores. SVS-ISCVS risk scores were not reported in the SVS dataset.

Table 10. SVS-ISCVS risk score classification

SVS-ISCVS Category	Percent Patients (number/total number)		
	Without Dissection Stent	**With Dissection Stent**	**Total**
Diabetes risk score			
0	100.0% (15/15)	93.1% (54/58)	94.5% (69/73)
1	0%	5.2% (3/58)	4.1% (3/73)
2	0%	0%	0%
3	0%	1.7% (1/58)	1.4% (1/73)
4	0%	0%	0%
Smoking risk score			
0	53.3% (8/15)	34.5% (20/58)	38.4% (28/73)
1	6.7% (1/15)	12.1% (7/58)	11.0% (8/73)
2	33.3% (5/15)	32.8% (19/58)	32.9% (24/73)
3	6.7% (1/15)	20.7% (12/58)	17.8% (13/73)
Hypertension risk score			
0	6.7% (1/15)	13.8% (8/58)	12.3% (9/73)
1	33.3% (5/15)	20.7% (12/58)	23.3% (17/73)
2	20.0% (3/15)	32.8% (19/58)	30.1% (22/73)
3	40.0% (6/15)	32.8% (19/58)	34.2% (25/73)
Hyperlipidemia risk score			
0	53.3% (8/15)	56.9% (33/58)	56.2% (41/73)
1	13.3% (2/15)	12.1% (7/58)	12.3% (9/73)
2	0%	1.7% (1/58)	1.4% (1/73)
3	33.3% (5/15)	29.3% (17/58)	30.1% (22/73)
Cardiac status risk score			
0	86.7% (13/15)	89.7% (52/58)	89.0% (65/73)
1	13.3% (2/15)	1.7% (1/58)	4.1% (3/73)
2	0%	6.9% (4/58)	5.5% (4/73)
3	0%	1.7% (1/58)	1.4% (1/73)
Carotid disease risk score			

SVS-ISCVS Category	Percent Patients (number/total number)		
	Without Dissection Stent	With Dissection Stent	Total
0	93.3% (14/15)	94.8% (55/58)	94.5% (69/73)
1	6.7% (1/15)	3.4% (2/58)	4.1% (3/73)
2	0%	0%	0% (0/73)
3	0%	1.7% (1/58)	1.4% (1/73)
Renal status risk score			
0	93.3% (14/15)	62.1% (36/58)	68.5% (50/73)
1	6.7% (1/15)	31.0% (18/58)	26.0% (19/73)
2	0%	5.2% (3/58)	4.1% (3/73)
3	0%	1.7% (1/58)	1.4% (1/73)
Pulmonary status risk score			
0	80.0% (12/15)	73.7% (42/57)	75.0% (54/72)
1	6.7% (1/15)	17.5% (10/57)	15.3% (11/72)
2	0%	5.3% (3/57)	4.2% (3/72)
3	13.3% (2/15)	3.5% (2/57)	5.6% (4/72)
Total SVS-ISCVS risk score (mean ± SD; N, range)	4.7 ± 2.4 (15, 1 - 9)	5.5 ± 2.9 (58, 0 - 12)	5.4 ± 2.8 (73, 0 - 12)

Presenting Complications

Presenting complications reported by the site are presented in Table 11. The percentage of patients with rupture, malperfusion, or rupture and malperfusion were comparable between the present study and the SVS dataset, though the patient population in the present study significantly more often presented with obstruction/compromise that also involved the gastrointestinal ($p < 0.001$) and renal/urologic branch vessels ($p = 0.011$). Patients who presented with rupture were less likely to receive a Dissection Stent than patients who presented with obstruction or compromise.

Table 11. Presenting complications

Complication	Percent Patients (number/total number)			
	Without Dissection Stent	With Dissection Stent	Total	SVS
Rupture	73.3% (11/15)	15.5% (9/58)	27.4% (20/73)	31.8% (27/85)
Obstruction/compromise of branch vessel	33.3% (5/15)	89.7% (52/58)	78.1% (57/73)	71.8% (61/85)
Gastrointestinal	40.0% (2/5)	59.6% (31/52)	57.9% (33/57)[a]	19.7% (12/61)[a]
Renal/urologic	60.0% (3/5)	57.7% (30/52)	57.9% (33/57)[a]	36.1% (22/61)[a]
Spinal cord	0%	5.8% (3/52)	5.3% (3/57)	3.3% (2/61)
Lower extremity	80.0% (4/5)	53.8% (28/52)	56.1% (32/57)	55.7% (34/61)
Other	0%	1.9% (1/52)	1.8% (1/57)	8.2% (5/61)
Rupture and obstruction of branch vessel	6.7% (1/15)	5.2% (3/58)	5.5% (4/73)	3.5% (3/85)
Persistent pain	93.3% (14/15)	91.4% (53/58)	91.8% (67/73)[a]	76.5% (65/85)[a]
Size/growth of the transaortic diameter	53.3% (8/15)	15.5% (9/58)	23.3% (17/73)	NC

Complication	Percent Patients (number/total number)			
	Without Dissection Stent	With Dissection Stent	Total	SVS
Periaortic effusion (without rupture)	60.0% (9/15)	12.1% (7/58)	21.9% (16/73)	NC
Resistant hypertension	40.0% (6/15)	27.6% (16/58)	30.1% (22/73)	43.5% (37/85)

NC: not collected.

[a] Persistent pain, gastrointestinal, and renal/urologic obstruction/compromise of branch vessel distribution differences were significant between the present study and the SVS dataset (p =0.010, $p < 0.001$, and p = 0.011, respectively).

Baseline Vessel Measurements

This section reports the results from core laboratory analysis of pre-procedure imaging.

Site vs Core Lab Measures

Imaging was reviewed by the clinical study sites to determine adherence to the study selection criteria. All patients enrolled in the study were reported by the sites to meet the selection criteria. However, a total of 33 patients were measured by the core laboratory as having a length < 20 mm from the left common carotid (LCC) to the most proximal extent of dissection (Table 12), 25 of which also had a dissection that extended proximal to the left subclavian artery (LSA) according to initial assessments relative to anatomical landmarks (Table 14) or based on the Zone classification[1] as also used to describe the extent of Dissection Endovascular Graft and Dissection Stent coverage at the time of the index procedure (Table 22, found in the Procedural Information Section). There were 11 additional patients (in whom the length from LCC to proximal extent was either not assessed or measured ≥ 20 mm by core lab) with a dissection that extended proximal the LSA based on the Zone classification. Refer to Figure 6 for an overview of these findings.

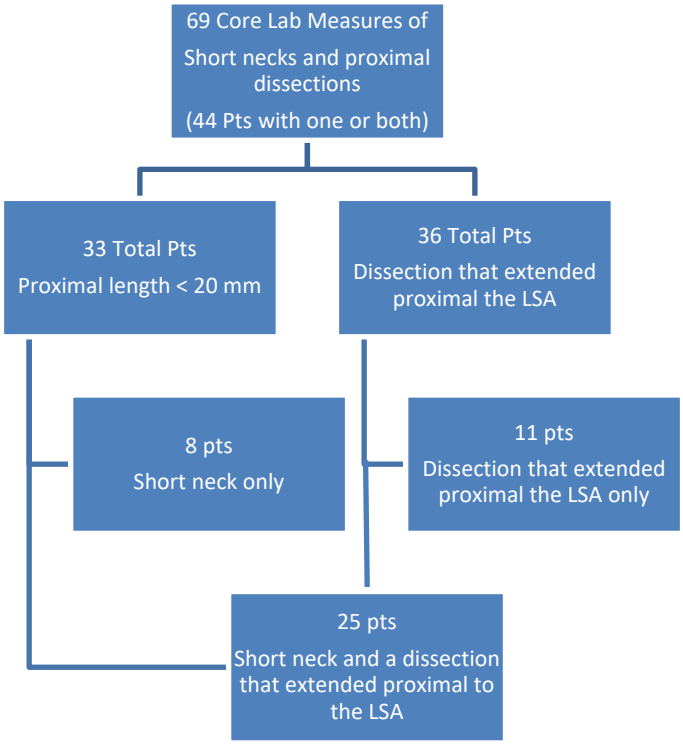


Figure 6. Core lab measurements of short necks and/or dissection proximal to the LSA

Also of note, the maximum total aortic diameters (Table 12) in locations expected to coincide with likely fixation/seal zones (i.e., just distal to the LCC and just distal to the LSA) exceeded the maximum allowable diameter of 38 mm at pre-procedure (n=14, which included 12 of the patients with a length < 20 mm from the LCC to proximal extent of dissection and/or a dissection that extended proximal to the LSA).
While patients were to be excluded from the study if the length from the LCC to the most proximal extent of dissection was < 20 mm, if the dissection extended proximal to the LSA, or if the total aortic diameter was > 38 mm in the proximal fixation zone, compliance with the protocol was based on information available at pre-procedure, as assessed by the site, and not the results from subsequent core laboratory analysis of pre-procedure imaging. All site assessments concurred with the requirements in the protocol. Nonetheless, it is important to note that all proximal post-treatment dissection events (4/4), ruptures (2/2), and proximal Type I entry-flow (7/7) within 365 days occurred in this subset of patients with anatomy beyond the intended use, underscoring the need to pay careful attention to these parameters during patient selection, as also emphasized in the labeling.

Length and Diameter

Table 12 reports baseline anatomical measurements per the core laboratory (similar data were not reported in the SVS dataset). The overall results from core laboratory analysis

of pre-procedure imaging appear consistent with expectations for the intended study patient population, and the majority of the anatomical measurements for patients who received a Dissection Stent and for those who did not appeared comparable, with the exception of some diameters and lengths, as follows.

With regards to length, patients who did not receive a Dissection Stent (patients who often presented with aortic rupture) typically exhibited more focal dissections (i.e., shorter length of dissected aorta) when compared to patients who received a Dissection Stent (patients who often presented with obstruction/compromise of branch vessels). Additionally, the average length of dissection (408.9 mm) in patients who received a Dissection Stent approached the total length of aorta from the left common carotid artery to the aortic bifurcation, thus indicating near complete involvement of the aorta with dissection. Overall, the trends in length were not surprising given the apparent difference in presenting complications between groups.

With regards to diameter, patients who did not receive a Dissection Stent were more likely to have presented with larger transaortic diameters in the descending thoracic aorta, which is not surprising considering these patients were more often treated for rupture when compared to the patients who received a Dissection Stent. Patients who received a Dissection Stent were more likely to display larger false lumen diameters in the aorta distal to the descending thoracic aorta, specifically within the region of the branch vessels (aorta at the level of the celiac artery, SMA, and both renal arteries) as well as in the abdominal aorta, which is also not surprising considering these patients were more often treated for malperfusion when compared to patients who did not receive a Dissection Stent.

Table 12. Baseline anatomical measurements per the core laboratory

Anatomical Measurements	Mean ± SD (N, range)		
	Without Dissection Stent	**With Dissection Stent**	**Total**
Length (mm)			
LCC to most proximal extent of dissection	26.8 ± 37.7 (13, -11.1 to 118.4)	23.9 ± 38.8 (53, -109.2 to 191.5)	24.5 ± 38.3 (66, -109.2 to 191.5)
LCC to most proximal aspect of primary tear	93.5 ± 56.8 (11, 5.9 - 208.8)	112.2 ± 69.4 (48, 0.9 - 281.7)	108.7 ± 67.2 (59, 0.9 - 281.7)
From most proximal to most distal aspect of dissection	315.9 ± 100.1 (13, 129.3 - 468.9)	408.9 ± 121.3 (40, 125.2 - 637.2)	386.1 ± 122.4 (53, 125.2 - 637.2)
Aortic arch radius of curvature (mm)	26.6 ± 4.9 (15, 19 - 40)	28.2 ± 7.0 (56, 13 - 47)	27.8 ± 6.6 (71, 13 - 47)
Largest angle in the descending thoracic aorta (degrees)	32.7 ± 27.1 (14, 0 - 99)	31.1 ± 26.6 (55, 0 - 175)	31.4 ± 26.5 (69, 0 - 175)

Anatomical Measurements	Mean ± SD (N, range)		
	Without Dissection Stent	**With Dissection Stent**	**Total**
Maximum aortic diameter (mm)			
Just distal to LCC origin			
True lumen	32.0 ± 5.0 (15, 19.0 - 40.5)	32.4 ± 4.3 (56, 16.3 - 43.8)	32.4 ± 4.4 (71, 16.3 - 43.8)
False lumen	1.6 ± 4.9 (15, 0 - 18.5)	0.6 ± 2.6 (56, 0 - 16.1)	0.8 ± 3.2 (71, 0 - 18.5)
Total	33.6 ± 3.4 (15, 26.3 - 40.5)	33.1 ± 4.1 (56, 25.7 - 43.8)	33.2 ± 3.9 (71, 25.7 - 43.8)
Just distal to LSA origin			
True lumen	27.8 ± 6.8 (15, 12.5 - 35.7)		
False lumen	6.1 ± 8.8 (15, 0 - 26.7)		
Total	33.9 ± 6.2 (15, 26.4 - 51.1)	27.9 ± 4.6 (56, 18.2 - 40.3)	27.9 ± 5.1 (71, 12.5 - 40.3)
Descending thoracic aorta			
True lumen	25.4 ± 12.9 (15, 4.0 - 44.6)	4.4 ± 4.9 (56, 0 - 17.9)	4.8 ± 5.9 (71, 0 - 26.7)
False lumen	19.2 ± 12.0 (15, 0 - 49.8)	32.3 ± 4.6 (56, 24.3 - 43.3)	32.6 ± 5.0 (71, 24.3 - 51.1)
Total	44.6 ± 10.9 (15, 29.5 - 64.4)		
Just distal to celiac artery origin	19.8 ± 8.7 (14, 3.6 - 32.6)	21.5 ± 10.0 (56, 6.2 - 65.9)	22.3 ± 10.7 (71, 4.0 - 65.9)
True lumen	10.0 ± 12.6 (14, 0 - 43.4)	18.2 ± 8.0 (56, 0 - 34.1)	18.4 ± 8.9 (71, 0 - 49.8)
False lumen	29.8 ± 8.6 (14, 21.9 - 55.3)	39.6 ± 5.7 (56, 26.8 - 65.9)	40.7 ± 7.3 (71, 26.8 - 65.9)
Total			
Just distal to SMA origin	19.2 ± 8.5 (14, 2.6 - 30.2)		
True lumen	7.4 ± 10.0 (14, 0 - 29.0)		
False lumen	26.6 ± 5.2 (14, 20.4 - 42.3)	14.3 ± 6.5 (55, 3.4 - 28.4)	15.5 ± 7.2 (69, 3.4 - 32.6)
Total		14.3 ± 6.4 (55, 0 - 28.1)	13.4 ± 8.1 (69, 0 - 43.4)
Just distal to right renal artery origin	17.4 ± 7.2 (14, 3.1 - 26.1)	28.6 ± 3.4 (55, 19.5 - 39.4)	28.9 ± 4.9 (69, 19.5 - 55.3)
True lumen	5.7 ± 7.6 (14, 0 - 20.1)		
False lumen	23.2 ± 4.1 (14, 17.2 - 32.0)	15.0 ± 6.6 (53, 2.1 - 26.9)	15.8 ± 7.2 (67, 2.1 - 30.2)
Total		12.2 ± 7.6 (53, 0 - 27.8)	11.2 ± 8.3 (67, 0 - 29.0)
Just distal to left renal artery origin	17.4 ± 7.6 (14, 2.4 - 26.1)	27.1 ± 3.7 (53, 20.0 - 37.9)	27.0 ± 4.1 (67, 20.0 - 42.3)
True lumen	5.9 ± 8.1 (14, 0 - 20.5)		
False lumen	23.3 ± 4.6 (14, 18.0 - 33.6)	14.9 ± 6.1 (52, 2.7 - 26.9)	15.4 ± 6.3 (66, 2.7 - 26.9)
Total		9.7 ± 6.9 (52, 0 - 29.2)	8.9 ± 7.2 (66, 0 - 29.2)
Abdominal aorta	25.0 ± 12.8 (14, 7.4 - 53.0)	24.6 ± 3.7 (52, 17.2 - 37.9)	24.3 ± 3.8 (66, 17.2 - 37.9)
True lumen	12.3 ± 12.5 (14, 0 - 43.4)		
False lumen	37.3 ± 11.6 (14, 24.1 - 55.3)		
Total		14.5 ± 6.3 (53, 3.2 - 27.8)	15.1 ± 6.6 (67, 2.4 - 27.8)
		9.7 ± 8.0 (53, 0 - 36.0)	8.9 ± 8.1 (67, 0 - 36.0)
		24.2 ± 4.1 (53, 17.1 - 40.1)	24.0 ± 4.2 (67, 17.1 - 40.1)
		16.5 ± 7.7 (48, 3.8 - 36.3)	18.4 ± 9.7 (62, 3.8 - 53.0)
		16.1 ± 7.9 (48, 0 - 36.6)	15.3 ± 9.2 (62, 0 - 43.4)
		32.6 ± 4.9 (48, 24.1 - 44.8)	33.6 ± 7.2 (62, 24.1 - 55.3)

LCC: left common carotid artery; LSA: left subclavian artery; SMA: superior mesenteric artery; CIA: common iliac artery.

Location of Primary Tear

Table 13 reports the location of the primary tear as assessed by the core laboratory. As expected for a study of patients with Type B dissection, the majority of primary tears for the total patient population occurred in the descending thoracic aorta. The distribution in primary tear location appeared to be similar for both patient populations based on core laboratory analysis.

Table 13. Location of primary tear per the core laboratory

Location	Percent Patients (number/total number)		
	Without Dissection Stent	With Dissection Stent[a]	Total
Aorta at LSA/in LSA	0%	1.8% (1/57)	1.4% (1/72)
Descending thoracic aorta, distal to LSA	86.7% (13/15)	86.0% (49/57)	86.1% (62/72)
Aorta at celiac artery/in celiac artery	0%	0%	0%
Aorta at SMA/in SMA	0%	0%	0%
Aorta at renal arteries/in renal arteries	0%	0%	0%
Infrarenal abdominal aorta	0%	0%	0%
Unknown	13.3% (2/15)	12.3% (7/57)	12.5% (9/72)

LCC: left common carotid artery; LSA: left subclavian artery; SMA: superior mesenteric artery.
[a] Patient 1130090 was unable to be assessed by the core laboratory due to inadequate imaging.

