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1 | ABBREVIATIONS AND DEFINITIONS

ARDS	Acute Respiratory Distress Syndrome
ASC	Ascending
BCA	Brachiocephalic Artery
BCT	Brachiocephalic Trunk
Caudal	Towards the legs
Cranial	Towards the head
CVA	Cerebral Vascular Accident
DE	Descending Extension
DESC	Descending
Distal (delivery system)	Distant, relatively to the user
Distal (implant)	Distant, relatively to the patient's heart
Dock/Docking Sleeve	Sleeve on the Arch Stent Graft that projects proximally towards the ascending aorta and that the Ascending Curved Stent Graft connects to.
DS	Delivery System
EtO	Ethylene Oxide
FR	French (units)
IFU	Instructions For Use
IMH	Intramural Hematoma
LAO	Left Anterior Oblique
LCCA	Left Common Carotid Artery
LSA	Left Subclavian Artery
MI	Myocardial Infarction
MOF	Multiple organ failure syndrome
MRI	Magnetic Resonance Imaging
NiTi	Nitinol
Proximal (delivery system)	Close, relatively to the user
Proximal (implant)	Close, relatively to the patient's heart
RAO	Right Anterior Oblique
RCCA	Right Common Carotid Artery
RHP	Rapid Heart Pacing
RSA	Right Subclavian Artery
SAR	Specific Absorption Rate
SG	Stent Graft
STJ	Sino-Tubular Junction
TA	Tantalum
TIA	Transient Ischemic Attack
WBA	Whole Body Average

Table 1

2 | DEVICE DESCRIPTION

Important!

- **CAUTION – USA Federal law restricts the sale, distribution, or use of this device, to, by, or on the order of a physician.**
- **Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.**
- **WARNING: The NEXUS® Aortic Arch Stent Graft System should only be delivered, positioned, and deployed by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate device training program which requires case planning/sizing and device training which includes positioning and deployment of the device. Physicians may be assisted in device preparation, delivery and deployment by surgical team members trained in these steps.**
- Do not attempt to use the NEXUS® Aortic Arch Stent Graft System before completely reading and understanding the information contained in these Instructions for Use.
- Carefully inspect all product packaging for damage or defects before use. Do not use product if any sign of damage or breach of the sterile barrier is observed.
- These devices are supplied STERILE for single use only. After use, dispose of the delivery system and packaging in accordance with hospital, administrative, and/or government policies. Do not re-sterilize.

The NEXUS® Aortic Arch Stent Graft System, or NEXUS®, is designed for the endovascular treatment of chronic dissections involving the aortic arch in patients who are at high risk for open surgical repair. When placed within the target lesion, the stent graft provides an alternative conduit for blood flow within the patient's vasculature by excluding the lesion from blood flow and pressure.

2.1 NEXUS® Stent Graft

The NEXUS® Aortic Arch Stent Graft System is comprised of two primary implantable stent grafts, and an optional extension. All stent grafts are provided pre-loaded in a disposable 20Fr. delivery system and each is provided sterilized and packaged individually. Each stent graft is introduced and implanted separately into the patient's vascular system. The stent grafts that make up the NEXUS® Aortic Arch Stent Graft System are:

- The **Arch Stent Graft,** whose cranial narrow end is intended to be deployed into the Brachiocephalic artery and whose distal end is to be deployed into the Descending Thoracic Aorta.
- The **Ascending Curved Stent Graft** intended to be deployed in the Ascending Aorta.
- Optional - **Descending Extension** can be used in case the aortic lesion elongates further distally and out of the covered length offered by the Arch Stent Graft. Multiple Descending Extensions can be used if needed to cover the entire length of the lesion

The pre-loaded stent graft components are sequentially advanced to the diseased location over a guide wire using fluoroscopic guidance. The sequence of delivery and implantation is the Arch Stent Graft System, followed by the Ascending Curved Stent Graft System and if needed the Descending Extension can be implanted overlapping and extending distally. In some cases it may be decided in advance to implant the Descending Extension Stent Graft in advance of the Arch Stent Graft, in these cases the Arch Stent Graft would be implanted second extending proximally overlapping and extending proximally from the Descending Extension, followed by an Ascending Curved Stent Graft implanted proximal to the Arch Stent Graft. The NEXUS® Stent Graft System is designed to be placed in the native vessel or within a previously implanted surgical graft such that the unconstrained stent graft diameter is larger than the internal diameter of the native vessel/surgical graft landing zone. This "oversizing" at the landing zone helps exclude the lesion from the aortic blood flow and ensures that the stent graft is held in place. The stent graft components are collectively intended to form proximal, distal and brachiocephalic artery (BCA) branch seal zones seal zones surrounding the diseased location (follow the shape and size of the true lumen and seal the primary entry tear). **(Figure 1).**

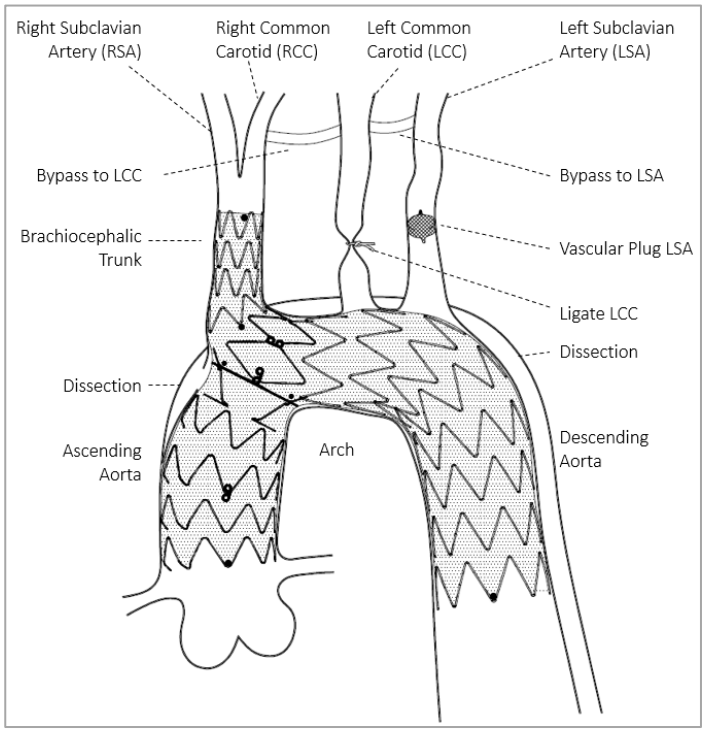


Figure 1: Configuration of the NEXUS® Arch & Ascending Curved Stent Grafts within the anatomy

Each stent graft is made of Nickel-Titanium (Nitinol) alloy stents, sewn to a polyester fabric, using surgical suture material. Each stent graft incorporates radiopaque markers to aid in visualization of the stent graft under fluoroscopy to facilitate accurate placement of the device components relative to each other and in relation to the patient's vascular system. The radiopaque markers consist of tantalum and are described as the B-markers, Dot markers and the Docking radiopaque ring. The B-markers are used to determine rotational alignment, the Dot markers are used to determine axial positioning, and the Docking radiopaque ring, located on the Arch Stent Graft is used for axial alignment with the Locking Stent of the Ascending Curved Arch Stent.

Table 2 – Stent Graft Materials

COMPONENT	MATERIAL
Stents	Nickel-Titanium (Nitinol) Alloy
Dot Markers	Tantalum
"B" Markers	Tantalum
Radiopaque Docking Ring (Arch stent graft only)	Tantalum
Graft Material	Polyester (PET= Polyethyleneterephthalate)
Suture for Stents (Arch Stent Graft)	Polyethylene with Polytetrafluoroethylene (PTFE) Coating
Suture for Stents and Radiopaque Markers (Arch, Ascending and Descending Extension Stent Grafts)	Ultra high molecular weight Polyethylene (UHMWPE)

The range of diameters and lengths is described in Section 2.2 Device Size, Section 2.3 Recommended Device Sizing.

2.1.1 Arch Stent Graft (Brachiocephalic Trunk to Descending Aorta)

The Arch Stent Graft is the main stent graft, implanted from the brachiocephalic trunk (cranially) to the descending aorta (caudally), and is aligned with the aortic arch region **(Figure 2)**. The Arch Stent Grafts are manufactured with equally spaced Nitinol stents which are sewn to the polyester graft using medical grade suture. The shape of the stent graft within the body is a thunderbolt shape (which is designed to assist with stability and fixation. This stent graft contains a sleeve named the "Dock" or "Docking Sleeve" with a single fenestration which opens toward the ascending aorta.

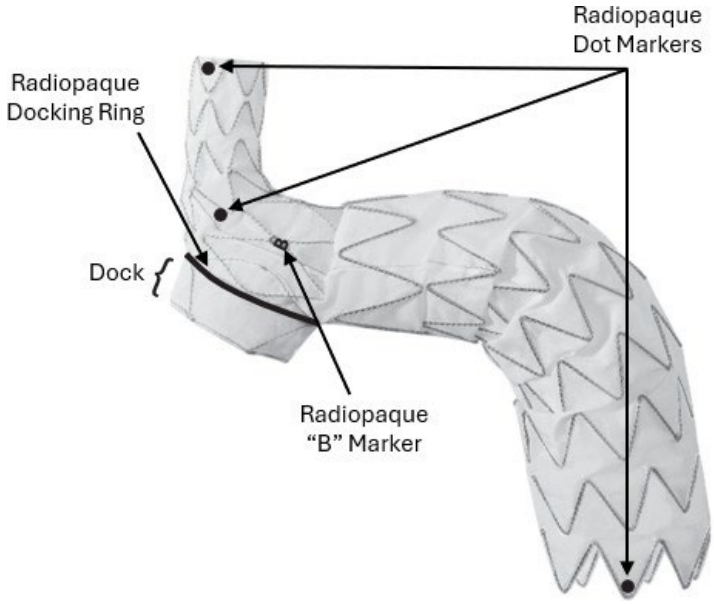


Figure 2: Arch Stent Graft (Brachiocephalic to Descending Aorta)

The positioning of the Arch Stent Graft should be such to allow blood flow to the brachiocephalic artery and to the descending aorta. Blood supply to the left carotid artery should flow through a bypass from the distal Brachiocephalic trunk (BCT) or Right common carotid (RCC) artery. Blood supply to the left subclavian artery (LSA) should made possible through bypass or it can be sacrificed, according to physician's discretion.

Note: Parallel Stent Grafts are not to be utilized with the NEXUS® System.

The Arch Stent Graft implantation is done over a bracheo-femoral wire (known as "Through & Through" technique) in which a stiff guide wire is placed into the vasculature from the axillary/brachial artery to the iliac-femoral artery of the patient **(Figure 3).**

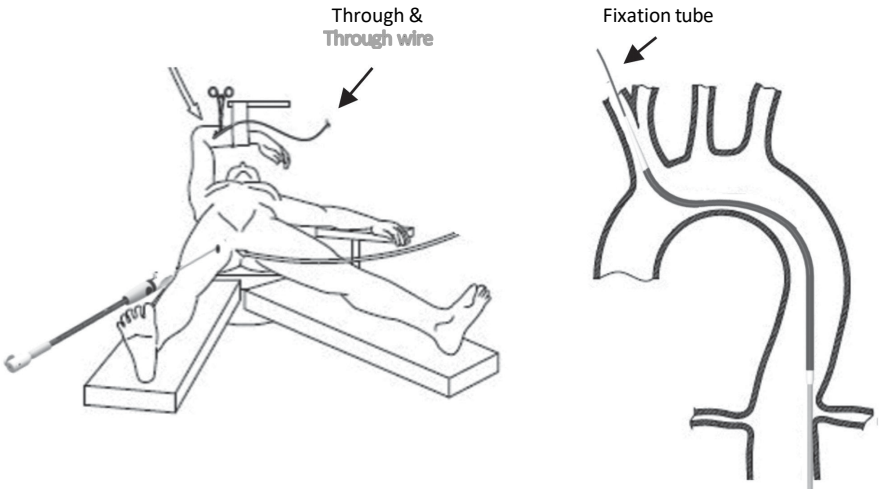


Figure 3: Through & Through Technique

2.1.2 Ascending Curved Stent Graft

The Ascending Curved Stent Graft is the most proximal stent graft of the stent graft system and is implanted in the ascending aorta. The Ascending Curved Stent Grafts are manufactured with equally spaced Nitinol stents which are sewn to the polyester graft using medical grade suture. The Ascending Curved Stent Graft has additional Compression and Anti-Buckling Springs sewn to the graft material.

The proximal stent of the Ascending Curved Stent Graft is slightly inwardly bent with the intent to prevent damage to the ascending aorta **(Figure 4).** The Ascending Curved Stent Graft is implanted distally to the coronary arteries and the sino-tubular junction, or distal to the most distal take-off of a coronary bypass and extends along the ascending aorta and into the Docking Sleeve of the Arch Stent Graft. The distal stent, called the Lock or Locking Stent is partially exposed and contains non traumatic, triangularly shaped latches. These latches are intermittently proximally and distally oriented, with the intent to provide bidirectional locking of the Ascending Curved Stent Graft inside the Dock of the Arch Stent Graft. The Sealing Stent of the Ascending Curved Stent Graft is located just proximal to the Locking Stent and is designed to seal against the proximal portion of the Arch Stent Graft Docking Sleeve **(see Figure 4)** for the location of the Locking and Sealing Stent).

Note: The Locking and Sealing Stent are the exact same design for all sizes of Ascending Curved Stent Grafts. Once deployed, the Locking and Sealing Stents engage the Dock of the Arch Stent Graft, with the goal of creating a secure connection between the two stent grafts.

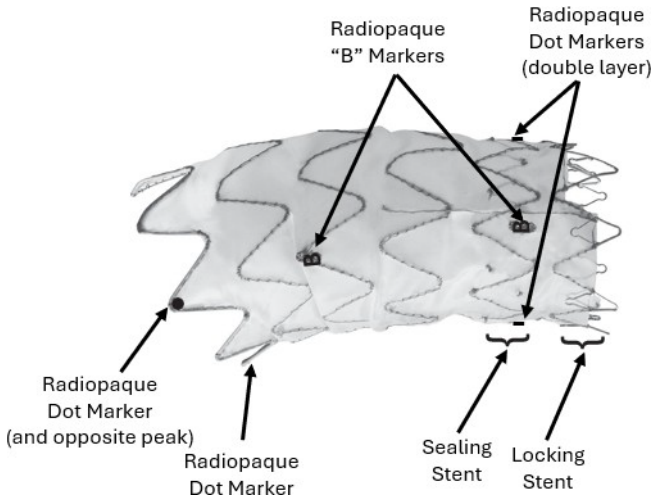


Figure 4: Ascending Curved Stent Graft

2.1.3 Descending Extension Stent Graft

The Descending Extension (DE) Stent Graft is used only in cases where the aortic lesion elongates further distally and out of the covered length offered by the distal portion of the Arch Stent Graft. The DE Stent Graft can be used in continuation to the Arch Stent Graft to ensure exclusion of the lesion from the blood flow. Multiple DE stent grafts may be utilized depending on the length of the dissection.

The DE Stent Graft is comprised of equally spaced Nitinol stents which are sewn to the polyester graft using medical grade suture. In addition, tantalum radiopaque markers; two opposite Dot markers indicate both ends of the prosthesis and a "B" shaped marker is positioned distal to the 4th stent and defines the minimum required overlap length. The minimum overlap length is defined by radiographically placing the B marker at the same axial level as the distal Dot marker on the Arch Stent Graft, this results in approximately a 6cm overlap. In all DE stent grafts, at both ends of the prosthesis, the graft follows the end stent's exact circumference to create a crown-like shape. The DE Stent Graft is available in two configurations: Straight and Tapered **(Figure 5).** Please refer to section 2.2 for device sizes.

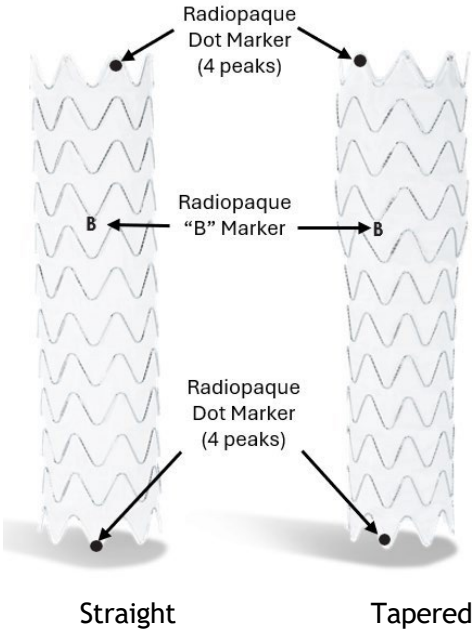


Figure 5: Both configurations of the Descending Extension Stent Graft

2.2 Device size

The NEXUS® stent graft systems are available in the sizes described in the Tables 3, 4 and 5 below. Recommended device sizing relative to the vessel sizing is provided below in Section 2.3.
Delivery System sizing information is provided below in Section 2.4, the delivery system is only available in one size (20Fr). For questions about device sizing, refer to contact information in the back of this Instructions for Use, info@endospan.com.

Stent Graft Sizing Charts

Arch Stent Graft: Branch to Descending Aorta (DESC)			
Branch sizes (mm)		**Descending aorta sizes (mm)**	
Diameter - $Ø_{Branch}$	14/17/20	Diameter - $Ø_{DESC}$	32/36/40/44
Length - L_{Branch}	20/30/40	Length - L_{DESC}	180

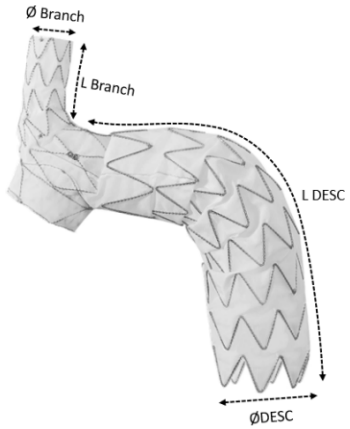


Table 3

Ascending Curved Stent Graft	
Parameter	**Curved - Size (mm)**
Diameter - $Ø_{Curved}$	36/40/43
Length - L_{Curved}	40*/55/70

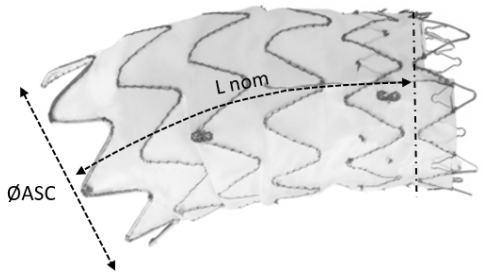


Table 4

Note: All Arch and Ascending Curved Stent Graft sizes are compatible with each other.
* For the shortest ascending stent graft, ascending Aorta landing zone diameter should be: 29 ≤ ø ≤ 36 mm.

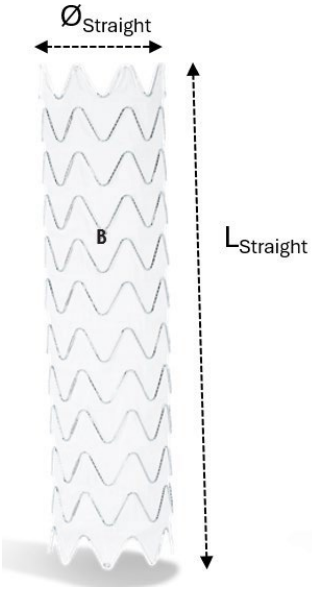
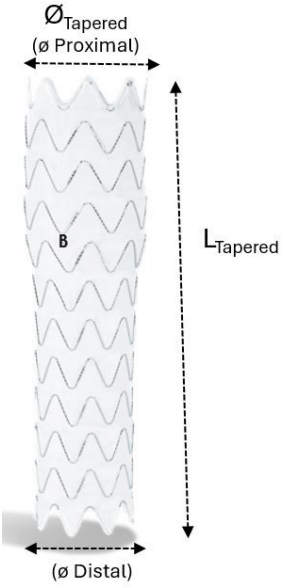
Descending Extension Stent Graft:						
Straight sizes (mm) (mm)			**Tapered sizes (mm)**			
Diameter - $Ø_{Straight}$	31/36/40	43	Diameter - $Ø_{Tapered}$	36 X 31	40 X 36	43 X 40
Length - $L_{Straight}$	125/157/189	132/166/200	Length - $L_{Tapered}$	125/157/189		130/162/194
						

Table 5

2.3 Recommended Device Sizing

The Tables 6-19 below address the selection of the appropriate stent-graft diameters and lengths for the NEXUS® Aortic Arch Stent Graft System. Appropriate oversizing has been incorporated into the recommended sizes. Adherence to these sizing guidelines is strongly recommended.

This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. Additional oversizing should not be incorporated. Sizing outside of this range can result in endoleak, fracture, migration, in folding, or graft wear.

To ensure appropriate radial fixation the specific stent graft diameter used for treatment should be sized relative to the landing zone by using the sizing guidelines in this section. Strict adherence to the sizing guidelines is expected when selecting the appropriate device size.

Key anatomic elements may affect successful exclusion of the thoracic lesion and are provided in the Indications For Use Section 3 and Pre-Implant Determinants Section 12.2 and **Figures 6a and 6b** below.

CAUTION: Proper sizing of the NEXUS® thoracic stent graft is the responsibility of the physician. The sizing recommendations provided in this document incorporate the recommended device sizing for anatomical dimension and are based on in vitro test data. Additional oversizing should not be incorporated.

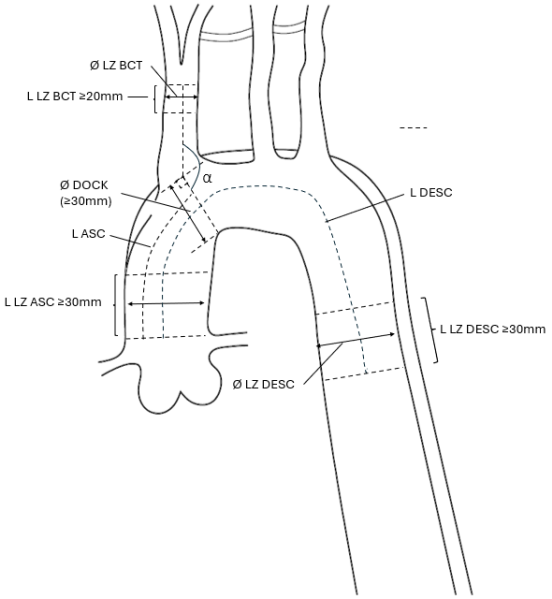


Figure 6a. Recommended sizing locations (additional details and definitions provided in Section 12.2 Pre-Implant Determinants)

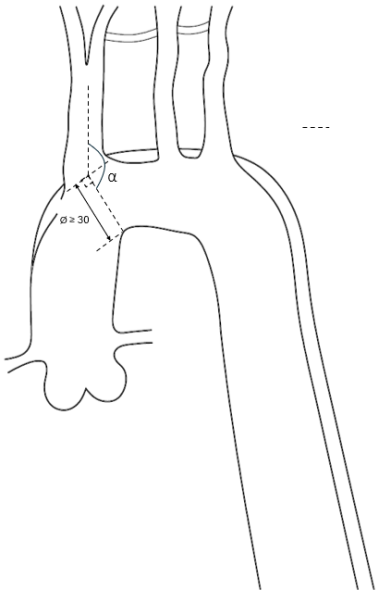


Figure 6b. The angle (α) between the Brachiocephalic Artery and the Aortic Arch Perpendicular ≥125°; Aorta ø ≥ 30mm

Figure 6: Sizing Considerations

Additional details related to Figures 6a and 6b can be found in Section 12.2 Pre-Implant Determinants

Ascending Curved Stent Graft Sizing Chart

Ascending Curved Stent Graft System products are identified on the label with a model designation. Any mix of length or diameter for each Ascending Curved Stent Graft is available. For example, reference number AC-4370 can be decoded as the following:

Example Catalogue Number	Stent Graft Type AC=Curved	Stent Graft Diameter (ø) (mm)	Stent Graft Length (mm)
AC-4370	AC	43	70

Table 6

Ascending Curved Stent Graft Sizing

Ascending Curved Stent Graft Sizing						
Ascending Curved Stent Graft (ø) (mm)	Smallest Vessel Intended diameter (ø) (mm)	Largest Vessel Intended diameter (ø) (mm)	Length of Stent Graft (L) (mm)			Landing zone (L)
36	*30	32	40**	55	70	≥30mm
40	33	36				
43	36	39				

Table 7

*Implants of the 36mm Ascending Curved Stent Grafts in previously implanted surgical grafts, can be implanted in minimum internal diameter of 26mm.

