

INSTRUCTIONS FOR USE FOR:



THORACIC ENDOPROSTHESIS



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English

INSTRUCTIONS FOR USE

GORE TAG THORACIC ENDOPROSTHESIS

CAUTION — Investigational device. Limited by United States law to investigational use.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

FIGURE 1: GORE TAG THORACIC ENDOPROSTHESIS

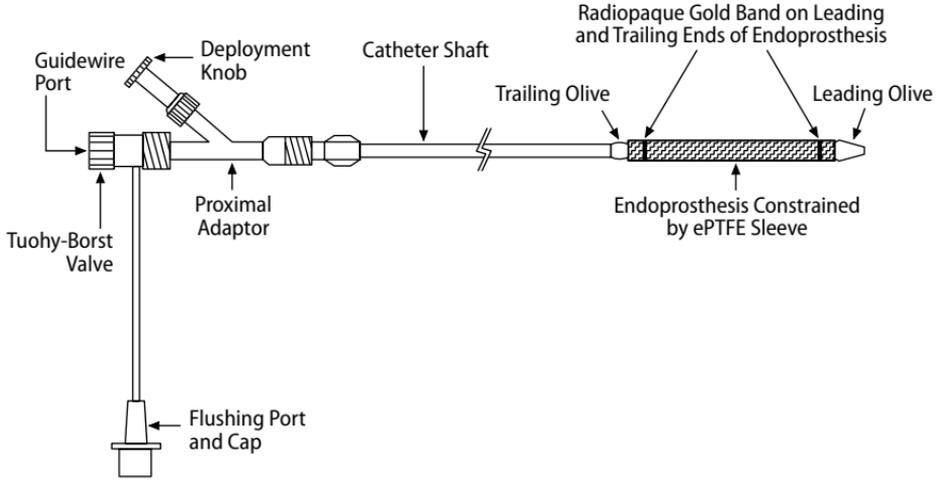


FIGURE 2: DEPLOYED GORE TAG THORACIC ENDOPROSTHESIS

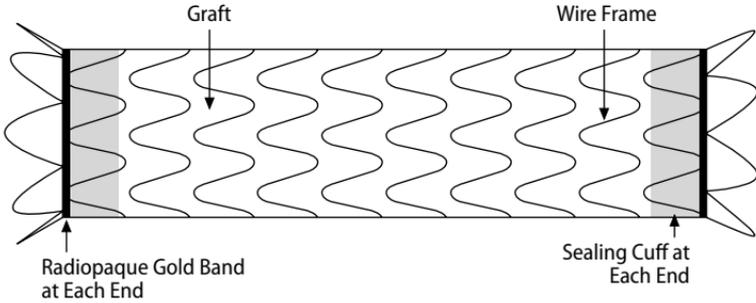


TABLE 1: SIZING GUIDE

Intended Aortic Inner Diameters (ID) (mm)	Endoprosthesis Diameter ¹ (mm)	Endoprosthesis Lengths ^{1,2} (cm)	Recommended GORE Introducer Sheath Size (Fr)
23 - 24	26	10	20
24 - 26	28	10 / 15	20
26 - 29	31	10 / 15	22
29 - 32	34	10 / 15 / 20	22
32 - 34	37	10 / 15 / 20	24
34 - 37	40	10 / 15 / 20	24

¹ All dimensions are nominal.

² A minimum of 2.0 cm non-aneurysmal aortic neck length is required both proximal and distal to the aneurysm. The length of the patient's aneurysm, plus a minimum of 4.0 cm for the non-aneurysmal necks, should be used when calculating the required endoprosthesis length. More than one endoprosthesis may be needed to cover the entire treatment area.

DESCRIPTION

The GORE TAG Thoracic Endoprosthesis provides endovascular repair of the descending thoracic aorta. The GORE TAG Thoracic Endoprosthesis may be used as a single device or in multiple device configurations to accommodate the intended treatment site.