Location of Proximal Extent of Dissection

Table 14 provides the distribution of the location of the proximal aspect of dissection as determined by the core laboratory. The majority of the total patient population had the proximal aspect of dissection either at or distal to the LSA, while some patients were noted by the core laboratory to have a dissection with the most proximal aspect in the ascending aorta, aortic arch (proximal to the LCC), or proximal to the LSA (distal to the LCC). Likewise, the majority of patients in both groups had the proximal aspect of the dissection either at or distal to the LSA.

Table 14. Location of the proximal aspect of dissection as determined by the core laboratory

Location	Percent Patients (number/total number)		
	Without Dissection Stent	With Dissection Stent[a]	Total
Ascending thoracic aorta	0%	3.5% (2/57)	2.8% (2/72)
Aortic arch, proximal to LCC	20.0% (3/15)	1.8% (1/57)	5.6% (4/72)
Proximal to LSA, distal to LCC	6.7% (1/15)	10.5% (6/57)	9.7% (7/72)
Aorta at LSA/in LSA	20.0% (3/15)	50.9% (29/57)	44.4% (32/72)
Descending thoracic aorta, distal to LSA	53.3% (8/15)	31.6% (18/57)	36.1% (26/72)
Aorta at celiac artery/in celiac artery	0%	0%	0%
Aorta at SMA/in SMA	0%	0%	0%
Aorta at renal arteries	0%	0%	0%
Infrarenal abdominal aorta	0%	0%	0%
Unknown	0%	1.8% (1/57)	1.4% (1/72)

LCC: left common carotid artery; LSA: left subclavian artery; SMA: superior mesenteric artery.
[a] Patient 1130090 was unable to be assessed by the core laboratory due to inadequate imaging.

Location of Distal Extent of Dissection

Table 15 provides the distribution of the location of the distal aspect of dissection as determined by the core laboratory. The dissection often extended distally to at least the level of the celiac artery, with the majority of dissections for the total patient population terminating distal to the renal arteries, in either the abdominal aorta or common/external iliac arteries. Compared to the patients who did not receive a Dissection Stent, those patients who did receive a Dissection Stent appeared to more often have a dissection that terminated in the external iliac arteries.

Table 15. Location of the most distal aspect of dissection as determined by the core laboratory

Location	Percent Patients (number/total number)		
	Without Dissection Stent[a]	With Dissection Stent[b]	Total
Aorta at celiac artery/in celiac artery	8.3% (1/12)	0%	1.5% (1/68)
Aorta at SMA/in SMA	16.7% (2/12)	3.6% (2/56)	5.9% (4/68)
Aorta at renal arteries/in renal arteries	8.3% (1/12)	12.5% (7/56)	11.8% (8/68)
Infrarenal abdominal aorta	25.0% (3/12)	19.6% (11/56)	20.6% (14/68)
Common iliac arteries (right or left)	25.0% (3/12)	17.9% (10/56)	19.1% (13/68)
External iliac arteries (right or left)	0%	28.6% (16/56)	23.5% (16/68)
Internal iliac arteries (right or left)	0%	1.8% (1/56)	1.5% (1/68)
Femoral arteries (right or left)	0%	0%	0%
Unknown	16.7% (2/12)	16.1% (9/56)	16.2% (11/68)

SMA: superior mesenteric artery.
[a] Patients 1130049, 1230003, and 1230007 were unable to be assessed by the core laboratory due to inadequate imaging.
[b] Patients 1130057 and 1130090 were unable to be assessed by the core laboratory due to inadequate imaging.

Secondary Tears

Table 16 provides the distribution of the location of the identified secondary/reentry tears as determined by the core laboratory. The majority of the total patient population presented with secondary tears, often in the descending thoracic aorta as well as in the abdominal aorta and at/near the renal arteries. While most patients in both groups had secondary tears in the descending thoracic aorta, it appeared that patients who received a Dissection Stent had a higher prevalence of secondary tears in the region of the branch vessels (renal arteries, SMA, celiac artery), abdominal aorta, and iliac arteries.

Table 16. Location of the secondary/reentry tears as determined by the core laboratory[a]

Location	Percent Patients (number/total number)		
	Without Dissection Stent	With Dissection Stent[b]	Total
None	13.3% (2/15)	3.5% (2/57)	5.6% (4/72)
Ascending thoracic aorta	0%	0%	0%
Aortic arch, proximal to LCC	0%	0%	0%
Proximal to LSA, distal to LCC	0%	0%	0%
Aorta at LSA/in LSA	0%	0%	0%

Location	Percent Patients (number/total number)		
	Without Dissection Stent	With Dissection Stent[b]	Total
Descending thoracic aorta, distal to LSA	80.0% (12/15)	84.2% (48/57)	83.3% (60/72)
Aorta at celiac artery/in celiac artery	6.7% (1/15)	28.1% (16/57)	23.6% (17/72)
Aorta at SMA/in SMA	0% (0/15)	28.1% (16/57)	22.2% (16/72)
Aorta at renal arteries/in renal arteries	13.3% (2/15)	43.9% (25/57)	37.5% (27/72)
Infrarenal abdominal aorta	13.3% (2/15)	49.1% (28/57)	41.7% (30/72)
Common iliac arteries (right or left)	0%	17.5% (10/57)	13.9% (10/72)
External iliac arteries (right or left)	0%	3.5% (2/57)	2.8% (2/72)
Internal iliac arteries (right or left)	0%	1.8% (1/57)	1.4% (1/72)
Femoral arteries (right or left)	0%	0%	0%
Unknown	6.7% (1/15)	10.5% (6/57)	9.7% (7/72)

LCC: left common carotid artery; SLA: left subclavian artery; SMA: superior mesenteric artery.
[a] Patients may have presented with multiple secondary/reentry tears.
[b] Patient 1130090 was unable to be assessed by the core laboratory due to inadequate imaging.

Procedural Information

Procedural information is summarized in Table 17. All procedures were performed under general anesthesia. Vascular access techniques employed during the procedure included femoral artery cutdown in 72.6% of patients, percutaneous access in 58.9% of patients, and use of a conduit in 2.7% of patients (multiple access methods were possible). A surgical cutdown appeared more common in patients without a Dissection Stent. Adjunctive techniques for spinal cord protection were performed in 39.7%, including primarily cerebrospinal fluid (CSF) drainage. The majority of patients had either partial of complete coverage of the left subclavian artery (LSA), often without a revascularization procedure.

Table 17. Procedural information

Item	Result n (%)
Anesthesia Method	
General	73 (100%)
Regional	0
Local	0
Access Method[a]	
Percutaneous	43 (58.9%)
Cut-Down	53 (72.6%)
Conduit	2 (2.7%)
Adjunctive Techniques to Prevent Paraplegia	
CSF Drainage	26 (35.6%)
Neurologic/Cerebral Monitoring	2 (2.7%)
Induced Hypertension	1 (1.4%)
LSA Coverage	
Complete	28 (38.4%)
Partial	15 (20.5%)

None	30 (41.1%)
LSA Revascularization Procedure	
None	58 (79.4%)
Transposed	4 (5.5%)
Bypassed	11 (15.1%)

[a] Multiple access methods may have been used in a patient.

The mean procedure time was 154.9 ± 91.3 minutes and the mean procedural blood loss was 242 ± 316 ml. The mean anesthesia time was 234 ± 97 minutes. Procedure times as well as procedural blood loss appeared greater on average in patients who received a Dissection Stent, which is reasonably expected given the differences between groups in terms of number of components placed, as further described below.

Devices Placed during Index Procedure

Tables 18-20 report the number and sizes of Dissection Endovascular Grafts (nontapered and tapered) and Dissection Endovascular Stents placed at the time of the index procedure. The largest (42 mm) and smallest (22 mm) diameters, the longest (218 mm) and shortest (79 mm) lengths, and both tapered options (4 mm and 8 mm) were used among the patients enrolled in the study, supporting the clinical relevance of the available sizes. All available Dissection Stent diameters and lengths were used.

Table 18. Number and sizes (diameters and lengths) of nontapered Dissection Endovascular Graft components implanted during index procedure

Diameter (mm)	Length (mm)	N
22	79	1
	117	0
24	79	0
	117	0
26	79	1
	136	2
28	82	1
	142	4
	202	1
30	82	1
	142	6
	202	2
32	82	2
	142	9
	202	5
34	79	2

	154	3
	204	7
36	79	1
	154	9
	204	3
38	79	0
	154	2
	204	3
40	83	0
	164	0
	218	1
42	83	1
	164	0
	218	1

Table 19. Number and sizes (diameters and lengths) of tapered Dissection Endovascular Graft components implanted during index procedure

Proximal Diameter (mm)	Distal Diameter (mm)	Length (mm)	N
32	28	162	0
		202	0
	24	158	0
		196	0
34	30	159	3
		199	5
	26	156	1
		194	0
36	32	159	2
		199	6
	28	159	1
		199	1
38	34	154	0
		204	1
	30	159	1
		199	0
40	36	160	1
		210	3
	32	165	1

		205	1
42	38	160	1
		210	1
	34	160	3
		210	2

Table 20. Number and sizes (diameters and lengths) of Dissection Stent components implanted during index procedure

Diameter (mm)	Length (mm)	N
36	80	13
	120	18
	180	27
46	80	3
	120	4
	185	13

Table 21 further describes the different main body component combinations used during the initial implant procedure, as selected at the discretion of the treating physician, for patients who did not receive a Dissection Stent and for patients who received a Dissection Stent. All patients received at least one stent-graft, with nearly 80% of patients also receiving at least one Dissection Stent. Two or more Dissection Endovascular Grafts were used in approximately one-third of patients. There appeared to be differences between groups in terms of the number of components placed, where three or more components were placed in half of the patients with a Dissection Stent, whereas none of the patients in the group without a Dissection Stent received more than two components (and 40% received one component).

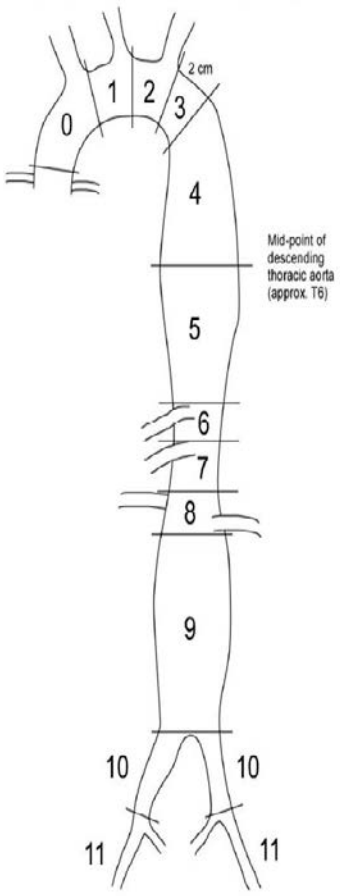
Table 21. Combination of components placed during the initial implant procedure

Main Body Combination	Percent Patients (number/total number)	
	Without Dissection Stent	With Dissection Stent
One Dissection Endovascular Graft (only)	40.0% (6/15)	NA
Two Dissection Endovascular Grafts (only)	60.0% (9/15)	NA
One Dissection Endovascular Graft and one Dissection Stent	NA	44.8% (26/58)
One Dissection Endovascular Graft and two Dissection Stents	NA	22.4% (13/58)
One Dissection Endovascular Graft and three Dissection Stents	NA	1.7% (1/58)
One Dissection Endovascular Graft and four Dissection Stents	NA	1.7% (1/58)
Two Dissection Endovascular Grafts and one Dissection Stent	NA	24.1% (14/58)
Two Dissection Endovascular Grafts and two Dissection Stents	NA	0%
Two Dissection Endovascular Grafts and three Dissection Stents	NA	1.7% (1/58)

Three Dissection Endovascular Grafts and one Dissection Stent	NA	3.4% (2/58)

Table 22 provides information pertaining to the location of dissection (proximal extent, primary tear, distal extent) as well as the location in which the Dissection Endovascular Graft and Dissection Stent were placed as assessed by the core laboratory according to the zone classification by Fillinger, et al.[1] Zones 2 through 4 were the most common locations for Dissection Endovascular Graft placement, while Zones 4 through 9 were the most common locations for Dissection Stent placement. Although the core laboratory noted graft placement extending into Zone 1 in 49.3%, none of the patients had coverage of the LCC, indicating only a portion of the graft (such as along the inner curvature) extended into Zone 1.

Table 22. Dissection Stent and Dissection Endovascular Graft coverage relative to extent of dissection and primary tear location according to zone classification based on core laboratory assessment

Zone[a]		Dissection Location (pre-procedure)[b]			Device Location (at first follow-up)[b]	
		Proximal Extent	Primary Tear	Distal Extent	Dissection Endovascular Graft	Dissection Stent
	**0**	4.2% (3/72)	-	-	-	-
	1	6.9% (5/72)	-	-	49.3% (34/69)	-
	2	38.9% (28/72)	2.8% (2/72)	-	82.6% (57/69)	-
	3	37.5% (27/72)	4.2% (3/72)	-	88.4% (61/69)	-
	4	5.6% (4/72)	70.8% (51/72)	1.4% (1/72)	94.2% (65/69)	61.8% (34/55)
	5	5.6% (4/72)	15.3% (11/72)	8.3% (6/72)	68.1% (47/69)	94.5% (52/55)
	6	-	-	2.8% (2/72)	5.8% (4/69)	65.5% (36/55)
	7	-	-	2.8% (2/72)	-	65.5% (36/55)
	8	-	-	9.7% (7/72)	-	60.0% (33/55)
	9	-	-	23.6% (17/72)	-	54.5% (30/55)
	10	-	-	19.4% (14/72)	-	1.8% (1/55)
	11	-	-	19.4% (14/72)	-	1.8% (1/55)

[a] Data are reported as zones 0-11 according to the diagram in Fillinger, et al.[1]

[b] Dashes indicate a value of 0%

Tables 23 and 24 report additional procedures performed (including accessory device usage) during the time of the index procedure among patients with a Dissection Stent and patients without a Dissection Stent, respectively. The majority of patients with procedures before device placement underwent carotid-subclavian bypass. Transposition of the LSA, iliac artery angioplasty/stent placement, and other procedure types were also reported. Procedures after device deployment included transposition of the LSA, celiac artery stent placement, iliac artery angioplasty/stent placement, SMA fenestration, and other procedure types, which often involved renal artery and/or SMA stent placement. Rates of additional procedures were generally comparable between the two patient populations. However, additional procedures involving the celiac artery, SMA, and/or renal arteries (i.e., fenestration, angioplasty, stent placement) appeared to be more common in patients who received a Dissection Stent, which is consistent with these patients more often presenting initially for treatment of malperfusion as compared to patients who did not receive a Dissection Stent, who often presented for treatment of rupture.

Table 23. Additional procedures performed and accessory device usage during the index procedure in patients with a Dissection Stent

Procedure	Percent Patients (number/total number)	
	Before Device Deployment	After Device Deployment
Carotid-subclavian bypass	15.5% (9/58)	0%
LSA transposition	5.2% (3/58)	1.7% (1/58)
Celiac artery stent	0%	1.7% (1/58)
Iliac artery angioplasty	1.7% (1/58)	1.7% (1/58)
Iliac artery stent or stent-graft	1.7% (1/58)	8.6% (5/58)
Renal artery fenestration	1.7% (1/58)	1.7% (1/58)
SMA fenestration	1.7% (1/58)	3.4% (2/58)
Vessel closure device	1.7% (1/58)	1.7% (1/58)
Other	8.6% (5/58)[a]	22.4% (13/58)[b]

LCC: left common carotid artery; LSA: left subclavian artery; SMA: superior mesenteric artery.

[a] Carotid-to-axillary bypass (n=1); transesophageal echo (n=1); exploratory laparotomy (n=1); Amplatzer plug placement to embolize the LSA (n=2).

[b] SMA stent placement (n=1); esophagogastroduodenoscopy and esophagectomy (n=1); renal artery stent placement (n=2); renal artery stent placement, common iliac artery thrombectomy, and femoral patch angioplasty (n=1); renal artery stent placement, SMA stent placement, and iliofemoral bypass (n=1); dialysis catheter insertion (n=1); common iliac artery endarterectomy and patching (n=1); chest tube placement (n=1); transesophageal echo (n=2); fasciotomy (n=1); renal artery stent placement and femoral artery endarterectomy (n=1).

Table 24. Additional procedures performed and accessory device usage during the index procedure in patients without a Dissection Stent

Procedure	Percent Patients (number/total number)	
	Before Device Deployment	After Device Deployment
Carotid-subclavian bypass	6.7% (1/15)	0%
SMA fenestration	0%	6.7% (1/15)
Vessel closure device	0%	13.3% (2/15)
Other	0%	13.3% (2/15)[a]

LCC: left common carotid artery; LSA: left subclavian artery; SMA: superior mesenteric artery.

[a] Femoral-femoral bypass (n=1); ballooning of true lumen of aorta in abdominal region (n=1).

The clinical utility results are presented in Table 25. The measures appeared to be comparable or generally higher in patients who received a Dissection Stent.