** For the shortest Ascending Curved Stent Graft, ascending aorta landing zone diameter should be: 30 ≤ ø < 36 mm.

Arch Stent Graft Sizing Chart

Arch Stent Graft System products are identified on the label with a model designation. Any mix of length or diameter for each Arch Stent Graft is available. For example, reference number M-B1420-D32180 can be decoded as the following:

Example Catalogue Number	Stent Graft Type A=Arch B=Branch D=Descending	Branch Stent Graft Diameter (ø) (mm)	Branch Stent Graft Length (mm)	Descending Stent Graft Diameter (ø) (mm)	Descending Stent Graft Length (mm)
A-B1420-D32180	A, B, D	14	20	32	180

Table 8

Arch Stent Graft Sizing

Branch Stent Graft Portion of Arch Stent Graft Sizing						
Branch Stent Graft Diameter (ø) (mm)	Intended Smallest BCT Vessel Size (ø) (mm)	Intended Largest BCT Vessel Size (ø) (mm)	Length of Branch Stent Graft (L) (mm)			Landing Zone (L)
14	12.5	13.5	20	30	40	≥20mm
17	14.5	16.5				
20	17.5	19.5				

Table 9

Arch Stent Graft - Distal Graft Portion Sizing				
Arch Stent Graft - Distal Portion Diameter (ø) (mm)	Intended Smallest Distal Vessel Size (ø) (mm)	Intended Largest Distal Vessel Size (ø) (mm)	Length of Stent Graft(L) (mm)	Landing Zone (L)
32	29	31	180	≥30mm
36	32	35		
40	36	38		
44	39	42		

Table 10

Descending Stent Graft Sizing Chart

Descending Stent Graft System products are identified on the label with a model designation. For example, reference number D-43-194-40 can be decoded as the following:

Example Catalogue Number	Stent Graft Type D=Descending Extension	Proximal Stent Graft Diameter (ø) (mm)	Distal Stent Graft Diameter (ø) (mm)	Stent Graft Length (mm)
D-43-194-40	D	43	40	194

Table 11

Descending Extension Sizing - Dissections

Descending Extension Sizing						
Stent Graft Diameter (ø) (mm)	Smallest Vessel Size (ø) (mm)	Largest Vessel Size (ø) (mm)	Stent Graft Length (mm)			Landing zone (L)
31	28	30	125	157	189	≥30mm
36	31	35				
40	36	38				
43	39	42	132	166	200	

Table 12

Descending Tapered Extension Sizing						
Stent Graft Diameter (ø) (mm)	Smallest Vessel Size (ø) (mm)	Largest Vessel Size (ø) (mm)	Length of Tapered Stent Graft (LT) (mm)			Landing zone (L)
36 x 31	31 x 28	35 x 30	125	157	189	≥30mm
40 x 36	36 x 31	38 x 35				
43 x 40	39 x 36	42 x 38	130	162	194	

Table 13

Overlapping NEXUS® Stent Graft Sizing Chart

When implanting overlapping NEXUS® Stent grafts, for example using a Descending Extension inside a previously implanted Arch Stent Graft, the following sizing configuration should be used.

1st implanted stent graft (outer stent graft)	Diameter of 1st implant (outer) (mm)	2nd implanted stent graft (inner stent graft)	Recommended Diameter of 2nd implant (inner) (mm)
Arch	Ø40	Descending Extension	Ø43
	Ø36		Ø40
	Ø32		Ø36
Descending Extension	Ø40	Descending Extension	Ø43
	Ø36		Ø40
	Ø31		Ø36
Descending Extension	Ø40	Arch	Ø44
	Ø36		Ø40
	Ø31		Ø36

Table 14

The sizing to the native vessel landing zone should be made according to the appropriate sizing tables outlined above

When implanting overlapping Ascending Curved Stent Grafts:

1. The labeled diameter of the second Ascending Curved Stent Graft should be equal to the labeled diameter of the

first Ascending Curved Stent Graft

2. The labeled length of the second Ascending Curved Stent Graft should be equal to or longer than labeled length of the first Ascending Curved Stent Graft

2.4 NEXUS® Delivery System

The NEXUS® Delivery System, which delivers all stent graft configurations, consists of a single-use, disposable catheter with an integrated handle to provide controlled deployment. Both the proximal shaft that contains the Stent Graft and the proximal tip are hydrophilic coated. The NEXUS® Delivery System is available in 20 Fr. (outer diameter) for all sizes, which enables a percutaneous approach. The catheter assembly is flexible and compatible with a 0.035 inch (0.89 mm) guidewire. **(Figure 7)**.

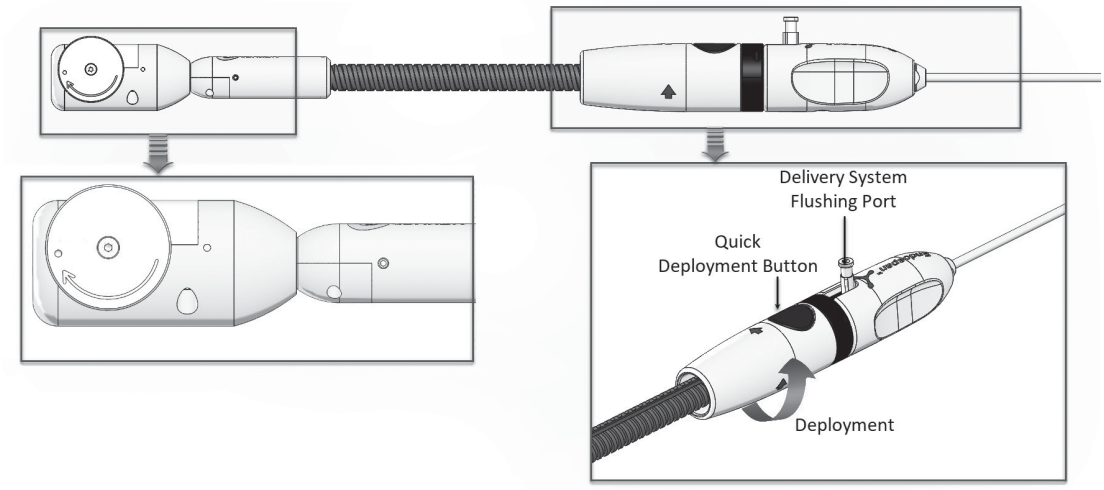


Figure 7 –NEXUS® Delivery System Handle

The NEXUS® Aortic Arch Stent Graft System consists of two single-use disposable delivery system **(Figures 9 and 10)** that are preloaded with the stent graft and are individually packaged and sterilized:

- Arch Stent Graft Delivery System
- Ascending Curved Stent Graft Delivery System
- Optional - if extended coverage is required for the descending aorta, additional delivery system(s) preloaded with the Descending Extension Stent Graft System should be made available.

The configuration of the Arch Stent Graft Delivery System is pre-shaped (thunderbolt shape) **(Figure 9)**. The Arch Stent Graft Delivery System also has a Fixation Tube **(Figure 3 and Figure 9)**, this fixation tube is delivered over the guide- wire that extends through the axillary/brachial in the through and through configuration **(Figure 3)**. The Fixation Tube is press-fit into the tip of the Arch Stent Graft Delivery System and remains in place, temporarily attached to the Branch Stent when the Arch Stent Graft Delivery System is removed. The Arch Stent Graft Delivery System also has 3 capture wires which hold down the most distal Branch Stent after its deployment, this allows for slight change in axial alignment. Once the intended axial alignment of the Branch Stent is achieved the Capture Release Knob **(Figure 8)** is rotated, pulling back the capture wires and releasing the distal stent of the Branch graft from the delivery System.

The configuration of the Ascending Stent Graft Delivery System is pre-curved **(Figure 10)**. The Delivery System also has 3 capture wires holding the proximal and distal stents of the Ascending Curved Stent Graft to the inner catheter of the Delivery System after deployment of the Stent Graft. With both proximal and distal ends of the Ascending Curved Stent Graft held by the capture release wires, the user can adjust the axial position of the Stent Graft prior to final release from the Delivery System. Once the intended axial position is achieved, the user rotates the Capture Release Knob **(Figure 8)** is rotated until the Ascending Curved Stent Graft is fully released from the Delivery System.

Both configurations shaped for the Arch Stent Graft Delivery Systems and curved for the Ascending Curved Stent Graft Delivery Systems allow accommodation to the anatomy.

The Descending Extension delivery system is straight and is delivered/unsheathed similar to the Arch or Ascending unsheathing. The Descending extension has 4 capture release wires holding down the most proximal stent, which also allows for some axial adjustment of the position of the Stent Graft prior to detachment from the Delivery System using the Capture Release Knob **(Figure 8)**.

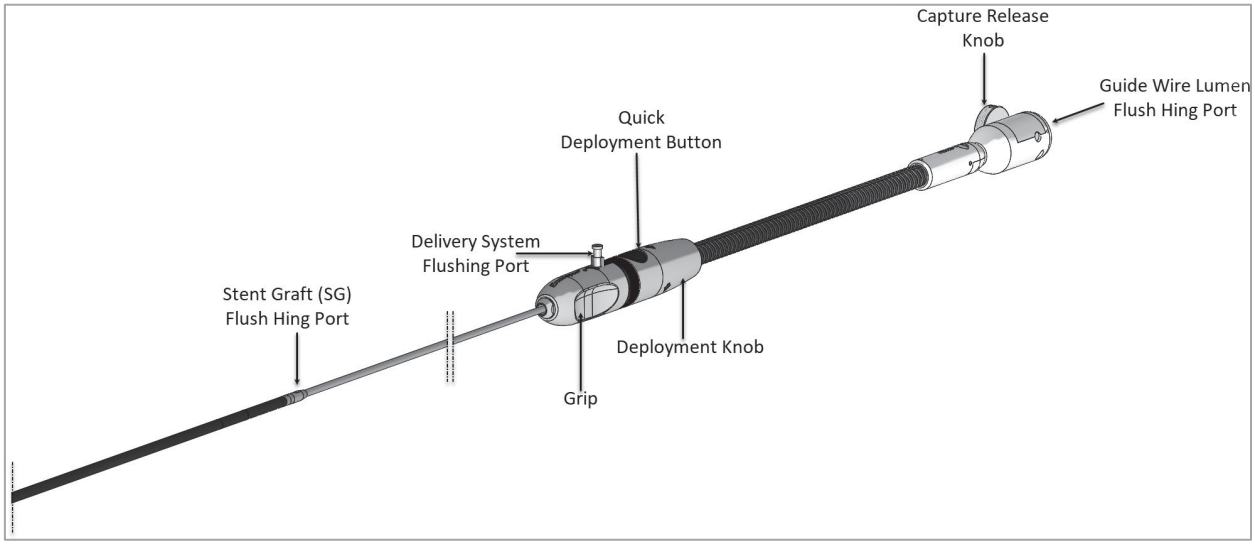


Figure 8. NEXUS Delivery System Handle Components

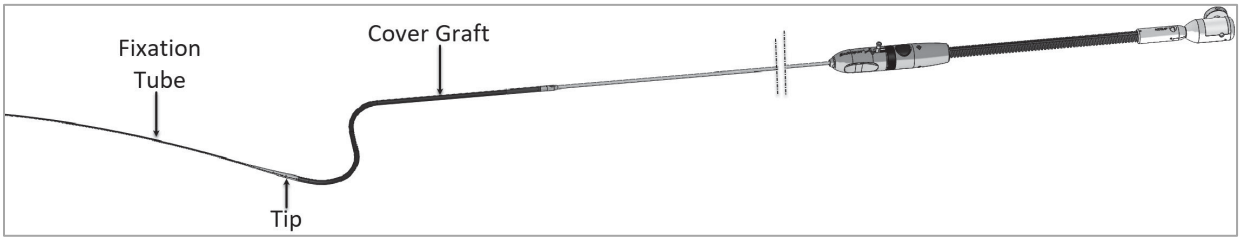


Figure 9. NEXUS® Arch Stent Graft Delivery System – Pre-Shaped

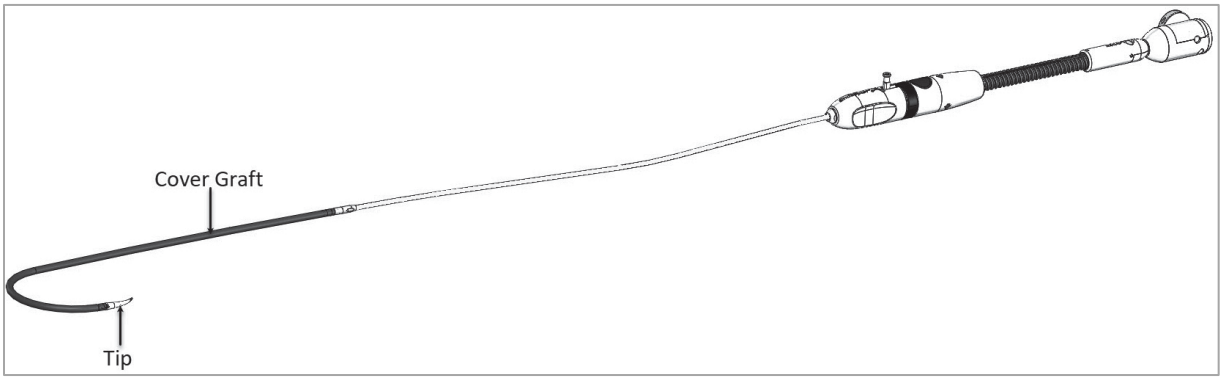


Figure 10. Ascending Stent Graft Delivery System – Pre-Curved

3 | INDICATIONS FOR USE

The NEXUS® Aortic Arch Stent Graft System is indicated for the endovascular treatment of chronic dissections involving the aortic arch in patients who are at high risk for open surgical repair and who have appropriate anatomy including:

- Adequate iliac or femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories.
- Proximal/ascending native landing zone aortic anatomy including:
  - 30 mm to 39 mm diameter;
  - ≥ 30mm length
  - Landing zone cannot be aneurysmal, dissected, heavily thrombosed and tortuous
- Proximal/ascending previously implanted surgical graft landing zone including:
  - 26 mm to 39 mm diameter;
  - ≥ 30mm length
- Brachiocephalic trunk native landing zone anatomy including:
  - 12.5mm to 19.5 mm diameter;
  - ≥ 20mm length
  - Landing zone cannot be aneurysmal, dissected, heavily thrombosed and tortuous
- Distal/descending native landing zone aortic anatomy including:
  - 28 mm to 42 mm diameter;
  - ≥ 30mm length

4 | CONTRAINDICATIONS

- Patient with known sensitivities or allergies to the device materials.
- Patient who has a condition that threatens to infect the graft.

Also consider the information in Section 5 (Warnings and Precautions – patient selection, treatment and follow up).

5 | WARNINGS AND PRECAUTIONS

Read all the instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences and/or injuries to the patient, deterioration in patient's health and even patient's death (See Section 7 Anticipated Adverse Events).

5.1 General (Warnings and Precautions)

- Patients without a formal diagnosis of connective tissue disease but who present with clinical features suggestive of such a condition (e.g., initial Type A dissection occurring at a young age) should not undergo implantation until the treating physician has confirmed that connective tissue disease is not present. The NEXUS® Aortic Arch Stent Graft System has not been evaluated in patients with connective tissue disease, and use in patients with known or suspected connective tissue disorders has resulted in serious adverse events, including death.
- Failure to comply with the IFU of the NEXUS® Aortic Arch Stent Graft System has resulted in poor performance, severe complications and even death.
- Compliance with device sizing recommendations is critical to optimal performance of the device (refer to Table 6 – Table 17). Successful patient selection requires specific imaging and accurate measurements (see Section 12.2 - Pre-Implant Determinants)

- All patients should be advised this treatment modality requires long term, regular follow-up visits to assess the patients' health status and device performance. Patients with specific clinical findings (e.g. endoleaks, enlarging lesions) should receive enhanced follow-up (see Section 9.2. Imaging Guidelines and Post-Operative Follow-up).
- Safety and effectiveness of the NEXUS device has not been demonstrated for use in treatment of other lesion types such as aneurysms and penetrating aortic ulcers. Furthermore, the sizing recommendations outlined in this document are not applicable for use of the device in treatment of other pathologies.
- The safety and effectiveness of the NEXUS® Aortic Arch Stent Graft System to treat chronic dissections involving the aortic arch, including in patients who are high risk for open repair, was determined based on a 30-day endpoint and 1 year follow-up. Due to the short-term nature of this data, all patients should be advised that long-term, regular follow-up is necessary to assess the patients' health status and device performance.
- The safety and effectiveness of the NEXUS® Aortic Arch Stent Graft System have not been evaluated in patients who are not considered high risk candidates for conventional open repair (e.g. prior sternotomy, current or former smoker, and/or inadequate pulmonary function)
- The NEXUS® Aortic Arch Stent Graft System should be used only by a physician with expertise in vascular interventional techniques and trained in the use of this system. Specific training expectations are described in Section 10.1, "Physician Training Requirements".
- The NEXUS® Aortic Arch Stent Graft System is not recommended in patients unable to undergo, or who will not be compliant with, the necessary pre- and post-operative imaging and follow-up described in Section 9.2. Imaging Guidelines and Post-Operative Follow-up.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aortas, endoleaks, dissection extension, or persistent false lumen perfusion. An increase in aortic size, persistent endoleak or continued false lumen perfusion may lead to aortic rupture, ischemia (such as peripheral malperfusion or ischemia or paraplegia/paraparesis), stroke, and/or death.
- Unique considerations may apply for evaluation of endoleaks in the chronic dissection patients. Contrast opacification adjacent to the stent graft may represent false lumen perfusion or a Type II endoleak rather than a Type I or Type III endoleak. In the clinical study, misclassification of endoleak type has resulted in unnecessary or incorrect reinterventions. Careful imaging evaluation is recommended prior to reintervention.
- Always have an appropriate surgical team readily available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- Prior to performing final angiography, ensure that all stiff guidewires have been fully withdrawn. Failure to remove stiff wires before final imaging has resulted in inaccurate assessment of stent graft positioning, which has lead to improper device placement and serious adverse events, including death.
- Patients experiencing reduced blood flow through the stent graft and/or leaks may be required to undergo secondary interventions or an open surgical procedure.

5.2 Patient Selection (Warnings and Precautions)

- Do not use the NEXUS® Aortic Arch Stent Graft System in patients who do not tolerate contrast agents necessary for preoperative, intra-operative and post-operative follow-up imaging. Not following this instruction may lead to serious injuries to the patient, deterioration in patient's health and even patient's death.
- The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency have an increased risk of renal failure postoperatively.
- The NEXUS® Aortic Arch Stent Graft System is not recommended in patients exceeding weight and/or size limits which compromise or prevent the necessary imaging requirements. Before the procedure, perform preoperative planning for access and placement. Refer to Section 2.2 (Recommended device sizing). Key anatomic elements that may affect successful exclusion of the aneurysm include tortuosity, short landing zones, and significant thrombus and/or calcium at the implantation sites. In the presence of anatomical limitations, a longer landing zone may be required to obtain adequate sealing and fixation.

- Key anatomic elements may affect successful exclusion of the thoracic lesion and are provided in the Indications For Use Section 3 and in the Recommended Device Sizing Section 2.3. (see Figure 6a)
- The Nexus device is not recommended in patients where the angle between the center line of Brachiocephalic Artery and a line perpendicular to the Aortic Arch center line is less than 125° (see Figure 6b) as this may result in the need for additional endovascular intervention (e.g., stenting of the BCT).
- The Nexus device is not recommended in patients where the aorta at the level of the BCT has a diameter (perpendicular to the aortic centerline) of less than 30mm as this may result in endoleak requiring further intervention, either endovascular or open. This is important to allow the Arch Docking Sleeve to fully expand (see Figure 6b).
- Patients who have a previously implanted surgical wrap of the ascending aorta should not be treated with the NEXUS® Aortic Arch Stent Graft System.
- Severe calcification in the access vessels may impede device delivery, and therefore, it should be evaluated while making decisions regarding access suitability.
- Blood vessels that are significantly calcified, stenosed, tortuous or thrombus-lined should be precluded from endovascular treatment.
- Additional key anatomic elements include presence of significant thrombus and/or calcium deposits at the implantation sites, specifically at the proximal aortic neck. Presence of calcification and/or plaque may compromise the fixation and sealing of the implantation site. It may also promote emboli formation and lead to occurrence of adverse events such as ischemia downstream. Surgical revascularization of the required supra-aortic vessels (e.g., right carotid–left carotid–left subclavian bypass) must be completed prior to implantation of the NEXUS® Aortic Arch Stent Graft System. Proximal ligation or endovascular occlusion of the left subclavian artery and ligation of the left common carotid artery should be performed to mitigate the risk of competitive flow that may compromise bypass patency and to reduce the risk of Type II endoleaks.
- The safety and effectiveness of NEXUS® have not been evaluated in the following patient conditions:
    - Acute dissections or conditions requiring emergent treatment (e.g., trauma or rupture)
    - Acute vascular injury of the aorta due to trauma
    - aortic fistulas
    - previous surgical repair in the descending thoracic aortic area
    - genetic connective tissue disease (e.g. Marfans and Ehlers-Danlos syndrome)
    - patients with active systemic infections
    - patients less than 18 years old
    - pregnant or nursing females
    - patients with mechanical aortic valves
    - patients that are not considered high risk candidates for conventional open surgical repair
    - Severe aortic valvular insufficiency
    - Severe atherosclerosis, severe calcification or extensive intraluminal thrombus of the aorta or in the brachiocephalic trunk
    - Patients that are high risk of a neurological event (e.g. stroke)
- Do not use NEXUS® in patients who have a condition that threatens to infect the graft.
- Inappropriate patient selection may lead to poor device performance or performance not in accordance with the specifications. This could result in injury to the patient, deterioration in patient's health and even patient's death.
- In the presence of anatomical limitations, a longer landing zone and additional stent grafts may be required to obtain adequate sealing and fixation.
- In case the difference between the proximal and distal intended landing diameters does not enable sufficient oversizing offered by a single DE endoprosthesis, a combination of multiple DE stent grafts of different diameters is required.

5.3 Before Implantation (Warnings and Precautions)

- A right carotid-left carotid- left subclavian bypass is recommended for surgical revascularization of the supra-aortic vessels. In the clinical study, higher rates of mortality were reported for patients who underwent mini-sternotomy as compared to the extra thoracic bypass procedure.
- Patients undergoing prior surgical bypass preparatory procedures may require variable recovery periods. The timing of subsequent NEXUS implantation should be determined by clinical judgment following a thorough assessment of the patient's recovery status. The implant procedure should be deferred until the patient is deemed sufficiently recovered from the bypass (e.g. could be discharged home). Insufficient recovery at the time of implantation has resulted in increased risk of adverse events, including death.
- BCA length should be carefully re-measured after completion of the preparatory bypass and prior to implantation of the NEXUS® Aortic Arch Stent Graft System to reconfirm the NEXUS® Arch Stent Graft branch length is appropriate for the patient's BCA anatomy. This step is particularly important if a mini-sternotomy was performed instead of the recommended right carotid-left carotid-left subclavian bypass. Failure to reconfirm BCA length has resulted in inadvertent coverage of the carotid artery or bypass origin and has led to serious adverse events, including death.
- Pre-operative planning for vascular access, for through & through access and for device placement should be performed before the operation.
- To reduce the risk of thromboembolism, it is recommended that patients be anticoagulated for the duration of the procedure to achieve an Activated Clotting Time of > 350 seconds, at the discretion of the physician.
- Prior to use, carefully inspect the NEXUS® Aortic Arch Stent Graft System packaging and the delivery system for damage or defects, including broken flushing luer lock, or detachments of the delivery system from the tray. Do not use product if any sign of damage or breach of the sterile barrier is observed. Do not attempt to re-sterilize the NEXUS® Aortic Arch Stent Graft System or its components.
- Do not bend, kink, or otherwise challenge the Delivery System prior to implantation because it may cause deployment difficulties.
- Size the aortic portion of the stent graft using the sizing guidelines in Section 2.3 (Recommended device sizing). Strictly adhere to the NEXUS® thoracic stent graft system sizing configurations and guidelines (section 2.2) when selecting the device size. The appropriate device oversizing is incorporated into the sizing guidelines. Sizing outside of this range can potentially result in endoleak, fracture, migration, in-folding, or graft wear.

5.4 During Implantation (Warnings and Precautions)

- Systemic anticoagulation should be used during the implantation procedure based on hospital or physician protocol.
- If heparin is contraindicated, an alternative anticoagulant should be considered.
- Exercise care in handling and in delivery technique to prevent blood vessel rupture.
- Do not advance the delivery system without having placed a guide wire first and without fluoroscopy. This may lead to major vascular complication, and even to patient's death.
- A suitable introducer sheath must be used for the Through & Through guide wire technique to accommodate the guide wire. In addition, the guide wire should remain in place and stressed until the Arch Stent Graft is deployed in-situ in order to avoid migration of the main stent graft during procedure. Migration can lead to inadequate sealing of the lesion and even to innominate artery occlusion which could result in stroke and even death.
- Do not deploy the stent graft components in a location that can cause an endoleak or can occlude arteries necessary to supply blood flow to vital organs. This has resulted in need for surgical removal of the device.
- Use fluoroscopic guidance to advance the delivery system in order to detect kinking or positioning problems with the stent graft components. Deviating from the image guided target location marking has resulted in the BCT branch being deployed too distally which has led to vascular injuries to the patient, deterioration in patient's health and even patient's death.
- Do not use excessive force to advance or withdraw the delivery system when resistance is encountered, it may lead to improper performance and may result in vascular injury to the patient and even patient's death. If

resistance is felt during advancement or withdrawal of the guidewire or delivery system, stop and assess the cause of resistance. If the delivery system kinks during insertion, do not attempt to deploy the stent graft component. Remove the system and insert a new delivery system.