The endoprosthesis is comprised of an expanded polytetrafluoroethylene (ePTFE) tube reinforced with ePTFE/FEP (fluorinated ethylene propylene) film that is supported by a self-expanding nitinol (nickel titanium alloy) wire-frame (stent) along its external surface. The endoprosthesis contains radiopaque gold marker bands at the base of the device flares (Figures 1 and 2) approximately 1 cm from each end of the endoprosthesis. An implantable ePTFE/FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter (Figure 1). Deployment of the endoprosthesis initiates in the middle of the device and simultaneously extends toward both ends of the endoprosthesis. The ePTFE/FEP sleeve remains in-situ between the exterior surface of the endoprosthesis and the intimal surface of the aorta. A device introducer sheath cap is included with the GORE TAG Thoracic Endoprosthesis. This cap should be used with the GORE Introducer Sheath with Silicone Pinch Valve to better accommodate the endoprosthesis delivery catheter.

INTENDED USE

The GORE TAG Thoracic Endoprosthesis is indicated for endovascular repair of aneurysms of the descending thoracic aorta.

CONTRAINDICATIONS

- There are no known contraindications.

INDIVIDUALIZATION OF TREATMENT

- Appropriate patient and device selection for the GORE TAG Thoracic Endoprosthesis is critical to procedural outcome. Risk and benefits should be carefully considered by the physician for each patient before the use of the GORE TAG Thoracic Endoprosthesis.
- Patient selection factors to be assessed include patient's age and life expectancy, co-morbidities (e.g. cardiac, pulmonary, renal), morphological suitability, and the risk of aneurysm rupture versus the risk of treatment with the GORE TAG Thoracic Endoprosthesis as listed in the WARNINGS and ADVERSE EVENTS sections below.
- Use of the GORE TAG Thoracic Endoprosthesis has not been studied in the following patient populations: unstable ruptured aneurysms, women of childbearing potential, genetic connective tissue disease (e.g., Marfans and Ehlers-Danlos syndrome), presence of mycotic aneurysm, active infection at the treatment site, renal failure with or without dialysis, acute and chronic dissections, aortic transections, or aortic fistulas.
- The final treatment decision is at the discretion of the physician and patient.

WARNINGS

- Read all instructions carefully, particularly the following sections: TABLE 1: SIZING GUIDE, and in the DIRECTIONS FOR USE: *Anatomical Requirements*, and *Using Multiple Devices*. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient. Compliance with device sizing recommendations is critical to performance of the device.
- Do not use GORE TAG Thoracic Endoprosthesis if significant thrombus and/or calcification is present in the proximal or distal aortic implantation sites.
- This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the GORE TAG Thoracic Endoprosthesis.
- Do not use the GORE TAG Thoracic Endoprosthesis in patients unable to undergo the necessary preoperative and postoperative imaging. All patients should be monitored closely and checked periodically for a change in the condition of their disease and the integrity of the endoprosthesis.
- Wire fractures have been reported on this type of endoprosthesis and may be more likely to occur in conditions with excessive endoprosthesis oversizing, flexion, kinking, or bending with cardiac or respiratory cycles. Wire fractures may have unknown clinical consequences which may include, but are not limited to; endoprosthesis migration, adjacent tissue damage including cardiac, vascular, pulmonary and gastrointestinal, disease progression, aneurysm rupture, or death.
- The physician must balance the risk associated with potential wire fractures against the risk to the patient of not using the GORE TAG Thoracic Endoprosthesis.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of infection.
- Do not rotate the delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or inadvertent deployment may occur.
- Do not rotate the delivery catheter with device outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.
- Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or endoprosthesis misplacement may result.
- Do not continue if resistance is felt during advancement of the guidewire, sheath, or delivery catheter. Stop and assess the cause of resistance. Vessel or delivery catheter damage may occur.