Table 25. Clinical utility measures

Variable	Mean ± SD (N, range)		
	Without Dissection Stent	**With Dissection Stent**	**Total**
Days in ICU	3.2 ± 2.3 (14, 1 - 10)	7.0 ± 7.3 (57, 0 - 30)	6.3 ± 6.7 (71, 0 - 30)
Days to discharge	12.5 ± 11.0 (15, 2 - 32)	11.6 ± 9.8 (58, 1 - 47)	11.8 ± 10.0 (73, 1 - 47)
Days to first bowel movement	4.1 ± 3.2 (15, 0 - 12)	4.7 ± 2.9 (48, 0 - 12)	4.6 ± 2.9 (63, 0 - 12)
Days to resumption of oral fluid intake	1.1 ± 1.0 (15, 0 - 3)	3.3 ± 6.1 (50, 0 - 35)	2.8 ± 5.5 (65, 0 - 35)
Days to resumption of regular diet	3.7 ± 4.1 (15, 0 - 16)	5.5 ± 7.3 (47, 0 - 35)	5.0 ± 6.7 (62, 0 - 35)
Mechanical ventilation (days)	0.5 ± 0.6 (15, 0 - 2)	2.0 ± 4.8 (58, 0 - 28)	1.7 ± 4.3 (73, 0 - 28)
Procedural intubation (hours)	7.7 ± 8.5 (15, 1.5 - 28)	25.8 ± 64.3 (56, 0 - 375)	22.0± 57.6 (71, 0 - 375)

D. Safety and Effectiveness Results

As explained above, the core lab-identified patients with dissection of the aorta proximal to the left subclavian artery, a length < 20 mm between the LCC and proximal extent of dissection, or with fixation site diameters >38 mm were not excluded from the hypotheses-driven and secondary endpoints analyses, because enrollment in the study was determined by site evaluation. In addition, inclusion of these patients would not favorably bias the study results.

The primary analysis of safety and effectiveness was based on the 67 evaluable patients at the 30-day time point, excluding the 6 patients without confirmed absence of bowel necrosis at the time of enrollment.

Table 26 presents the results of hypothesis testing for the primary endpoint for the Zenith Dissection Endovascular System. The 30-day survival rate was 95.5%, which met the performance goal of 79.4% ($p < 0.001$).

Table 26. Results from primary effectiveness hypothesis testing (30-day survival)

Performance Goal	30-day Survival Rate	95% Confidence Interval	*P*-value	Performance Goal Met
79.4%	95.5% (64/67)	87%, 99%[a]	< 0.001	Yes

[a] 95% confidence interval was computed using the Exact method.

There were three patients who died within 30 days, the details of which are provided in Table 27. Each death within 30 days occurred in a patient who received a Dissection Stent.

Table 27. Patient deaths within 30 days

Patient Number	Days Post-procedure	Cause of Death	CEC Adjudication
1130012*	21	Aortic rupture	Unable to be adjudicated
1130036*	1	Aortic dissection with resultant respiratory failure, cardiac arrest	Not related: related to presenting aortic dissection
1130060	5	Brain dead due to stroke	Procedure-related

*Patient had a length < 20 mm from LCC to proximal extent of dissection, a dissection that extended proximal to the LSA, and a total aortic diameter >38 mm at level of LCC/LSA at pre-procedure based on core laboratory analysis.

Two of the six patients excluded from assessment of the primary effectiveness hypothesis also died within 30 days.

1. Additional Safety Results

Protocol Defined MAEs

The additional hypothesis-driven analysis of safety (30-day freedom from MAEs) was based on the results from 67 patients. Data from 73 patients are presented for all other safety endpoints.

The 30-day freedom from MAE rate was 71.6%, which met the performance goal of 51.2% ($p < 0.001$).

The key safety outcomes for this study are presented below in Tables 28 and 29. Adverse effects are reported in Table 31.

Table 28. Results from primary safety hypothesis testing (30-day freedom from MAEs)

Performance Goal	30-day Freedom from MAE Rate	95% Confidence Interval	*P*-value	Performance Goal Met
51.2%	71.6% (48/67)	59%, 82%[a]	< 0.001	Yes

[a] 95% confidence interval was computed using the Exact method.

There were 19 patients who experienced MAEs within 30 days (17 patients who received a Dissection Stent and 2 patients without a Dissection Stent), as summarized below in Table 29. None of the six patients excluded from assessment of the primary safety hypothesis had a MAE within 30 days.

Table 29. Patients experiencing MAEs within 30 days

Major Adverse Event	Patients without Dissection Stent	Patients with Dissection Stent	Total	SVS Acute Patients
Bowel ischemia	0%	0%	0%	3.5% (3/85)
MI	0%	1.9% (1/52)[a]	1.5% (1/67)	1.2% (1/85)

Paraparesis/Paraplegia	6.7% (1/15)	5.8% (3/52)	6.0% (4/67)	9.4% (8/85)
Prolonged (> 72 hours) ventilatory support	0%	19.2% (10/52)[b]	14.9% (10/67)	2.4% (2/85)
Renal failure requiring dialysis	6.7% (1/15)	7.7% (4/52)[c]	7.5% (5/67)	9.4% (8/85)
Stroke	0%	9.6% (5/52)[d]	7.5% (5/67)	9.4% (8/85)

MI: myocardial infarction.
[a]Patient had a length < 20 mm from LCC to proximal extent of dissection and a dissection that extended proximal to the LSA at pre-procedure based on core laboratory analysis.
[b]Five patients had a length < 20 mm from LCC to proximal extent of dissection, a dissection that extended proximal to the LSA and/or a total aortic diameter > 38 mm at the level of the LCC/LSA at pre-procedure based on core laboratory analysis.
[c]Four patients had a length < 20 mm from LCC to proximal extent of dissection, a dissection that extended proximal to the LSA, and/or a total aortic diameter > 38 mm at the level of the LCC/LSA at pre-procedure based on core laboratory analysis.
[d]Two patients had a length < 20 mm from LCC to proximal extent of dissection and/or a dissection that extended proximal to the LSA at pre-procedure based on core laboratory analysis.

Of the MAEs that were assessed, stroke and paraplegia/paraparesis are considered the most serious. While the risk of either one occurring following endovascular repair of Type B aortic dissection is well known, further investigation into the possible circumstances was warranted.

Five patients experienced stroke within 30 days. Each stroke occurred in a patient who received a Dissection Stent and was adjudicated by the CEC to be procedure-related; no stroke was adjudicated as related to the device. The LSA was covered in three of the five patients with stroke, two of which had undergone revascularization. Two patients appear to have recovered based on normal neurological exams reported at subsequent follow-up. The other three, each without recovery, were notable for potential contributing factors such as preexisting Type A dissection, presence of calcification and thrombus in the proximal seal zone at pre-procedure, and induced hypotension during the procedure. Four patients experienced paraplegia/paraparesis within 30 days, two recovered and two were unresolved. The two patients without resolution of symptoms had both received spinal cord protection (CSF drainage) at the time of procedure. The pre-procedure imaging for both patients was notable for spinal arteries perfused by the true and false lumens, and on follow-up imaging, both had false lumen thrombosis that extended beyond the level of spinal cord injury, suggesting the deficits in both may have resulted from decreased perfusion of the spinal arteries secondary to false lumen thrombosis.

Not Protocol Defined MAEs

While not protocol-defined as MAEs, additional (vascular) events of interest that were reported by the sites within 30 days included rupture in 1.4% (1/52 with a Dissection Stent, 0/15 without a Dissection Stent) and retrograde dissection in 1.4% (1/52 with a Dissection Stent, 0/15 without a Dissection Stent). While there were additional reports of rupture (n=1) and retrograde dissection (n=3) between 31-365 days, each occurred in a

patient with preexisting Type A dissection (i.e., none of the retrograde dissections were progression of Type B dissection to Type A dissection, as also noted in Table 27 – Morbidity by category and type in all patients), underscoring the importance of an adequate proximal landing zone in non-dissected aorta.

All-Cause Mortality

With regards to the entire study population (n=73), deaths between 0-30 days, 31-180 days, and 181-365 days occurred in 6.8% (1 related, 3 unrelated, 1 unable to be adjudicated), 7.5% (1 related, 3 unrelated, 1 unable to be adjudicated by the CEC) and 6.7% (2 unrelated, 2 unable to be adjudicated by the CEC), respectively, and included patients from both groups (11 with a Dissection Stent, 3 without a Dissection Stent). Deaths rates between 0-30 days and 31-365 days were reported in the SVS dataset at 10.6% and 15.8%, respectively. Table 30 provides the details for all patient who died within 365 days.

Table 30. Patient deaths within 365 days

Patient Number	Days Post-procedure	Cause of Death	CEC Adjudication
1130001[a]	57	Type A aortic dissection with rupture	Not related: related to preexisting Type A dissection prior to device deployment
1130012[a]	21	Aortic rupture	Unable to be adjudicated
1130015[a]	1	Ischemic bowel	Not related: related to a preexisting condition
1130022[a]	3	Multiple organ failure	Not related: related to celiac artery and SMA occlusions prior to Dissection Stent placement
1130036[a]	1	Aortic dissection with resultant respiratory failure, cardiac arrest	Not related: related to presenting aortic dissection
1130039[a]	220	Multiple organ failure	Not related: patient did not meet inclusion criteria
1130049	170	Angiosarcoma, cancer	Not related: related to other condition
1130060[a]	5	Brain dead due to stroke	Procedure-related
1130065	66	Unknown	Procedure-related: post-operatively the patient was ventilated and had a stroke; however, the terminal event is not clear
1130067	96	Unknown, found dead at home	Unable to be adjudicated
1130084[a]	330	Atherosclerotic cardiovascular disease	Unable to be adjudicated
1130087[a]	306	Unknown	Unable to be adjudicated
1230007	240	Respiratory failure	Not related: related to pneumonia with preexisting lung cancer and COPD

Patient Number	Days Post-procedure	Cause of Death	CEC Adjudication
1230009	177	Ischemic heart disease	Not related: related to preexisting condition

Note: Patient numbers that are italicized indicate those who did not have confirmed absence of bowel necrosis at the time of enrollment and were therefore excluded from hypothesis testing.

[a]Patient had a length < 20 mm from LCC to proximal extent of dissection, a dissection that extended proximal to the LSA, and/or a total aortic diameter > 38 mm at the level of the LCC/LSA at pre-procedure based on core laboratory analysis.

Adverse Effects that Occurred in the PMA Clinical Study

Table 31 reports the frequency of all adverse events according to organ system category and event type in the overall patient population through 12 months. The occurrence of adverse events was not unexpected given the extent of comorbid medical conditions and disease among the total patient population as well as the prevalence of early and late events in similar categories for patients undergoing endovascular treatment for acute, complicated Type B aortic dissection, as reported in the SVS dataset.

Table 31. Morbidity by category and type in all patients

Category	Type	Percent Patients (number/total number)		
		0-30 Days	31-180 Days	181-365 Days
Access site/vessel		9.6% (7/73)	3.0% (2/67)	0%
	Dehiscence	0%	0%	0%
	Hematoma	5.5% (4/73)	0%	0%
	Hernia	0%	0%)	0%
	Infection	0%	1.5% (1/67)	0%
	Pseudoaneurysm	2.7% (2/73)	0%	0%
	Seroma	2.7% (2/73)	1.5% (1/67)	0%
Cardiovascular		13.7% (10/73)	4.5% (3/67)	1.7% (1/60)
	Cardiac arrhythmia	6.8% (5/73)	1.5% (1/67)	1.7% (1/60)
	Cardiac ischemia	1.4% (1/73)	1.5% (1/67)	0%
	Congestive heart failure	0%	1.5% (1/67)	0%
	Myocardial infarction	1.4% (1/73)	0%	0%
	Refractory hypertension	4.1% (3/73)	0%	0%
Neurologic		11.0% (8/73)	0%	1.7% (1/60)
	Paraplegia	2.7% (2/73)	0%	0%
	Paraparesis	4.1% (3/73)	0%	0%
	Transient ischemic attack	0%	0%	0%
	Stroke	6.8% (5/73)	0%	1.7% (1/60)
Gastrointestinal		12.3% (9/73)	0%	3.3% (2/60)
	Bleeding	1.4% (1/73)	0%	0%
	Bowel ischemia	1.4% (1/73)	0%	3.3% (2/60)
	Infection	4.1% (3/73)	0%	0%
	Bowel obstruction	0%	0%	0%
	Paralytic ileus > 4 days	5.5% (4/73)	0%	0%
Pulmonary		21.9% (16/73)	3.0% (2/67)	1.7% (1/60)
	COPD	0% (0/73)	3.0% (2/67)	1.7% (1/60)

Category / Type	Percent Patients (number/total number)		
	0-30 Days	31-180 Days	181-365 Days
Hemothorax	1.4% (1/73)	0%	0%
Pleural effusion	16.4% (12/73)	0%	0%
Pneumonia	2.7% (2/73)	0%	0%
Pneumothorax	0%	0%	0%
Pulmonary edema	1.4% (1/73)	0%	0%
Pulmonary embolism	1.4% (1/73)	0%	0%
Renal	17.8% (13/73)	6.0% (4/67)	5.0% (3/60)
Renal failure[a]	8.2% (6/73)	1.5% (1/67)	1.7% (1/60)
Urinary tract infection[b]	8.2% (6/73)	4.5% (3/67)	3.3% (2/60)
Serum creatinine rise[c]	2.7% (2/73)	0% (0/67)	1.7% (1/60)
Vascular	8.2% (6/73)	4.5% (3/67)	3.3% (2/60)
Aortic aneurysm	1.4% (1/73)	1.5% (1/67)	1.7% (1/60)
Aortic rupture	1.4% (1/73)	1.5% (1/67)	0%
Aortobronchial fistula	0%	0%	0%
Aortoesophageal fistula	0%	0%	0%
Aortoenteric fistula	0%	0%	0%
Arterial thrombosis	0%	0%	0%
Coagulopathy	0%	0%	0%
Deep vein thrombosis	2.7% (2/73)	0%	0%
Distal embolization[d]	0%	0%	0%
Hematoma	0%	0%	0%
Pseudoaneurysm[e]	1.4% (1/73)	0%	0%
Retrograde dissection[f]	1.4% (1/73)	3.0% (2/67)	1.7% (1/60)
Miscellaneous/other[g]	68.5% (50/73)	31.3% (21/67)	33.3% (20/60)

[a] With or without dialysis.
[b] Requiring antibiotic treatment.
[c] > 30% above baseline resulting in a persistent value > 2.0 mg/dL.
[d] With tissue loss.
[e] Requiring intervention.
[f] Includes retrograde progression of pre-existing Type A dissection in 3 and new Type A dissection in 1; none were considered retrograde progression of Type B dissection to Type A dissection.
[g] Miscellaneous morbidity category comprises the following prespecified events: hypersensitivity/allergic reaction, multi-organ failure, sepsis, and other.

2. Additional Effectiveness Results

Additional effectiveness outcomes are presented in Tables 30 to 71, as follows.

Aortic Diameters (Total Aortic, True Lumen, False Lumen) at Follow-up

The maximum aortic diameters just distal to the celiac artery, just distal to the SMA, just distal to the right renal artery, just distal to the left renal artery, within the Dissection Endovascular Graft, and distal to the treated segment (i.e., most distal stent-graft or Dissection Stent, and within dissected aorta) were measured by the core laboratory at each time point for all patients. Compared to pre-procedure, the true lumen diameters trended larger throughout the visceral aortic segment at post-procedure. From post-procedure through 12 months, there appeared an increase (> 5 mm) in mean true lumen

diameter and a decrease (> 5 mm) in mean false lumen diameter within the stent-graft. Distal to the treated segment, there appeared to be an increase (> 5 mm) in the mean total aortic diameter, with no change (≤ 5 mm) in the true and false lumen diameters. Figure 7 plots the average true and false lumen diameters at the location of the maximum total aortic diameter within and distal to treated segment.

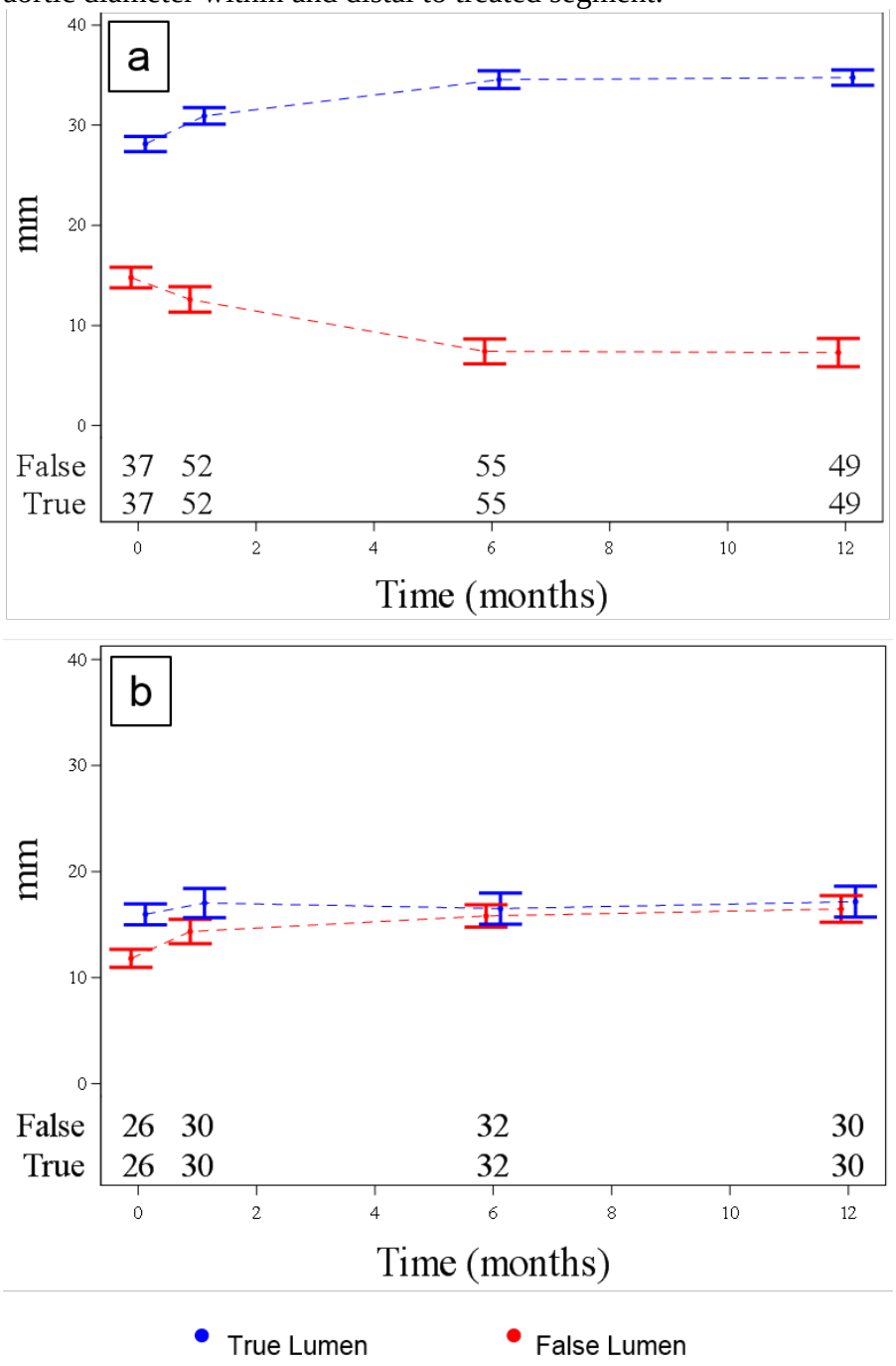


Figure 7. True and false lumen diameters over time at the location of the maximum total aortic diameter within the stent-graft (a) and distal to the treated segment (b) in the total patient population. Numbers above the x-axis represent sample number.