- Improper alignment of the radiopaque dot markers of the Ascending Curved Stent Graft with the radiopaque large ring of the Arch-Stent Graft and/or improper direction of "B" marker of the Ascending Curved Stent Graft (must be turned toward the cranial side of the aorta) may impair the connection of the two stent grafts and may result in endoleak or occlusion of the innominate artery which can result in stroke and even death.
- Improper alignment of the radiopaque "B" marker of the DE Stent Graft with the radiopaque dot marker of its overlapping stent graft may impair the connection of the two stent grafts and may result in endoleak.
- While in situ and for the purpose of correct orientation of the markers, do not rotate the Arch Stent Graft and the Ascending Curved Stent Graft delivery systems grip more than 360 degrees. In case the delivery system does not rotate, gently pull the delivery system backward out of the aortic arch and correct the marker orientation by rotating the delivery system grip (not more than 360 degrees), and advance the delivery system to the correct position. While in place, verify correct orientation before deployment.
- Inadequate seal zone could increase the risk of endoleak or migration of the stent graft. Migration may also be caused by deployment of the proximal stent into a thrombus filled or severely angled vessel. Refer to section 5.2 (Patient selection).
- When deploying the stent graft, be sure to hold the front Grip of the delivery system stationary in order to ensure adequate implantation and avoid inaccurate positioning of the stent grafts and as a result endoleak or occlusion of the innominate artery which can result in stroke and even death.
- Rapid Heart Pacing or other available techniques to reduce cardiac output and blood pressure, is recommended to be used during the deployment of the Ascending Curved Stent Graft.
- Ensure that the Arch Stent Graft and the DE Stent Graft are deployed against the outer curve of the vasculature, e.g. by applying forward pressure on either the delivery system or both ends of its corresponding guidewire. As default, it is possible to deploy the overlapping segment of the DE stent graft for primary fixation then carefully apply minor pressure on the DS to accommodate the outer curve before completing the deployment. Note: avoid excess force that might result in relative stent graft migration or other hazardous disposition of adjacent implants.
- Stent graft components cannot be replaced or drawn back into the delivery system, even if the stent graft component is only partially deployed.
- If a balloon catheter is used, it should be inflated only inside the stent graft. Do not inflate outside the stent graft nor in the border area of the stent graft with the aortic wall. Do not over inflate the balloon catheter within or outside of the graft material. Follow the balloon catheter manufacturer Instructions for Use.
- Manipulation of wires, balloons, catheters, and endografts in the thoracic aorta has resulted in vascular trauma including aortic dissection, embolization, and cardiac perforation.
- Renal complications may occur from excess use of contrast agents, or as a result of embolization.
- Studies indicate that the danger of micro-embolization or stroke increases with increased catheter and guidewire manipulation[1,2.].
- Ensure that extra extensions and stents of suitable diameters are available in the operating room.

1. *Cerebral embolization during endovascular infrarenal, juxtarenal, and suprarenal aortic aneurysm repair, high-risk maneuvers, and associated neurologic outcomes*; Benson, Ruth A. et al.; Journal of Vascular Surgery, 2018, Volume 68, Issue 5, 1374 - 1381,
2. *Complications and Management of the Thoracic Endovascular Aortic Repair.* Chen SW et al; Aorta (Stamford). 2020 Jun;8(3):49-58.

6 | MRI SAFETY INFORMATION  Conditional

Non-clinical testing has demonstrated that the NEXUS® Aortic Arch Stent Graft System is MR Conditional. Immediately or any time after a patient is implanted with the NEXUS® can be safely scanned in an MR system under the following conditions. Failure to follow these conditions may result in injury:

Device Name:	NEXUS® Aortic Arch Stent Graft System
Static Magnetic Field Strength (B_o):	1.5 Tesla or 3.0 Tesla, cylindrical bore MR system
Maximum Spatial Field Gradient:	30 T/m (3,000 gauss/cm)
RF Excitation:	There are no RF excitation restrictions
RF Transmit Coil Type:	There are no Transmit Coil restrictions
Operating Mode:	Normal Operating Mode
Maximum Whole-Body SAR:	2 W/kg (Normal Operating Mode)
Scan Duration:	Testing showed a maximum temperature rise of <2°C after 15 minutes. 2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact:	The presence of this implant may produce an image artifact. With a gradient echo pulse sequence in a 3.0T MR System, the artifact may extend up to 4mm from the implant. Under these conditions, the central portion of the lumen of the aortic component was visible.

A patient with the NEXUS® Aortic Stent Graft System, including Arch component (with integral branch), Ascending Component and one Descending Extension Component can be scanned safely under the above conditions immediately after or any time after implantation

If information about a specific parameter is not included, there are no conditions associated with that parameter.

An implant card with the MRI Safety is included in packaging and should be filled out with the implant device information and provided to the patient.

7 | ANTICIPATED ADVERSE EVENTS

As for all medical devices and procedures, complications may occur with the implantation of the NEXUS® Aortic Arch Stent Graft System. The following adverse events may occur for conventional similar procedures with endovascular stent- graft devices, as well as with the NEXUS®. As the patient may undergo additional medical treatments for other underlying disease conditions, each of these medical conditions may cause a multitude of complications and adverse events. The potential adverse events, which may occur with the use of the NEXUS® include, but are not limited to:

- Abscess formation
- Acute respiratory distress syndrome (ARDS)
- Adverse foreign body response
- Allergies (including
- Amputation
- Anesthetic complications and subsequent attendant problems
- Aneurysm enlargement or rupture
- Angina
- Aortic damage
- Aortic enlargement
- Aortic regurgitation
- Aortic valve damage and/or functional impairment
- Arrhythmia
- Arteriovenous fistula
- Aortoesophageal fistula
- Bleeding/bleeding com
- Cardiac complications and subsequent attendant
- Inflammation (localized or general)
- Ischemia transient or permanent
- Ischemic effects to the limbs, genitourinary system including kidneys, myocardium, mesentery, brain and spinal cord
- Lymphatic complications and subsequent attendant problems (lymphocele)
- Multiple organ failure syndrome (MOF)
- Myocardial infarction
- Myocardial perforation
- Necrosis
- Neurologic complications including lipothymy and encephalopathy
- Obstruction/occlusion
- Pain
- Paralysis including vocal cords and diaphragm
- Paralysis of vocal cords
- Paraparesis
- Paraplegia

problems
- Claudication (e.g. buttock, lower limb)
- Congestive heart failure
- Contrast Toxicity
- Coronary arteries occlusion
- Coronary arteries stenosis
- Death
- Dissection Extension
- Dissection of a vessel
- Edema
- Embolization (micro and macro)
- Emergency operation including surgical conversion to open repair
- Endoleak
- Erosion
- Fistula
- Fever
- Genitourinary complications and subsequent attendant problems including erosion
- Hematoma
- Hematuria
- Hemorrhage, requiring blood transfusion
- Hemorrhagic pleural effusion
- Heparin-induced thrombocytopenia (HIT)
- Hepatic Failure
- Hypertension
- Hypotension
- Ileus
- Impotence
- Incontinence
- Infarction
- Infection
- Pericardial tamponade
- Perforation of a vessel wall
- Peritonitis
- Persistent False Lumen
- Pseudoaneurysm
- Pulmonary complications and subsequent attendant problems
- Radiation exposure risks / repetitive radiation sessions
- Renal Insufficiency/failure
- Rupture of a vessel
- Sepsis
- Seroma
- Stenosis
- Stent graft complications: improper component placement; incomplete component deployment; inadequate apposition, "beaking" and subsequent collapse of the component; clinically significant component migration; suture break; stent fracture; graft twisting or kinking; insertion and removal difficulties; graft material wear; dilatation; erosion; puncture and perigraft flow
- Stroke
- Syncope
- Temporary Neurological Deficit (TND)
- Thrombosis
- Transient ischemic attack (TIA)
- Vascular access site complications including lymphocele
- Vascular spasm or vascular trauma
- Ventricular fibrillation
- Ventricular tachycardia
- Vessel damage
- Wound complications including dehiscence and cellulitis

Device Related Adverse Event Reporting

Any adverse event involving the NEXUS® Aortic Arch Stent Graft System should be reported to the manufacturer and the country specific regulatory authorities immediately. To report an event to Endospan, email: info@endospan.com or contact: US: Phone: 1-800-374-0570 or Israel: +972-9-7884620

8 | SUMMARY OF CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of the NEXUS® Aortic Arch Stent Graft System (NEXUS) for endovascular repair of chronic dissections of the aortic arch in the United States and New Zealand under IDE #G200105. Data from this clinical study were the basis for the Premarket Approval (PMA) approval decision.

A summary of the clinical study is presented below.

A. Study Design

Subjects were treated between February 2021 and October 2024. The database for this PMA reflected data

collected through November 12, 2025, and included 60 subjects with chronic dissection who were considered high risk for open repair. There were 31 investigational sites: 30 in the United States (US) and one (1) in New Zealand. The clinical study also included enrollment of subjects with aneurysms, penetrating aortic ulcers and intramural hematomas; those lesion types are not within scope of the current PMA.

The TRIOMPHE study was a prospective, multi-center, non-randomized clinical study with comparison to a performance goal. There were two co-primary endpoints: 1) Device Technical Failure and 2) Clinical Failure. These co-primary endpoints were defined as:

- **Device Technical Failure (through 30 days)**:
    - Failure to accurately deliver, track and deploy all required endovascular device components at the intended implantation site and failure to retrieve the device delivery systems without the need for unplanned additional procedures
    - Device occlusion
    - Failed exclusion of primary entry tear
    - Additional unanticipated surgical or interventional procedure related to the device or procedure, to prevent life-threatening or permanent disabling event. Specifically, the below were counted against the endpoint:
        - Surgical conversion
        - Re-intervention to treat migration
        - Re-intervention to treat stenosis or occlusion
        - Re-intervention to treat type Ia, Ib, III, IV endoleaks.
        - Re-intervention for loss of device integrity
- **Clinical Failure (through 30 days)**: Subjects experiencing early mortality or at least one of the following major adverse events (MAEs) through 30-Day of Phase 1 Procedure* and 30-Day of Index procedure:
    - Disabling Stroke
    - Permanent Paralysis/Paraplegia
    - Renal Failure
    - Aortic Rupture
    - Development of new dissections in the thoracic aorta or brachiocephalic artery

  *Phase 1 Procedure was defined as the supra-aortic bypass procedure. If a subject has a supra-aortic bypass however, did not have Index Procedure due to non-device related issues or adverse events (e.g. voluntary withdrawal), the subject was excluded from the primary endpoint analysis. Also, any subjects where the Index Procedure was not initiated due to death after Phase 1 Procedure they were not included in the primary endpoint analysis because the analysis was conducted on subjects where there was an attempt to place the NEXUS device into the subject.

The results of the study were tested against Performance Goals derived from published data on other approved devices and literature reported rates. The hypotheses tested for the co-primary endpoints are presented below:

<u>Device Technical Failure</u>:

- Null Hypothesis (H_o): $P_t \geq 0.30$
- Alternative Hypothesis (H_1): $P_t < 0.30$

Where P_t represents the proportion of subjects experiencing a device failure event.

Clinical Failure:

- Null Hypothesis (H_o): $P_t \geq 0.35$
- Alternative Hypothesis (H_1): $P_t < 0.35$

Where P_t represents the proportion of subjects experiencing a clinical failure event.

The null hypothesis for both endpoints needed to be rejected for the study to be considered a success.

The sample size was based on statistical power calculations for two co-primary endpoints, each evaluated at a one-sided alpha of 0.025, ensuring a minimum desired power of 80%. Sample size calculations were completed based on the exact binomial test calculated via the normal approximation.

- Device Technical Failure Endpoint: With an estimated device technical failure rate of 13%, a sample size of 51 evaluable subjects provided >80% power to test against the 30% performance goal.
- Clinical Failure Endpoint: With an estimated clinical failure rate of 18%, a sample size of 54 evaluable subjects provided ~80% power to test against the 35% performance goal.

A total of 60 subjects were enrolled in the study. The co-primary endpoints were formally evaluated in the "as treated population" which was defined as "any subject where there is an attempt to place the device into the subject (Index procedure)." Accordingly, any subjects wherein the Index Procedure was not initiated due to adverse events or death after Phase 1 Procedure were not included in the primary endpoint analysis.

Evaluation groups used during the course of the pivotal study are described below:

- During the screening process, all subjects who were assessed by an Investigator to meet all inclusion/exclusion criteria were submitted to Endospan for review and case approval. A Subject Eligibility Committee (SEC) reviewed the pre-treatment Computed Tomography (CT) imaging and made recommendations to Endospan whether the subject should be excluded based on anatomical criteria. The SEC comprised of at least one physician with prior NEXUS experience. Members included an Interventional Radiologist, Vascular Surgeons and Cardiothoracic Surgeons. At the conclusion of the process, the site was notified by Endospan on the subject's eligibility (Accept/Reject).
- An independent Clinical Events Committee (CEC) was established to provide unbiased adjudication. The CEC reviewed and adjudicated device and/or procedure related AEs, SAEs, MAEs, specified clinical endpoints and death data. Members included a Neurologist, Vascular Surgeons and Cardiothoracic Surgeons.
- A Data Safety Monitoring Board (DSMB) was established to provide independent oversight of subject safety and study conduct throughout the TRIOMPHE study. The DSBM was responsible for periodic review of cumulative safety data, including Adverse Events (AEs), Serious Adverse Events (SAEs), Protocol Deviations (PDs), deaths, and device- or procedure-related complications. Members included an independent statistician, Vascular Surgeons and Cardiothoracic Surgeons.
- All imaging data for the TRIOMPHE study were evaluated by an independent core laboratory. The core lab was responsible for evaluations on all CT images submitted by the clinical sites. The Core Lab reported all evaluations to Endospan.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the TRIOMPHE study was limited to subjects who met the following inclusion criteria:

   - Male and female age ≥ 18.
   - Subject with chronic dissections who is considered to be at high risk for open repair, with at least one of the following conditions:
     - An aortic aneurysm with a maximum diameter ≥ 55 mm.
     - Rapidly expanding false lumen (growth of > 0.5 cm/6 months)
     - Compressed true lumen associated with end organ malperfusion
     - Symptomatic
   - Must have appropriate proximal, distal and brachiocephalic landing zone
   - Subject is willing and able to comply with procedures specified in the protocol and is able to return for follow-up visits as specified by the protocol

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

   - Acute dissection
   - Lesions that can be safely treated with TEVAR landing in zone 2 (with or without LSA vascularization)
   - Required emergent treatment (e.g., trauma, rupture)
   - Acute vascular injury of the aorta due to trauma
   - Aortic rupture
   - Received a previous stent or stent graft in the treated area (including planned landing area)
   - Any major surgical or interventional procedure 6 weeks before the NEXUS® implantation, exclusive of planned procedures that are needed for the safe and effective placement of the stent graft (e.g. supra-aortic bypass)
   - Subject has had a MI or cerebral vascular accident (CVA) within 90 days prior to the planned implantation
   - Subjects with severe aortic valvular insufficiency as determined by echocardiography
   - Mechanical valve that precludes safe delivery of NEXUS
   - Known Connective tissue disease (e.g., Marfan's or Ehler's-Danlos syndromes)
   - Subject has an active systemic infection at the time of the procedure documented by pain, fever, drainage, positive culture
   - Pregnant
   - Life expectancy of less than 2 years
   - Unsuitable vascular anatomy
   - Subject with hostile groins/axilla (scarring, obesity, or previous failed puncture) unless conduit are used.
   - Subjects with severe atherosclerosis, severe calcification or extensive intraluminal thrombus of the aorta or in the brachiocephalic trunk
   - Subject with known hypersensitivity or contraindication to anticoagulants, antiplatelets, or contrast media, which is not amenable to pre-treatment
   - Subject with known sensitivities or allergies to the device materials
   - Subject has history of bleeding diathesis or coagulopathy that may limit the use of dual antiplatelet or anticoagulant therapy by the decision of the investigator
   - Acute renal failure; chronic renal failure (excluding dialysis); Creatinine > 2.00 mg/dl

2. Follow-up Schedule

All subjects were scheduled to return for follow-up examinations at 1, 6, 12, 24, 36, 48, and 60 months postoperatively. **Table 15** outlines the required screening evaluations and follow-up visit procedures for subjects. Adverse events and complications were recorded at all visits. The key timepoints are shown below in the tables summarizing safety and effectiveness.

Table 15. Schedule of Events

	Screening/ Baseline	Phase 1 Procedure	Index Procedure	Pre-discharge	30 days	6 Months	1 year	Annual visits: 2-5 years
Physical Exam	X			X	X	X	X	X
Neurological Assessment	X				X	X*	X*	X*
Clinical Laboratory Tests	X				X	X		
CT Angiogram of Chest, Abdomen and Pelvis	X			X	X	X	X	X
CT Angiogram of Head and Neck	X							
Ultrasound	X		X					
Angiography			X					

* Performed only if a neurologic problem occurred, subject has symptoms indicating a neurological issue or if suspected stroke was seen on imaging

3. Clinical Endpoints

With regards to safety and effectiveness, there were two co-primary endpoints:
1) Device Technical Failure and 2) Clinical Failure.

Device Technical Failure was defined as any of the following occurring through 30 days:

- Failure to accurately deliver, track and deploy all required endovascular device components at the intended implantation site and failure to retrieve the device delivery systems without the need for unplanned additional procedures
- Device occlusion
- Failed exclusion of primary entry tear
- Additional unanticipated surgical or interventional procedure related to the device or procedure, to prevent life-threatening or permanent disabling event.
  Specifically, the below were counted:
  - Surgical conversion
  - Re-intervention to treat migration
  - Re-intervention to treat stenosis or occlusion
  - Re-intervention to treat type Ia, Ib, III, IV endoleaks.
    - Type I: Perigraft blood flow caused by inadequate seal at either the proximal or distal graft end (Type Ia: Proximal; Type Ib: Distal)
    - Type III: Occurs in the midgraft region due to leakage through a defect in the graft

fabric or between the segments of multisegmental graft (Type IIIa: Junctional leak or disconnect between devices; Type IIIb: through hole or tear)
    - Type IV: Blush of contrast that is presumed to emanate from blood diffusion across the porous graft fabric or through small holes in the graft caused by sutures or stent struts.
- Re-intervention for loss of device integrity
    - Stent-Graft Fracture
    - Stent-Graft Kink
    - Stent-Graft Twist
    - Misalignment/Birdbeaking
    - Component Separation
    - Stent-Graft Docking
    - Stent-Graft Dilation
    - Suture Break

The statistical analysis aimed to test the null hypothesis that the device failure rate was greater than or equal to the predefined Performance goal of 30%.

Clinical Failure was defined as the occurrence of any MAEs within 30-Day of Phase 1 Procedure (supra-aortic bypass procedure) and 30-Day of Index Procedure (NEXUS procedure) in subjects where there is an attempt to place the NEXUS device into the subject:

- Early Mortality: a lesion related death or any death that occurs within 30-Days or within initial hospitalization following the Index Procedure, unless there is evidence of accidental or self-inflicted death.
- Disabling Stroke: a stroke with a modified Rankin Scale (mRS) score of two or more at 30 days and an increase in at least one mRS category from an individual's pre-stroke baseline
- Permanent Paralysis/Paraplegia: Spinal Cord Ischemia Scale > 3 (Non-ambulatory and/or wheelchair bound), persisting at least 30 days.
- Renal failure: new onset requiring permanent dialysis
- Aortic rupture: catastrophic rupture or tear of the aorta as confirmed by new hematoma or pericardial effusion based upon CT, MRI or Echocardiographic imaging.
- Development of new dissections in the thoracic aorta or brachiocephalic artery: any great vessel or brachiocephalic artery that clinically requires intervention

The statistical analysis aimed to test the null hypothesis that the clinical failure rate was greater than or equal to the predefined Performance Goal of 35%.

B. Accountability of PMA Cohort

At the time of database lock, 60 subjects were eligible and included for analysis.
Table 16 below provides the disposition and compliance at the time of the database lock.

Table 16. Follow-Up Compliance

	Subject Follow-Up [2]				Imaging Performed [2]	Imaging Adequate to Assess the Parameter [2] [3]					Subject Status [4]				
Visit [1]	**Eligible for follow-up [5]**	**Visit Performed**	**No Visit, Still in Window**	**Missed visit**	**CT Scan**	**Size Changes**	**False Lumen Perfusion**	**Endoleak**	**Migration**	**Fracture**	**Death**	**LTFU/ Early Withdrawal**	**Surgical Conversion**	**Not due for next visit**	**One or More Reason for Future Visit Ineligibility [6]**
Index Procedure (1-27)	60	100.0% (60/60)	0.0% (0/60)	0.0% (0/60)	100.0% (60/60)	NA	NA	NA	NA	NA	8.3% (5/60)	0.0% (0/60)	1.7% (1/60)	0.0% (0/60)	8.3% (5/60)
30 Days (28-45) [7]	55	100.0% (55/55)	0.0% (0/55)	0.0% (0/55)	100.0% (55/55)	NA	92.7% (51/55)	92.7% (51/55)	NA	100.0% (55/55)	0.0% (0/55)	0.0% (0/55)	0.0% (0/55)	0.0% (0/55)	0.0% (0/55)
6 Months (150-210)	55	83.6% (46/55)	0.0% (0/55)	3.6% (2/55)	83.6% (46/55)	83.6% (46/55)	76.4% (42/55)	78.2% (43/55)	80.0% (44/55)	83.6% (46/55)	10.9% (6/55)	1.8% (1/55)	3.6% (2/55)	0.0% (0/55)	12.7% (7/55)
1 Year (305-425)	48	97.9% (47/48)	0.0% (0/48)	2.1% (1/48)	97.9% (47/48)	97.9% (47/48)	93.8% (45/48)	95.8% (46/48)	93.8% (45/48)	97.9% (47/48)	4.2% (2/48)	2.1% (1/48)	0.0% (0/48)	27.1% (13/48)	33.3% (16/48)
2 Years (670-790)	32	90.6% (29/32)	6.3% (2/32)	0.0% (0/32)	87.5% (28/32)	81.3% (26/32)	75.0% (24/32)	71.9% (23/32)	81.3% (26/32)	87.5% (28/32)	3.1% (1/32)	0.0% (0/32)	0.0% (0/32)	43.8% (14/32)	46.9% (15/32)
3 Years (1035-1155)	17	76.5% (13/17)	11.8% (2/17)	0.0% (0/17)	76.5% (13/17)	76.5% (13/17)	76.5% (13/17)	76.5% (13/17)	76.5% (13/17)	76.5% (13/17)	5.9% (1/17)	5.9% (1/17)	0.0% (0/17)	35.3% (6/17)	47.1% (8/17)
4 Years (1400-1520)	9	66.7% (6/9)	33.3% (3/9)	0.0% (0/9)	66.7% (6/9)	66.7% (6/9)	66.7% (6/9)	66.7% (6/9)	66.7% (6/9)	66.7% (6/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	100.0% (9/9)	100.0% (9/9)
5 Years (1825-1945)	0	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Note: NA – Not Applicable, LTFU – Lost to Follow-Up
Note: Percentages = (Subjects with Adequate Imaging) / (Subjects Eligible)
[1] Windows for visits are as follows: Study period definitions: 30 Days (28-45 days) 6 Months (150-210 days) 1 Year (305-425 days) 2 Years (670-790 days) 3 Years (1035-1155) 4 Years (1400-1520 days) 5 Years (1825-1945 days)
NOTE: When reporting data for subjects with more than one imaging study in a window, all imaging observations should be reported, irrespective of which image is closest to the midpoint of the window.
[2] Denominator is the number of subjects who are eligible.
[3] Not the number of Subjects with these reported events, but rather, the number with adequate imaging as assessed by Core Lab.
[4] These columns reflect subjects that are not eligible at the start of the next visit window due to death, loss to follow-up/ early withdrawal, open surgical conversion, or who are not yet due for the next visit (e.g., the duration between the index procedure and the date of analysis was less than the days for the start of the next window). The last column is necessary to calculate the number of subjects eligible for the subsequent interval, since subjects may experience more than one event (e.g. surgical conversion and death). NOTE: One subject (126001) had a surgical conversion at 6 months but stayed enrolled in the study. They are being included in subsequent visits.
[5] Eligible subjects are those eligible at the prior interval minus those with one or more reason for future ineligibility within the prior visit window.
[6] A subject with multiple reasons for ineligibility is only counted once.
[7] When reporting 1-month endpoint data, the numerator is the number of subjects with an observation between the procedure and the end of the 1-month window. The denominator is includes subjects who did not have adequate imaging within the window but had an observation.

C. Study Population Demographics and Baseline Parameters

1. Demographics

The demographics of the study population are typical for a thoracic endovascular graft study performed in the US on high surgical risk subjects with chronic dissection involving the aortic arch.

A summary of subject demographics can be found in **Table 17**. Across the study population (N=60), the mean age was 65.9 ± 9.61 years (range 41–89). The cohort was predominantly male, with 81.7% (49/60) men, and had a mean Body Mass Index (BMI) of 30.0 ± 7.01 kg/m².

Table 17. Baseline Demographics

Age, years	
Mean ± SD (N)	65.9 ± 9.61 (60)
Median (Q1, Q3)	67.0 (59.0, 74.0)
(Min, Max)	(41.0, 89.0)
Gender	
Male	81.7% (49/60)
Female	18.3% (11/60)
Race	
American Indian/Alaska Native	0.0% (0/60)
Asian	3.3% (2/60)
Black/African American	38.3% (23/60)
Native Hawaiian/Other Pacific Islander	8.3% (5/60)
White	41.7% (25/60)
Other	6.7% (4/60)
Not Answered	1.7% (1/60)
Ethnicity	
Hispanic/Latino	10.0% (6/60)
Not Hispanic/Latino	86.7% (52/60)
Not Answered	3.3% (2/60)
BMI (kg/m2)	
Mean ± SD (N)	30.0 ± 7.01 (60)
Median (Q1, Q3)	28.6 (25.1, 33.7)
(Min, Max)	(18.0, 48.8)
Clinical Presentation of Arch Pathology	
Asymptomatic	88.3% (53/60)
Symptomatic	11.7% (7/60)
NEXUS Proximal Landing Zone	
Native Aorta	38.3% (23/60)
Previously Implanted Surgical Graft	61.7% (37/60)

Note: Subjects may have more than one race indicated

2. Baseline Medical History

Subjects were eligible for enrollment if they were classified as high-risk surgical candidates. Baseline medical history (**Table 18**) and Baseline Risk Factors (**Table 19**) confirmed a substantial burden of comorbidities. Coronary artery disease was present in 40.0% (24/60), significant valvular heart disease in 20.0% (12/60), and 33.3% (20/60) had a history of arrhythmia. A prior history of vascular intervention was reported in 28.3% (17/60). Additionally, 51.7% (31/60) of subjects were either current or former smokers, and 11.7% (7/60) were symptomatic at baseline. Other prevalent comorbidities included hypertension in 98.3% (59/60), hyperlipidemia in 80.0% (48/60), and chronic obstructive pulmonary disease (COPD) in 18.3% (11/60). Furthermore, 71.7% (43/60) had undergone a previous aortic intervention, and 70.0% (42/60) had a history of prior sternotomy.