- Use caution if removing the undeployed endoprosthesis through the introducer sheath. Inadvertent endoprosthesis deployment may occur. If resistance is felt during removal of delivery catheter, stop and withdraw delivery catheter and introducer sheath together.
- Inadvertent partial deployment or migration of the endoprosthesis may require surgical removal.
- Do not cross significant arterial branches which do not have collateral or protected perfusion to end organs or body structures. Vessel occlusion may occur.
- If using an introducer sheath with a soft hemostasis pinch tube, ensure that the pinch tube is not twisted, collapsed, or bent during advancing or withdrawing the delivery catheter. Device damage and/or delivery catheter breakage may occur.
- Do not use an introducer sheath incompatible with the supplied introducer cap. Damage may occur to the leading edge of the endoprosthesis, which may cause flaring of the end or inadvertent deployment.
- If resistance is felt, stop and assess the cause. Otherwise, device displacement may occur.

MRI SAFETY AND COMPATIBILITY

- The GORE TAG Thoracic Endoprosthesis has been determined to be MR safe when evaluated in MRI systems with static fields of ≤ 1.5 Tesla, gradient magnetic fields of ≤ 20 Tesla/second, and whole body averaged specific absorption rate (SAR) of 1.4 W/kg for 15 minutes of imaging.
- The GORE TAG Thoracic Endoprosthesis may affect image quality (image artifact) depending on the imaging parameters used for MRI.

PRECAUTIONS

- For single use only; do not re-sterilize.
- Do not use if damaged or if sterile barrier has been compromised.
- Do not use after the "use by" (expiration) date printed on the box.
- When catheters are in the body, manipulate only under fluoroscopic guidance.
- A late type III endoleak was observed within 24 hours after DC cardioversion. Close surveillance is recommended to watch for symptoms of endoleaks post DC cardioversion or defibrillation.

ADVERSE EVENTS

Adverse events which may require intervention and/or conversion to open repair include, but are not limited to: contrast medium toxicity, reactions to anesthesia, excessive or inappropriate radiation exposure, hematoma, coagulopathy, bleeding complications, respiratory complications, pulmonary embolism, angina, arrhythmia, congestive heart failure, myocardial infarction, renal failure or other renal complications, wound infection, chylous ascites, dehiscence, leg edema, lymphocele, bowel ischemia, bowel obstruction, adynamic ileus, amputation, arteriovenous fistula, embolism, pseudoaneurysm, restenosis, vascular trauma, venous thrombosis, nerve injury, change in mental status, cerebrovascular accident, paraplegia/paraparesis, spinal neurological deficit, transient-ischemic attack, anastomotic false aneurysm, aortoenteric fistula, erectile dysfunction, Post-Implant Syndrome, endoprosthesis infection, endoprosthesis thrombosis, hepatic failure, access failure, aneurysm enlargement, aneurysm rupture, branch vessel occlusion, catheter breakage, deployment failure, endoleak, extrusion/erosion, lumen obstruction, endoprosthesis material failure including graft tear and wire fracture, endoprosthesis dilation, endoprosthesis migration or realignment, and death.

CONTENTS/HOW SUPPLIED

The GORE TAG Thoracic Endoprosthesis and introducer sheath cap are supplied sterile and non-pyrogenic.

STORAGE AND HANDLING

Store in a cool dry place.

MATERIALS REQUIRED FOR DEVICE PLACEMENT

- GORE TAG Thoracic Endoprosthesis in the appropriate diameter and length (Table 1)
- GORE Introducer Sheath Cap (supplied with endoprosthesis)
- GORE Tri-Lobe Balloon Catheter or GORE Thoracic EXCLUDER Balloon Catheter (supplied separately)
- GORE Introducer Sheath with Silicone Pinch Valve 30 cm long of appropriate french size for the selected endoprosthesis diameter (or equivalent) (supplied separately) (Table 1)
- Hemostatic vascular clamp with soft jaws
- 0.035" (0.89 mm) Medi-Tech Amplatz Super Stiff Guidewire ('super-stiff'), 250 cm or longer
- Heparin and heparinized saline solution
- Contrast medium
- Sterile syringes
- 3 way stopcock
- Appropriate diagnostic catheters and accessories