Diameters measured at the specified locations by the core laboratory at each time point for the patients without a Dissection Stent and patients with a Dissection Stent, respectively. Compared to pre-procedure, the true lumen diameter trended smaller at the level of the SMA and both renal arteries at post-procedure in the patients without a Dissection Stent, whereas the true lumen diameter trended larger throughout the visceral aortic segment at post-procedure in the patients with a Dissection Stent. In the stent-graft region, there was an increase (> 5 mm) in average true lumen diameter, with no change (≤ 5 mm) in the average false lumen or transaortic diameters for the patients without a Dissections Stent, compared to an increase (> 5 mm) in average true lumen diameter and a decrease (> 5 mm) in the average false lumen diameter, with no change (≤ 5 mm) in total aortic diameter for patients with a Dissection Stent. In the Dissection Stent region, there was no change (≤ 5 mm) in the average total aortic, true lumen, or false lumen diameters from post-procedure to 12 months. Distal to the treated segment, there appeared an increase (> 5 mm) in the total and false lumen diameters with no change (≤ 5 mm) in true lumen diameter for patients without a Dissection Stent, compared to no change (≤ 5 mm) in the total, true, and false lumen diameters from post-procedure through 12 months for patients with a Dissection Stent. Given these data, it appears that the Dissection Graft results in favorable remodeling within the region adjacent to the Dissection Endovascular Graft, with the Dissection Stent additionally providing for further stabilization of aortic diameters distal to the stent-graft.

Figure 8 illustrates the average true and false lumen diameters at the maximum transaortic diameter within the Dissection Endovascular Graft, Dissection Stent (if applicable), and distal to the treated segment over time for the patients with a Dissection Stent and the patients without a Dissection Stent.

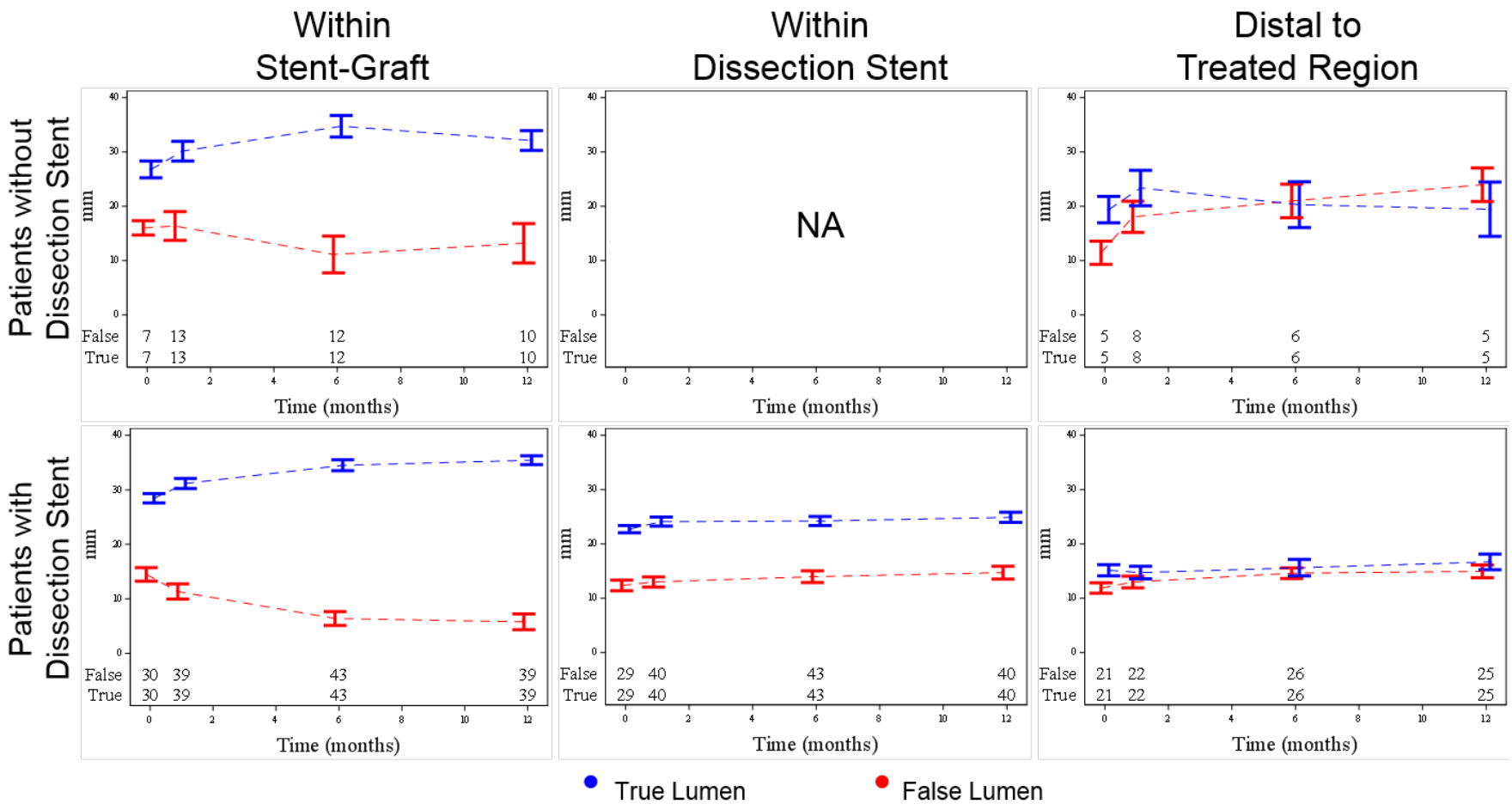


Figure 8. True and false lumen diameters over time at the location of the maximum total aortic diameter within and distal to the specified treated segments for patients who did not receive a Dissection Stent (labeled as Patients without Dissection Stent) and for patient who received a Dissection Stent (labeled as Patients with Dissection Stent). Numbers above the x-axis represent sample number.

Change in Transaortic Diameter

Tables 32, 33, and 34 report the percentage of patients with a greater than 5 mm increase, a greater than 5 mm decrease, or no change (≤ 5 mm) in largest size in the transaortic diameter within the stent-graft region (depicted in Figure 9) for patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively, at each time point analyzed. Transaortic diameter growth (> 5 mm) in the stent-graft region was observed in 14.9% at 12 months (6/37 with a Dissection Stent, 1/10 without a Dissection Stent), including two with a net increase (> 5 mm) in false lumen diameter (both in the setting of Proximal Type I entry flow), whereas the remaining five patients had either no change (≤ 5 mm) or a net decrease (> 5 mm) in false lumen diameter.

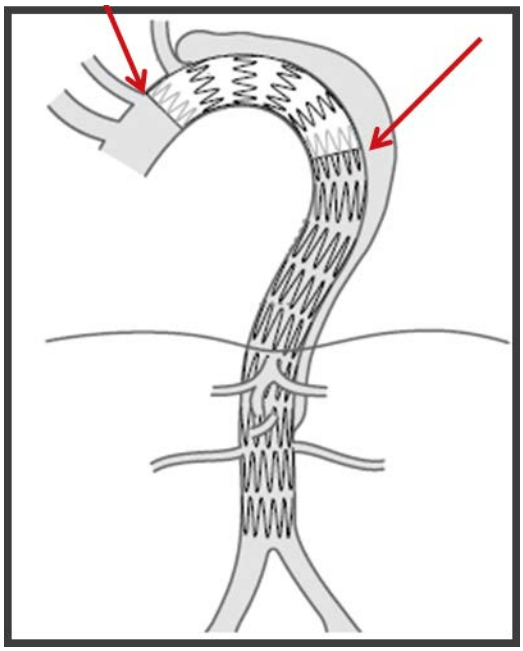


Figure 9. Diagram of the Zenith Dissection Endovascular System depicting stent-graft region (between the red arrows)

Table 32. Change in transaortic diameter within the stent-graft for patients who did not receive a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)	
	6-month	12-month
Increase	25.0% (3/12)[a,b,c]	10.0% (1/10)[a]
Decrease	16.7% (2/12)	20.0% (2/10)
No change	58.3% (7/12)	70.0% (7/10)

Note: Footnotes provide the changes in true and false lumen diameters as of 12-month follow-up.
[a] Patient 1130081: True lumen: -2.7 mm, False Lumen: +12.8 mm. Patient has a Type I proximal entry-flow, secondary tear in the descending thoracic aorta, and collateral flow from intercostal and paraspinal arteries. Patient had a length < 20 mm from LCC to proximal extent of dissection and a dissection that extended proximal to the LSA at pre-procedure based on core laboratory analysis.
[b] Patient 1230007: True lumen: +7.8 mm, False Lumen: -2.0 mm.
[c] Patient 1230010: True lumen: +12.0 mm, False Lumen: -8.4 mm.

Table 33. Change in transaortic diameter within the stent-graft for patients who received a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)	
	6-month	12-month
Increase	16.3% (7/43)[a,b,c,d,e,f,g]	16.2% (6/37)[b,c,d,f,g,h]
Decrease	20.9% (9/43)	27.0% (10/37)
No change	62.8% (27/43)	56.8% (21/37)

[a] Patient 1130017: True lumen: -0.6 mm, False Lumen: +8.3 mm. The true lumen has expanded and the false lumen has decreased. The thoracic false lumen is completely thrombosed.
[b] Patient 1130074: True lumen: +11.6 mm, False Lumen: -3.7 mm.
[c] Patient 1130006: True lumen: +5.7 mm, False Lumen: -0.5 mm.
[d] Patient 1130044: True lumen: -1.2 mm, False Lumen: +7.6 mm. Patient has a Type I proximal entry-flow. Patient had a length < 20 mm from LCC to proximal extent of dissection and a dissection that extended proximal to the LSA at pre-procedure based on core laboratory analysis.
[e] Patient 1130057: True lumen: -2.6 mm, False Lumen: +6.9 mm. Patient has collateral flow from the paraspinal arteries.
[f] Patient 1130037: True lumen: +19.5 mm, False Lumen: -7.0 mm.
[g] Patient 1130052: True lumen: +24.3 mm, False Lumen: -17.9 mm.
[h] Patient 1130050: True lumen: +1.2 mm, False Lumen: +4.5 mm. Patient has collateral flow from the spinal arteries.

Table 34. Change in transaortic diameter within the stent-graft for all patients based on results from core laboratory analysis

Status	Percent Patients (number/total number)	
	6-month	12-month
Increase	18.2% (10/55)	14.9% (7/47)
Decrease	20.0% (11/55)	25.5% (12/47)
No change	61.8% (34/55)	59.6% (28/47)

Table 35 reports the percentage of patients with a greater than 5 mm increase, a greater than 5 mm decrease, or no change (≤ 5 mm) in largest size in the transaortic diameter within the Dissection Stent region (depicted in Figure 10). Transaortic diameter growth (> 5 mm) in the Dissection Stent region was observed in 38.5% at 12 months, including six with a net increase (> 5 mm) in false lumen diameter (each in the setting of false lumen perfusion from secondary tears and patent collateral vessels), whereas the remaining nine patients had no change (≤ 5 mm) in false lumen diameter.

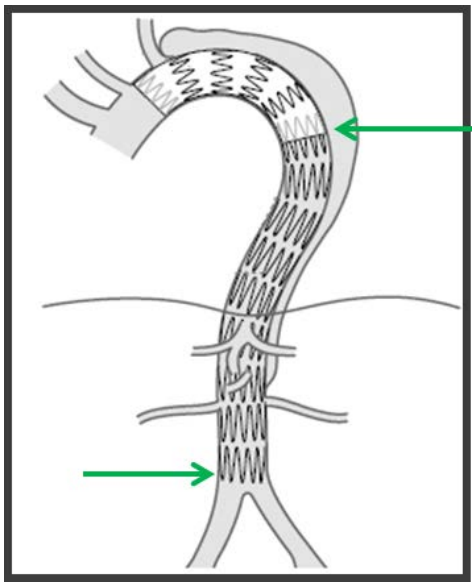


Figure 10. Diagram of Zenith Dissection Endovascular System depicting Dissection Stent region (between the green arrows)

Table 35. Change in transaortic diameter within the Dissection Stent region based on results from core laboratory analysis

Status	Percent Patients (number/total number)	
	6-month	12-month
Increase	20.5% (9/44)[a-i]	38.5% (15/39)[d-r]
Decrease	4.5% (2/44)	5.1% (2/39)
No change	75.0% (33/44)	56.4% (22/39)

Note: Footnotes provide the changes in true and false lumen diameters as of 12-month follow-up.

[a] Patient 1130020: True lumen: +3.6 mm, False Lumen: -3.8 mm.

[b] Patient 1130007: True lumen: +2.6 mm, False Lumen: +0.9 mm. At 6 months, growth was potentially due to a secondary tear in the descending thoracic aorta. At 12 months, the true lumen had expanded and the thoracic false lumen was completely thrombosed.

[c] Patient 1130017: True lumen: -0.6 mm, False Lumen: +10.5 mm. Patient has a secondary tear at the right renal artery and collateral flow from the lumbar arteries.

[d] Patient 1130035: True lumen: +2.4 mm, False Lumen: +5.0 mm. Patient has a completely thrombosed thoracic false lumen, but a secondary tear at the right renal artery and collateral flow from the paraspinal and lumbar arteries.

[e] Patient 1130038: True lumen: +4.0 mm, False Lumen: +4.5 mm. Patient has a completely thrombosed thoracic false lumen, but a secondary tear at the infrarenal aorta and collateral flow from the lumbar arteries.

[f] Patient 1130085: True lumen: -1.9 mm, False Lumen: 14.3 mm. Patient has secondary tears in the descending thoracic and infrarenal aorta and collateral flow from the paraspinal and lumbar arteries.

[g] Patient 1130074: True lumen: +6.0 mm, False Lumen: +8.1 mm. Patient has a secondary tear in the infrarenal aorta and collateral flow from the paraspinal and lumbar arteries.

[h] Patient 1130086: True lumen: +7.4 mm, False Lumen: +4.0 mm. Patient has secondary tears in the descending thoracic aorta and at the SMA as well as collateral flow from the paraspinal and lumbar arteries.
[i] Patient 1130037: True lumen: +3.8 mm, False Lumen: +2.0 mm. Patient has a completely thrombosed thoracic false lumen, but has a secondary tear at the right renal artery and collateral flow from the lumbar arteries.
[j] Patient 1130006: True lumen: -1.8 mm, False Lumen: +9.2 mm. Patient has a Type I proximal entry-flow and collateral flow from the lumbar arteries. Patient had a length < 20 mm from LCC to proximal extent of dissection, a dissection that extended proximal to the LSA, and an aortic diameter >38 mm at the level of the LCC/LSA at pre-procedure based on core laboratory analysis.
[k] Patient 1130043: True lumen: +1.0 mm, False Lumen: +4.5 mm. Patient has a completely thrombosed thoracic false lumen, but has a secondary tear at the infrarenal aorta and celiac artery and collateral flow from the lumbar arteries.
[l] Patient 1130064: True lumen: -0.9 mm, False Lumen: +6.0 mm. Patient has secondary tears in the descending thoracic and infrarenal aorta and collateral flow from the paraspinal and lumbar arteries.
[m] Patient 1130069: True lumen: +7.6 mm, False Lumen: +2.2 mm.
[n] Patient 1130002: True lumen: +1.0 mm, False Lumen: +4.9 mm. Patient has a completely thrombosed thoracic false lumen, but has secondary tears at the celiac artery and SMA and collateral flow from the lumbar arteries.
[o] Patient 1130057: True lumen: +2.8 mm, False Lumen: +4.4 mm. Patient has a partially thrombosed abdominal false lumen, but has collateral flow from the paraspinal artery.
[p] Patient *1130023*: True lumen: -1.6 mm, False Lumen: +10.2 mm. Patient has an unknown entry-flow, a secondary tear at the SMA, and collateral flow from the paraspinal and lumbar arteries.
[q] Patient 1130070: True lumen: -3.5 mm, False Lumen: +8.8 mm. Patient has a secondary tear at the left renal artery and collateral flow from the paraspinal and lumbar arteries.
[r] Patient 1130058: True lumen: +2.2 mm, False Lumen: +3.0 mm. Patient has a completely thrombosed thoracic false lumen, but has secondary tears at the right renal and celiac arteries and collateral flow from the lumbar arteries.