All subjects were classified as American Society of Anesthesiologist (ASA) Class IV (severe systemic disease that is a constant threat to life, e.g., unstable angina), or ASA Class III (severe systemic disease with definite functional

limitation, e.g., chronic obstructive pulmonary disease), reflecting the high-risk nature of the treated population. Specifically, 55.0% (33/60) were ASA Class IV and 45.0% were ASA Class III (27/60).

Table 18. Subject Baseline Medical History

Chronic Obstructive Pulmonary Disease (COPD)	18.3% (11/60)
Diabetes Mellitus	21.7% (13/60)
Hypertension	98.3% (59/60)
Hyperlipidemia	80.0% (48/60)
Chronic Angina	3.3% (2/60)
Myocardial Infarction	11.7% (7/60)
Coronary Artery Disease (CAD)	40.0% (24/60)
Percutaneous Coronary Intervention (PCI)	10.0% (6/60)
Coronary Artery Bypass Graft	8.3% (5/60)
Congestive Heart Failure (CHF)	15.0% (9/60)
Transient Ischemic Attack	8.3% (5/60)
Cerebrovascular Accident	16.7% (10/60)
Peripheral Vascular Disease	20.0% (12/60)
Valvular Heart Disease	20.0% (12/60)
Arrhythmia	33.3% (20/60)
Carotid Arterial Disease	10.0% (6/60)
History of Malignancy	20.0% (12/60)
Previous Vascular Intervention	28.3% (17/60)
Previous Aortic Intervention	71.7% (43/60)
Previous Sternotomy	70.0% (42/60)
Previous Thoracotomy	3.3% (2/60)
Renal Insufficiency	38.3% (23/60)
Connective Tissue Disorder	0.0% (0/60)
Family History of Aortic Disease	6.7% (4/60)
Aortic Dissection	91.7% (55/60)
Paraplegia/Paraparesis	1.7% (1/60)

Table 19. Baseline Risk Factors

Smoking Status	
Current (within 30 days)	8.3% (5/60)
Former (>30 days)	43.3% (26/60)
Never smoked	48.3% (29/60)
Incomplete Circle of Willis [1]	12.1% (7/58)
ASA Classification	
I – Healthy subject	0.0% (0/60)
II – Mild systemic disease – no functional limitation	0.0% (0/60)
III – Severe systemic disease – definite functional limitation	45.0% (27/60)
IV – Severe systemic disease that is constant threat to life	55.0% (33/60)
V – Moribund subject unlikely to survive 24 hours with or without operation	0.0% (0/60)
New York Heart Association (NYHA) Classification	
I – Cardiac disease, physical activity not limited	46.7% (28/60)
II – Cardiac disease, physical activity slightly limited	36.7% (22/60)
III – Cardiac disease, physical activity markedly limited	0.0% (0/60)
IV – Cardiac disease, physical activity very limited	0.0% (0/60)
Not Applicable [2]	16.7% (10/60)

[1] Restricted to those with information known

[2] The Electronic Data Capture (EDC) allows you to indicate the NYHA classification as Not Applicable; however, a follow-up question asks "If Not Applicable, please confirm for eligibility that the subject does not have NYHA Classification of III of IV. Currently 15 patients have indicated they are not applicable and confirm the subject met the NYHA eligibility.

Common reasons investigators deemed the subject as high surgical risk are listed in **Table 20.** Other reasons are refusal of open repair or general frailty; however, this information was not captured in the study.

Table 20. Reasons For High Risk in Open Repair

ASA Score III or IV	100% (60/60)
Current or Former Smoker	51.7% (31/60)
Prior Sternotomy	70.0% (42/60)
Advanced Age (>75)	18.3% (11/60)
COPD	18.3% (11/60)
BMI (>30)	43.3% (26/60)
Female	18.3% (11/60)
Arrythmia	33.3% (20/60)
Prior Cerebrovascular Event	25.0% (15/60)
Inadequate Cardiac Function	
MI	11.7% (7/60)
PCI	10.0% (6/60)
CHF	15.0% (9/60)
Valvular Heart Disease	20.0% (12/60)
CAD	40.0% (24/60)

3. Lesion Characteristics

Table 21 presents core lab–reported baseline characteristics describing the extent of the aortic disease. Sixty percent (60.0%, 36/60) had proximal disease involvement beginning in Zone 0, and 80.4% (45/56) had distal disease extending to Zone 9 or beyond. All subjects in the TRIOMPHE study required a Zone 0 landing zone.

Table 21. Core Lab Reported Disease Extension

Proximal End of Disease	
Zone 0	36/60 (60.0%)
Zone 1	6/60 (10.0%)
Zone 2	9/60 (15.0%)
Zone 3	9/60 (15.0%)
Other	-
Distal End of Disease	
Zone 0	-
Zone 1	-
Zone 2	-
Zone 3	1/56 (1.8%)
Zone 4	2/56 (3.6%)
Zone 5	3/56 (5.4%)
Zone 6	1/56 (1.8%)
Zone 7	2/56 (3.6%)
Zone 8	1/56 (1.8%)
Zone 9	7/56 (12.5%)
Zone 10 - Right	4/56 (7.1%)
Zone 10 - Left	10/56 (17.9%)
Zone 11 - Right	12/56 (21.4%)
Zone 11 - Left	12/56 (21.4%)
Other	1/56 (1.8%)

Note: For subjects with the proximal extent of disease in Zone 2 or Zone 3, an adequate proximal landing zone was not available; therefore, device implantation required a proximal landing in Zone 0.

4. Device Usage

Table 22 provides a summary of the Stent Graft configurations implanted in subjects during the Index Procedure. Arch Stent Grafts implanted in subjects are summarized in **Table 23** Ascending Stent Grafts in **Table 24**, and optional Descending Extension Stent Grafts in **Table 25**.

Table 22. Stent Graft Configurations Implanted During Index Procedure

	# implanted
Arch Stent Graft and 1 Ascending Stent Graft	26.7% (16/60)
Arch Stent Graft and 2 Ascending Stent Grafts	0.0% (0/60)
Arch Stent Graft, 1 Ascending Stent Graft, and 1 Descending Extension	58.3% (35/60)
Arch Stent Graft, 1 Ascending Stent Graft, and 2 Descending Extensions	10.0% (6/60)
Arch Stent Graft, 2 Ascending Stent Grafts, and 1 Descending Extension	3.3% (2/60)
Arch Stent Graft, 2 Ascending Stent Grafts, and 2 Descending Extensions	1.7% (1/60)

Table 23. Arch Stent Graft Implanted

Branch Diameter	Branch Length	Descending Aorta Diameter	Descending Aorta Length	# Implanted
14	20	32	180	1.7% (1/60)
14	20	36	180	0.0% (0/60)
14	20	40	180	0.0% (0/60)
14	30	32	180	20.0% (12/60)
14	30	36	180	8.3% (5/60)
17	20	32	180	5.0% (3/60)
17	20	36	180	1.7% (1/60)
17	30	32	180	21.7% (13/60)
17	30	36	180	10.0% (6/60)
17	30	40	180	1.7% (1/60)
17	40	32	180	1.7% (1/60)
17	40	36	180	5.0% (3/60)
20	20	32	180	1.7% (1/60)
20	20	36	180	5.0% (3/60)
20	30	32	180	8.3% (5/60)
20	30	36	180	1.7% (1/60)
20	30	40	180	1.7% (1/60)
20	40	32	180	5.0% (3/60)
20	40	36	180	0.0% (0/60)

Table 24. Ascending Stent Graft Sizes Implanted

Ascending Diameter	Length	Configuration	# Implanted
36	40	Curved	12.7% (8/63)

36	55	Curved	20.6% (13/63)
36	70	Curved	3.2% (2/63)
40	40	Curved	7.9% (5/63)
40	55	Curved	25.4% (16/63)
40	70	Curved	12.7% (8/63)
43	55	Curved	9.5% (6/63)
43	70	Curved	7.9% (5/63)

Note: Denominators are based on the number of Ascending Stent Grafts used

Table 25. Descending Extension Stent Graft Sizes Implanted

Tapered			
Proximal Diameter	**Length**	**Distal Diameter**	**#Implanted**
36	125	31	7.1% (3/42)
36	157	31	19.0% (8/42)
36	189	31	38.1% (16/42)
36	189	36	4.8% (2/42)
40	125	36	2.4% (1/42)
40	157	36	4.8% (2/42)
40	157	40	2.4% (1/42)
40	189	36	11.9% (5/42)
40	189	40	7.1% (3/42)
43	162	40	2.4% (1/42)
43	194	40	0.0% (0/42)
Straight			
Diameter	**Length**		
31	189		0.0% (0/9)
36	125		11.1% (1/9)
36	157		0.0% (0/9)
36	189		22.2% (2/9)
40	157		11.1% (1/9)
40	189		33.3% (3/9)
43	166		11.1% (1/9)
43	200		11.1% (1/9)

Note: Denominators are based on the number of Descending Extension Stent Grafts used

5. Procedure Characteristics

Supra-aortic bypass (Phase 1)

Phase 1 Procedure was defined as the supra-aortic bypass procedure. Phase 1 Procedural information is provided in **Table 26.**

Table 26. Phase 1 Parameters

Length of Surgical Procedure (min)	
Mean ± SD (N)	230.9 ± 84.71 (60)
Median (Q1, Q3)	220.5 (178.5, 273.0)
(Min, Max)	(73.0, 455.0)
Intubation Time (min)	
Mean ± SD (N)	286.5 ± 80.07 (57)
Median (Q1, Q3)	287.0 (223.0, 324.0)

(Min, Max)	(141.0, 466.0)
Estimated Blood Loss (ml)	
Mean ± SD (N)	299.7 ± 307.38 (59)
Median (Q1, Q3)	200.0 (100.0, 350.0)
(Min, Max)	(25.0, 1500.0)
Transfusion Required	8.3% (5/60)
Transfusion Amount (ml)	
Mean ± SD (N)	535.8 ± 292.47 (4)
Median (Q1, Q3)	535.0 (285.0, 786.5)
(Min, Max)	(250.0, 823.0)
RCC-Left Common Carotid (LCC)	
Native	2.5% (1/40)
Graft	97.5% (39/40)
Diameter	
Mean ± SD (N)	7.9 ± 0.27 (39)
Median (Q1, Q3)	8.0 (8.0, 8.0)
(Min, Max)	(7.0, 8.0)
LCC-LSA	
Native	11.1% (4/36)
Graft	88.9% (32/36)
Diameter	
Mean ± SD (N)	7.8 ± 0.45 (32)
Median (Q1, Q3)	8.0 (8.0, 8.0)
(Min, Max)	(6.0, 8.0)
RCC-LSA	
Native	0.0% (0/20)
Graft	100.0% (20/20)
Diameter	
Mean ± SD (N)	7.9 ± 0.72 (20)
Median (Q1, Q3)	8.0 (8.0, 8.0)
(Min, Max)	(6.0, 10.0)
Other Anatomic Locations	
Native	50.0% (10/20)
Graft	50.0% (10/20)
Diameter	
Mean ± SD (N)	8.0 ± 0.00 (10)
Median (Q1, Q3)	8.0 (8.0, 8.0)
(Min, Max)	(8.0, 8.0)
Was Mini Sternotomy Performed?	
Yes	6.7% (4/60)
No	93.3% (56/60)
Retropharyngeal bypass performed?	
Yes	76.7% (46/60)
No	23.3% (14/60)
Bypass Patent at End	100.0% (60/60)

Note: Information in this table is limited to study subjects who proceeded to the index procedure.

One subject was initially enrolled for treatment with NEXUS. This subject completed the Phase 1 Procedure, in preparation for the Index Procedure, it was noticed the subject no longer met anatomical eligibility. The subject was withdrawn from the study and was treated with NEXUS under expanded access/compassionate use. Data from this subject is not included in the analysis. All other subjects who underwent the Phase 1 procedure proceeded to the index procedure.

Index Procedure (NEXUS Procedure)

The mean time from insertion of the first stent graft delivery system to withdrawal of the final delivery system (Ascending, or Descending, if applicable) was 85 minutes overall. Use of the optional descending stent graft was implanted in 73.3% (44/60). Rapid pacing, performed at three predefined time points during the procedure, had an overall mean cumulative duration of 102.9 seconds.

In 61.7% (37/60) the proximal landing zone was within a surgical graft. Conversely, the native aorta served as the proximal landing zone in 38.3% (23/60) of subjects (**Table 27**).

Table 27. Procedural Parameters

Device Deployment Time (min) [1]	
Mean ± SD (N)	85.0 ± 41.68 (59)
Median (Q1, Q3)	75.0 (57.0, 103.0)
(Min, Max)	(21.0, 250.0)
Rapid Pace Time (Sec)	
Mean ± SD (N)	102.9 ± 70.25 (60)
Median (Q1, Q3)	90.0 (63.0, 130.0)
(Min, Max)	(12.0, 420.0)
Length of Procedure (min) [2]	
Mean ± SD (N)	229.8 ± 69.61 (60)
Median (Q1, Q3)	213.0 (179.5, 263.0)
(Min, Max)	(131.0, 470.0)
Intubation Time (min)	
Mean ± SD (N)	333.5 ± 194.73 (55)
Median (Q1, Q3)	305.0 (254.0, 352.0)
(Min, Max)	(153.0, 1583.0)
Fluoroscopy Time (min)	
Mean ± SD (N)	50.1 ± 18.97 (59)
Median (Q1, Q3)	46.0 (36.0, 64.0)
(Min, Max)	(1.0, 96.0)
Volume of Contrast (ml)	
Mean ± SD (N)	150.1 ± 68.70 (60)
Median (Q1, Q3)	135.0 (100.0, 190.0)
(Min, Max)	(33.0, 337.0)
Estimated Blood Loss (ml)	
Mean ± SD (N)	214.8 ± 185.88 (58)
Median (Q1, Q3)	200.0 (100.0, 300.0)
(Min, Max)	(0.0, 900.0)
Transfusion Required	23.3% (14/60)
Transfusion Amount (ml)	
Mean ± SD (N)	1214.6 ± 1994.16 (13)
Median (Q1, Q3)	620.0 (350.0, 1000.0)
(Min, Max)	(340.0, 7750.0)
Anesthesia	
General	100.0% (60/60)
Local	0.0% (0/60)
Main Access Method	
Cutdown	95.0% (57/60)
Percutaneous	5.0% (3/60)
Main Access Vessel	
Right Femoral	85.0% (51/60)
Left Femoral	15.0% (9/60)
Additional Access Sites	
Right Femoral	15.3% (9/59)
Left Femoral	84.7% (50/59)
Axillary Access Method	

Cutdown	33.9% (19/56)
Percutaneous	66.1% (37/56)
Axillary Access Sites	
Right	94.5% (52/55)
Left	5.5% (3/55)
Additional Access Used?	60.0% (36/60)
Proximal Landing Zone	
Within Surgical Graft	61.7% (37/60)
Within Native Aorta	38.3% (23/60)
Distal Extension Used?	
Yes	73.3% (44/60)
No	26.7% (16/60)
Surgical Conversion [3]	0.0% (0/60)

[1] First insertion of Arch Stent Graft delivery to withdrawal of Ascending Stent graft delivery system.
If Descending stent is being used, then withdrawal of Descending Stent graft delivery.
[2] Skin to skin time.
[3] At time of Index Procedure.
[4] Extended procedure time due to non-device related adverse events, estimated blood loss was 250 mL, Hemoglobin decreased from 13.0 g/dL to a nadir of 10.5 g/dL.

Table 28 presents the hospitalization period. The median hospital stay after Index Procedure was 8.0 days (5.0, 12.0), with a median ICU stay of 3.0 days (1.0, 4.5).

Table 28. Hospitalization Period

Number of Days between Phase 1 and Index Procedures	
Mean ± SD (N)	11.6 ± 27.92 (60)
Median (Q1, Q3)	4.5 (3.0, 9.0)
(Min, Max)	(2.0, 212.0)
Phase 1 Procedure	
Length of ICU Stay (days)	
Mean ± SD (N)	3.6 ± 5.04 (60)
Median (Q1, Q3)	2.0 (1.0, 4.0)
(Min, Max)	(0.0, 23.0)
Phase 1 and Index procedure in same admission?	
Yes	73.3% (44/60)
No	26.7% (16/60)
Index Procedure	
Length of Intensive Care Unit (ICU) Stay (days) [1]	
Mean ± SD (N)	3.8 ± 3.82 (56)
Median (Q1, Q3)	3.0 (1.0, 4.5)
(Min, Max)	(0.0, 22.0)
Length of Hospital Stay (days) [1]	
Mean ± SD (N)	9.4 ± 7.00 (56)
Median (Q1, Q3)	8.0 (5.0, 12.0)
(Min, Max)	(1.0, 40.0)
[1] Subjects who experienced early mortality are not included in the length of ICU or hospital stay	

Table 29 Lists the unanticipated and anticipated adjunctive procedures that occurred during the Phase 1 Procedure (5.0%, 3/60) or during the Index Procedure (15.0%, 9/60).

Table 29. Adjunctive Procedures by Subject

	Time Point	Event (n)	Anticipated	Intervention
110003	Phase 1	Clamp injury	Yes	Stent

	Time Point	Event (n)	Anticipated	Intervention
120011	Phase 1	Dissection flap seen on imaging of the right carotid artery	Yes	Patch angioplasty of right carotid artery
124011	Phase 1	Acute pulmonary oedema	Yes	Reintubation
102008	Index Procedure	Femoral artery access was high	Yes	Stent across the access site via a contralateral approach
103002	Index Procedure	Right brachial occlusion	Yes	Graft repair
103005	Index Procedure	Right brachial dissection	Yes	Repair sutures and bovine patch
103013	Index Procedure	Commercial catheter breakage	Yes	Retrieval
103020	Index Procedure	Bend at the NEXUS BCT origin	Yes	Stent in BCT[1]
105001	Index Procedure	Left renal artery occlusion	Yes	Stent
111016	Index Procedure	Cardiac perforation	Yes	Pericardial window, cardiopulmonary bypass
115012	Index Procedure	1) Acute compartment syndrome; 2) CVA	1) No 2) Yes	1)Forearm fasciotomy and decompression with carpel tunnel release 2) Reintubation
124011	Index Procedure	Transient Paraparesis	Yes	Lumbar Drain Placed

[1]Subject also met device technical failure, site does not consider this an adverse event

D. Safety and Effectiveness Results

This study (CIP009) had two co-primary endpoints: 1) Device Technical Failure and 2) Clinical Failure through 30 days. These capture both safety and effectiveness.

1. Safety and Effectiveness Results

The analysis of safety and effectiveness was based on the chronic dissection cohort of 60 subjects available for the 30-day evaluation. The co-primary endpoint results are presented below in **Table 30** with details of each endpoint event in **Table 31**.

Device Technical Failure (through 30-Day):

- Failure to accurately deliver, track and deploy all required endovascular device components at the intended implantation site and failure to retrieve the delivery systems without the need for unplanned additional procedures
    - Including the placement of a commercial stent in the BCT
- Device occlusion (complete absence of blood flow at any point)
- Failed exclusion of primary entry tear
- Additional unanticipated surgical or interventional procedure related to the device or procedure, to prevent life-threatening or permanent disabling event.
    - Surgical Conversion
    - Re-Intervention to treat migration (movement greater than 10mm)
    - Re-Intervention to treat stenosis (>50% narrowing) or occlusion (complete absence of blood flow at any point)
    - Re-Intervention to treat Type Ia, Ib, III, IV Endoleaks
    - Re-Intervention to treat for loss of device integrity

Clinical Failure: Subjects experiencing at least one of the following MAEs through 30-Day of Phase 1 Procedure and 30-Day of Index Procedure:

- Early Mortality
- Disabling Stroke
- Permanent Paralysis/Paraplegia
- Renal failure
- Aortic rupture
- Development of new dissections in the thoracic aorta or brachiocephalic artery

The null hypothesis was rejected for both co-primary endpoints.

Freedom from device technical failure, was met in 95.0% (57/60) of subjects, with a failure rate of 5.0% (3/60; 95% CI: 1.04–13.92; p<0.001 versus the 30% performance goal). Technical failure events included failure to deliver/track/deploy system (3.3%, 2/60), additional unanticipated procedures: surgical conversion (1.7%, 1/60).

Freedom from clinical failure, was met in 85.0% (51/60) of subjects, with a clinical failure rate of 15.0% (9/60; 95% CI: 7.10–26.57; p<0.001 versus the 35% performance goal). Contributing events included death (10.0%, 6/60), disabling stroke (8.3%, 5/60), and development of new dissection (1.7%, 1/60). Two strokes and the dissection resulted in fatalities. No cases of permanent paralysis/paraplegia, renal failure, or aortic rupture were reported.

There were no occurrences of device occlusion, failed exclusion of the primary entry tear, or reinterventions for type I, III or IV endoleak, stenosis, migration, or loss of device integrity through 30 days. Of the two deployment-related failures, one involved intraoperative placement of a stent in the BCT following NEXUS deployment. In the second case, the device failed to deploy and was removed, and a new device was successfully implanted, all without any associated complications or adverse events.

The Co-Primary Endpoints (30 Days) are provided in **Table 30**. The components of the primary endpoints over time are provided in **Table 33.**

Table 30. Co-Primary Endpoints (30 Days)

	% (n/N)	95% CI	p-value
Device Technical Failure [1]	5.0% (3/60)	1.04, 13.92	<0.001
Failure to deliver/track/deploy components or retrieve delivery system	3.3% (2/60)	0.41, 11.53	
Device Occlusion	0.0% (0/60)	0.00, 5.96	
Failed Exclusion of Primary Entry Tear	0.0% (0/60)	0.00, 5.96	
Additional Unanticipated Procedure	1.7% (1/60)	0.04, 8.94	
Surgical Conversion	1.7% (1/60)	0.04, 8.94	
Re-intervention for Migration	0.0% (0/60)	0.00, 5.96	
Re-intervention for Stenosis or Occlusion	0.0% (0/60)	0.00, 5.96	
Re-intervention for Type Ia, Ib, III, IV Endoleaks	0.0% (0/60)	0.00, 5.96	
Re-intervention for Loss of Device Integrity	0.0% (0/60)	0.00, 5.96	
Clinical Failure [2], [3]	15.0% (9/60)	7.10, 26.57	<0.001
Death	10.0% (6/60)	3.76, 20.51	
Disabling Stroke	8.3% (5/60)	2.76, 18.39	
Permanent Paralysis/Paraplegia	0.0% (0/60)	0.00, 5.96	
Renal Failure	0.0% (0/60)	0.00, 5.96	
Aortic Rupture	0.0% (0/60)	0.00, 5.96	
Development of New Dissection	1.7% (1/60)	0.04, 8.94	

[1] p-value is derived from a one sample, one-sided exact binomial test against a reference safety goal of 30%.

[2] p-value is derived from a one sample, one-sided exact binomial test against a reference safety goal of 35%
[3] The clinical failure events include any MAE occurring through 30 days of the Phase 1 (supra-aortic bypass) procedure and though 30 days of Index (NEXUS) procedure. One MAE (disabling stroke) occurred following the Phase 1 Procedure. All other MAEs occurred following the Index procedure.

Table 31 provides a description of the events considered device technical or clinical failure. **Table 33** provides the primary endpoint components through 12 months.

Table 31. Event Descriptions for Subjects Who Met Endpoint

Subject #	Device Technical Failure	Clinical Failure	Description of Event
103002	Yes – Surgical Conversion	Yes - Development of a New Dissection Requiring Treatment (Surgical Conversion) and Early Mortality (Anoxic Brain Injury)	Uneventful Phase 1 and Index Procedure. On Post Operative Day (POD) 1, Computed Tomography Angiography (CTA) demonstrated an acute Type A aortic dissection requiring surgical repair. The subject expired on POD 14 due to anoxic brain injury.
103020	Yes - Failure to Deliver/Track/Deploy Components or Retrieve Delivery System (including placement of a commercial stent in the BCT)	No	Uneventful Phase 1 Procedure. During Index Procedure, imaging suggested a bend at the NEXUS BCT origin; a commercial stent was placed in the BCT without complication. Post-placement imaging showed good flow. No adverse events occurred.
110012	No	Yes -Disabling Stroke	Uneventful Phase 1 and Index Procedure. On POD 2, CT demonstrated new hypodense foci in the right cerebellar hemisphere and left frontal lobe. mRS went from 1 to 3.
110018	No	Yes – Disabling Stroke Resulting in Early Mortality	Uneventful Phase 1 and Index Procedure. On POD 3, a seizure occurred and imaging demonstrated a right temporoparietal intraparenchymal hemorrhage. Hemicraniectomy and hematoma evacuation were performed. Subject expired on POD 55 without hospital discharge. Note: After the Index Procedure and prior to death the subject was diagnosed with cerebral amyloid angiopathy, a condition associated with increased risk of intracerebral bleeding.
111014	No	Yes - Early Mortality (Hypertension)	Uneventful Phase 1 and Index Procedure. Subject was discharged to home on POD 3 following uneventful hospital course. Subject expired on POD 11. Site was notified of the death through the electronic medical records system. Cause of death was indicated as hypertension.
112011	Yes - Failure to Deliver/Track/Deploy Components or Retrieve Delivery System	No	Uneventful Phase 1 Procedure. During the Index Procedure, the initial arch device did not deploy and was removed without complication. A new arch device was implanted without issue. No adverse events occurred.
115012	No	Yes -Disabling Stroke (after phase 1 prior to Index Procedure)	Uneventful Phase 1 Procedure. Later that day, CT demonstrated an acute right parietal stroke. mRS increased from 0 to 4. Over time, mRS improved and the Index Procedure was successfully performed 211 days later.
120013	No	Yes - Disabling Stroke	Uneventful Phase 1 and Index Procedure. On POD 6, seizure-like activity occurred and CT demonstrated a trace acute left frontal subarachnoid hemorrhage

Subject #	Device Technical Failure	Clinical Failure	Description of Event
			without large vessel occlusion. Baseline mRS was 0; no post-event mRS was recorded.
122010	No	Yes - Early Mortality (Bradycardia)	Uneventful Phase 1 Procedure. The subject had a prolonged recovery from the Phase 1 Procedure and remained intubated and on inotropic support on POD 3 when the Index Procedure was performed. Following the Index Procedure, the subject experienced respiratory and hemodynamic instability. The family elected to withdraw care on POD 14 and the subject expired.
126002	No	Yes – Disabling Stroke and Early Mortality (Hemorrhage Intracranial)	Uneventful Phase 1 and Index Procedure. On POD 4, the subject experienced a disabling hemorrhagic stroke. The subject expired on POD 6 due to left lobar intracranial hemorrhage.
130012	No	Yes - Early Mortality (Cardiac Failure)	Uneventful Phase 1 Procedure, though technically challenging due to prior cervical fusion and limited neck mobility. Postoperatively, the subject required inotropic support and experienced airway swelling. Recovery was complicated by reduced cardiac function. The Index Procedure was performed on POD 2 with difficult intubation but was otherwise uneventful. The subject subsequently developed progressive heart failure and multi-organ failure. The family elected withdrawal of life support and the subject expired on POD 18 due to cardiac failure.