DIRECTIONS FOR USE

Anatomical Requirements

- Proximal and distal aortic neck lengths should be a minimum of 2.0 cm
- Aortic neck inner diameters (ID) in the range of 23–37 mm (Table 1)
- Differing proximal and distal neck diameters (aortic taper) outside the intended aortic diameter requirements for a single endoprosthesis diameter (Table 1) requires the use of multiple endoprostheses of different diameters

Using Multiple Devices

When multiple endoprostheses are used to compensate for aortic taper or treatment length, adhere to the sizing guide (Table 1) in conjunction with the recommended guidelines below:

- Overlapped endoprostheses in an aneurysmal section should be 1 to 2 sizes different in diameter with an overlap of at least 3 cm.
- Always deploy the larger diameter endoprosthesis into the smaller diameter endoprosthesis.
- If overlapping devices of the same diameter, overlap by at least 5 cm.

Catheter Preparation and Arterial Access

1. Perform surgical exposure of the vessel selected for device insertion, according to standard practice.
2. Administer heparin, according to standard practice.
3. Perform angiography to determine the correct placement location of the device, according to standard practice.
4. Advance the appropriate introducer sheath through the vasculature until just below the renal arteries, according to standard practice.
5. Remove the GORE TAG Thoracic Endoprosthesis delivery catheter from the packaging, and examine for possible damage.
6. Flush heparinized saline through the flushing port. The delivery catheter is now ready for use.

GORE TAG Thoracic Endoprosthesis Deployment

1. Insert the endoprosthesis delivery catheter over a 0.035" (0.89 mm) 'super-stiff' guidewire, through the introducer sheath into the aorta. **Warning: Do not rotate the delivery catheter while device is inside introducer sheath. Catheter breakage or inadvertent deployment may occur.**
2. Position the endoprosthesis across the aneurysm using the radiopaque gold bands to identify the base of the flares which are located approximately 1 cm from each end of the endoprosthesis (Figure 2). The end of the endoprosthesis should extend at least 2-cm into non-aneurysmal proximal and distal necks. Care should be taken not to cover the origin of any major arterial branches in the vicinity of the treatment area. **Warning: Do not rotate the delivery catheter outside of the introducer sheath more than 180° in either direction. Catheter breakage or inadvertent deployment may occur.**
3. Stabilize the delivery catheter at the introducer sheath to prevent delivery catheter movement prior to deploying the endoprosthesis. Loosen the luer lock on the deployment knob. While maintaining the exposed delivery catheter as straight as possible, deploy the endoprosthesis by pulling the deployment knob in a steady, continuous motion. Deployment initiates from the middle of the device and extends simultaneously to the proximal and distal ends.
4. Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the endoprosthesis.
5. Additional endoprostheses may be deployed to treat longer segments. (Refer to "Using Multiple Devices" section.)

Completion of Procedure

1. After deployment, use the GORE Tri-Lobe Balloon Catheter or GORE Thoracic EXCLUDER Balloon Catheter to smooth and seat the endoprosthesis against the aortic wall in the proximal and distal necks. Center the balloon at the radiopaque gold band on the endoprosthesis and inflate to the recommended volume (see GORE Tri-Lobe Balloon Catheter or GORE Thoracic EXCLUDER Balloon Catheter Instructions for Use). Deflate the balloon, rotate the balloon approximately 60° and repeat the inflation. **Warning: If resistance is felt, stop and assess the cause. Otherwise, device displacement may occur.**
2. Perform arteriography in two views to assess exclusion of the aneurysmal segment, luminal patency of the aorta, and endoprosthesis position.
3. Close arterial access site, according to standard practice.

DEFINITIONS

 Use By

 Attention, See Instructions for Use

 Do Not Reuse

REF Catalogue Number

 Batch Code

 European Authorized Representative

 STERILE

Contents sterile unless package has been opened or damaged.

 STERILE EO

Contents sterile unless enclosed package has been opened or damaged. Sterilized by ethylene oxide.

 Store in a cool dry place



AG4988-PM



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