Tables 36, 37, and 38 report the percentage of patients with a greater than 5 mm increase, a greater than 5 mm decrease, or no change (≤ 5 mm) in largest size in the transaortic diameter distal to the treated segment for patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively, at each time point analyzed. As with the other tables reporting a change in size, the denominators reflect the number of patients with a baseline exam who also had adequate imaging extending to the level of interest, which in this case was beyond the level of the treated segment. Transaortic diameter growth (> 5 mm) distal to the treated segment was observed in 40.7% at 12 months (8 with a Dissection Stent, 3 without a Dissection Stent), including seven with a net increase (> 5 mm) in false lumen diameter (each in the setting of false lumen perfusion from secondary tears and patent collateral vessels), one with a net decrease (> 5 mm) in false lumen diameter, and three with no change (≤ 5 mm) in false lumen diameter.

Table 36. Change in transaortic diameter distal to the treated segment and within dissected aorta for patients who did not receive a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)	
	6-month	12-month
Increase	16.7% (1/6)[a]	60.0% (3/5)[a-c]
Decrease	0%	0%
No change	83.3% (5/6)	40.0% (2/5)

Note: Footnotes provide the changes in true and false lumen diameters as of 12-month follow-up.

[a] Patient 1230010: True lumen: +1.1 mm, False Lumen: +5.7 mm. Patient has secondary tears at the infrarenal aorta and at the celiac artery and collateral flow from the intercostal, paraspinal, and lumbar arteries.
[b] Patient 1130027: True lumen: -0.6 mm, False Lumen: +6.4 mm. Patient has collateral flow from the intercostal arteries.
[c] Patient 1130081: True lumen: -3.0 mm, False Lumen: +9.7 mm. Patient has a Type I proximal entry-flow, a secondary tear in the descending thoracic aorta, and collateral flow from the intercostal and paraspinal arteries. Patient had a length < 20 mm from LCC to proximal extent of dissection and a dissection that extended proximal to the LSA at pre-procedure based on core laboratory analysis.

Table 37. Change in transaortic diameter distal to the treated segment and within dissected aorta for patients who received a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)	
	6-month	12-month
Increase	13.0% (3/23)[a-c]	36.4% (8/22)[a-h]
Decrease	0%	0%
No change	87.0% (20/23)	63.6% (14/22)

Note: Footnotes provide the changes in true and false lumen diameters as of 12-month follow-up.
[a] Patient 1130076: True lumen: +7.3 mm, False Lumen: +1.9 mm. Patient has a partially thrombosed thoracic false lumen, but has a secondary tear at the left renal artery and collateral flow from the lumbar arteries.
[b] Patient 1130037: True lumen: +9.3 mm, False Lumen: +10.8 mm. Patient has a completely thrombosed thoracic false lumen, but has a secondary tear at the right renal artery and collateral flow from the lumbar arteries.
[c] Patient 1130052: True lumen: +0.4 mm, False Lumen: +5.0 mm. Patient has secondary tears in the infrarenal aorta and at the celiac artery and collateral flow from the lumbar arteries.
[d] Patient 1130058: True lumen: +0.3 mm, False Lumen: +5.1 mm. Patient has secondary tear at the right renal and celiac arteries and collateral flow from the lumbar arteries.
[e] Patient 1130038: True lumen: +3.7 mm, False Lumen: +1.8 mm. Patient has a completely thrombosed thoracic false lumen, but has a secondary tear in the infrarenal aorta and collateral flow from the lumbar arteries.
[f] Patient 1130085: True lumen: +0.9 mm, False Lumen: +13.2 mm. Patient has secondary tears in the descending thoracic and infrarenal aorta and collateral flow from the paraspinal and collateral arteries.
[g] Patient 1130043: True lumen: -2.4 mm, False Lumen: +11.1 mm. Patient has a completely thrombosed thoracic false lumen, but has secondary tears in the infrarenal aorta and at the celiac artery and collateral flow from the lumbar arteries.
[h] Patient 1130089: True lumen: +13.0 mm, False Lumen: -7.5 mm.

Table 38. Change in transaortic diameter distal to the treated segment and within dissected aorta for all patients based on results from core laboratory analysis

Status	Percent Patients (number/total number)	
	6-month	12-month
Increase	13.8% (4/29)	40.7% (11/27)
Decrease	0%	0%
No change	86.2% (25/29)	59.3% (16/27)

False Lumen Perfusion

Tables 39, 40, and 41 detail the sources of flow in the thoracic false lumen in patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively. It should be noted that per the definitions in the study protocol, Types I through IV are intended to describe the source(s) for flow into the false lumen via the primary entry tear, and therefore speaks to the effectiveness of the endovascular graft component in sealing the primary entry tear (analogous to the

endoleak types for aneurysm repair – i.e., Type I = proximal and/or distal seal; Type II = vessels covered by graft; Type III = graft defect/hole or overlap; Type IV = graft porosity). However, recognizing the primary entry tear is not the only source for false lumen perfusion, it was necessary to further describe sources for false lumen flow not specifically associated with the effectiveness of the stent-graft to seal the primary entry tear. Therefore, the core laboratory also noted any incidences of flow directly into the false lumen via secondary tears or collateral vessels. The majority of reports of false lumen flow during follow-up were through secondary tears or collateral vessels, the coverage/occlusion of which were at physician discretion. Seven cases of Type I proximal entry flow into the thoracic false lumen were observed through 12 months. However, each patient had evidence of an inadequate proximal landing zone (i.e., aortic diameter > 38 mm and/or length of non-dissected aorta < 20 mm) and often times also graft undersizing. Overall, the proximal Type I entry-flow rate was 6.4% at 12 months (2 with a Dissection Stent, 1 without a Dissection Stent).

Table 39. Entry-flow in the thoracic aorta for patients who did not receive a Dissection Stent based on results from core laboratory analysis

Source	Percent Patients (number/total number)			
	Post-procedure	**1-month**	**6-month**	**12-month**
Multiple	16.7% (1/6)	25.0% (3/12)	10.0% (1/10)	11.1% (1/9)
Type I proximal	0%	8.3% (1/12)[a]	10.0% (1/10)[b]	11.1% (1/9)[b]
Type I distal	0%	0%	0%	0%
Type II	0%	0%	0%	0%
Type III	0%	0%	0%	0%
Type IV	0%	0%	0%	0%
Type unknown	0%	0%	0%	0%
Collateral	66.7% (4/6)	41.7% (5/12)	40.0% (4/10)	44.4% (4/9)
Secondary tear	16.7% (1/6)	33.3% (4/12)	10.0% (1/10)	11.1% (1/9)
Total patients	66.7% (4/6)	50.0% (6/12)	50.0% (5/10)	44.4% (4/9)

[a] Patient 1130079 had a Type I proximal entry-flow noted at 1 month in the likely setting of graft undersizing as well as an inadequate proximal landing zone (diameter and length) relative to the location of graft placement according to measurements by the core laboratory. The patient was treated with ancillary devices to mitigate the entry-flow. The patient also presented with preexisting Type A dissection according to CEC adjudication.

[b] Patient 1130081 had a Type I proximal entry-flow first noted at 54 days post-procedure (unscheduled visit) in the likely setting of an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. This entry-flow has persisted through 12 months. No secondary interventions have been performed at this time to treat this entry-flow.

Table 40. Entry-flow in the thoracic aorta for patients who received a Dissection Stent based on results from core laboratory analysis

Source	Percent Patients (number/total number)			
	Post-procedure	**1-month**	**6-month**	**12-month**
Multiple	33.3% (9/27)	16.2% (6/37)	26.8% (11/41)	15.8% (6/38)
Type I proximal	3.7% (1/27)[a]	8.1% (3/37)[b-d]	4.9% (2/41)[a,c]	5.3% (2/38)[c,e]
Type I distal	0%	0%	0%	0%
Type II	0%	0%	0%	0%
Type III	0%	0%	0%	0%
Type IV	0%	0%	0%	0%

Source	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Type unknown	0%	2.7%	2.4% (1/41)	2.6% (1/38)
Collateral	55.6% (15/27)	43.2% (16/37)	41.5% (17/41)	36.8% (14/38)
Secondary tear	37.0% (10/27)	27.0% (10/37)	34.1% (14/41)	18.4% (7/38)
Total patients	63.0% (17/27)	62.2% (23/37)	51.2% (21/41)	47.4% (18/38)

[a] Patient 1130087 had a Type I proximal entry-flow noted at post-procedure and at 6 months in the likely setting of an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. The patient died 306 days post-procedure (CEC unable to adjudicate) with no secondary interventions performed to treat this entry-flow.

[b] Patient *1130025* had a Type I proximal entry-flow noted at 1 month in the likely setting of graft undersizing as well as an inadequate proximal landing zone (diameter and length) relative to the location of graft placement according to measurements by the core laboratory. The entry-flow was completely resolved at 6 months.

[c] Patient 1130006 had a Type I proximal entry-flow that was treated with surgical repair in the likely setting of graft undersizing as well as an inadequate proximal landing zone (diameter and length) relative to the location of graft placement according to measurements by the core laboratory. The patient underwent a surgical repair involving the ascending aorta and arch 153 days post-procedure. The Type I proximal entry-flow has persisted through 2years.

[d] Patient 1130082 had a Type I proximal entry-flow noted at 1 month in the likely setting of graft undersizing as well as an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. No secondary interventions have been performed at this time to treat this entry-flow.

[e] Patient 1130044 had a Type I proximal entry-flow noted at 12 months in the likely setting of graft undersizing as well as an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. The Type I proximal entry-flow has persisted through 2 years. No secondary interventions have been performed at this time to treat this entry-flow.

Table 41. Entry-flow in the thoracic aorta for all patients based on results from core laboratory analysis

Source	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Multiple	30.3% (10/33)	18.4% (9/49)	23.5% (12/51)	14.9% (7/47)
Type I proximal	3.0% (1/33)	8.2% (4/49)	5.9% (3/51)	6.4% (3/47)
Type I distal	0%	0%	0%	0%
Type II	0%	0%	0%	0%
Type III	0%	0%	0%	0%
Type IV	0%	0%	0%	0%
Type unknown	0%	2.0% (1/49)	2.0% (1/51)	2.1% (1/47)
Collateral	57.6% (19/33)	42.9% (21/49)	41.2% (21/51)	38.3% (18/47)
Secondary tear	33.3% (11/33)	28.6% (14/49)	29.4% (15/51)	17.0% (8/47)
Total patients	63.6% (21/33)	59.2% (29/49)	51.0% (26/51)	46.8% (22/47)

Tables 42, 43, and 44 detail the sources of entry-flow in the abdominal false lumen in patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively. The majority of patients had abdominal false lumen flow through secondary tears and/or collateral vessels, the coverage/occlusion of which were at physician discretion. The single patient with Type I proximal entry-flow in the abdominal aorta is one of the same patients who was noted to have thoracic false lumen perfusion through proximal Type I entry-flow in the setting of

apparent graft undersizing as well as an inadequate proximal landing zone (diameter and length) based on core laboratory measurements relative to the location of graft placement.

Table 42. Entry-flow in the abdominal aorta for patients who did not receive a Dissection Stent based on results from core laboratory analysis

Source	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Multiple	33.3% (2/6)	20.0% (2/10)	22.2% (2/9)	33.3% (2/6)
Type I proximal	0%	0%	0%	0%
Type I distal	0%	0%	0%	0%
Type II	0%	0%	0%	0%
Type III	0%	0%	0%	0%
Type IV	0%	0%	0%	0%
Type unknown	0%	0%	0%	0%
Collateral	50.0% (3/6)	40.0% (4/10)	44.4% (4/9)	33.3% (2/6)
Secondary tear	33.3% (2/6)	20.0% (2/10)	33.3% (3/9)	50.0% (3/6)
Total patients	50.0% (3/6)	40.0% (4/10)	55.6% (5/9)	50.0% (3/6)

Table 43. Entry-flow in the abdominal aorta for patients who received a Dissection Stent based on results from core laboratory analysis

Source	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Multiple	81.5% (22/27)	70.3% (26/37)	63.2% (24/38)	66.7% (26/39)
Type I proximal	0%	2.7% (1/37)[a]	0%	0%
Type I distal	0%	0%	0%	0%
Type II	0%	0%	0%	0%
Type III	0%	0%	0%	0%
Type IV	0%	0%	0%	0%
Type unknown	0%	0%	2.6% (1/38)	0% (0/39)
Collateral	92.6% (25/27)	81.1% (30/37)	84.2% (32/38)	76.9% (30/39)
Secondary tear	88.9% (24/27)	75.7% (28/37)	71.1% (27/38)	74.4% (29/39)
Total patients	100.0% (27/27)	89.2% (33/37)	92.1% (35/38)	84.6% (33/39)

[a] Patient 1130006 underwent a surgical repair 153 days post-procedure in the likely setting of graft undersizing as well as an inadequate proximal landing zone (diameter and length) relative to the location of graft placement according to measurements by the core laboratory. The patient underwent a surgical repair involving the ascending aorta and arch 153 days post-procedure.

Table 44. Entry-flow in the abdominal aorta for all patients based on results from core laboratory analysis

Source	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Multiple	72.7% (24/33)	59.6% (28/47)	55.3% (26/47)	62.2% (28/45)
Type I proximal	0%	2.1% (1/47)	0%	0%
Type I distal	0%	0%	0%	0%
Type II	0%	0%	0%	0%
Type III	0%	0%	0%	0%
Type IV	0%	0%	0%	0%
Type unknown	0%	0%	2.1% (1/47)	0%
Collateral	84.8% (28/33)	72.3% (34/47)	76.6% (36/47)	71.1% (32/45)

Source	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Secondary tear	78.8% (26/33)	63.8% (30/47)	63.8% (30/47)	71.1% (32/45)
Total patients	90.9% (30/33)	78.7% (37/47)	85.1% (40/47)	80.0% (36/45)

False Lumen Status

Tables 45, 46, and 47 present data for false lumen status within the stent-graft region for patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively. There were no patients with a patent false lumen in the region of the stent-graft at 12 months, and 80.4% had complete thrombosis (including those no longer with an apparent false lumen), which appeared greater in the patients with a Dissection Stent (89.2%) compared to the patients without a Dissection Stent (44.4%).

Table 45. Status of false lumen within the stent-graft for patients who did not receive a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Patent	0%	8.3% (1/12)[a]	0%	0%
Partially thrombosed	66.6% (4/6)	41.7% (5/12)	50.0% (5/10)	55.6% (5/9)
Completely thrombosed	33.3% (2/6)	50.0% (6/12)	40.0% (4/10)	33.3% (3/9)
No apparent false lumen	0%	0%	10.0% (1/10)	11.1% (1/9)

[a] Patient 1230010: false lumen flow through a secondary tear in the descending thoracic aorta as well as collateral vessels reported at this time point; the false lumen in the stent-graft region was partially thrombosed at 6 and 12 months.

Table 46. Status of false lumen within the stent-graft for patients who received a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Patent	0%	0%	0%	0%
Partially thrombosed	46.4% (13/28)	38.9% (14/36)	26.8% (11/41)	10.8% (4/37)
Completely thrombosed	53.6% (15/28)	55.6% (20/36)	63.4% (26/41)	81.1% (30/37)
No apparent false lumen	0%	5.6% (2/36)	9.8% (4/41)	8.1% (3/37)

Table 47. Status of false lumen within the stent-graft for all patients based on results from core laboratory analysis

Status	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Patent	0%	2.1% (1/48)	0%	0%
Partially thrombosed	50.0% (17/34)	39.6% (19/48)	31.4% (16/51)	19.6% (9/46)
Completely thrombosed	50.0% (17/34)	54.2% (26/48)	58.8% (30/51)	71.7% (33/46)
No apparent false lumen	0%	2.1% (2/48)	9.8% (5/51)	8.7% (4/46)

Figure 11 depicts the percentages for false lumen status within the stent-graft region for each group over time, as reported in Tables 45, 46, and 47.

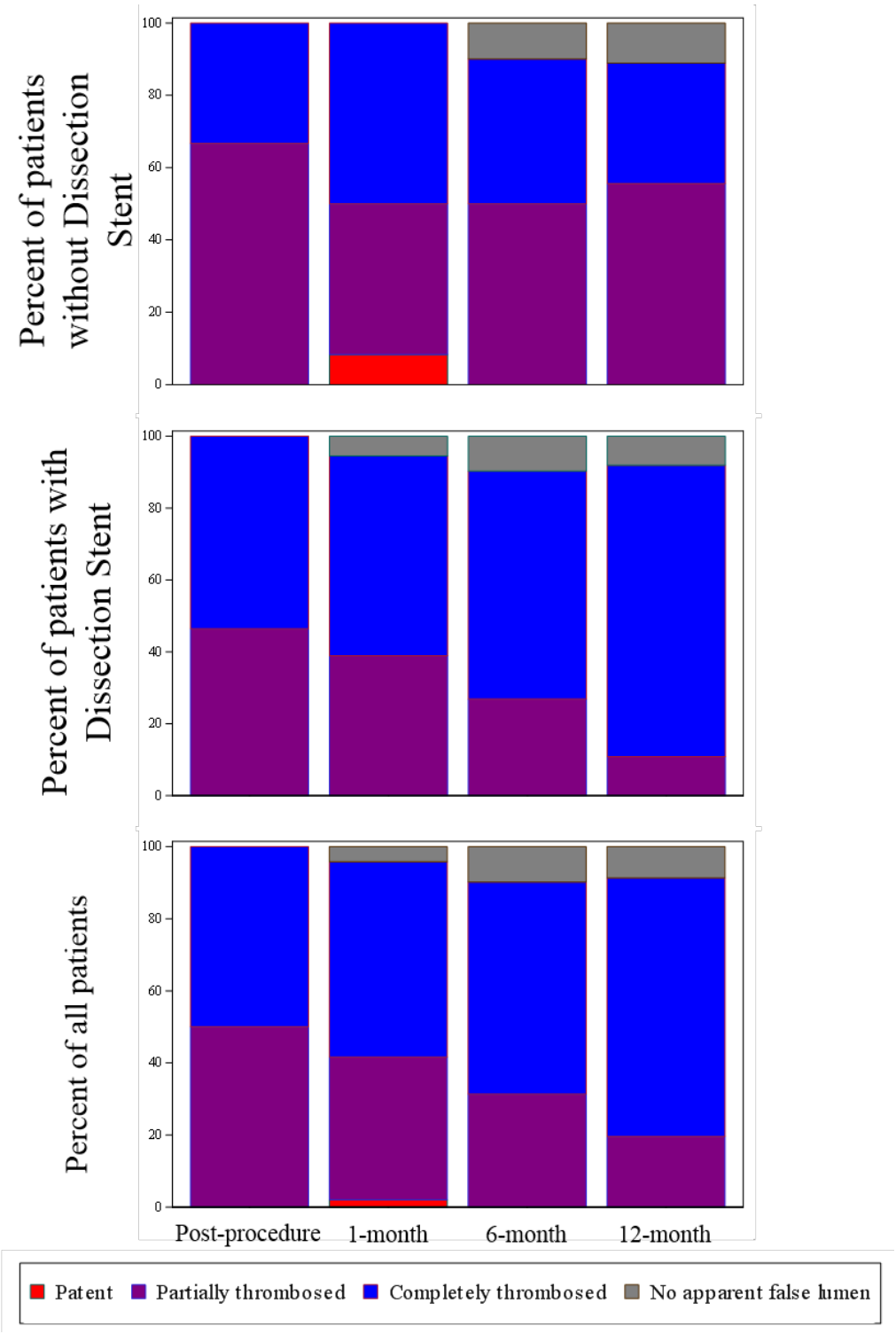


Figure 11. False lumen status within the stent-graft for patients who did not receive a Dissection Stent (labeled as patients without Dissection Stent), patients who received a Dissection Stent (labeled as patients with Dissection Stent), and the total patient population

Table 48 presents data for false lumen status within the Dissection Stent region over time based on core laboratory analysis. The rate of false lumen patency decreased over time whereby the majority of patients (97.5%) had either partial thrombosis, complete thrombosis, or no apparent false lumen any longer within the Dissection Stent region at 12 months. The one patient (2.6%) with a patent false lumen at 12 months (also with false lumen perfusion from secondary tears and patent collaterals) had a partially thrombosed false lumen in this region at subsequent follow-up.