Sensitivity Analysis

A sensitivity analysis was conducted to assess the potential impact of missing data on the co-primary endpoint of 'device technical failure'. The only subjects who did not complete 30 days of follow-up were those who experienced early mortality and were therefore counted as events for the co-primary endpoint of 'clinical failure'. Among these subjects, one had already experienced a device technical failure and one died on Day 55 during the index hospitalization and was classified as early mortality, leaving four subjects who could potentially be considered as having missing 'device technical failure' endpoint data. As described in the table below, even assuming all four subjects experienced device technical failure, the upper bound of the 95% confidence interval remained below the prespecified performance goal of 30%.

Table 32. Device Technical Failure Tipping Point Analysis

	% (n/N)	95% CI	p-value [1]
No Imputation	5.0% (3/60)	1.04, 13.92	<0.001
Impute 1 Failure	6.7% (4/60)	1.85, 16.20	<0.001
Impute 2 Failures	8.3% (5/60)	2.76, 18.39	<0.001
Impute 3 Failures	10.0% (6/60)	3.76, 20.51	<0.001
Impute 4 Failures	11.7% (7/60)	4.82, 22.57	<0.001

[1]p-value is derived from a one sample, one-sided exact binomial test against a reference safety goal of 30%.

Note: A total of 4 subjects had potential missing data for device technical failure.

2. Primary Endpoint Component Event Results through 12-Months

The device technical failure rate was 5.0% (3/60) at 30 days and 8.3% (5/60) at 12 months. The two additional events observed after 30 days were surgical conversions occurring on POD 67 and POD 92. No subjects experienced device

occlusion, failure to exclude the primary entry tear per Core Laboratory assessment, or reinterventions for migration, stenosis or occlusion, loss of device integrity, or Type Ia, Ib, III, or IV endoleaks.

The 30-day clinical failure rate was 15.0% (9/60). By 12 months, six additional subjects experienced a clinical failure, including one disabling stroke, one new dissection, and five deaths. The disabling stroke and all deaths were adjudicated by the CEC as not related to the investigational device. No subjects experienced permanent paralysis/paraplegia, renal failure requiring permanent dialysis, or aortic rupture.

Table 33. Primary Endpoint Component Events through 12-Months

Primary Endpoint Analysis	Phase 1	Index Procedure (1)	Pre-Discharge	30 Days (2-30)	6 Months (31-180)	12 Months (181-365)	Total (Through 12 Months)
Number of Enrolled Subjects	60	60	60	60	55	48	60
Number of Subject with Imaging	-	-	49	55	46	47	58
Subjects with Device Technical Failure Co-Primary Endpoint	-	3.3% (2/60)	-	1.7% (1/60)	3.6% (2/55)	0.0% (0/48)	8.3% (5/60)
Subject with Clinical Failure Co-Primary Endpoint	-	0.0% (0/60)	-	13.3% (8/60)	14.5% (8/55)	4.2% (2/48)	26.7% (16/60)
Device Technical Failure	-	3.3% (2/60)	-	1.7% (1/60)	3.6% (2/55)	0.0% (0/48)	8.3% (5/60)
Failure to Deliver/Track/Deploy Components or Retrieve Delivery System	-	3.3% (2/60)	-	-	-	-	3.3% (2/60)
Device Occlusion	-	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Failed Exclusion of Primary Entry Tear	-	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Additional Unanticipated Procedure	-	0.0% (0/60)	-	1.7% (1/60)	3.6% (2/55)	0.0% (0/48)	5.0% (3/60)
Surgical Conversion	-	0.0% (0/60)	-	1.7% (1/60)	3.6% (2/55)	0.0% (0/48)	5.0% (3/60)
Re-intervention for Migration	-	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Re-intervention for Stenosis or Occlusion	-	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Re-intervention for Type Ia, Ib, III, IV Endoleaks [2]	-	0.0% (0/60)	-	0.0% (0/60)	3.6% (2/55)	2.1% (1/48)	5.0% (3/60)
Re-intervention for Loss of Device Integrity	-	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Clinical Failure	1.7% (1/60)	0.0% (0/60)	-	13.3% (8/60)	14.5% (8/55)	4.2% (2/48)	28.3% (17/60)
Death [1]	0.0% (0/60)	0.0% (0/60)	-	8.3% (5/60)	10.9% (6/55)	4.2% (2/48)	21.7% (13/60)
Disabling Stroke	1.7% (1/60)	0.0% (0/60)	-	6.7% (4/60)	1.8% (1/55)	0.0% (0/48)	10.0% (6/60)
Permanent Paralysis/Paraplegia	0.0% (0/60)	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Renal Failure	0.0% (0/60)	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Aortic Rupture	0.0% (0/60)	0.0% (0/60)	-	0.0% (0/60)	0.0% (0/55)	0.0% (0/48)	0.0% (0/60)
Development of New Dissection	0.0% (0/60)	0.0% (0/60)	-	1.7% (1/60)	1.8% (1/55)	0.0% (0/48)	3.3% (2/60)

[1] One subject expired on POD55; however, was never discharged. Thus, this subject counts towards the 30-day Clinical Endpoint.

[2] Endoleak Assessment by Site. Core laboratory reported these subjects as having Type II endoleaks; however, site assessments in these subjects raised concern for Type III endoleaks and led to reintervention. Specifically:115034: The PI attributed the endoleak to the carotid artery, false lumen of the LSA, and partially the vertebral artery; however, the relative contribution of each source was uncertain. Based on this assessment, a reintervention was performed, which resolved the endoleak. The core laboratory reported this as a Type II endoleak with inflow from intercostal/lumbar vessels.116011: The site initially assessed the endoleak as Type II; however, subsequent concern for a possible Type III endoleak led to endovascular intervention. The endoleak remained unchanged following reintervention. The core laboratory reported this as a Type II endoleak with the LSA as the source.100004: The site initially reported an unknown endoleak and later determined a possible Type III endoleak, prompting endovascular intervention. The core laboratory reported this as a Type II endoleak with the LSA as the source.

3. Intraprocedural and Post Procedural Adverse Events

Nine subjects (15.0%, 9/60) experienced a site reported complication during the Phase 1 Procedure resulting in an adverse event related to the bypass procedure. These included neck hematoma requiring evacuation or exploration (n=3), clamp-related injury to the left subclavian artery requiring stenting (n=1), dysphagia requiring airway monitoring (n=1), acute pulmonary edema requiring reintubation (n=1), coagulopathy requiring transfusion (n=1), acute kidney injury (n=1), and one disabling stroke (n=1).

Eight subjects (13.3%, 8/60) experienced a site reported complication occurring during the Index Procedure resulting in an adverse event. These included ventricular fibrillation requiring defibrillation and chest compressions and blood loss anemia requiring transfusion and medical management, in addition to the events listed in Table 18 (Adjunctive Procedures).

None of the Intra-Index Procedure complications described above were classified as device-related.

Separately, five SAEs were adjudicated by the CEC as related (n=4) or possibly related (n=1) to the NEXUS device. The related events included two aortic dissections that resulted in surgical conversion and two Type II endoleaks requiring reintervention. The event was adjudicated as possibly related was a non-disabling stroke that occurred on POD 11 and resolved without intervention.

4. Additional Outcomes

In addition to the Primary Endpoints noted above, secondary endpoints were evaluated through 30 days. No events of prolonged intubation, extension of a dissection, distal device-related thromboembolic events requiring reintervention or a surgery, MI, life threatening bleeding, fistula formation or false lumen perfusion through the primary entry tear, false lumen perfusion through an aortic arch branch vessel without distal entry tear were reported within 30 days, as assessed by the site or core laboratory, as applicable. **Table 34** provides a summary of secondary endpoints with observed occurrences.

Table 34. Secondary Endpoints: Proportion of Subjects Free from Event At 30 Days

	% (n/N)
Renal dysfunction or volume overload requiring ultrafiltration	98.3% (59/60)
Laryngeal or Phrenic Nerve injury post Index Procedure	95.0% (57/60)
Severe Heart Failure/Hypertension	95.0% (57/60)
Type II endoleaks from supraortic arch vessels	95.0% (57/60)

The following endpoints were evaluated through 30 days and all subsequent intervals:

Table 35. CEC Adjudicated and Core Lab Reported Secondary Endpoints Over Time

	Index Procedure (1)	30 Days (2-30)	6 Months (31-180)	1 Year (181-365)	2 Years (366-730)	3 Years (731-1095)	4 Years (1096-1460)	Total [1]
	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)
All-cause mortality	- (0/60)	8.3% (5/60)	10.9% (6/55)	4.2% (2/48)	2.2% (1/46)	3.2% (1/31)	- (0/14)	25.0% (15/60)
Lesion related mortality	- (0/60)	6.7% (4/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	6.7% (4/60)
Rupture within or adjacent to the treated segment	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Any neurological event	- (0/60)	13.3% (8/60)	3.6% (2/55)	2.1% (1/48)	4.3% (2/46)	3.2% (1/31)	- (0/14)	18.3% (11/60)
Any paralysis/paraplegia	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Renal failure [2]	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Development of new dissection proximal or distal to the treatment zone	3.3% (2/60)	1.7% (1/60)	1.8% (1/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	6.7% (4/60)
Unintentional rupture of the dissection septum	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Endoleaks	- (0/60)	11.7% (7/60)	7.3% (4/55)	2.1% (1/48)	6.5% (3/46)	- (0/31)	7.1% (1/14)	18.3% (11/60)
Type Ia	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Type Ib	- (0/60)	- (0/60)	- (0/55)	- (0/48)	2.2% (1/46)	- (0/31)	- (0/14)	1.7% (1/60)

	Index Procedure (1)	30 Days (2-30)	6 Months (31-180)	1 Year (181-365)	2 Years (366-730)	3 Years (731-1095)	4 Years (1096-1460)	Total [1]
	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)	% (n/N)
Type II	- (0/60)	6.7% (4/60)	5.5% (3/55)	2.1% (1/48)	2.2% (1/46)	- (0/31)	- (0/14)	8.3% (5/60)
Type IIIa	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	7.1% (1/14)	1.7% (1/60)
Type IIIb	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Type IV	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Type V	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Type Undetermined	- (0/60)	5.0% (3/60)	1.8% (1/55)	- (0/48)	2.2% (1/46)	- (0/31)	- (0/14)	6.7% (4/60)
Migration [3]	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Patency-related events	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Conversion to open repair	- (0/60)	1.7% (1/60)	3.6% (2/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	5.0% (3/60)
Secondary procedures in the treatment area/treatment branches [4]	- (0/60)	3.3% (2/60)	7.3% (4/55)	2.1% (1/48)	- (0/46)	3.2% (1/31)	- (0/14)	11.7% (7/60)
Fistula formation	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
Loss of stent graft integrity [5]	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)
New ischemia	- (0/60)	- (0/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/60)

[1] Event percentages in this column may be an underestimation as 5-year follow-up is not complete, [2] New onset requiring permanent dialysis. [3] Greater than 10 mm or clinically significant migration, [4] Includes reintervention to treat endoleaks, stenosis, or occlusion of the investigational device, does not include reintervention for planned staged treatment of LSA or DE
Note: Core lab data is summarized per assigned visit, not study day.
Note: Subjects are included in the denominator if they reached the opening of the visit window.

5. Key Events: Information presented below is inclusive of key events reported after Phase 1 procedure and the index procedure:

Neurological Events

All reported neurological events were reviewed and adjudicated by the independent CEC which includes a neurologist. Five subjects (8.3%, 5/60) experienced a disabling stroke within 30-days of the Phase 1 Procedure or Index Procedure. One subject (1.7%, 1/60) had a disabling stroke after 30 days post the Index Procedure. Five subjects (8.3%, 5/60) experienced a non-disabling neurological event within 1 year of the Index Procedure.

Table 36 shows the CEC adjudicated neurological events across all timepoints.

Table 36. CEC Adjudication Details: Neurological Events

Subject	AE Description	Onset POD Index Procedure	Status (days to resolution)	Phase I Procedure Related	Device Related	Index Procedure Related	Disabling
103005	Subarachnoid Hemorrhage	987	Death	Not Related	Not Related	Not Related	N
103005	Acute/Early Subacute Embolic Infarcts in the Cerebrum and Cerebellum	35	Recovered/Resolved with Sequelae (44)	Possibly	Not Related	Possibly	Y
103007	Acute Cerebellar Embolic Infarcts	365	Recovered/Resolved (4)	Not Related	Not Related	Not Related	N
105008	Stroke	11	Recovered/Resolved (5)	Possibly	Possibly	Related	N
110012	Stroke	3	Recovered/Resolved with Sequelae (5)	Probably	Not Related	Not Related	Y
110015	Stroke	7	Recovered/Resolved (193)	Probably	Not Related	Probably	N
110018	Ischemic Stroke with Hemorrhagic Conversion	3	Death	Probably	Not Related	Probably	Y
111016	Stroke	9	Recovered/Resolved with Sequelae (45)	Not Related	Not Related	Related	N
111016	General Brain Infarctions	53	Recovered/Resolved with Sequelae (1)	Not Related	Not Related	Probably	N
115012	Post Phase 1 CVA	-211[1]	Recovered/Resolved with	Related	Not Applicable	Not Applicable	Y

Subject	AE Description	Onset POD Index Procedure	Status (days to resolution)	Phase I Procedure Related	Device Related	Index Procedure Related	Disabling
			Sequelae (398)				
116006	Basilar Artery Occlusion	530	Death	Not Related	Not Related	Not Related	N
120013	Left frontal Subarachnoid Hemorrhage	7	Recovered/Resolved with Sequelae (42)	Probably	Not Related	Probably	Y
126002	Intracranial Hemorrhage, Intraparenchymal, Large Acute	5	Death	Possibly	Not Related	Related	Y
130012	Watershed Stroke	16	Recovered/Resolved (2)	Probably	Not Related	Probably	N
[1] Occurred day of Phase 1 Procedure, subject completed Index Procedure 211 days after the disabling stroke							

New Dissections, Extension of Dissection

Four subjects had a new dissection event as described below:

- Two (3.3%, 2/60) were Retrograde Type A requiring conversion to open surgery within 92 days of the NEXUS procedure.
- The third (1.7%, 1/60) was a dSINE occurring 2-years after implantation with NEXUS and was treated with a TEVAR.
- One subject had a new dissection in the BCT identified by the core lab on the discharge CT. No reintervention was performed; subject remains stable at the 2-year follow-up visit.

Core lab identified one subject with proximal extension of the original dissection first observed at the 1-year follow-up (1.7%, 1/60). The extension remains stable at the 2-year follow-up. No reintervention was performed. No subjects experienced distal extension.

Open Conversions

Three Subjects had open conversions as described below:

- Two (3.3%, 2/60) were Retrograde Type A requiring conversion to open surgery within 92 days of the NEXUS procedure.
- One (1.7%, 3/60) was an Endoleak (Type II – intercostal/lumbar endoleak) treated with a surgical conversion.

Additional information on these three occurrences can be found in **Table 42.**

Mortality Over Time

Subjects enrolled in the study were considered high risk for open surgical repair, and the mortality reflects a clinically complex and medically fragile population. **Table 37** summarizes all-cause mortality over time. Most subjects who died were classified as ASA Class IV, indicating severe systemic disease posing a constant threat to life. The most common causes of death were cardiac arrest or cardiac failure (10.0%, 6/60), followed by stroke (6.7%, 4/60).

All-cause mortality by follow-up period is shown below in **Table 37.** The CEC adjudicated relatedness and cause of death per Medical Dictionary for Regulatory Activities (MedDRA) coding are also provided (**Table 38**).

Table 37. Mortality

	Index Procedure (1)	30 Days (2-30)	6 Months (31-180)	1 Year (181-365)	2 Years (366-730)	3 Years (731-1095)	4 Years (1096-1460)	5 Years (>1460)	Total [1]
All-Cause Death	- (0/60)	8.3% (5/60) [2]	10.9% (6/55)	4.2% (2/48)	2.2% (1/46)	3.2% (1/31)	- (0/14)	- (0/9)	25.0% (15/60)
Lesion Related Mortality	- (0/60)	6.7% (4/60)	- (0/55)	- (0/48)	- (0/46)	- (0/31)	- (0/14)	- (0/9)	6.7% (4/60)

[1] Event percentages in this column may be an underestimation as 5-year follow-up is not complete

[2] One subject died post 30 days of Index Procedure but death was during original index hospitalization. It is included in the 6 Months window but is considered a primary endpoint event.

Table 38. All-Cause Mortality Over Time with CEC Adjudication

Subject ID	# Days Post-Index Procedure Death Occurred	Cause of Death	CEC Adjudicated Lesion Related Mortality (LRM)	CEC Adjudicated Phase 1 Relatedness	CEC Adjudicated Device Relatedness	CEC Adjudicated Procedure Relatedness
103002	14	Brain Injury	Yes	Not Related	Not Related	Related
103005	1056	Subarachnoid Hemorrhage	No	Not Related	Not Related	Not Related
103020	317	Cardiac Arrest	Unable to assess [1]	Not Related	Not Related	Not Related
105012	104	Cardiac Arrest	Unable to Assess	Not Related	Not Related	Not Related
110018	55	Ischemic Stroke	No	Probably	Not Related	Probably
111014	11	Hypertension	Yes	Not Related	Not Related	Related
111016	54	Cardiac Failure	No	Not Related	Not Related	Related
112011	310	Cardiac Arrest	No	Not Related	Not Related	Not Related
116006	531	Basilar Artery Occlusion	No	Not Related	Not Related	Not Related
116011	81	Unknown Cause	No	Not Related	Not Related	Not Related
120013	49	Cardiac Arrest	Unable to assess	Probably	Not Related	Probably
122010	14	Bradycardia	Yes	Probably	Not Related	Probably
124002	74	Unknown Cause	Unable to assess	Not Related	Not Related	Not Related
126002	6	Hemorrhage Intracranial	No	Possibly	Not Related	Related
130012	18	Cardiac Failure	Yes	Probably	Not Related	Probably

[1]The CEC adjudicated this event as "unable to assess" for LRM. An Independent Consulting Physician conducted an comprehensive review of all available imaging and source documentation. As stated in the death report, "In conclusion, the NEXUS device successfully sealed the proximal and distal extents of the aortic segment it was intended to treat. The false lumen subsequently recanalized, leading to re-pressurization and rupture. This event should not be classified as lesion-related mortality, as the source of rupture occurred outside the treatment zone of the NEXUS system."

Additional details on subjects with undetermined cause of death or where the lesion related mortality is adjudicated as "unable to assess" by the CEC are presented below:

- **Subject 103020:** The subject underwent an uneventful Phase 1 and Index Procedure apart from an additional BCT stent that was placed, and the subject was subsequently discharged. Follow-up CT scan on postoperative day 312 showed an occluded false lumen. On POD 317, the subject experienced acute left flank pain, and CT imaging revealed acute false lumen reperfusion from an entry in the peri-visceral aorta, beyond the aorta treated with the stent. The subject died rapidly from cardiac arrest.

- **Subject 105012:** The subject had a medical history significant for COPD, atrial fibrillation, first-degree heart block, chronic kidney disease stage 3, left ventricular ejection fraction of 32%, abnormal right ventricular function, and severe global hypokinesis of the left ventricle. The subject was discharged home after Index Procedure but presented acutely to the hospital on POD 87 with chest pain, which subsequently settled. Imaging at that time revealed expansion of the distal descending aorta, and a branched repair was planned. The subject died prior to this planned procedure on POD105, which was reported as a myocardial infarction.

- **Subject 120013:** The subject underwent an uneventful Phase 1 and Index Procedure . On postoperative day 7, the subject developed urinary retention and required catheterization. This was followed by Klebsiella sepsis complicated by pulseless electrical activity arrest and subsequent anoxic brain injury. The subject was

discharged to long-term care on POD 26, experienced gradual deterioration, and received palliative care before dying on POD 49.

- **Subject 124002:** The subject was a 64-year-old female with a previously implanted surgical graft due to history of type A aortic dissection in November 2012, hypertension, deep vein thrombosis, asthma, and active smoking with a 50 pack-year history. Subject underwent an uneventful Index Procedure completed in 96 minutes and was discharged on POD 3. Subject was readmitted on POD 10 with a chest infection and again on postoperative day 29 with ground-glass lung changes on CT, along with multi-chamber cardiomegaly and pulmonary hypertension. Follow-up aortic CT on POD 38 was unremarkable. The subject death on POD 74 was reported with no further details available.

- **Subject 116011:** This subject was a 56-year-old male subject with an extensive medical history including peripheral vascular disease, a right axillary-femoral bypass that was subsequently explanted due to infection with residual sections remaining in place, an arteriovenous fistula, prior sternotomy for thoracic aortic dissection, end-stage renal disease on hemodialysis before receiving a renal transplant (requiring immunosuppression), and a history of mesenteric ischemia. The subject underwent an uneventful Index Procedure but developed urinary retention on POD 5, necessitating urinary catheter insertion, and was discharged on POD 6. He was readmitted on POD 11; CTA revealed a Type 2 endoleak originating from the left subclavian artery. On POD 28, the subject underwent left subclavian artery occlusion but subsequently developed esophagitis and gastritis. The subject required one additional treatment for the Type 2 endoleak, followed by a third intervention for what was suspected to be a Type III endoleak, though the Core Lab classified it as a Type 2 endoleak with the left subclavian artery as the source. On POD67, he was readmitted and was noted to have lost notable weight over the preceding six months. The subject died in a skilled nursing facility on POD 80, and no post-mortem examination was performed. Possible causes of death include chronic sepsis masked by immunosuppression, upper gastrointestinal bleeding, or aortic complications, though the latter seems less likely given the prolonged clinical deterioration.

Endoleaks

Table 39 provides the endoleaks by timepoint evaluated by the core lab. The most common endoleak was Type II and it was seen in five subjects (8.3%, 5/60). Six subjects had non-type II endoleaks (10.0%, 6/60). Two subjects (3.3%, 2/60) had Type 1b endoleaks involving thoracic aortic locations which were planned as a staged procedure to reduce the risk of Spinal Cord Ischemia (SCI). The majority of endoleaks were seen at the discharge or 30-day visit with many resolving spontaneously.

Table 40 provides the endoleaks by timepoint as assessed by the site. Site-reported endoleak rates were higher than those reported by the Core Laboratory. Site investigators were instructed to report endoleaks conservatively; if there was uncertainty regarding the presence of an endoleak, it was reported as an endoleak to ensure subject safety and close monitoring. In contrast, the Core Laboratory performed independent centralized image review using a predefined, standardized, and blinded adjudication process conducted by experienced reviewers. These differences in reporting approach likely contributed to the higher rate of site-reported endoleaks compared with Core Laboratory assessments.

A total of 11 subjects (18.3%, 11/60) experienced core lab reported endoleaks over time . Of these 5.0% (3/60) resolved without intervention, and 3.3% (2/60) subjects expired with ongoing endoleaks, neither death was assessed as related to the endoleak.

Two subjects (103013, 124012) had reported endoleak with reintervention and aortic enlargement. Additional information can be found in the Aortic enlargement section and **Table 42.**

A total of 30 subjects (50%) experience site reported endoleak across all timepoints. Out of these, 11.7% (7/60) underwent reintervention for a site reported endoleak, of which 85.7% (6/7) were performed using an endovascular approach. Within the first year, 5.0% (3/60) of subjects (115034, 116011, 100004) required reintervention for an endoleak.

Beyond the first year, the next reintervention for an endoleak occurred on POD806 due to a dSINE, which the core laboratory classified as a Type Ib endoleak. Additionally, two subjects underwent TEVAR reinterventions at approximately 3 and 4 years of follow-up, respectively. The reintervention at 4-years was performed to address an endoleak involving commercial (not NEXUS) stent grafts. These cases are summarized in **Table 42**.

