VALIANT NAVION™
DEPLOYMENT STEPS
QUICK GUIDE
1a. Slowly advance the delivery system to the targeted landing zone and ensure delivery system is along the greater curve in order to maintain stability during deployment.

1b. It may be appropriate to momentarily decrease the patient’s mean arterial pressure (MAP).

Tip: The wire should be positioned on the greater curve to maintain stability. The soft section at the end of the stiff wire may loop against the aortic valve. However, do not advance delivery system tip or guidewire across the aortic valve.
STEP 2: DEPLOYING THE FIRST TWO STENTS

2a. The delivery system should be stabilized and remain stationary during stent graft deployment. Slight forward pressure may be applied to maintain the delivery system’s position along the greater curve.

2b. Position the proximal radiopaque (RO) marker of the stent graft at the target proximal landing zone.

2c. Hold the delivery system stationary with one hand on the grey front grip.

2d. Then, slowly withdraw the graft cover with the other hand by rotating the blue slider handle counterclockwise. There is an arrow on the blue slider handle indicating the rotation direction as well.

Caution: For stent grafts that are shorter than 90 mm, it is important not to deploy more than one covered stent before repositioning the stent graft. Further deployment of the graft can impair the ability to move the graft to the desired landing zone.
**STEP 3: DEPLOYING THE REMAINDER OF THE STENT GRAFT**

3a. The delivery system should be stabilized and remain along the greater curve during stent graft deployment.

3b. To rapidly deploy the stent graft, place one hand firmly on the grey front grip and hold the system stationary. While maintaining support on the grey front grip, pull the trigger back to engage the quick release function of the blue slider handle.

3c. Pull the blue slider handle away from the grey front grip until the RO marker band on the graft cover is beyond the distal stent.

**Note:**
- If excessive resistance is felt, stop rapid deployment by releasing the trigger. Then, rotate the blue slider handle to complete deployment of the stent graft.
- Deployment forces can be further increased by excessive tortuosity and a small aortic arch radius.
- Operator may need to restore system position on the greater curve by applying forward pressure.
4a. Using the guidewire as an indicator, relax the guidewire and delivery system by pulling back until the catheter and guidewire lumen move off of the greater curve.

4b. Once the wire/guidewire lumen are off of the greater curve, unlock the tip capture handle by rotating the blue tip capture release handle in the direction of the arrow and pull in one smooth motion.
STEP 5: SAFELY RETRACTING THE DELIVERY SYSTEM

5a. Pull back the trigger and hold the blue slider handle stationary while bringing the grey front grip toward the slider handle — “grey to blue.”

5b. To ensure a smooth stiffness transition of the delivery system for withdrawal, reset the tip capture release handle by pushing the tip capture release handle forward and locking it.

5c. Gently remove the delivery system.

Caution: Perform steps in the listed order; otherwise, the tip capture mechanism may get caught on the proximal stents.
Valiant Navion™ Thoracic Stent Graft System

Indications
The Valiant Navion™ thoracic stent graft system is indicated for the endovascular repair of all lesions of the descending thoracic aorta (DTA) in patients having the appropriate anatomy including:

- Iliac or femoral artery access vessel morphology that is compatible with vascular access techniques, devices, or accessories;
- Nonaneurysmal aortic diameter in the range of:
  - 16 mm to 42 mm for fusiform and saccular aneurysms/penetrating ulcers
  - 16 mm to 44 mm for blunt traumatic aortic injuries
  - 19 mm to 45 mm for dissections;
- Proximal landing zone (nonaneurysmal aortic proximal neck length for fusiform and saccular aneurysms/penetrating ulcers or nondissected length of aortic vessel and surrounding vasculature; the primary entry tear for blunt traumatic aortic injuries and dissections) of:
  - ≥ 20 mm for FreeFlo configuration
  - ≥ 25 mm for CoveredSeal configuration; and
- Nonaneurysmal aortic distal neck length ≥ 20 mm for FreeFlo and CoveredSeal configurations for fusiform and saccular aneurysms/penetrating ulcers.

Contraindications
The Valiant Navion thoracic stent graft system is contraindicated in the following patient populations:

- Patients who have a condition that threatens to infect the graft.
- Patients who are sensitive to or have allergies to the device materials.