Table 48. Status of false lumen within the Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)			
	Post-procedure	**1-month**	**6-month**	**12-month**
Patent	10.7% (3/28)[a,b,c]	11.1% (4/36)[c,d,e,f]	2.4% (1/41)[g]	2.6% (1/39)[h]
Partially thrombosed	85.7% (24/28)	83.3% (30/36)	80.5% (33/41)	79.5% (31/39)
Completely thrombosed	3.6% (1/28)	5.6% (2/36)	14.6% (6/41)	15.4% (6/39)
No apparent false lumen	0%	0%	2.4% (1/41)[i]	2.6% (1/39)[i]

[a] Patient 1130074: the false lumen in the Dissection Stent region was not assessed at 1 month and was partially thrombosed at 6 and 12 months.
[b] Patient 1130067: the patient died 96 days post-procedure (CEC unable to adjudicate), prior to completing any additional follow-up visits.
[c] Patient 1130082: the patient was lost-to-follow up following the 1-month imaging.
[d] Patient 1130038: the false lumen in the Dissection Stent region was partially thrombosed at 6 and 12 months.
[e] Patient 1130084: the false lumen in the Dissection Stent region was partially thrombosed at post-procedure and 6 months; the patient died 330 days post-procedure (CEC unable to adjudicate), prior to completing the 12-month follow-up visit.
[f] Patient 1130057: the false lumen in the Dissection Stent region was partially thrombosed at 6 and 12 months.
[g] Patient 1130058: the false lumen in the Dissection Stent region was partially thrombosed at post procedure, 1 month, and 12 months.
[h] Patient 1130069: the false lumen in the Dissection Stent region was partially thrombosed at post-procedure, 1 month, and 2 years. The false lumen in this region was not assessed at 6 months.

Figure 12 provides a visual representation of the data for false lumen status within the Dissection Stent region over time, as reported in Table 48.

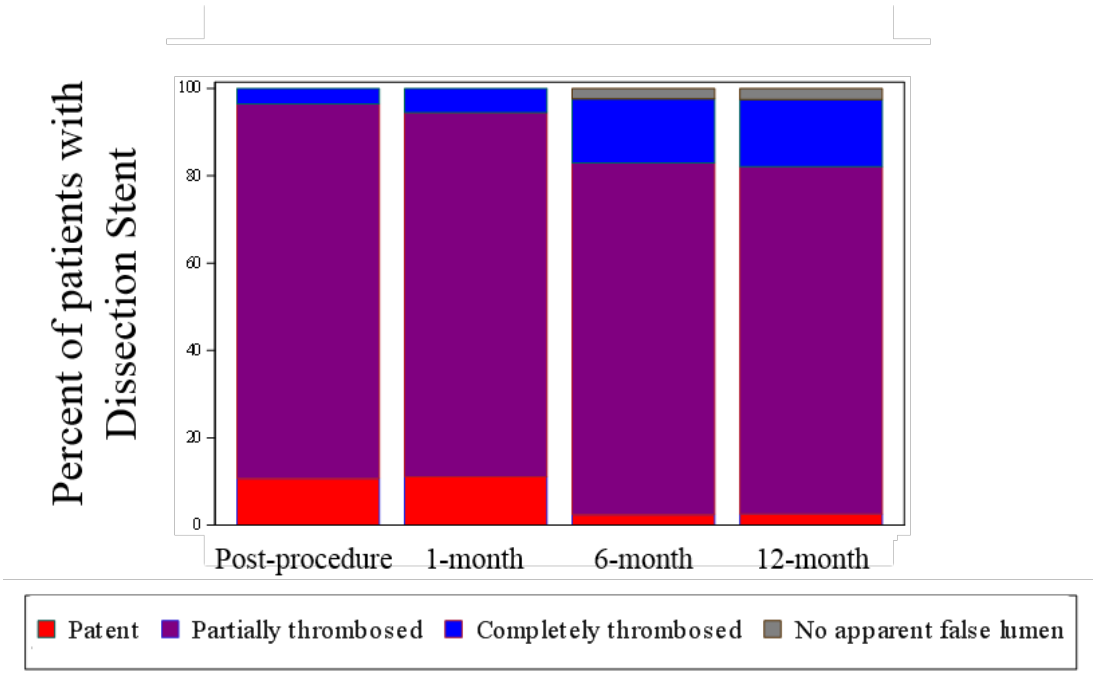


Figure 12. False lumen status within the Dissection Stent

Tables 49, 50, and 51 present data for false lumen status distal to the treated segment for patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively. Distal to the treated segment, false lumen patency was noted in 17% of patients at 12 months (7 with a Dissection Stent, 1 without a Dissection Stent). While the rate of false lumen patency distal to the treated segment initially appeared higher (at post-procedure) in the patients with a Dissection Stent, the rates were more comparable between groups by 12 months; a trend towards a higher percentage of patients with a patent false lumen distal to the treated segment is not unexpected for the group with a Dissection Stent as these patients tended to more often present with secondary tears, particularly in locations distal to the stent-graft (i.e., in the region of the branch vessels and abdominal aorta) as compared to patients who did not receive a Dissection Stent.

Table 49. Status of false lumen distal to the treated segment for patients who did not receive a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)			
	Post-procedure	**1-month**	**6-month**	**12-month**
Patent	16.7% (1/6)[a]	16.7% (2/12)[b,c]	10.0% (1/10)[a]	11.1% (1/9)[a]
Partially thrombosed	33.3% (2/6)	25.0% (3/12)	40.0% (4/10)	22.2% (2/9)
Completely thrombosed	33.3% (2/6)	33.3% (4/12)	10.0% (1/10)	22.2% (2/9)
No apparent false lumen	16.7% (1/6)	25.0% (3/12)	40.0% (4/10)	44.4% (4/9)

[a] Patient 1130081
[b] Patient 1130079
[c] Patient 1230010: partially thrombosed at subsequent time points

Table 50. Status of false lumen distal to the treated segment for patients who received a Dissection Stent based on results from core laboratory analysis

Status	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Patent	57.1% (16/28)[a-p]	22.7% (9/35)[i-l,o-s]	25.6% (10/39)[e,f,i,l,o,p,r,t,u,v]	18.4% (7/38)[b,i,p,r,s,t,w]
Partially thrombosed	21.4% (6/28)	37.1% (13/35)	48.7% (19/39)	50.0% (19/38)
Completely thrombosed	3.6% (1/28)	0%	5.1% (2/39)	5.3% (2/38)
No apparent false lumen	19.7% (5/28)	37.1% (13/35)	20.5% (8/39)	26.3% (10/38)

[a] Patient 1130047: partially thrombosed at subsequent time points.
[b] Patient 1130085.
[c] Patient 1130088: partially thrombosed at subsequent time points.
[d] Patient 1130066.
[e] Patient 1130074: n/a at 1-month, partially thrombosed at subsequent time points.
[f] Patient 1130087.
[g] Patient 1130067.
[h] Patient 1130043: partially thrombosed at subsequent time points.
[i] Patient 1130044.
[j] Patient 1130064: partially thrombosed at subsequent time points.
[k] Patient 1130082.
[l] Patient 1130084.
[m] Patient 1130060.
[n] Patient 1130052: n/a at 1-month, partially thrombosed at subsequent time points.
[o] Patient 1130053: partially thrombosed at subsequent time points.
[p] Patient 1130058: partially thrombosed at subsequent time points.
[q] Patient 1130034: n/a at 6-month, partially thrombosed at 12-month.
[r] Patient 1130038.
[s] Patient 1130013.
[t] Patient *1130024.*
[u] Patient 1130039.
[v] Patient 1130035: partially thrombosed at subsequent time points.
[w] Patient 1130068.

Table 51. Status of false lumen distal to the treated segment for all patients based on results from core laboratory analysis

Status	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Patent	50.0% (17/34)	23.4% (11/47)	22.4% (11/49)	17.0% (8/47)
Partially thrombosed	23.3% (8/34)	34.0% (16/47)	46.9% (23/49)	44.7% (21/47)
Completely thrombosed	8.8% (3/34)	8.5% (4/47)	6.1% (3/49)	8.5% (4/47)
No apparent false lumen	17.6% (6/34)	34.0% (16/47)	24.5% (12/49)	29.8% (14/47)

Figure 13 provides a visual representation of the data for false lumen status distal to the treated segment for each group over time, as reported in Tables 49, 50, and 51.

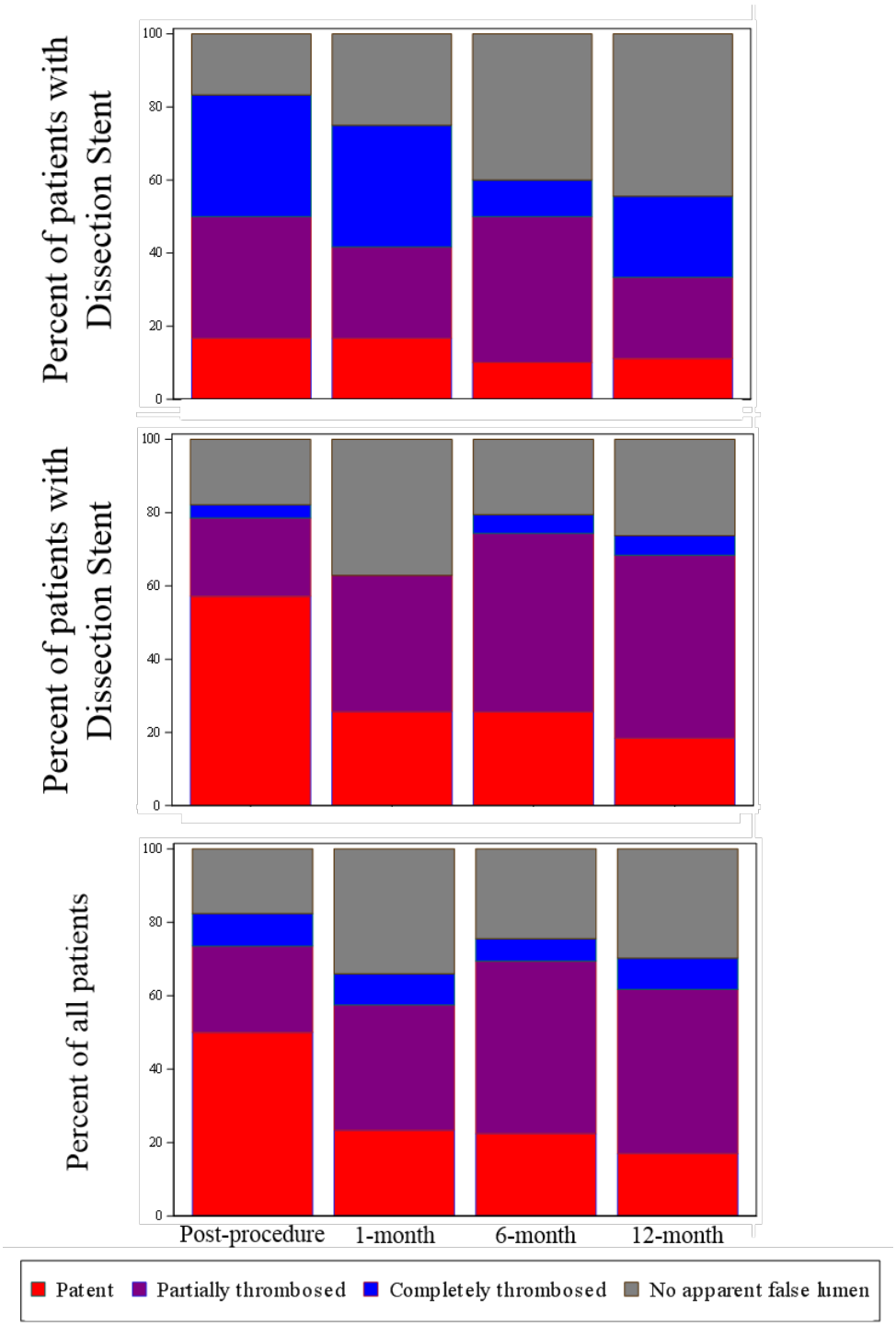


Figure 13. False lumen status distal to the treated segment for patients who did not receive a Dissection Stent (labeled as patients without Dissection Stent), patients who received a Dissection Stent (labeled as patients with Dissection Stent), and the total patient population

Progression of Dissection

Tables 52, 53, and 54 report the results from qualitative assessment by the core laboratory for progression of dissection during follow-up for patients who did not

receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively. The counts in this section are based on imaging assessment by the core laboratory (refer also to the discussion of site-reported events as provided in the following sections: "Not Protocol Defined MAEs" and "Adverse Effects that Occurred in the PMA Clinical Study"). Two patients with progression of dissection proximally and two patients with progression of dissection distally were reported by the core laboratory within 12 months. Each report occurred in a patient with a Dissection Stent, though in none of the patients did the progression appear associated with placement of the Dissection Stent (or Dissection Endovascular Graft) given the details described in the footnotes below.

Table 52. Progression of dissection in patients who did not receive a Dissection Stent based on results from core laboratory analysis

Progression	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Yes	0%	0%	0%	0%
No	100% (3/3)	100% (10/10)	100% (10/10)	100% (8/8)

Table 53. Progression of dissection in patients who received a Dissection Stent based on results from core laboratory analysis

Progression	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Yes	6.7% (1/15)[a]	6.1% (2/33)[b,c]	2.9% (1/35)[d]	0%
No	93.3% (14/15)	93.9% (31/33)	97.1% (34/35)	100% (35/35)

[a] Patient 1130060 had progression of dissection proximally, extending to Zone 0 (also with a new tear in this zone) as compared to Zone 2 at pre-procedure. The ascending aortic diameter (36.3 mm) appeared notably larger than the aortic arch diameter (28.8 mm) at pre-procedure, such that the potential for underlying disease in the ascending aortic segment cannot be ruled out as a potential contributing factor to progression of dissection proximally.

[b] Patient 1130088 had progression of dissection distally, extending to Zone 10 as compared to Zone 9 at pre-procedure, whereas the Dissection Stent had only extended to Zone 5. Abdominal false lumen perfusion through a secondary tear as well as collateral vessels was noted at the same follow-up time point, which cannot be ruled out as a potential contributing factor to progression of dissection distally.

[c] Patient 1130002 had progression of dissection distally, but only within the celiac artery, not the aorta.

[d] Patient 1130039 had progression of dissection proximally. The patient had preexisting Type A dissection prior to the index procedure (per CEC adjudication) as well as a patent false lumen proximal and distal to the treated segment at 6 months.

Table 54. Progression of dissection in all patients based on results from core laboratory analysis

Progression	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Yes	5.6% (1/18)	4.7% (2/43)	2.2% (1/45)	0%
No	94.4% (17/18)	95.3% (41/43)	97.8% (44/45)	100% (43/43)

Branch Vessel Patency

Table 55 reports the patency status of the branch vessels (left subclavian, spinal, celiac, superior mesenteric, renal, and common iliac arteries), as assessed by the core laboratory at each time point for all patients. The only aortic branch vessel occlusions noted by the core laboratory during follow-up involved the left subclavian artery; there

were no spinal, celiac, SMA, or renal artery occlusions, and the few patients with common iliac artery occlusions at follow-up also had occlusion noted at pre-procedure.