Table 39. Core Lab Reported Endoleaks

	Pre-Discharge	30-Day	6-Month	1-Year	2-Year	3-Year	4-Year	Total (Subjects) [1]
Subjects with Adequate Imaging	43	51	43	46	23	13	6	60
Subjects with Endoleak Ongoing in Window	11.6% (5/43)	13.7% (7/51)	11.6% (5/43)	2.2% (1/46)	13.0% (3/23)	0	16.7% (1/6)	18.3% (11/60)
New	11.6% (5/43)	5.9% (3/51)	2.3% (1/43)	0	4.3% (1/23)	0	16.7% (1/6)	-
Persistent	-	7.8% (4/51)	9.3% (4/43)	2.2% (1/46)	4.3% (1/23)	0	0	-
Type I	2.3% (1/43)	0	0	0	4.3% (1/23)	0	0	3.3% (2/60)
New	2.3% (1/43)	0	0	0	4.3% (1/23)	0	0	-
Type Ia	0	0	0	0	0	0	0	-
Type Ib	2.3% (1/43)	0	0	0	4.3% (1/23)	0	0	-
Persistent	-	0	0	0	0	0	0	-
Type II	7.0% (3/43)	7.8% (4/51)	9.3% (4/43)	2.2% (1/46)	4.3% (1/23)	0	0	8.3% (5/60)
New	7.0% (3/43)	2.0% (1/51)	2.3% (1/43)	0	0	0	0	-
Persistent	-	5.9% (3/51)	7.0% (3/43)	2.2% (1/46)	4.3% (1/23)	0	0	-
Type III	0	0	0	0	0	0	16.7% (1/6)	1.7% (1/60)
New	0	0	0	0	0	0	16.7% (1/6)	-
Type IIIa	0	0	0	0	0	0	16.7% (1/6)	-
Type IIIb	0	0	0	0	0	0	0	-
Persistent	-	0	0	0	0	0	0	-
Type IV	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	-
Type V	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	-
Undetermined	2.3% (1/43)	5.9% (3/51)	2.3% (1/43)	0	0	0	0	5.0% (3/60)
New	2.3% (1/43)	3.9% (2/51)	0	0	0	0	0	-
Persistent	-	2.0% (1/51)	2.3% (1/43)	0	0	0	0	-
Subjects with no Endoleak Ongoing in Window	88.3% (38/43)	86.3% (44/51)	88.4% (38/43)	97.6% (41/42)	86.9% (20/23)	100% (13/13))	83.3% (5/6)	81.6% (49/60)
[1] Event percentages in this column may be an underestimation as 5-year follow-up is not complete								

Table 40. Site Reported Endoleaks

	Pre-Discharge	30 Days	6 Months	1 Year	2 Years	3 Years	4 Years	Total [1]
Subjects with Adequate Imaging	45	55	45	43	23	11	3	60
Subjects with Endoleak Ongoing in Window	37.8% (17/45)	30.9% (17/55)	17.8% (8/45)	25.6% (11/43)	13.0% (3/23)	18.2% (2/11)	33.3% (1/3)	50.0% (30/60)
New	37.8% (17/45)	14.5% (8/55)	2.2% (1/45)	7.0% (3/43)	0	9.1% (1/11)	-0	-
Persistent	-	16.4% (9/55)	15.6% (7/45)	18.6% (8/43)	13.0% (3/23)	9.1% (1/11)	33.3% (1/3)	-
Type I	17.8% (8/45)	18.2% (10/55)	6.7% (3/45)	7.0% (3/43)	4.3% (1/23)	9.1% (1/11)	0	26.7% (16/60)
New	17.8% (8/45)	10.9% (6/55)	- (0/45)	4.7% (2/43)	0	0	0	-
Persistent	-	7.3% (4/55)	6.7% (3/45)	2.3% (1/43)	4.3% (1/23)	9.1% (1/11)	0	-
Type Ia	6.7% (3/45)	7.3% (4/55)	2.2% (1/45)	2.3% (1/43)	0	0	0	-
Type Ib	11.1% (5/45)	10.9% (6/55)	4.4% (2/45)	4.7% (2/43)	4.3% (1/23)	9.1% (1/11)	0	-
Type II	13.3% (6/45)	5.5% (3/55)	6.7% (3/45)	9.3% (4/43)	4.3% (1/23)	9.1% (1/11)	0	23.3% (14/60)
New	13.3% (6/45)	1.8% (1/55)	6.7% (3/45)	6.7% (3/45)	0	9.1% (1/11)	0	-
Persistent	-	3.6% (2/55)	0	0	4.3% (1/23)	0	0	-
Type III	4.4% (2/45)	5.5% (3/55)	0	2.3% (1/43)	0	0	33.3% (1/3)	8.3% (5/60)
New	4.4% (2/45)	3.6% (2/55)	0	0	0	0	33.3% (1/3)	-
Persistent	-	1.8% (1/55)	0	2.3% (1/43)	0	0	0	-
Type IIIa	4.4% (2/45)	5.5% (3/55)	0	2.3% (1/43)	0	0	33.3% (1/3)	-
Type IIIb	0	0	0	0	0	0	0	-
Type IV	0	0	0	0	0	0	0	0
New	0	0	0	0	0	0	0	-
Persistent	-	0	-0	0	0	0	0	-
Type Undetermined	2.2% (1/45)	1.8% (1/55)	4.4% (2/45)	4.7% (2/43)	4.3% (1/23)	0	0)	5.0% (3/60)
New	2.2% (1/45)	1.8% (1/55)	2.2% (1/45)	0	0	0	0	-
Persistent	-	0	2.2% (1/45)	4.7% (2/43)	4.3% (1/23)	0	0	-
Subjects with no Endoleak Ongoing in Window	62.2% (28/45)	69.1% (38/55)	82.2% (37/45)	74.4% (32/43)	87.0% (20/23)	81.8% (9/11)	66.7% (2/3)	43.3% (26/60)

[1] Event percentages in this column may be an underestimation as 5-year follow-up is not complete
Note: Site reported data is summarized per assigned visit, not study day.
Note: Subjects are included in the denominator if they had imaging available.
Note: Type V Endoleak was not an option for the site to select.

False Lumen Perfusion

Table 41 provides a summary of false lumen perfusion and false lumen status by follow-up period, as reported by the core lab. No cases of perfusion from the primary intimal tear were identified. At 30 days, three subjects (3/33; 9.1%) demonstrated FLP attributed to an aortic arch branch vessel. Among these subjects, one subject had perfusion from the LCC, two had perfusion from both the LCC and LSA. All three subjects also had concurrent perfusion from a distal entry tear.

Most subjects at 1-year (80.0%, 36/45) demonstrated FLP through a distal entry tear. This finding is consistent with baseline anatomy, as 80.4% of subjects (45/56) presented with dissections extending distally to Zone 9 or beyond, outside the treated segment, thereby providing a persistent potential source for false lumen perfusion.

By the 1-year follow-up window, all subjects demonstrated either partial thrombosis (57.8%, 26/45), complete

thrombosis (40.0%, 18/45), or no longer had a visible false lumen (2.2%, 1/45) within the treated segment, yielding 100% (45/45) with favorable remodeling.

In the untreated distal aorta at 1-year 15.6% (7/45) of subjects exhibited a patent false lumen, consistent with expectations for chronic dissections extending beyond the treated segment.

It is important to note subjects may demonstrate FLP even when the perfused false lumen is located beyond the distal extent of the NEXUS stent graft. The NEXUS system is designed to seal the primary entry tear and protect the aortic arch wall; persistent perfusion in the distal descending thoracic aorta reflects underlying disease outside the treated segment.

Table 41. Core Lab Reported False Lumen Perfusion and Patency Over Time

	Pre-Discharge	30-Day	6-Month	1-Year	2-Year	3-Year	4-Year	Total [1]
Number of Subjects with Adequate Imaging	44	51	42	45	24	13	6	60
False Lumen Perfusion through Primary Intimal Tear	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
False Lumen Perfusion Proximal Aorta	1 (2.3%)	1 (2.0%)	-	1 (2.2%)	-	-	-	2
False Lumen Perfusion through a Distal Entry Tear	40 (90.9%)	35 (68.6%)	37 (88.1%)	33 (73.3%)	21 (87.5%)	10 (76.9%)	4 (66.7%)	50
False Lumen Perfusion through an Aortic Branch Vessel	39 (88.6%)	33 (64.7%)	35 (83.3%)	36 (80.0%)	19 (79.2%)	10 (76.9%)	4 (66.7%)	51
Through Aortic Arch Branch Vessel Only (Without Distal Entry Tear)[2]	0	0	0	0	0	0	0	0
Through Aortic Arch Branch Vessel and Distal Entry Tear[2]	11 (28.2%)	3 (9.1%)	2 (5.7%)	3 (8.3%)	3 (15.8%)	1 (10.0%)	0 (0.0%)	15
LSA		0	0	0	1	1	-	
LCC		1	1	1	1	0	-	
LCC + LSA		2	0	1	1	0	-	
Undetermined		0	1	1	0	0	-	
Through Non-Arch Aortic Branch Vessel[2]	23 (59.0%)	20 (60.6%)	20 (57.1%)	23 (63.9%)	11 (57.9%)	7 (70.0%)	3 (75.0%)	38
False Lumen Perfusion Undetermined	-	1 (2.0%)	-	-	-	-	-	1
False Lumen Status: Treated Segment								
No False Lumen	-	-	-	1 (2.2%)	1 (4.2%)	-	-	1
Patent	-	-	-	-	-	-	-	0
Partially Thrombosed	38 (86.4%)	36 (70.6%)	25 (59.5%)	26 (57.8%)	16 (66.7%)	8 (61.5%)	3 (50.0%)	49
Completely Thrombosed[3]	6 (13.6%)	15 (29.4%)	17 (40.5%)	18 (40.0%)	6 (25.0%)	5 (38.5%)	3 (50.0%)	34
False Lumen Status: Untreated Distal Aorta								
No False Lumen	1 (2.3%)	1 (2.0%)	2 (4.8%)	3 (6.7%)	1 (4.2%)	-	-	4
Patent	15 (34.1%)	13 (25.5%)	9 (21.4%)	7 (15.6%)	6 (25.0%)	4 (30.8%)	1 (16.7%)	23
Partially Thrombosed	27 (61.4%)	33 (64.7%)	29 (69.0%)	31 (68.9%)	14 (58.3%)	6 (46.2%)	5 (83.3%)	47
Completely Thrombosed	-	2 (3.9%)	2 (4.8%)	3 (6.7%)	-	2 (15.4%)	-	6
False Lumen Perfusion (New + Persistent)								
New	1 (2.3%)	1 (2.0%)	2 (4.8%)	6 (13.3%)	2 (8.3%)	2 (15.4%)	0 (0.0%)	13
Persistent	43 (97.7%)	39 (76.5%)	38 (90.5%)	37 (82.2%)	21 (87.5%)	10 (76.9%)	4 (66.7%)	51

	Pre-Discharge	30-Day	6-Month	1-Year	2-Year	3-Year	4-Year	Total [1]
New+Persistent	43 (97.7%)	39 (76.5%)	38 (90.5%)	37 (82.2%)	21 (87.5%)	10 (76.9%)	4 (66.7%)	51
[1] Event percentages in this column may be an underestimation as 5-year follow-up is not complete Note: USFU images were reviewed by core lab and are reflected in the number of subjects with adequate imaging								

Aortic Enlargement

Across all timepoints 11.7% (7/60) of subjects treated with NEXUS demonstrated aortic diameter enlargement (more than 5 mm compared to 30-day) as assessed by the core lab. Four subjects (105001, 112011, 124012, 126001) had re-interventions for aortic enlargement within the first year (6.7%, 4/60). Six of the seven subjects with enlarging aortas had distal false lumen perfusion present (FLP). No aortic ruptures or unexplained sudden deaths were reported among these subjects. Additional details on these subjects are as follows:

- Subject 103007 (distal end of disease: Zone 9) had aortic enlargement observed at 1-year follow-up with distal FLP. On POD614 false lumen embolization using shape memory and ruby coils and Impede- FX embolization plug. Aortic enlargement continues at most recent 4-year follow-up.
- Subject 103013 (distal end of disease: Zone 11) had aortic enlargement observed at 2-year follow-up with distal FLP and unknown type endoleak per core lab. On POD 957 TEVAR (C-TAG) was placed. The next follow-up visit post endovascular reintervention has not yet happened.
- Subject 105001 (distal end of disease: Zone 9) had aortic enlargement observed at 6 months with distal FLP. On POD173 a TEVAR (NEXUS) was placed, POD419 a custom Fenestrated Endovascular Aortic Repair (FEVAR) was placed to extend, on POD706 Endovascular Aneurysm Repair (EVAR) to extend further and left renal and celiac stent extensions were performed. On POD1156 relining of left renal and celiac extensions, right iliac limb extension and embolization was performed. Next follow-up visit post recent reintervention has not yet happened.
- Subject 110003 (distal end of disease: Zone 11) had aortic enlargement observed at 2-years with distal FLP and distal stent graft-induced new entry (dSINE). TEVAR (C-TAG) placed and at the 4-year follow-up the aorta remains stable without further expansion.
- Subject 112011 (distal end of disease: Zone 11) had aortic enlargement observed at 1-year follow-up due to distal FLP. Prior to the 1-year follow-up the subject had a TAA repair with four-vessel branched endograft (TAMBE). At the time of the data cut, the 2-year visit had not yet occurred.
- Subject 124012 (distal end of disease: Zone 11) had a Type II endoleak reported at 6 months and aortic enlargement observed at 1 year follow-up. Prior to this visit, the subject had False Lumen (FL) embolization for Type II intercostal sources. The 2-year visit showed a continued increase in the aortic enlargement but no further action was taken.
- Subject 126001 (distal end of disease: Right Iliac) had aortic enlargement observed at 6 months. On POD 92 subject had a surgical conversion from a delayed retrograde type A. The 3-year scan showed a decrease in the aortic diameter compared to the 2-year scan.

Reinterventions

Through 12 months, 25% (15/60) of subjects underwent reintervention, of which 10% (6/60) were planned:

- 3 subjects (5.0%, 3/60) had a reintervention after the Phase 1 Procedure and prior to the Index Procedure. All involved neck exploration.
- 3 subjects (5.0%) had a reintervention for endoleaks
- 4 subjects (6.7%) had a reintervention for aortic enlargement
- 2 subjects (3.3%) had surgical conversions
- 6 (10%) subjects had planned re-interventions after being discharged from the Index Procedure. These include staged exclusion of the LSA or DE.

Reinterventions reported for the study subjects through all timepoints are described in **Table 42.**

Table 42. Additional Procedures Post Phase 1 Procedure and Reinterventions Post Index Procedure

Event	Subject ID	POD from Index Procedure	Comment
Acute Respiratory Distress Post Phase 1 Procedure	105027	-9 [1]	Acute respiratory distress post Phase 1 Procedure, emergent neck exploration performed. Index procedure occurred nine days later.
Left Neck Hematoma Post Phase 1 Procedure	103002	-5 [1]	Bilateral neck exploration and hematoma evacuation due to neck swelling and complaints of difficulty with swallowing and breathing. Index Procedure was performed five days later.
Left Neck Hematoma Post Phase 1 Procedure	122010	-3 [1]	Exploration of neck wounds of bypass surgery which didn't show evidence of active bleeding. Index Procedure was performed 3 days later.
Type A Retrograde Dissection	103002	2	Acute type A aortic dissection, underwent a surgical conversion with an aortic root and valve replacement, a two-vessel coronary artery bypass graft (left anterior descending & ramus intermedius) and ligation of the proximal LSA.
Planned Occlusion LSA	132002	13	LSA was not occluded at time of Phase 1 or Index Procedure as recommended by protocol. Principal Investigator (PI) preferred to stage placement of plug in LSA.
Endoleak	116011	15	LSA was not occluded at time of Phase 1 or Index Procedure as recommended by protocol.
		29	CTA taken two weeks later on showed continued endoleak coils were added to the LSA.
		39	Endoleak persisted 10 days later, site became concerned was possible Type III Endoleak instead of Type II endoleak. The site used a commercial graft to reline the NEXUS (TBE and C-TAG). Endoleak remained. Core Lab reported Endoleak as Type II with LSA as source.
Planned DE Extension	108006	43	PI preferred to stage the NEXUS distal extension from the index procedure.
Planned Occlusion LSA	129001	47	LSA was not occluded at time of Phase 1 or Index Procedure as recommended by protocol. PI preferred to stage coiling of LSA.
Planned DE Extension	122006	50	PI preferred to stage the NEXUS distal extension with knickerbocker from the index procedure.
Endoleak	115034	67	PI assessed a Type III endoleak and noted flow involving the carotid artery, false lumen of the LSA, and partially the vertebral artery; however, the relative contribution of each source was uncertain. Based on this assessment, a surgical conversion was performed, which resolved the endoleak. The core laboratory reported this as a Type II endoleak with inflow from intercostal/lumbar vessels.
Planned DE Extension	130008	86	PI preferred to stage the NEXUS distal extension with knickerbocker from the index procedure.
Surgical Conversion	126001	92	Developed a subacute type A aortic dissection, underwent a surgical conversion with a 28mm Gelweave graft, continues in the study.
Aortic Enlargement		499	Left heart bypass and elective surgical repair of thoracoabdominal aortic aneurysm (TAA)
Aortic Enlargement	112011	99	Repair of thoracoabdominal aortic aneurysm using 4 vessel branched endograft (TAMBE)
Persistent FLP	116006	170	TEVAR (Valiant) placed due to false lumen perfusion not from primary entry tear and coil embolization in LSA. Site Reported event as resolved.
Aortic Enlargement	124012	172	Candy Plug used to embolize FL. Due to persistent FL perfusion with aneurysm growth.

Event	Subject ID	POD from Index Procedure	Comment
Planned DE Extension, Aortic Enlargement and Commercial Graft Type IIIa Endoleak	105001	174	Planned TEVAR (NEXUS) Extension to treat ongoing thoracoabdominal aortic dissection
		419	Treat ongoing thoracoabdominal aortic dissection with custom four vessel FEVAR
		706	EVAR extension, left renal stent extension, celiac stent extension
		1156	Treat lumbar vessel Type II Endoleak and continued enlargement. Relining left renal, celiac extension, right iliac limb extension, right iliac limb coil embolization in the descending thoracic aorta
		1506	Type IIIa Endoleak of commercial (not NEXUS) device and Left Gastric Artery Aneurysm
Endoleak	100004	197	PI initially reported an unknown endoleak and later determined a possible Type III endoleak, prompting endovascular intervention (ballooning). The core laboratory reported a Type II endoleak with the LSA as the source.
Descending Thoracic Aorta – Enlargement	120012	301	Extension TEVAR (NEXUS) performed for descending thoracic aortic diameter measuring 5.1 cm. Site reported event as resolved.
Aortic Enlargement	103007	614	Persistent FL filling via multiple fenestrations with increased diameter of descending thoracic aorta. FL embolization using shape memory and ruby coils and Impede- FX embolization plug.
dSINE with Aortic Enlargement	110003	806	**S**tent graft induced tear in flap at the distal portion of treatment area with growth of the descending thoracic. Asymptomatic at this time. Re-intervention of an endograft extension (C-TAG) was completed. Note: Core Lab reported this as a Type Ib endoleak.
Endoleak with Aortic Enlargement	103013	957	CT showed unknown type endoleak and enlargement of the aortic arch. The patient underwent TEVAR (C-TAG) with retrograde plug placement into false lumen. Post-op CTA showed successful endoleak occlusion, stable residual dissection.
[1] Occurred after Phase 1 Procedure and Prior to Index Procedure			

6. Subgroup Analyses

Subgroup analyses of the co-primary device technical failure and clinical failure endpoints were performed for the following subgroups: gender, subjects with an existing graft, and subjects receiving an extension device. Neither co-primary endpoint differed notably between any of the subgroups.

7. Supplementary Clinical Information

NEXUS is CE Marked and has been evaluated in a comprehensive European clinical program encompassing prospective feasibility studies and compassionate use, with follow-up extending to 5 years. A total of 28 subjects (17 aneurysms, 6 chronic dissections, 4 mixed etiology, 1 penetrating aortic ulcers (PAU)) with complex aortic arch pathology were included. Imaging follow-up compliance was approximately 80% at 30 days and 100% at 1 year in the feasibly study with robust follow-up maintained through 5 years. The clinical study included CT imaging assessed by an independent reviewer acting as a core lab, adverse event adjudication by an independent CEC, and monitoring to ensure data accuracy. The results for 28 subjects demonstrated 100% technical success, a 30-day mortality rate of 7.1% and a single additional death between 30 days and 1 year bringing the overall 1-year mortality rate to 10.7%. Rate of unplanned reintervention within the first year was 7.1%, and rate of disabling stroke, non-disabling stroke, conversion to open surgery, and device migration was 3.6% respectively. There were no reported cases of aneurysm rupture, stent graft occlusion, stent graft fracture or deformity, renal failure requiring dialysis, paraplegia,

myocardial infarction, or new aortic dissection.

In addition, there is an ongoing post-market clinical study to collect standard of care clinical data of subjects treated with the NEXUS and the NEXUS Multi-Branch devices. The study includes 16 NEXUS subjects, 12 of whom have completed at least one year of follow-up. Clinical data is generated through CT imaging and assessed by an independent reviewer acting as a core lab, adverse event adjudication by an independent CEC, and monitoring to ensure data accuracy. The results demonstrated 100% technical success, no events of early mortality, and one subject experienced disabling stroke. In addition, no events of conversion to open surgery and no unanticipated surgical or interventional procedure to treat endoleak, occlusion, migration or loss of device integrity. There was one event of spinal cord ischemia (SCI). There were no reported cases of aneurysm rupture, stent graft occlusion, stent graft fracture or deformity and renal failure requiring dialysis.

Finally, the NEXUS device remains under IDE investigation for use in treatment of high surgical risk subjects with aneurysms, PAUs and intramural hematomas. A total of 34 subjects have been treated (27 aneurysms and 7 PAUs) as of November 2025. Out of these, 100% (16/16) of the eligible aneurysm subjects and 100% of the eligible PAU subjects (4/4) have completed their 1-year visit. Analysis of the baseline characteristics (age, comorbidities, BMI etc.) indicate that the aneurysm cohort exhibited a distinctly higher-risk clinical profile, which may contribute to the increased mortality observed in this group. Targeted risk mitigations have been identified and implemented in the clinical study protocol and training materials. In terms of outcomes available to date, a total of 7 subjects (6 aneurysms and 1 PAU) reported device technical failure at the end of index procedure. These events were primarily associated with need for unplanned BCT stenting with a commercial device (n=5). In terms of clinical events reported within 30 days of Phase 1 procedure and within 30-days of index procedure, 7 all cause mortalities (6 aneurysms and 1 PAU) were reported, out of which 2 were adjudicated by the CEC as lesion related mortalities (1 aneurysm and 1 PAU). Additionally, 2 disabling strokes (1 aneurysm and 1 PAU) and 1 new dissection event (aneurysm subject) have been reported within 30 days of index procedure. No cases of renal failure, aortic rupture, device occlusion, failed exclusion of the primary entry tear, or reintervention for device-related issues were reported through 30 days.

9 | TREATMENT AND FOLLOW-UP

9.1 Individualization of Treatment

Each NEXUS® component must fit the patient's anatomy and size. Proper sizing of the device is under the responsibility of the treating physician.

The aortic stent graft components should be over-sized according to the inner diameter of the vessel and the NEXUS® stent graft component intended for extension. Please refer to section 2.2 for Device Size. The recommended overall length of multiple deployed in situ assembled stent graft components of the NEXUS® should extend from just below the bifurcation of Brachiocephalic-RCCA arteries, Aortic Arch to LCCA to Descending Aorta, and Aortic Arch to the Ascending Aorta, adjacently and distally to the Coronary Arteries. All lengths and diameters of the stent graft components necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters/lengths) are un-certain.

Physicians may consult Endospan Ltd. in their efforts to determine proper stent graft component dimensions based on the physician's assessment of the patient's anatomical measurements. The risks and benefits should be carefully considered for each patient before use of the NEXUS® Aortic Arch Stent Graft System.

Patient selection factors to be assessed include those identified above in Section 5.2 Patient Selection.

CAUTION: Vessel damage such as dissection, perforation, or rupture may be caused by excessive oversizing of the stent graft in relation to the diameter of the blood vessel. Excessive or insufficient oversizing may also result in Type I endoleak. Consider vessel tortuosity when selecting stent graft length. If preoperative case planning measurements are not certain, an

inventory of stent graft lengths and diameters necessary to complete the procedure should be available to the physician. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. Using the device outside the recommended anatomical sizing may result in serious device-related adverse events. Physicians may consult with Endospan representative to determine proper stent graft component dimensions based on the physician's assessment of the patient's anatomical measurements. However, the final treatment decision is at the discretion of the physician and patient. The benefits and risks previously described should be carefully considered for each patient before using the NEXUS® Aortic Arch Stent Graft System.

9.2 Imaging Guidelines and Post-Operative Follow-up

All patients should be advised this treatment modality requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical finding (e.g. endoleaks, enlarging aorta or changes in structure or position of the endovascular graft) should receive enhanced follow-up. Patients should be counseled on the need for regular follow-up, even in the absence of obvious symptoms (e.g. pain, numbness, weakness).

Regular and consistent follow-up is a critical part of ensuring continuing safety and effectiveness of aortic endovascular repair. Physicians should tailor patient follow-up to the needs and imaging findings (e.g. endoleaks, loss of patency) and circumstances of each individual patient. In the US clinical study, at least one annual physician visit and the imaging schedule (**Table 43**) were employed. Additional surveillance and potential treatment is recommended for certain findings (see section 9.3 Additional surveillance and Potential Treatment). Follow-up modalities include CT/CTA or MRA. Data from these modalities is acquired and used to compare changes over time and their effects on exclusion of the lesion.

Table 43. Recommended Schedule for Patient Follow-up

Diagnostic Test	Pre-Treatment	Treatment	Pre-discharge	30-Days	6 Months	1-Year and Annually Thereafter
CTA	X		X[1]	X[1]	X[1]	X[1]
Angiography		X[2]				

[1]Spiral CT/MRI without contrast may be performed for subjects with impaired renal function

[2]Assess for any thrombus within the supra-aortic bypass prior to initiation of the NEXUS® procedure. Alternative imaging modalities may be used for this assessment if deemed appropriate by the implanting physician.

9.2.1 CT/CTA Imaging

- CT films should include all sequential images at the lowest possible slice thickness (≤ 2mm). DO NOT perform scans having large slice thicknesses (> 2mm) and/or omission of CT images/film sets (non-consecutive).
- **If an endoleak is suspected or there is lesion enlargement, both non-contrast and contrast runs should be performed.**
- Non-contrast and contrast run slice thickness and interval must match.
- DO NOT change patient orientation or re-landmark patient between non-contrast and contrast runs.
- Pre and Post-treatment CT/CTA imaging should be performed according to the guidelines listed in **Table 44**.