Warnings and Precautions
- The long-term safety and effectiveness of the Valiant Navion thoracic stent graft system has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the integrity and performance of the implanted endovascular stent graft. Specific follow-up guidelines are described in the Instructions for Use. Of note, patients with specific clinical findings should receive enhanced follow-up.
- The Valiant Navion thoracic stent graft system is not recommended in patients who cannot undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures described in the Instructions for Use.
- The safety and effectiveness of the Valiant Navion thoracic stent graft system has not been evaluated in certain patient situations and/or populations. Please refer to product Instructions for Use for details.
- Strictly adhere to the Valiant Navion thoracic stent graft system sizing configurations and guidelines as described in the Instructions for Use 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, infolding, or graft wear.
- Never use a balloon when treating a dissection.

Please refer to the product Instructions for Use for details.

MRI Safety and Compatibility
MRI may be used on the Valiant Navion thoracic stent graft only under specific conditions. It can be scanned safely in both 1.5T and 3.0T MR systems under certain conditions as described in the product Instructions for Use. For additional information regarding MRI, please refer to the product Instructions for Use.

Refer to the IFU approved in your geography for detailed directions for use, notes, and cautions to be followed during Valiant Navion use.

For U.S. audiences only.

Adverse Events
Adverse events or complications associated with the use of the Valiant Navion thoracic stent graft system that may occur or require intervention include, but are not limited to: Access failure; Access site complications (for example: spasm, trauma, bleeding, rupture, dissection); Adynamic ileus; Allergic reaction (to contrast, antiplatelet therapy, stent graft material); Amputation; Anaphylaxis; Anesthetic complications; Aneurysm rupture; Angina; Aortic expansion (for example: aneurysm, false lumen); Aortic valve damage; Aortic vessel rupture; Arrhythmia; Arterial stenosis; Atelecstasis; Balloon rupture; Blinding; Bowel ischemia; Bowel necrosis; Bowel obstruction; Branch vessel occlusion; Breakeage of the metal portion of the device; Buttock claudication; Cardiac tamponade; Catheter breakage; Cerebrovascular accident (CVA); Stroke; Change in mental status; Coagulopathy; Congestive heart failure; Contrast toxicity; Conversion to surgical repair; Damage to the vessel; Death; Deployment difficulties/failures; Dissection, perforation, or rupture of the aortic vessel and surrounding vasculature; Embolism; Endoleaks; Excessive or inappropriate radiation exposure; Extrusion/erosion; Failure to deliver the stent graft; Femoral neuropathy; Fistula (including aortobronchial, aortoenteric, aortoesophageal, arteriovenous, and lymph); Gastrointestinal bleeding/ complications; Genitourinary complications; Hematoma; Hemorrhage/bleeding; Hypotension/hypertension; Infection or fever; Insertion or removal difficulty; Intercostal pain; Intramural hematoma; Leg edema/foot edema; Loss of patency; Lymphoceles; Myocardial infarction; Neck enlargement; Nerve injury; Neuropathy; Occlusion — venous or arterial; Pain/reaction at catheter insertion site; Paralysis; Paraparesis; Paraplegia; Paresthesia; Perfusion of the false lumen; Peripheral ischemia; Peripheral nerve injury; Pneumonia; Postimplant syndrome; Post-procedural bleeding; Procedural bleeding; Prosthesis dilatation; Prosthesis infection; Prosthesis rupture; Prosthesis thrombosis; Pseudoaneurysm; Pulmonary edema; Pulmonary embolism; Reaction to anesthesia; Renal failure; Renal insufficiency; Recovery; Respiratory depression or failure; Retrograde type A dissection; Septis; Sepsis; Sero; Sexual dysfunction; Shock; Spinal neurological deficit; Stenosis; Stent graft migration; Stent graft misplacement; Stent graft occlusion; Stent graft rupture (or example: holes, tears); Stent graft twisting or kinking; Transient ischemic attack (TIA); Thrombosis; Tissue necrosis; Vascular ischemia; Vascular trauma; Wound dehiscence; Wound healing complications; and wound infection.

Please reference the product Instructions for Use for more information regarding indications, warnings, precautions, contraindications, and adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

For OUS audiences, please refer to the IFU approved in your geography for product-specific indications.