Table 55. Patency of branch vessels in all patients based on results from core laboratory analysis

Artery Status	Percent Patients (number/total number)				
	Pre-procedure	**Post-procedure**	**1-month**	**6-month**	**12-month**
LSA					
Patent	100% (71/71)	66.7% (22/33)	69.4% (34/49)	76.5% (39/51)	75.0% (36/48)
Occluded	0%	3.0% (1/33)	6.1% (3/49)	7.8% (4/51)	4.2% (2/48)
Revascularization	0%	30.3% (10/33)	24.5% (12/49)	15.7% (8/51)	18.8% (9/48)
Unknown	0%	0%	0%	0%	2.1% (1/48)
Spinal artery					
Patent	100.0% (72/72)	100% (33/33)	100% (49/49)	100% (51/51)	100% (48/48)
Occluded	0%	0%	0%	0%	0%
Unknown	0%	0%	0%	0%	0%
Celiac artery					
Patent	98.6% (69/70)	100% (32/33)	100% (48/48)	100% (51/51)	95.8% (46/48)
Occluded	1.4% (1/70)	0%	0%	0%	0% 4.2% (2/48)
Unknown	0%	0%	0%	0%	
SMA					
Patent	100% (68/68)	100% (33/33)	100% (49/49)	100% (50/50)	97.9% (47/48)
Occluded	0%	0%	0%	0%	0%
Unknown	0%	0%	0%	0%	2.1% (1/48)
Left renal artery					
Patent	100% (68/68)	100% (33/33)	100% (48/48)	100% (50/50)	100% (47/47)
Occluded	0%	0%	0%	0%	0%
Unknown	0%	0%	0%	0%	0%
Right renal artery					
Patent	98.5% (66/67)	100% (33/33)	100% (49/49)	100% (50/50)	100% (46/46)
Occluded	1.5% (1/67)	0%	0%	0%	0%
Unknown	0%	0%	0%	0%	0%
Left CIA					
Patent	100% (62/62)	100% (32/32)	100% (48/48)	98.0% (48/49)	100% (46/46)
Occluded	0%	0%	0%	0%	0%
Unknown	0%	0%	0%	2.0% (1/49)	0%
Right CIA					
Patent	93.5% (58/62)	100% (32/32)	97.9% (47/48)	96.0% (47/49)	95.7% (44/46)
Occluded	6.5% (4/62)	0%	2.1% (1/48)	2.0% (1/49)	4.3% (2/46)
Unknown	0%	0%	0%	2.0% (1/49)	0%

Device Integrity

Tables 56, 57, and 58 report the occurrence of device integrity findings at each follow-up time point for patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively, as determined by the core laboratory. There were no device integrity losses (i.e., stent fractures) within 12 months, only isolated observations of graft kink in one patient, device compression in two patients (involving the Dissection Endovascular Graft in one and the Dissection Stent in one), and increasing overlap between adjacent z-stent segments of a Dissection Stent in one, none of which were associated with adverse clinical sequelae or the need for reintervention.

Table 56. Device integrity findings in patients who did not receive a Dissection Stent based on results from core laboratory analysis

Finding	Number of Occurrences			
	Post-procedure	1-month	6-month	12-month
Kink	0	0	0	0
Stent fracture	0	0	0	0
Device compression	0	0	0	0
Device infolding	0	0	0	0
Other	0	0	0	0

Table 57. Device integrity findings in patients who received a Dissection Stent based on results from core laboratory analysis

Finding	Number of Occurrences			
	Post-procedure	1-month	6-month	12-month
Kink	0	0	0	1[c]
Stent fracture	0	0	0	0
Device compression	0	0	2[a,d]	1[d]
Device infolding	0	0	0	0
Other	0	0	1[b]	0

[a] Patient 1130039 had device compression of the stent-graft; patient had pre-existing Type A dissection.
[b] Patient 1130017 had increasing overlap of the 5th and 6th rings of the proximal Dissection Stent; no migration or component separation noted.
[c] Patient 1130069 had a kink in the stent-graft; descending thoracic aorta with notable angulation/curvature at pre-procedure.
[d] Patient 1130058 had device compression of the Dissection Stent; patient had slight true lumen diameter decrease in setting of false lumen perfusion from secondary tears and collateral vessels as well as false lumen diameter increase along treated region.

Table 58. Device integrity findings in all patients based on results from core laboratory analysis

Finding	Number of Occurrences			
	Post-procedure	1-month	6-month	12-month
Kink	0	0	0	1
Stent fracture	0	0	0	0
Device compression	0	0	2	1
Device infolding	0	0	0	0
Other	0	0	1	0

Device Migration

Migration was defined as antegrade or retrograde movement of the proximal or distal component of the endoprosthesis greater than 10 mm relative to anatomical landmarks identified on the first post-operative CT scan, as identified by the core laboratory and confirmed by the CEC. Tables 59, 60, and 61 report device migration results based on core laboratory analysis and CEC confirmation for patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively. There were 4 reports of CEC-confirmed migration > 10 mm within 12 months, each of which occurred in a patient who received a Dissection Stent, though there was no migration of the Dissection Stent, only migration of the Dissection Endovascular Graft. However, in all cases, there appeared an inadequate proximal

landing zone length (< 20 mm of nondissected aorta) as well as graft undersizing in three based on measurements of the core laboratory relative to the location of graft placement. None of the patients required a secondary intervention to treat migration according to the site. The rates of migration in the current study (5.4% at 6 months, 2.0% at 12 months) appear comparable to the rates observed in the acute patient cohort from the feasibility study (described in Section XI) involving the previous graft design that had barbs (6.8% at 6 months, 4.8% at 12 months).

Table 59. Device migration in patients who did not receive a Dissection Stent based on results from core laboratory analysis and CEC confirmation

Finding	Percent Patients (number/total number)	
	6-month	12-month
Migration (> 10 mm)	0% (0/9)	0% (0/8)

Table 60. Device migration in patients who received a Dissection Stent based on results from core laboratory analysis and CEC confirmation

Finding	Percent Patients (number/total number)	
	6-month	12-month
Migration (> 10 mm)	7.3% (3/41)[a,b,c]	2.6% (1/38)[d]

[a] Patient 1130020 had caudal migration of the Dissection Endovascular Graft in the likely setting of graft undersizing as well as an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. No secondary interventions have been performed to treat this migration

[b] Patient 1130074 had caudal migration of the Dissection Endovascular Graft in the likely setting of an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. The patient underwent a secondary intervention 131 days post-procedure to treat device separation attributed to an expanding false lumen. The patient was treated with coil embolization and stent placement.

[c] Patient 1130084 had caudal migration of the Dissection Endovascular Graft in the likely setting of graft undersizing as well as an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. No secondary interventions have been performed to treat this migration. The patient died 330 days post-procedure due to atherosclerotic cardiovascular disease.

[d] Patient 1130044 had caudal migration of the Dissection Endovascular Graft in the likely setting of graft undersizing as well as an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory. No secondary interventions have been performed to treat this migration.

Table 61. Device migration in all patients based on results from core laboratory analysis and CEC confirmation

Finding	Percent Patients (number/total number)	
	6-month	12-month
Migration (> 10 mm)	5.4% (3/56)	2.0% (1/51)

Component Separation

Tables 62, 63, and 64 present data for the occurrence of component separation findings for patients who did not receive a Dissection Stent, patients who received a Dissection Stent, and the total patient population, respectively, as determined by the core laboratory. Component separation occurred in 5.9% at 6 months (2 with a Dissection Stent, 0 without a Dissection Stent) and 2.0% at 12 months (1 with a Dissection stent, 0

without a Dissection Stent). Two reports involved separation between the Dissection Endovascular Graft and Dissection Stent, while one report involved separation between two Dissection Endovascular Grafts. In each case, there appeared aortic elongation, and there were no new tears or branch vessel occlusions noted in conjunction with the separation.

Table 62. Component separation for patients who did not receive a Dissection Stent based on results from core laboratory analysis

Finding	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Component separation	0% (0/5)	0% (0/8)	0% (0/7)	0% (0/9)

Table 63. Component separation for patients who received a Dissection Stent based on results from core laboratory analysis

Finding	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Component separation	0% (0/29)	0% (0/40)	6.8% (3/44)[a,b,c]	2.5% (1/40)[a]

[a] Patient 1130020 had separation between the Dissection Endovascular Graft and Dissection Stent in the setting of approximately 15 mm of apparent aortic elongation between the left common carotid and celiac (23 mm at 12 months), as compared to 11.9 mm of separation between components at 6 months (18.1 mm at 12 months).
[b] Patient 1130074 had separation between the Dissection Endovascular Graft and Dissection Stent in the setting of approximately 23 mm of apparent aortic elongation between the left common carotid and celiac, as compared to 8.9 mm of separation between components.
[c] Patient 1130084 had separation between two Dissection Endovascular Grafts in the setting of approximately 52 mm of apparent aortic elongation between the left common carotid and celiac, as compared to 29.5 mm of separation between components.

Table 64. Component separation for all patients based on results from core laboratory analysis

Finding	Percent Patients (number/total number)			
	Post-procedure	1-month	6-month	12-month
Component separation	0% (0/34)	0% (0/48)	5.9% (3/51)	2.0% (1/49)

Secondary Interventions

The percent of patients who required a secondary intervention within 12 months was 12.3% (9/73). This included 6.7% (1/15) of patients who did not receive a Dissection Stent and 13.8% (8/58) of patients who did receive a Dissection Stent.

Tables 65 and 66 list the patient-level details for each reintervention (days to reintervention, site-reported reasons for reintervention, and type of reintervention) for those without a Dissection Stent and those with a Dissection Stent, respectively.

Table 65. Site-reported reasons for secondary intervention in patients who did not receive a Dissection Stent

Patient	Days Post-procedure	Reason for Intervention (as reported by the site)	Type of Intervention
1130079[a]	50	Back pain, obstruction/compromise of branch vessels, Type I proximal	Three ancillary components placed and ascending aorta to innominate and LCC artery bypass

Patient	Days Post-procedure	Reason for Intervention (as reported by the site)	Type of Intervention
		and distal entry-flow, and sealing re-entry tear	

[a] Patient had graft undersizing as well as an inadequate proximal landing zone (diameter and length) relative to the location of graft placement according to measurements by the core laboratory. The patient also presented with preexisting Type A dissection according to CEC adjudication.

Table 66. Site-reported reasons for secondary intervention in patients who received a Dissection Stent

Patient	Days Post-procedure	Reason for Intervention (as reported by the site)	Type of Intervention
1130006[a]	153	Secondary entry-tear and Type I proximal entry-flow	Ascending aorta and total arch replacement; innominate, LCC artery, and LSA reconstruction
1130038	12	Bleeding from right groin, right femoral pseudoaneurysm	Right groin exploration with bovine patch repair of the right femoral artery
1130044[b]	65	Secondary entry-tear just distal to the covered stent	Placement of two covered endografts
1130050	17	Pain in left arm with no signals in the left wrist; sensory slightly diminished	Left carotid to subclavian bypass and left brachial artery embolectomy
1130074[c]	131	Device/component separation attributed to expanding false lumen	Coil embolization and stent placement
1130082[d]	6	Right retained hemothorax	Right video-assisted thoracoscopic surgery evacuation of hematoma, decortication of right lung, flexible bronchoscopy
1130084	5	Right common iliac artery true lumen compression	Stent placement
1130086	2	Abdominal discomfort and rapid expansion of the abdominal false lumen with probable pseudoaneurysm	Coil embolization
	15	Rapidly expanding AAA, possible pseudoaneurysm	Abdominal aortic and bilateral iliac artery replacement with removal of old EVAR stent-graft system

[a] Patient had graft undersizing as well as an inadequate proximal landing zone (diameter and length) relative to the location of graft placement according to measurements by the core laboratory.
[b] Patient had graft undersizing as well as an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory.
[c] Patient had separation between the Dissection Graft and Stent in the setting of approximately 23 mm of apparent aortic elongation between the left common carotid and celiac, as compared to 8.9 mm of separation between components based on the results from core lab analysis.
[d] Patient had graft undersizing as well as an inadequate proximal landing zone (length) relative to the location of graft placement according to measurements by the core laboratory.

Longer-term Follow-up (> 12 months)

Long-term follow-up of pivotal study patients out to 5 years is ongoing, the eligibility for which is summarized in Table 67.

Table 67. Longer-term follow-up availability

Timepoint	Patients Eligible for Follow-up	Percent of Data Available		Adequate Imaging to Assess the Parameter						Events Occurring Before Next Interval			
		Clinical Assessment	CT	Size Increase in Stent-graft	Size Increase in Dissection Stent[a]	Entry-flow in Thoracic Aorta	Entry-flow in Abdominal Aorta	Migration	Device Integrity	Death	Conversion	LTF/ WTHD	Not Due for Next Visit
2-year	50	82.0% (41/50)	84.0% (42/50)	82.0% (41/50)	75.0% (30/40)	78.0% (39/50)	70.0% (35/50)	74.0% (37/50)	82.0% (41/50)	1	0	3	8
3-year	38	73.7% (28/38)	76.3% (29/38)	63.2% (24/38)	56.3% (18/32)	60.5% (23/38)	55.3% (21/38)	60.5% (23/38)	63.2% (24/38)	1	0	1	24
4-year	12	25.0% (3/12)	16.7% (2/12)	25.0% (3/12)	20.0% (2/10)	25.0% (3/12)	25.0% (3/12)	16.7% (2/12)	25.0% (3/12)	0	0	0	12

LTF: lost to follow-up; WTHD: withdrawal.

[a] Size increase in Dissection Stent assessment only applies to patients who received a Dissection Stent.

Three deaths and one conversion to open repair were reported beyond 12 months (>365 days). All patient deaths were adjudicated by the CEC as not related to dissection repair. The conversion to open repair occurred 650 days post-procedure due to graft infection in a patient who earlier had a urinary tract infection, pneumonia, heal ulcers, and sepsis 518 days post-procedure, followed by an additional report of sepsis 577 days post-procedure and wound infection 617 days post-procedure. The patient survived the conversion and exited the study 680 days post-procedure.

Other notable adverse events reported beyond 12 months included stroke in one patient (adjudicated by the CEC as not related to dissection repair), bowel ischemia in one patient (adjudicated by the CEC as not related to dissection repair), and renal failure requiring dialysis in two patients (adjudicated by the CEC as not related to dissection repair in one patient; the event was not adjudicated in the other patient who was the same patient that underwent conversion to open surgical repair due to graft infection 650 days post-procedure).

There were four patients with newly identified transaortic growth in the Dissection Endovascular Graft region beyond 12 months, including one with a net increase (> 5 mm) in false lumen diameter (in setting of false lumen flow from unknown entry-flow source, secondary tear, and patent collaterals based on core laboratory analysis), two with either no change (≤ 5 mm) or a net decrease (> 5 mm) in false lumen diameter, and one with an indeterminate change in false lumen diameter due to a non-contrast study having been performed, such that an assessment for the presence/absence of false lumen flow was also indeterminate.

There were five patients with newly identified transaortic growth in the Dissection Stent region beyond 12 months, including two patients with a net increase (> 5 mm) in false lumen diameter (both in the setting of a secondary tear, and one also with patent collaterals), two with either no change (≤ 5 mm) or a net decrease (> 5 mm) in false lumen diameter, and one with an indeterminate amount of growth in the false lumen due to a non-contrast study; however, this patient also has an abdominal aortic aneurysm that had not been treated, and which may be a contributing factor to aortic growth in this region.

There were six patients with newly identified transaortic growth distal to the treated segment and within the dissected aorta beyond 12 months, including four patients with an increase (> 5 mm) in the false lumen diameter in the setting of false lumen perfusion from secondary tears and patent collateral vessels, and two patients no net change (≤ 5 mm) in false lumen diameter.

There were two patients with newly identified proximal Type I entry-flow and graft migration beyond 12 months, both in the setting of an inadequate proximal landing zone. Three additional patients had newly identified graft migration beyond 12 months, two in the setting of inadequate proximal landing zone and one in the setting of aortic dilatation. There were no instances of a patent false lumen within either the Dissection Endovascular Graft or Dissection Stent regions beyond 12 months. There were three

patients with a patent false lumen distal to the treated segment, each of which had a patent false lumen at earlier follow-up.

In total, five patients underwent nine secondary interventions beyond 12 months, including the patient who underwent conversion due to graft infection. Three of the four remaining patients underwent other types of surgical procedures, as follows. Composite aortic root replacement and total arch replacement in one patient was performed due to sinus of Valsalva aneurysm with aortic valve insufficiency (secondary to bicuspid aortic valve) and Type I entry-flow according to the site; the core laboratory reported no progression of dissection, no new tears, and noted only unknown entry-flow types as well as flow from secondary tears and collaterals throughout follow-up. Another patient underwent ascending aorta replacement along with aortic valve replacement due to a new tear in the ascending thoracic aorta and intermittent chest pressure per the site; the thoracic and abdominal false lumens were completely thrombosed both prior to and following observation of the newly reported tear in the ascending aorta, and there was no progression of dissection reported by the core laboratory. The third patient experienced worsening abdominal pain with radiation to the back and right thigh, paresthesia and numbness in the right leg when trying to walk, and thrombus in the right common femoral artery (CFA) extending into the profundal and superficial femoral artery (SFA), which was treated with embolectomy and thrombectomy of the right femoropopliteal artery. Prior to this (but still beyond 12 months), the patient had undergone multiple percutaneous reinterventions also for abdominal pain as well as treatment of secondary tears and reported collapse of a stent in the SMA; no new tears or progression of dissection were noted by the core laboratory throughout the follow-up for this patient. The last patient with reintervention beyond 12 months had an additional stent-graft component placed for the site-reported reason of penetrating ulcer and aneurysmal degeneration; there was no dilatation, progression of dissection, or new tears noted by the core laboratory.

The available longer-term follow-up data provide additional information supporting the safety and effectiveness of the Zenith® Dissection Endovascular System.

3. Subgroup Analyses

Treatment with or without a Dissection Stent

Although the study was not powered to assess for differences in outcomes based on the different component combinations (namely the presence vs. absence of a Dissection Stent), the results were analyzed and reported separately in the preceding sections where appropriate. In summary, there appeared no additional risks from use of the Dissection Stent, which instead appeared to provide for more favorable aortic remodeling in patients who more often presented with malperfusion, longer dissections, larger false lumen diameters, and more secondary tears in the region of the branch vessels and abdominal aorta as compared to the patients who were treated with the Dissection Endovascular Graft alone, often in the setting of rupture. Favorable aortic remodeling may improve the ease of performing additional interventions if needed.

Gender

There was a reasonable representation in the population of males (n = 45, 67.2%) and females (n = 22, 32.8%) enrolled in this study who were evaluable for the primary safety and effectiveness endpoints, allowing for further analysis of outcomes by gender.