Table 44. CT/CTA Imaging Guidelines

Start Position	Angle of the mandible with the head in neutral position
End Position	Pre-Treatment: Femoral heads Post-Treatment: Superior Mesenteric Artery
Scan Field	Large
Field of Vision	240mm or as appropriate for patient
Scan Type	Helical
Slice Thickness	≤ 2mm

9.3 Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Branch vessel stenosis or occlusion
- Type I endoleak
- Type II endoleak
- Type III endoleak
- Persistent false lumen perfusion
- Lesions enlargement $\geq$ 5mm increase in maximum diameter (regardless of endoleak status) compared to any previous measurement.

Considerations for reintervention or open surgical repair should include the attending physicians' assessment of an individual patient's co-morbidities, life expectancy, and the patient's personal choices. Patients should be counseled as to the possibility of subsequent reinterventions including catheter-based and open surgical procedures, including conversions.

9.4 Patient Counseling Information

The physician should review the following risks and benefits when counseling the patient about this endovascular device and procedure:

- Age and life expectancy.
- Risks and benefits related to open surgical repair.
- Risks and benefits related to endovascular repair.
- Differences between endovascular repair and surgical repair.
- Treatment requires a staged approach, including completion of the Phase 1 bypass procedure followed by an appropriate recovery period prior to undergoing the Index Procedure.
- Risks of spontaneous aortic rupture compared to surgical repair.
- Risks related to non-interventional treatment (medical management).
- Possibility that subsequent endovascular or open surgical repair of the lesion may be required.
- Symptoms of aortic rupture.
- The long-term safety and effectiveness of aortic arch endovascular repair has not been established.
- Physicians should advise all patients that this treatment modality requires long-term, regular follow up to assess patients' health status and stent graft performance.
- Physicians should provide description of symptoms of stent graft occlusion, aneurysm enlargement or rupture
- Patients with specific clinical findings (e.g., endoleaks, enlarging aortas) should be monitored closely.
- Physicians must advise all patients that it is important to seek prompt medical attention if they experience signs of:
  - Symptoms of stent graft occlusion, aortic enlargement or rupture.
  - Chest pain.
  - Chest pressure.
  - Difficulty in Breathing.
  - Tiredness.
  - Claudication.
  - Neurological symptoms such as Confusion, syncope, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis, including vocal cord paralysis.
- Patients should be counseled on the importance of adhering to the follow-up schedule.
- Patients should be counselled on the risks related to the Phase 1 Procedure, including but not limited to acute kidney injury, acute pulmonary edema, bleeding, bypass graft occlusion, clamp-related vessel injury (e.g.,

dissection), coagulopathy, death, dysphagia, infection, myocardial infarction, neck hematoma requiring evacuation or surgical exploration, nerve injury (including thoracic duct injury), stroke (disabling or non-disabling), transient ischemic attack, and vessel injury. These events may require additional medical or surgical intervention and may result in prolonged hospitalization or recovery.

- Physicians are encouraged to refer the patient to the Patient Brochure regarding risks occurring during or after implantation of the device. Procedure related risks include cardiac, pulmonary, neurologic, bowel, and bleeding complications. Device related risks include occlusion, endoleak, lesion enlargement or progression, pseudoaneurysm formation, fracture, potential for reintervention and open surgical conversion, rupture and death (See Anticipated Adverse Events). Physicians are encouraged to complete the Patient Implant Card and give it to the patient so that they can carry it with them at all times. The patient should refer to the implant card anytime they visit additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

10 | HOW SUPPLIED

10.1 Contents and Sterility

The NEXUS® Aortic Arch Stent Graft System includes at least two preloaded individually packaged and sterilized delivery systems (and additional delivery system in case of using the Descending Extension Stent Graft and/or Ascending Curved Stent Graft), each with an integral handle. Each delivery system is dedicated to and incorporates one of the stent grafts.

The NEXUS® is supplied STERILE and non-pyrogenic, and is sterilized by ethylene oxide. Do not resterilize.

Do not use after the "Use By" date (expiration date) printed on the label.

The device is intended for single use only, do not reuse the device or attempt to re-sterilize.

If the device is damaged or the integrity of the sterilization barrier has been compromised, do not use the product and contact Endospan Ltd.

10.2 Storage

Store the system at room temperature in a dark, dry place.

11 | CLINICAL USE INFORMATION

11.1 Physician Training Requirements

WARNING: A (cardio) vascular surgery team should always be available during endovascular grafting procedures in case a conversion to open surgical repair is necessary. It is strongly recommended that an interventional cardiologist is available in case of acute heart dysfunction such as arrhythmia or pericardial hemorrhage occurs.

WARNING: The NEXUS® Aortic Arch Aneurysm Stent Graft System should be used only by physicians experienced in vascular interventional techniques, and who have successfully completed the appropriate physician training program which requires case planning/sizing and device training which includes positioning and deployment of the device. Physicians may be assisted in device preparation, delivery, and deployment by surgical team members trained on these steps.

Below are the recommended skills/knowledge requirements for physicians using the NEXUS® System:

11.1.1 Patient Selection

- Knowledge of the natural history of aortic arch and thoracic aortic diseases, including but not limited to aortic dissections and comorbidities associated with thoracic lesion repair, arch aneurysms and co-morbidities associated with aortic arch repair
- Knowledge of radiographic image interpretation, device selection and sizing.

11.1.2 A multi-disciplinary team that has combined procedural experience with:

- Vascular access techniques
- Guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Appropriate use of radiographic contrast material
- Arterial cut-down, arteriotomy, and repair
- Percutaneous access and closure techniques
- Nonselective and selective guide wire and catheter techniques
- Embolization
- Angioplasty
- Snare techniques
- Endovascular (aortic) stent placement
- Techniques to minimize radiation exposure
- Device selection and sizing
- Rapid Heart Pacing, or other available techniques to reduce cardiac output and blood pressure
- Conventional open surgery and surgical conversion: a Cardiothoracic Surgeon (or physician with experience in ascending aortic and arch surgery) and Vascular Surgeon (or physician with experience in managing vascular complications) should be present during the procedure or be notified of the procedure in advance and readily available should any emergent procedures be required peri-procedurally. Cardiac Anesthesiology (or specialty experienced in supporting ascending/aortic arch procedures and transesophageal echocardiography (TEE)) should be present during the procedure or be notified of the procedure in advance and readily available to provide support should any emergent procedures be required periprocedurally.

11.2 Inspection Prior Use

Inspect the device and packaging to verify that no damage or defect has occurred. If the "Use by" date has elapsed, if the device is damaged, or if the sterilization barrier has been compromised, do not use the device and contact Endospan Ltd. for return or replacement.

11.3 Additional Materials and Equipment Required for Device Placement

At the time of surgery, it is recommended that the physicians have the following materials available:

- All lengths and diameters of the NEXUS® Aortic Arch Aneurysm Stent Graft System necessary to complete the procedure, especially when preoperative case planning measurements (treatment diameters/lengths) are not certain.
- Fluoroscopic imaging with digital angiographic capabilities (fixed units are recommended) and the ability to record and recall all imaging (including radiopaque ruler with centimeter) increments.
- Assortment of guidewires and guiding catheters.
- Introducer sheaths including at least a minimum 7 Fr and a minimum 20 Fr introducer sheath
- Assortment of compliant and non-compliant balloon catheters.
- Sterile syringes (both locking and slip tip)
- Contrast media.
- Heparin and heparinized saline solution.
- Heart Pacing equipment, including electrodes (Cardiac Pacing).
- Surgical suite in the event that emergency open conversion surgery is necessary.
- Various .035 in (0.89mm) diameter guidewires, ≥260cm including ≥400cm.
- Power Injector.
- Intravascular Ultrasound.
- Surgical suite in the event that emergency open conversion surgery is necessary

11.4 Following Usage

After use, dispose of the product and packaging in accordance with hospital, administrative and/or local government policy.

12 | DIRECTIONS FOR USE

The following instructions contain a basic guideline for device placement. These instructions are intended to guide the physician and do not take the place of physician judgment.

12.1 General Use Information

Standard techniques for placement of arterial access sheaths, guiding catheters, angiographic catheters and guide wires are applicable.

12.2 Pre-Implant Determinants

Correct sizing of the aortic arch, supra-aortic and Iliofemoral access vessels must be determined before implantation of the stent graft components using contrast-enhanced computer-aided tomography (CT) or MRA, as well as angiograms of vessels (see **Figures 11, 12 and 13**). 3D imaging may also be beneficial. These images should be available for review during the procedure. Vascular instruments and other surgical supplies needed to gain access to the artery should also be available.

Determine access paths (Iliofemoral vessels as well as branchial and axillary vessels) and compatibility for an endovascular procedure through a ≥20Fr sheath, the suitable device sizing based on patient's anatomical measurements (see also Section 2.2 Device Size, Section 2.3 Recommended Device Sizing and below **Figures 11, 12 and 13**).
To reduce the risk of thromboembolism, it is recommended that the patient be heparinized for the duration of the procedure.

CAUTION: Never advance or retract equipment from the vasculature without using fluoroscopy. This may result in a major vascular complication and may lead to patient's death.

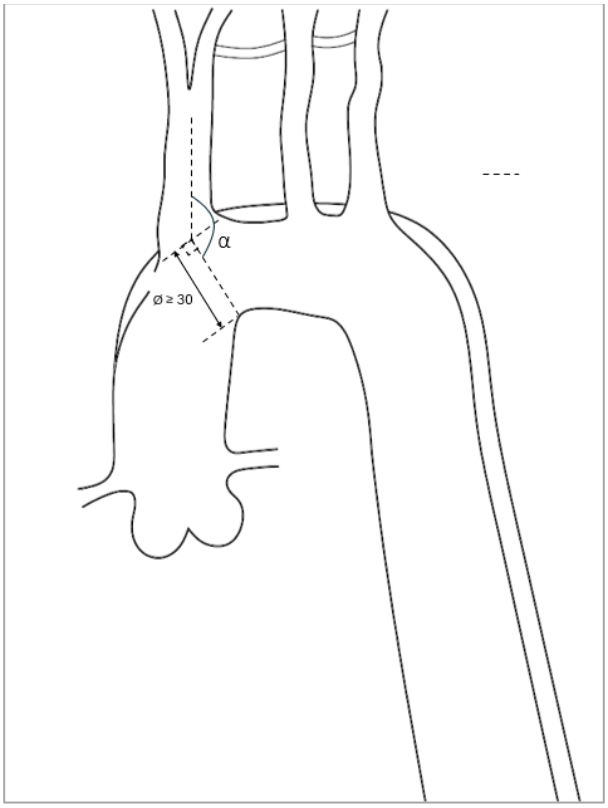


Figure 11 - Screening measurements (Dock ø≥30mm, α Angle ≥125°)

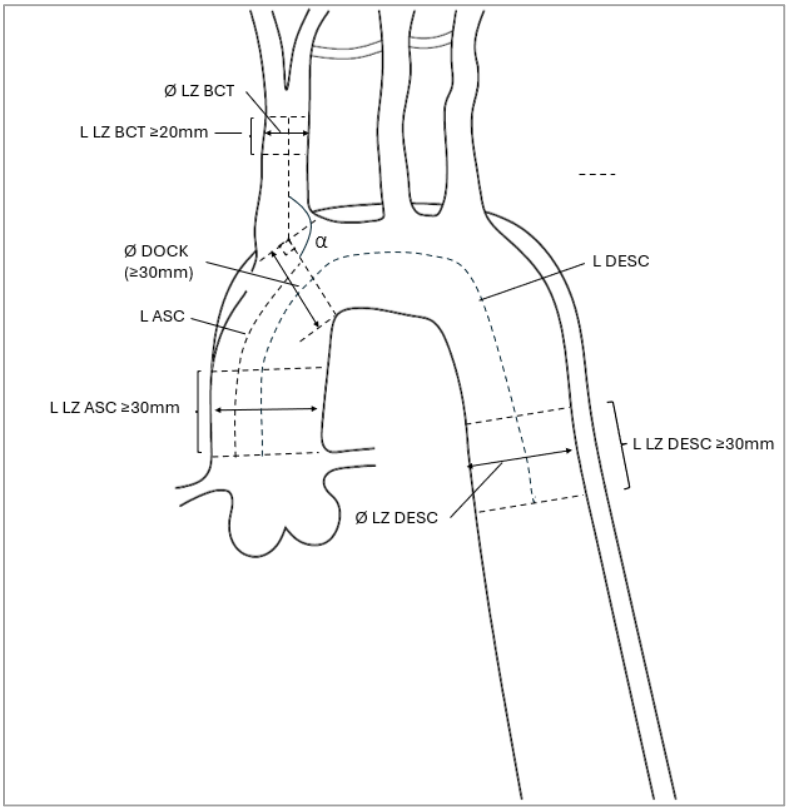


Figure 12- Screening measurements (Ascending and Arch Stent Grafts)

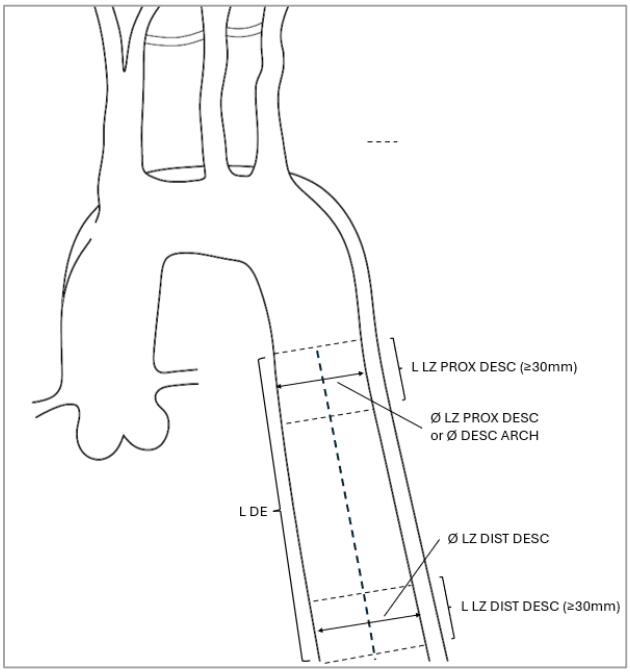


Figure 13 – Screening measurements (Descending Extension)

Refer to Section 2.2 Device Size for the sizes of the configurations of the NEXUS® Aortic Arch Stent Grafts and Section 2.3 Recommended Device Sizing for landing zone sizing.

Ascending Stent Graft Measurements (Figure 12)

Measurement ø LZ ASC – Ascending Aorta Landing Zone Diameter for the Ascending Stent Graft, this determines the diameter of the Ascending Stent Graft (see Section 2.3 for sizing)

Measurement L LZ ASC – Centerline length of the Ascending Aorta Landing Zone Length (must be ≥30mm)

Measurement L ASC – Centerline Length of Ascending Stent Graft

Arch Stent Graft Measurements (Figure 11and 12)

Measurement α Angle – The measurement of angle between the center line of Brachiocephalic Trunk Artery and a line perpendicular to the Aortic Arch center line ≥125°.

Measurement ø DOCK – Aorta diameter at the location of Dock Expansion, measured from the inner curve of the aorta to the BCT ostium and perpendicular to the center line of the aorta

Measurement L BCT – Length of Branch Graft - Centerline length from the ostium of the BCT to below the bifurcation of the BCT, this determines the length of the Branch Graft

Measurement L LZ BCT – Centerline length of the Landing Zone of the Branch Stent

Measurement ø LZ BCT – Branch Landing Zone diameter of the Branch Stent, this determines the diameter of the Branch Stent (see Section 2.3 for sizing)

Measurement L DESC – Centerline measurement from the BCT to the end of the Landing Zone in the descending aorta, if > 180mm a Descending Extension may be required to extend the Landing Zone

Measurement ø LZ DESC – Descending aorta landing zone diameter, this determines the diameter of the Arch Stent Graft - Distal Graft Portion Sizing (see Section 2.3 for sizing)

Descending Extension Measurements (Figure 13)

Measurement ø LZ PROX DESC – Descending aorta landing zone diameter or previously implanted Arch Stent Graft diameter, this determines the proximal diameter of the Descending Extension (see Section 2.3 for sizing)

Measurement L LZ PROX DESC – Centerline length of the proximal landing zone of the Descending Extension (must be ≥30mm). If placed in a previously implanted Arch Stent Graft then 3 stent overlap (B marker of Descending Extension aligned with Dot Marker of descending portion of the Arch Stent Graft)

Measurement L DE – Centerline measurement between proximal end of the proximal landing zone and distal end of the distal landing zone, this determines the minimum length of Descending Extension.

Measurement ø LZ DIST DESC - Descending aorta distal landing zone diameter this determines the distal diameter of the Descending Extension (see Section 2.3 for sizing)

Measurement L LZ DIST DESC - Centerline length of the distal landing zone of the Descending Extension (must be ≥30mm).

12.3 Patient Preparation

12.3.1 Refer to institutional protocols relating to anesthesia, anticoagulation and monitoring of vital signs.

12.3.2 Position patient in supine position and imaging table allowing fluoroscopic visualization from the aortic arch to the iliac arteries.

12.4 Vascular Access

12.4.1 Establish bilateral femoral access (ipsilateral 7Fr upgradable to minimum 20Fr, contralateral minimum 5Fr).

12.4.2 Establish right brachial/axillary access (minimum 7Fr). Fixate the introducer sheath.

12.5 Device Preparation

Note: This section refers to both Arch and Ascending Curved Stent Graft delivery systems, as well as for the Descending Extension delivery system, if used.

12.5.1 Inspect the device packaging for any sign of damage or breach of the sterile barrier. If damage is observed, replace with another device.

12.5.2 Flush the delivery sheath with at least 50ml of heparinized saline through each of the three flushing ports (**see Figure 8 above and Figure 14 below**). Use a flexible extension tube with inline valve for connecting the flushing syringe to both the flushing ports.

Note: for a longer and thorough flushing using a heparinized saline, connect the flushing device to the stent graft flushing port, see **Figure 14** below.

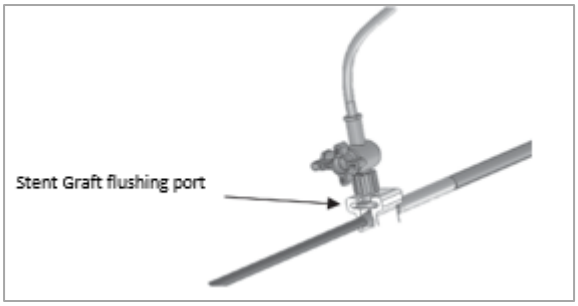


Figure 14: Flushing through the stent graft flushing port

WARNING: Avoiding the flushing method proposed in this manual may result in an excess amount of air bubbles within the delivery system. This may result in major neurological complications, e.g. stroke.

12.5.3 Prior to insertion, assess visualization and orientation of the radiopaque markers of the stent-graft under direct fluoroscopy of the delivery system. The radiopaque markers indicate the position of the proximal and distal edges of the graft material, and the orientation of stent grafts in the delivery system.

12.5.4 Wet the shaft of the delivery system with heparinized saline to activate its hydrophilic coating prior or during the delivery system introduction. Materials Recommended for Through & Through procedure: Guide wire, stiff, 400/450cm for Through & Through.

12.6 Through & Through

12.6.1 Through the 7Fr brachial/axillary access sheath, perform a Through & Through; brachial-ipsilateral femoral/iliac, using guide wire 0.035'', ≥400cm. The floppy end of the 0.035" guidewire should be exposed at the femoral/iliac artery access.

12.6.2 Fixate the wire in the brachial side, leaving ~30cm emerging from the brachial introducer.

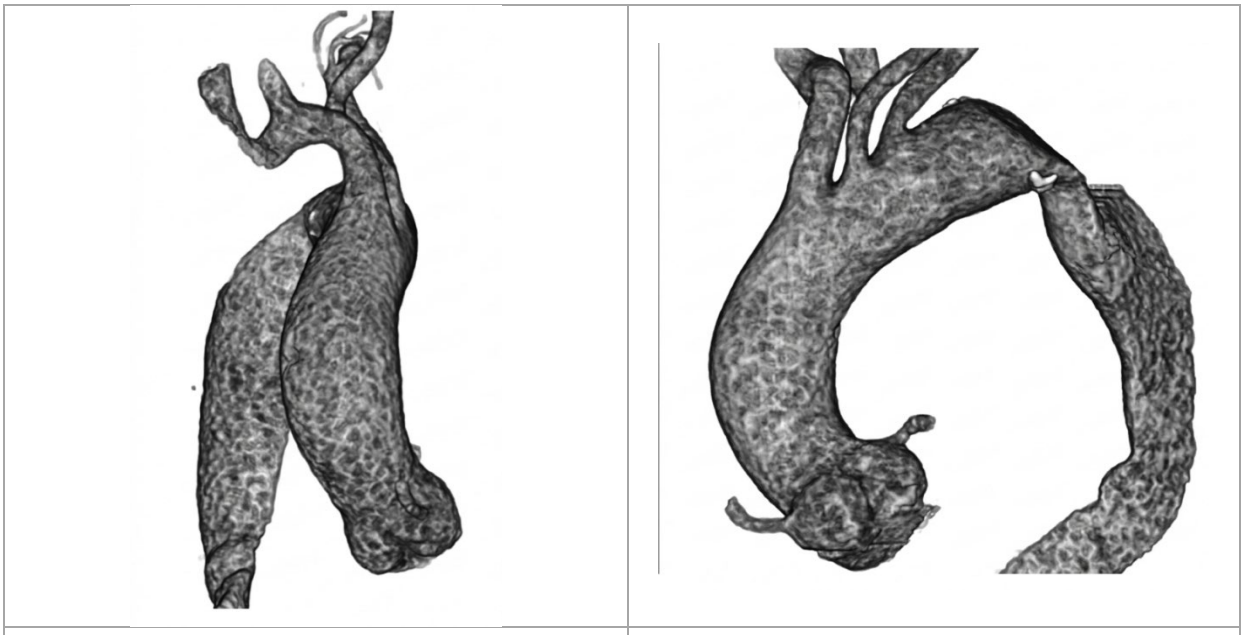
12.7 Arch Stent Graft Insertion & Positioning

WARNING: Do not advance the delivery system without using a guide wire and fluoroscopy. This may result in a major vascular complication to the patient and even death.

WARNING: The vessels should be imaged as completely as possible, during the deployment of the Arch Stent Graft, it is recommended to have two C-ARM configurations that allow accurate placement of the stent graft. (Figure 15).

Working view 1: "RCCA – RSA Plane" used for positioning of cranial end ("Brachiocephalic branch") of Arch Stent Graft. This angle should allow the maximal angle between RCCA & RSA.

Working view 2: "BCT – ASC Plane" used for continued deployment of Arch Stent Graft. This angle should allow the maximal angle between BCT & ASC.



Working View 1: RAO XX°, Caudal YY° Definition - Maximize angle between RCC & RSA. When in use - BCT segment deployment of Main Module.	**Working View 2: LAO XX°, Caudal YY°** Definition - Maximize angle between BCT & ASC. When in use - Completion deployment of Main Module.

Figure 15 – C-Arm Working Views (example)

12.7.1 Mount the delivery system over the Through & Through guide wire.

12.7.2 When the guidewire is exposed at the handle side of the delivery system, apply and tighten a guidewire torquer, or apply a hemostatic clamp to the end of the wire against the handle.

12.7.3 Just prior to insertion of the DS and during its insertion to the introducer sheath, perform simultaneous flushing with heparinized saline using a 20ml syringe each, through the flushing ports according to the following stages: **(Figure 8 and Figure 14).**

a. Flush the DS flushing port until drops are seen in the stent graft port.

Note: Do not disconnect the injector at the end of this stage.

b. Flush the SG flushing port simultaneously with flushing the DS flushing port, while advancing the DS into the introducer.

c. When reaching with the SG flushing port to introducer sheath remove SG flushing syringe.

Note: To avoid excess blood loss, during the procedure do not disconnect the syringe/ flexible extension tube with inline valve from the DS flushing port.

12.7.4 Using continuous fluoroscopic guidance, advance the delivery system into the introducer until the SG flushing port enters the introducer.

12.7.5 Using continuous fluoroscopic guidance, advance the delivery system by pulling the guidewire which, the guidewire torquer applied at the handle end, will advance the delivery system toward the right brachial/axillary access; simultaneously support the delivery system at the femoral access until the Fixation tube **(Figure 9)** emerges from the brachial/axillary introducer sheath.

12.7.6 Ensure that the Arch Stent Graft Delivery System is against the outer curve of the vasculature by applying forward pressure on either the delivery system and/ or both ends of its corresponding guidewire.

12.7.7 Verify the radiopaque markers are visualized in the target location **(Figure 16):**

a. Caudal dot marker of the Branch Stent is aligned with its ostia.

b. "B" marker is oriented with the cranial side of the arch.

c. Verify the most cranial stent is below (caudal) the bifurcation of Brachiocephalic artery (bifurcation to RSA-RCC).

d. Radiopaque Docking ring wire is facing the ascending arch.

Note: if the B marker is not positioned correctly rotate the delivery system grip no more than 360 degrees. In case the delivery system does not rotate, gently pull the delivery system backward out of the aortic arch and correct the marker orientation by rotating the delivery system grip (not more than 360 degrees). Then advance the delivery system to the correct position.

WARNING: verify correct orientation of the markers before deployment. Failure to properly align the radiopaque markers has resulted in improper deployment of the stent graft.

Inject contrast media through an angiographic (pigtail) catheter into the brachiocephalic/aortic arch and mark the position of the target location on the imaging screen.

12.7.8 Refine positioning of the stent graft so that the cranial edge of the graft fabric (dot marker for the cranial edge of graft, see **Figure 16** below) is just below the brachiocephalic/RCCA bifurcation.

CAUTION: The angiographic catheter can be removed prior to deployment. However, if the angiographic catheter is not removed until after deployment, ensure that the catheter is not obstructing in any way the delivery of the stent graft.

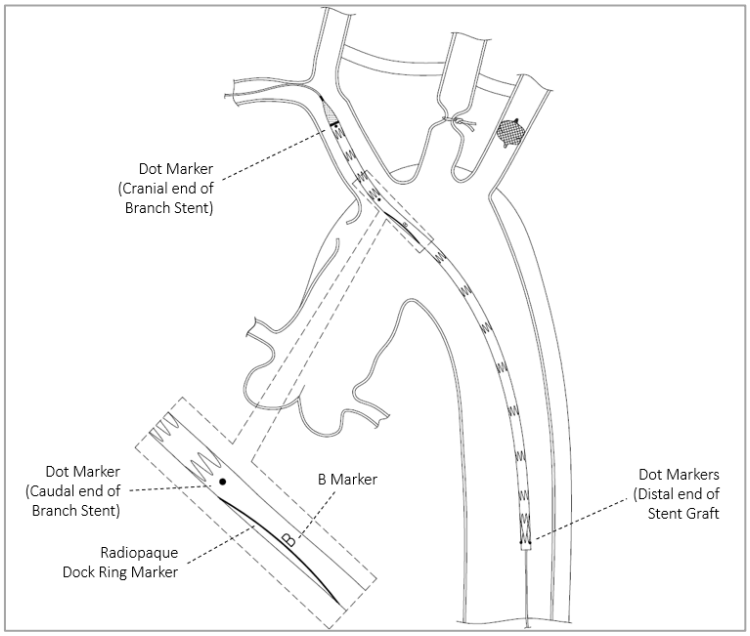


Figure 16 – Radiopaque Markers of Arch Stent Graft

12.8 Arch Stent Graft Deployment

12.8.1 Use angiography to verify position of the stent graft in relation to the RSA-RCCA bifurcation (**Figure 11**, Working View 1).

12.8.2 With one hand on the front grip, hold the delivery system stationary.

12.8.3 In Working View 2 **(Figure 15),** with the other hand, slowly withdraw the graft cover by rotating the deployment knob counterclockwise, until the constrained cranial stent is exposed and 1 to 2 of the covered struts have been fully deployed **(Figure 17.a)**.

12.8.4 The cranial end of the Arch Stent Graft is restrained against the inner part of the Delivery System by 3 capture wires

12.8.5 Use angiography to verify position of the stent graft in relation to the brachiocephalic - LCC bifurcation and release capture mechanism by turning the capture release knob: Turn until the cranial end of the stent graft is fully released.

CAUTION: In rare cases, loss of tension in the capture release mechanism may prevent release of the cranial stent. If this occurs, use the bailout technique described below to maintain wire tension and achieve release.

12.8.5.1 Bailout Technique – Capture Mechanism

If the capture release mechanism fails to maintain release wire tension, rotate the roller knob to build tension on the release wires. While maintaining tension with one hand, reposition your other hand to continue rotating without reverse rotation of the knob. This process should be repeated until full stent-graft release is confirmed under fluoroscopy.

12.8.6 Continue deployment of Arch Stent Graft, allowing the Dock to open towards the ascending aorta, as proximally as possible/needed (**Figure 15** Working View 2 and **Figure 17.b).**

12.8.7 Complete deployment by deploying the distal end of the stent graft either by rotating the deployment knob or by pressing the quick deployment button and pulling down (**Figure 15** Working View 2 and **Figure 18)**.

CAUTION: When using the quick deployment button to rapidly deploy the stent graft, be sure to hold the delivery system stationary in order to ensure adequate implantation and avoid inaccurate positioning of the stent grafts and as a result endoleak or occlusion of the innominate artery which can result in stroke and even death.

CAUTION: Do not rotate the delivery system after deployment has started, as this may torque the device and cause it to rotate during deployment. This can cause a delivery system damage or failure which will not allow complete deployment and may result in need for conversion to open repair.

CAUTION: If the graft cover is accidentally withdrawn, the stent graft will prematurely deploy and may be incorrectly positioned. This may lead to inaccurate positioning of the stent grafts and as a result endoleak or occlusion of the innominate artery which can result in stroke and even death.

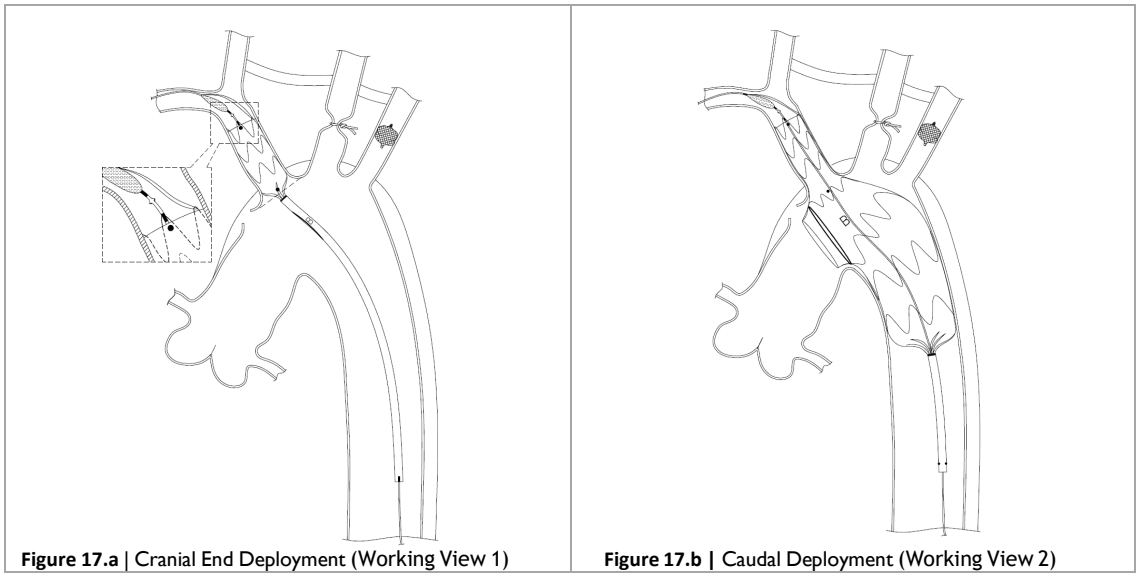


Figure 17.a | Cranial End Deployment (Working View 1)

Figure 17.b | Caudal Deployment (Working View 2)

Figure 17. Deployment of Arch Stent Graft

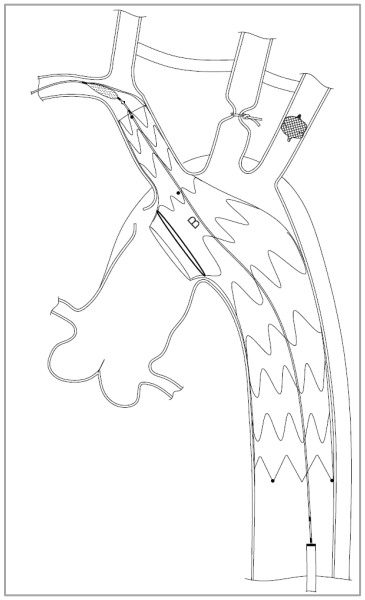


Figure 18 – Cranial Capture Release of Arch Stent Graft

12.9 Arch Stent Graft Delivery System Removal

CAUTION: In order to avoid stent graft migration during this stage, verify, prior to delivery system removal and using fluoroscopy, that the Arch stent graft was completely deployed and there is no attachment between the stent graft and the delivery system: gently try to retract the system, no movement of the stent graft should be seen. Migration can lead to inadequate sealing of the lesion and in extreme cases to innominate artery occlusion which can eventually result in stroke and even death.

12.9.1 Remove the torquer from the 0.035" guidewire that is attached at the handle.

12.9.2 Gently apply tension on the Fixation Tube of the Arch Delivery System

12.9.3 While keeping tension on the Fixation Tube, withdraw the delivery system of the Arch Stent Graft without releasing the fixation tube, until it is completely out of the Arch Stent Graft.

12.9.4 When the delivery system is distal (below) to the implanted Arch Stent Graft, re-sheath the delivery system.

12.9.5 Remove completely the delivery system over the 0.035" guidewire and from the introducer sheath.

12.9.6 Release the Through & Through guidewire from the iliac access and pull it partially back from the brachial access, so that the soft extremity of the guide wire is located in the descending aorta.

12.9.7 Dilate balloon in the Arch Stent Graft as needed.

12.10 Ascending Curved Stent Graft Insertion & Positioning

12.10.1 Deliver a 0.035" x 300cm extra-stiff guidewire to the ascending aorta

12.10.2 Follow the instruction in Section 10.5 Device preparation.

12.10.3 Insert the delivery system over the guidewire and use fluoroscopy.

12.10.4 Using continuous fluoroscopic guidance, advance the delivery system to Ascending aorta.

12.10.5 Adjust position of the C-arm so that the Docking ring radiopaque wire is visualized as a line **(Figure 19)**

12.10.6 Verify the radiopaque markers are visualized in the target location **(Figure 19)**:

a. Radiopaque dot markers are visualized in both ends of the graft.
b. "B" marker belly is oriented cranially.

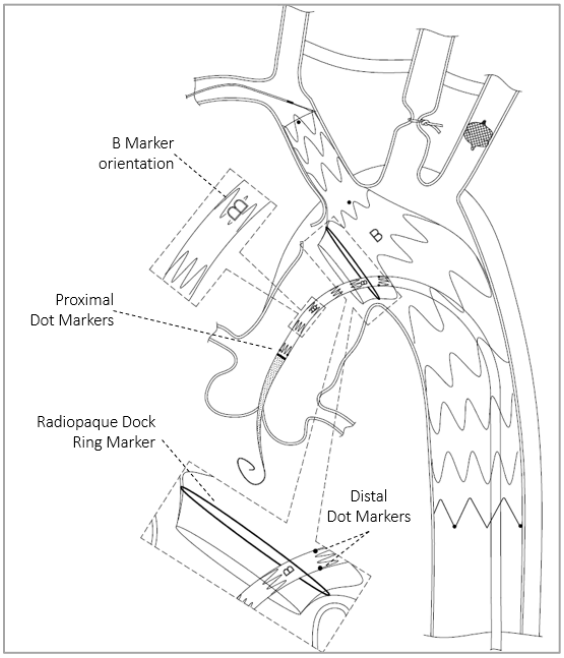


Figure 19 – Radiopaque Markers of Ascending Curved Stent Graft

12.10.7 Adjust position of the stent graft so that the distal end of the fabric, identified by the distal dot marker, is aligned with the radiopaque ring wire of the Arch Stent Graft.

12.10.8 Inject contrast media through an angiographic (pigtail) catheter into the ascending aorta and mark the position of the target location, on the imaging screen.

12.10.9 Refine the position of the stent graft so that the proximal end of the graft fabric is just distally to the Sino-Tubular Junction, verifying that the coronary arteries origin is not obstructed by the device. The distal end of the fabric, identified by a dot marker, is aligned with the radiopaque Docking wire of the Arch Stent Graft.

CAUTION: Pay attention to floppy end of wire to reduce the risk of any damage or perforation to the heart and/or aorta, as traditionally addressed in similar procedures (e.g. TAVI). Alternatively, use techniques that provide stability and fixation of the guide wire inside the LV (such as snaring or looping).

CAUTION: Do not rotate the delivery system after deployment has started as this may torque the stent graft and cause it to rotate during deployment. This can also cause a delivery system damage or failure which will not allow complete deployment and may result in need for conversion to open repair.

12.11 Ascending Curved Stent Graft Deployment

12.11.1 With one hand on the front grip, hold the delivery system stationary, while with the other hand slowly with- draw the graft cover by rotating the deployment knob counterclockwise.

12.11.2 During unsheathing and stent graft release, perform Rapid Heart Pacing.

Note: Throughout the deployment verify alignment of the distal end of the fabric (identified by two dot markers) with the large tantalum oval marker (Docking Ring) of the Arch Stent Graft body (preferably in high magnification).

12.11.3 The proximal & distal capture mechanisms remain active after device deployment (**Figure 20**) (3 proximal stent peaks are restrained in the Ascending Curved Stent Graft; 6 stent peaks are restrained by 3 capture wires at the distal end of the Ascending Curved Stent Graft).

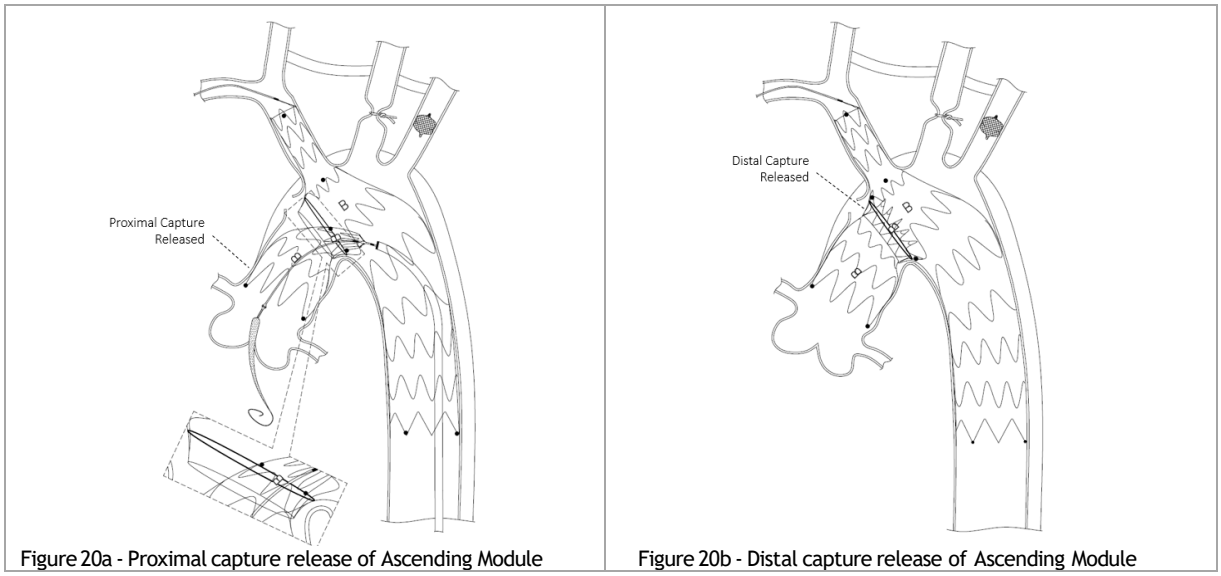


Figure 20a - Proximal capture release of Ascending Module

Figure 20b - Distal capture release of Ascending Module

Figure 20 – Capture Mechanism of Ascending Curved Stent Graft

12.11.4 Release the capture mechanism by turning the capture release knob in the direction of the arrow. Verify using fluoroscopy that both proximal and distal captures are released.

CAUTION: In rare cases, loss of tension in the capture release mechanism may prevent release of the proximal and distal stents. If this occurs, use the bailout technique described below to maintain wire tension and achieve release.

12.11.4.1 **Bailout Technique – Capture Mechanism**

If the capture release mechanism fails to maintain release wire tension, rotate the roller knob to build tension on the release wires. While maintaining tension with one hand, reposition your other hand to continue rotating without reverse rotation of the knob. This process should be repeated until full stent-graft release is confirmed under fluoroscopy.

12.12 Ascending Stent Graft Delivery System Removal

CAUTION: In order to avoid stent graft migration during this stage, verify, prior to delivery system removal and by using fluoroscopy, that the stent graft was completely deployed and there is no attachment between the stent graft and the delivery system: gently try to retract the system, no movement of the stent graft should be seen. Stent Graft migration can lead to inadequate sealing of the lesion and in extreme cases to innominate artery occlusion which can eventually result in stroke and even death.

12.12.1 Pull the delivery system until it is distally to the Arch Stent Graft.

12.12.2 Re-sheath the delivery system and remove the delivery system over the wire.

12.12.3 Procedure finalization: Dilate the assembled Arch and Ascending Stent Graft system using balloon catheters as needed.

12.13 Second Ascending Curved Stent Graft Insertion & Positioning

12.13.1 A second Ascending Curved Stent Graft can be used, however it must have the same diameter, and be of equal or longer length. A second Ascending Stent Graft of equal or longer length to the first Ascending can be used if the initial ascending graft was deployed proximal or distal to the target.

12.13.2 For insertion and positioning of the second Ascending Curved Stent Graft, follow the instructions provided above in Section 12.10 Ascending Stent Graft Insertion & Positioning. The positioning of the second Ascending Curved should be such that the Locking and Sealing Stents of the second Ascending align with the Locking and Sealing Stents of the first or primary implanted Ascending.

12.13.3 For deployment of the second Ascending Curved Stent Graft, follow the instructions provided above in Section

12.11 Ascending Stent Graft Deployment.

12.13.4 For removal of the second Ascending Curved Stent Graft Delivery System, follow the instructions provided above in Section 12.12 Ascending Stent Graft Delivery System Removal.

12.14 Descending Extension

12.14.1 Insert the delivery system over a 0.035" (0.89mm) guidewire (either the guidewire used for the Ascending System, or the guidewire used for the Arch System) and using continuous fluoroscopic guidance, advance the delivery system to descending aorta.

12.14.2 Verify true entry into the already deployed stent graft (either Arch or previously implanted DE) by applying slight tension on Through & Through wire or by using a super stiff wire.

12.14.3 For ideal visualization, position C-arm so that both distal dot markers of the already deployed stent graft are aligned (relatively appear as one).

12.14.4 Acquire minimum overlap between the already deployed stent graft and DE stent graft by positioning the B marker of the DE in visual contact with the deployed stent graft's distal dot marker.

Note: in Distal-to-Proximal order of deployment, the positioning is of the DE stent graft's distal dot marker or Arch Stent Graft's distal dot marker in alignment with the already deployed DE stent graft's "B" marker (**Figure 21**).

12.14.5 With one hand on the front grip, hold the delivery system stationary, while with the other hand slowly withdraw the graft cover by rotating the deployment knob counterclockwise.

12.14.6 Ensure that the DE stent graft is deployed against the outer curve of the vasculature by applying forward pressure on either the delivery system or both ends of its corresponding guidewire. As a default, it is possible to deploy the overlapping segment of the DE stent graft for initial fixation then carefully apply minor pressure on the DS to accommodate the aortic outer curve and continue deployment.

Note: Avoid excessive force that might result in stent graft migration or other hazardous disposition of adjacent implants. Stent Graft migration can lead to endoleak and inadequate sealing of the lesion.

12.14.7 Once stent graft's overlap segment is deployed and secured, move C-arm position to designated landing zone to follow and finalize the deployment with accuracy.

12.14.8 Release proximal end of the DE stent graft, the proximal stent of the DE is restrained by 4 capture wires , by turning the capture release knob (arrow direction): At least two turns for releasing the proximal capture of the Stent Graft. Verify using fluoroscopy that the proximal capture is fully released.

CAUTION: In rare cases, loss of tension in the capture release mechanism may prevent release of the proximal and distal stents. If this occurs, use the bailout technique described below to maintain wire tension and achieve release.

12.11.4.1 **Bailout Technique – Capture Mechanism**

If the capture release mechanism fails to maintain release wire tension, rotate the roller knob to build tension on the release wires. While maintaining tension with one hand, reposition your other hand to continue rotating without reverse rotation of the knob. This process should be repeated until full stent-graft release is confirmed under fluoroscopy

CAUTION: When using the quick deployment button to rapidly deploy the stent graft, be sure to hold the delivery system stationary in order to avoid inaccurate positioning of the stent graft and as a result endoleak and inadequate sealing of the lesion.

CAUTION: Do not rotate the delivery system after deployment has started as this may torque the device and cause it to rotate during deployment. This can also cause a delivery system damage or failure which will not allow complete deployment of the stent graft and may result in procedure conversion.

CAUTION: If the stent graft cover is accidentally withdrawn, the stent graft will prematurely deploy and may be incorrectly positioned. This may lead to endoleak and inadequate sealing of the lesion.

12.14.9 Use fluoroscopic guidance to safely pull back the delivery system until the tip is a safe distance from the DE endoprosthesis.

12.14.10 Re-sheath the delivery system – firmly hold the deployment knob stationary and simultaneously press the 'quick deployment button' while bringing the front grip backwards. Once completed, remove the delivery system over the wire and out of the introducer.

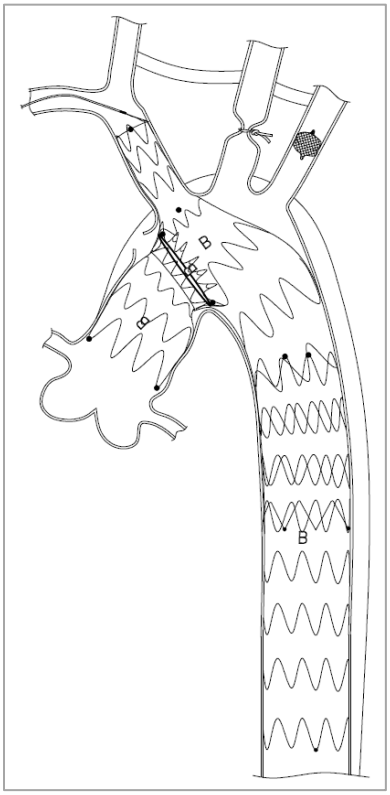


Figure 21 – Full assembly (Arch Stent Graft, Ascending Curved Stent Graft and Descending Stent Graft)

12.15 Fixation Tube Removal

12.15.1 Grasp the suture ends visible at the proximal end of the Fixation Tube (**Figure 22**) with forceps (**Figure 23**)

12.15.2 With the forceps, pull the suture away from the Fixation Tube until it tears away from the clear wrap around the fixation tube **and** until the knot is revealed (**Figure 22).**

12.15.3 While holding the suture with the forceps, cut the suture beyond the knot (Cut only one suturing thread beyond the knot, not both) (see **Figure 24**).

12.15.4 While continuing to hold the suture with the forceps, remove the Fixation Tube gently over the guidewire outside the introducer, this will pull the thread from the end of the Branch stent of the Arch Stent Graft, continue until the thread is totally removed out of the introducer.

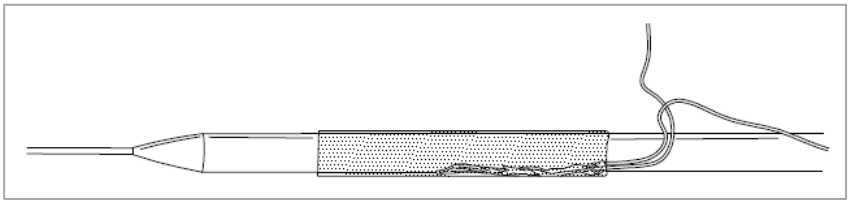


Figure 22– Fixation Tube Release

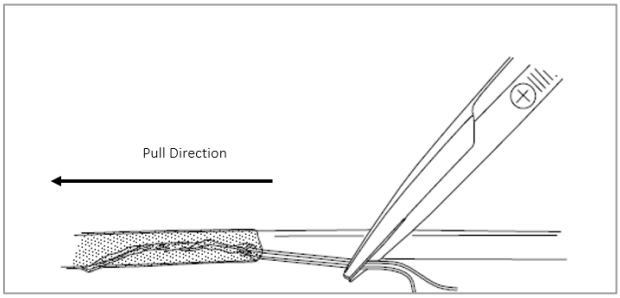


Figure 23– Grasp the end of the tether suture with forceps and pull suture away from the clear wrap around the fixation tube

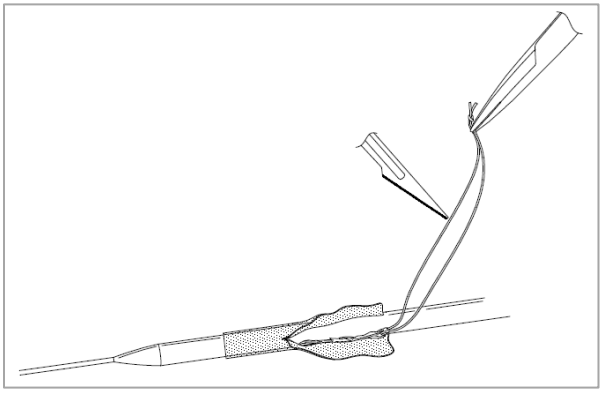


Figure 24– Cut one side of the suture below the knot, continue holding the suture with the forceps and peal away the Fixation Tube from the suture and off of the guidewire

13 | DISPOSAL

13.1 After use, dispose of the device and packaging, taking into account any infectious or microbial hazard risks, with the necessary precautionary measures in accordance with acceptable medical practice and with applicable hospital, administrative, local, state, and federal laws and regulations.

14 | EXPLANATION OF SYMBOLS

	Consult the Instructions for Use		Serial Number
	Do Not Use If Package Is Damaged		Catalogue Number
	Do Not Reuse		Quantity
	Do Not resterilize		Keep away from sunlight
	CAUTION: see instruction for use		Keep Dry
	Sterilized using Ethylene Oxide		Storage Temperature Limitation
	Date of manufacture		Manufacturer
	Use By		MR Conditional
	Medical device is intended prescription use only		Non-Pyrogenic

Table 45

15 | DISCLAIMER OF WARRANTY

ALTHOUGH The NEXUS® AORTIC ARCH STENT GRAFT SYSTEM HEREAFTER REFERRED TO AS THE 'PRODUCT', HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, ENDOSPAN LTD. AND THEIR RESPECTIVE AFFILIATES, (COLLECTIVELY "ENDOSPAN") HAVE NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. ENDOSPAN, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ENDOSPAN SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND ENDOSPAN TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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