No significant differences between males and females with respect to primary safety and effectiveness endpoints were found. For the primary safety endpoint, the 30-day freedom from MAE rate was 71.1% (32/45) for males and 72.7% (16/22) for females. For the primary effectiveness endpoint, the 12-month device success rate was 96.9% (62/64) for males and 95.5% (21/22) for females.

Overall, the results appeared to be comparable between males and females treated with the Zenith Dissection Endovascular System.

4. Pediatric Extrapolation

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

F. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR Part 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 study included 143 investigators of which zero (0) were full-time or part-time employees of the sponsor and 12 had disclosable financial interests/arrangements as defined in 21 CFR Part 54.2(a), (b), (c), and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: none.
- Significant payment of other sorts: 12 investigators.
- Proprietary interest in the product tested held by the investigator: none.
- Significant equity interest held by investigator in sponsor of covered study: none.

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Continued Access

Ten (10) patients were enrolled under continued access using the same device and inclusion/exclusion criteria as the pivotal study. There were two deaths. The reported causes were ruptured retrograde Type A dissection and aortic dissection. In both cases, the

results from core laboratory analysis of the pre-procedure imaging indicated a length < 20 mm between the left common carotid artery and proximal extent of dissection as well as a proximal extent of dissection that extended proximal to the LSA. One patient had proximal Type I entry-flow and two patients had graft migration during follow-up, each of which occurred in the setting of a proximal landing zone within dissected aorta as well as graft undersizing. While the event rates in the continued access study appeared higher than in the pivotal study, the results did not raise new safety or effectiveness concerns with respect to treatment of acute dissections, because similar to the pivotal study, the events were isolated to patients treated outside of the intended use (proximal landing zone in dissected aorta, pre-existing extension of dissection proximal to the LSA, graft undersizing).

Feasibility Study

Prior to the pivotal study for the subject device, a feasibility study involving a previous stent-graft design with barbs (TX2) (compared to no barbs for the device used in the pivotal study) and bare stent made of stainless steel (compared to nitinol for the device used in the pivotal study), was performed. The patient selection criteria for the feasibility study were broader than the patient selection criteria for the pivotal study. Specifically, the feasibility study included acute Type B dissection patients treated within 14 days of symptom onset (n=55), as well as non-acute Type B dissection patients who were treated within 90 days of symptom onset (n=31). Additionally, patients were eligible for enrollment if they had any one of the following conditions: branch vessel obstruction/compromise; periaortic effusion/hematoma; resistant hypertension; persistent pain/symptoms; transaortic growth ≥ 5 mm within 3 months; or transaortic diameter ≥ 40 mm. Reported events in the non-acute dissection cohort of patients from the feasibility study included retrograde dissection in four subjects (1 with new Type A dissection that was not continuous with the originally treated Type B dissection, and 3 with a proximal landing zone in dissected aorta; with death in 1 and both rupture and death in 1), proximal Type I entry flow in two subjects (both with a proximal landing zone in dissected aorta and graft undersizing), and migration in four subjects (each with a proximal landing zone in dissected aorta and graft undersizing). While the event rates in the chronic patient cohort from the feasibility study appeared higher than in the pivotal study for acute patients, the results did not raise any safety or effectiveness concerns with respect to the treatment of chronic dissections because the events were isolated to patients treated outside of the intended use (proximal landing zone in dissected aorta, graft undersizing).

Sponsor-Investigator Experience

The previous graft design with barbs (TX2) was also used for the treatment of chronic dissection in a sponsor-investigator IDE. In total, 28 patients received the TX2 or a one-piece version of TX2 (referred to as TX1) for the treatment of chronic dissection with aneurysmal degeneration.2 The mean length of follow-up was nearly 5 years. One aneurysm-related mortality was reported, resulting in a rate similar to that for the pivotal study (with shorter-term follow-up). The other reported events through 5 years included two migrations. The results raised no safety or effectiveness concerns with respect to the treatment of chronic dissections.

Japan Post-Market Study

The previous graft design with barbs (TX2) and bare stent made of stainless steel were the subject of a post-market study in Japan. While the device was indicated for acute, complicated Type B aortic dissection and enrollment was to be in accordance with the intended use, a proportion of the patients enrolled in the study had chronic dissections. Specifically, 23 patients were treated >14 days after symptom onset, including 14 patients treated > 6 weeks after symptom onset. No ruptures or Type I endoleaks were reported and one migration was reported in the cranial direction,, which compares favorably to the results from the pivotal study, thus raising no safety or effectiveness concerns with respect to the treatment of chronic dissections.

Clinical experience with the TX2

In order to support an indication for chronic dissection, clinical experience from the Zenith TX2 TAA Endovascular Graft (TX2) was leveraged. The covered component of the Zenith Dissection Endovascular System is predicated on the TX2, specifically the proximal component of the two-piece (proximal component and distal component) system. The TX2 has been indicated for the endovascular treatment of aneurysms and ulcers of the descending thoracic aorta in the US since 2008, Canada since 2009, and Japan since 2011. Prior to approval in these countries, the TX2 was CE Marked (in 2004) for a broader indication that included treatment of patients with atherosclerotic or enlarging aneurysms, symptomatic acute or chronic dissections, and contained ruptures. Approximately 85,000 TX2 components have been distributed globally since approval in the US, and the device was not removed from any market for any reason.

The original US PMA approval of TX2 for treatment of aneurysms/ulcers was based on results from 160 aneurysm/ulcer patients treated with TX2 as compared to 70 aneurysm/ulcer patients who underwent open surgical repair. The results from the study established safety and effectiveness of TX2 as described in the SSED for P070016.
Since the Zenith TX2 Dissection Endovascular Graft is intended to seal entry tears and to exclude aneurysms associated with chronic dissection, the vascular anatomy suitability for endovascular repair (e.g., landing zones, aortic diameters) is very similar to that required for safe and effective use of the TX2.Additionally, the designs of the Zenith Dissection Endovascular Graft and the commercially available Zenith TX2 TAA Endovascular Graft are the same except for the availability of additional sizes (smaller diameter graft components and more tapered components) and the removal of barbs. Based on the combination of available bench testing data and clinical data, there are no evident safety or effectiveness concerns associated with these differences and therefore building on prior experience from the Zenith TX2 Endovascular Graft is appropriate to support the use of the device to exclude aneurysms associated with chronic dissections for the current device PMA.

XII. 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 was not referred to the panel, an FDA advisory

committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The 30-day survival rate (primary study endpoint) was 95.5% (64/67), which met the performance goal of 79.4% ($p < 0.001$).

Secondary endpoints to evaluate effectiveness included evaluation of total, true lumen and false lumen diameters throughout the aorta, branch patency, and absence of migration, false lumen perfusion, false lumen patency, dissection progression, device integrity observations, component separation, and secondary interventions. With respect to aortic dimensions, generally favorable remodeling was observed, with increases in the true lumen diameters and decreases in the false lumen diameters, which was most pronounced in patients who received a Dissection Stent. Overall, transaortic diameter growth (> 5 mm) in the stent-graft region was observed in 14.9% of patients at 12 months (6 with a Dissection Stent, 1 without a Dissection Stent), including two with a net increase (> 5 mm) in false lumen diameter (both in the setting of Proximal Type I entry flow), whereas the remaining five patients had either no change (≤ 5 mm) or a net decrease (> 5 mm) in false lumen diameter.

In the Dissection Stent region, there was no change (≤ 5 mm) in the average total aortic, true lumen, or false lumen diameters from post-procedure to 12 months. Overall, transaortic diameter growth (> 5 mm) in the Dissection Stent region was observed in 38.5% of patients at 12 months, including six with a net increase (> 5 mm) in false lumen diameter (each in the setting of false lumen perfusion for secondary tears and patent collateral vessels), whereas the remaining nine patients had no change (≤ 5 mm) in false lumen diameter.

Distal to the treated segment, there appeared an increase (> 5 mm) in the total and false lumen diameters with no change (≤ 5 mm) in true lumen diameter for patients without a Dissection Stent, compared to no change (≤ 5 mm) in the total, true, and false lumen diameters from post-procedure through 12 months for patients with a Dissection Stent. Overall, transaortic diameter growth (> 5 mm) distal to the treated segment was observed in 40.7% of patients at 12 months (8 with a Dissection Stent, 3 without a Dissection Stent), including seven with a net increase (> 5 mm) in false lumen diameter (each in the setting of false lumen perfusion from secondary tears and patent collateral vessels), with the remaining four either having a net decrease (> 5 mm) or no change (≤ 5 mm) in false lumen diameter.

There were no spinal, celiac, superior mesenteric, or renal artery occlusions noted by the core laboratory during follow-up. The only aortic branch vessel occlusions noted by the core laboratory during follow-up involved the left subclavian artery.
There were 4 reports of CEC-confirmed stent-graft migration > 10 mm within 12 months. In all cases, there appeared an inadequate proximal landing zone length (< 20 mm of

nondissected aorta) as well as graft undersizing in three, based on measurements of the core laboratory relative to the location of graft placement. None of the patients required a secondary intervention to treat migration according to site reports.

Seven cases of Type I proximal entry flow into the thoracic false lumen were observed through 12 months. Each patient had evidence of an inadequate proximal landing zone (i.e., aortic diameter > 38 mm and/or length of non-dissected aorta < 20 mm) and often times also graft undersizing. Overall, the proximal Type I entry-flow rate was 6.4% at 12 months (2 with a Dissection Stent, 1 without a Dissection Stent).

There were no patients with a patent false lumen in the region of the Dissection Endovascular Graft at 12 months, and 80.4% had complete thrombosis (including those no longer with an apparent false lumen), which appeared greater in the patients with a Dissection Stent (89.2%) compared to the patients without a Dissection Stent (44.4%). Within the Dissection Stent region, false lumen patency was noted in 2.6% of patients at 12 months. Distal to the treated segment, false lumen patency was noted in 17% of patients at 12 months (7 with a Dissection Stent, 1 without a Dissection Stent).

Two patients with progression of dissection proximally and two patients with progression of dissection distally were reported by the core laboratory within 12 months. In none of the patients did the progression appear associated with placement of the Dissection Stent (or Endovascular Graft). Notably, site-reported extensions of dissections are addressed in the Safety Conclusions.

There were no device integrity losses (i.e., stent fractures) within 12 months, only isolated observations of graft kink in one patient, device compression in two patients (involving the Dissection Endovascular Graft in 1 and the Dissection Stent in 1), and increasing overlap between adjacent z-stent segments of a Dissection Stent in one, none of which were associated with adverse clinical sequelae or the need for reintervention.

Component separation occurred in 5.9% of patients at 6 months (2 with a Dissection Stent, 0 without a Dissection Stent) and 2.0% of patients at 12 months (1 with a Dissection Stent, 0 without a Dissection Stent). Two reports involved separation between the Dissection Endovascular Graft and Dissection Stent, while one report involved separation between two stent-grafts. In each case, there appeared aortic elongation, and there were no new tears or branch vessel occlusions noted in conjunction with the separation.

The percent of patients who required a secondary intervention within 12 months was 12.3% (8 with a Dissection Stent, 1 without a Dissection Stent).

The results beyond 12 months were consistent with the findings through 12 months, raising no new effectiveness concerns.

The migrations and Type I proximal entry flow into the false lumen associated with inadequate proximal landing zone (i.e., aortic diameter > 38 mm and/or length of non-

dissected aorta < 20 mm) and graft undersizing underscore the importance of adhering to the patient selection and sizing recommendations in the device label.

B. Safety Conclusions

The risks of the device are based on laboratory studies and data collected in the clinical study to support PMA approval as described above. The 30-day freedom from MAE rate (additional hypothesis-driven safety endpoint) was 71.6% (48/67), which met the performance goal of 51.2% ($p < 0.001$).

Protocol-defined MAEs of particular interest that occurred within 30 days are as follows:

- Stroke in 6.8% of patients (5/52 with a Dissection Stent, 0/15 without a Dissection Stent)
- Paraplegia in 2.7% of patients (2/52 with a Dissection Stent, 0/15 without a Dissection Stent)
- Paraparesis in 4.1% of patients (2/52 with a Dissection Stent, 1/15 without a Dissection Stent).

While not protocol-defined MAEs, additional (vascular) site-reported events of interest that occurred within 30 days included rupture in 1.4% of patients (1/52 with a Dissection Stent, 0/15 without a Dissection Stent) and retrograde dissection in 1.4% of patients (1/52 with a Dissection Stent, 0/15 without a Dissection Stent). While there were additional reports of rupture (n=1) and retrograde dissection (n=3) between 31-365 days, each occurred in a patient with preexisting Type A dissection, underscoring the importance of an adequate proximal landing zone in non-dissected aorta.

The results beyond 12 months raise no new safety concerns.

C. Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in the clinical study conducted to support PMA approval as described above. The probable benefit of the Zenith Dissection Endovascular System is the endovascular treatment of aortic dissections, thereby avoiding open surgery and the mortality and morbidity associated with untreated Type B aortic dissection.

The probable risks of the device are also based on data collected in the clinical study conducted to support PMA approval as described above. Notably, information regarding dissections outside of the treated segment was presented in both the safety and effectiveness results sections above. In summary:

There were four safety-related events associated with dissections outside of the treated area reported by the sites. These events included three retrograde progression of pre-existing Type A dissection and one new Type A dissection. None were considered retrograde progression of Type B dissection to Type A dissection. These events were reported as "retrograde dissections." In other studies, retrograde dissection would normally be defined

as proximal extension of a treated Type B dissection.The core lab reported two proximal and two distal progressions of dissection (with 1 of the distal dissections being within the celiac artery), based on imaging assessment done to evaluate device effectiveness. Two of these patients died within 365 days. In none of the patients did the progression appear associated with placement of the Dissection Stent or Endovascular Graft and instead were associated with secondary tears, collateral flow, false lumen patency and pre-existing conditions.

Although there was a total of eight reports of retrograde dissection/dissection extension, the four site-reported events were remote from the treated segment and the four core-lab-reported progressions of dissection had contributing factors that led to the conclusion that they were not caused by the dissection treatment. Based on this information, as well as the risks described above, the risks associated with use of the Zenith Dissection Endovascular System are consistent with other endovascular grafts intended to treat Type B dissections. Major events, such as rupture, were infrequent in the clinical study, but often associated with inappropriate patient selection.

Additional factors to be considered in determining probable risks and benefits for the Zenith Dissection Endovascular System included the availability of a bare stent component, which can further assist in the treatment of aortic dissection and be placed without risk for coverage of branch vessels in the visceral aortic segment through which Type B aortic dissections often extend. In addition to contributing to the remodeling of the aorta, presence of the bare stent may facilitate necessary additional interventions.

1.Patient Perspectives

Patient perspectives considered during the review included preference for a less invasive treatment option in the form of endovascular repair over alternative treatments such as open surgical repair.

In conclusion, given the available information above, the data support that for the treatment of Type B aortic dissection the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data provided in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. Specifically, the primary (30-day survival) and additional hypothesis-driven safety (30-day freedom from MAEs) endpoints were met and the other outcomes assessed were consistent with expectations for endovascular treatment of Type B aortic dissection, including adverse events rates beyond 30 days, reinterventions, and the results from follow-up imaging assessments.

XIV. CDRH DECISION

CDRH issued an approval order on December 31, 2018. The final conditions of approval cited in the approval order are described below.

The sponsor has agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include, for the Zenith Dissection Endovascular System clinical studies, a summary of the number of patients for whom data are available, with a summary of false lumen characteristics (i.e., diameter change, patency, and source of persistent flow), dissection-related deaths, aortic ruptures, aortic enlargements, extension of the dissection, major adverse events (i.e., paraparesis, paraplegia, new ischemia), losses of device integrity, and additional dissection-related interventions, including the reasons for the interventions. A summary of any explant analysis findings is to be included. Additional relevant information from commercial experience within and outside of the U.S. is also to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.
In addition to providing information regarding the dissection study in the clinical updates to physician users, the sponsor agreed to report any significant observations from the post approval study described below of the use of the Zenith Dissection Endovascular System to repair Type B dissections in the descending thoracic aorta.

In addition, the sponsor agreed to the following:

1. *Continued Follow-up of the Zenith Dissection Endovascular System Pivotal Study:* This is a prospective, consecutively enrolling, single-arm, multi-center study that consists of continued follow-up of all available subjects from the Zenith Dissection Endovascular System pivotal study. A total of 73 subjects were enrolled in the study and remaining subjects will be followed for 5 years. Secondary endpoints through 5 years will include false lumen characteristics (i.e., diameter change, patency, and source of persistent flow), dissection-related deaths, aortic ruptures, aortic enlargements, extension of the dissection, major adverse events (i.e., paraparesis, paraplegia, new ischemia), losses of device integrity, and additional dissection-related interventions, including the reasons for the interventions. No formal hypothesis testing will be performed for the longer-term follow-up.

2. *SVS VQI Post market Surveillance:* The sponsor agreed to support and actively participate as a stakeholder in the Society for Vascular Surgery Patient Safety Organization governed Vascular Quality Initiative and undertake such activities to ensure that surveillance occurs for the Zenith Dissection Endovascular System when used to repair Type B dissections in the descending thoracic aorta in 120 patients with acute dissections (using the complete Zenith Dissection Endovascular System) and 60 patients with chronic dissections (using any component of the Zenith Dissection Endovascular System).

   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, device technical success at the time of the procedure, and device procedural success. The reports will include data at the following timepoints: pre-operative, 30-day, 1-year, and yearly thereafter through 5 years.

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

XV. 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.

XVI. REFERENCES

1. Fillinger MF, Greenberg RK, McKinsey JF, Chaikof EL; for the Society for Vascular Surgery Ad Hoc Committee on TEVAR Reporting Standards. Reporting standards for thoracic endovascular aortic repair (TEVAR). J Vasc Surg. 2010;52:1022-33.

2. Beach JM, Kuramochi Y, Brier C, Roselli EE, Eagleton MJ. Durable outcomes of thoracic endovascular aortic repair with Zenith TX1 and TX2 devices. J Vasc Surg. 2017;65:1287-1296.