The Endurant Stent Graft System

Instructions for Use (IFU)

IMPORTANT!
• Do not attempt to use the Endurant Stent Graft System before completely reading and understanding the information contained in this booklet.
• Carefully inspect all product packaging for damage or defects prior to 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 catheters in accordance with hospital, administrative, and/or government policy. Do not resterilize.
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1 DEVICE DESCRIPTION

The Endurant Stent Graft System is designed to treat infrarenal abdominal aortic or aorto-iliac aneurysms using an endovascular approach. When placed within the aneurysm, the Endurant Stent Graft provides a permanent, alternative conduit for blood flow within the patient’s vasculature by excluding the aneurysmal sac from blood flow and pressure.

The Endurant Stent Graft System is comprised of two key components, the Endurant Stent Graft and the Endurant Delivery System. An Endurant Stent Graft is the final in situ configuration of one or more physician selected modular Endurant stent graft components. Some stent graft components include a suprarenal stent with anchoring pins. The Endurant Delivery System delivers the Endurant Stent Graft. Each stent graft component is compressed and held constrained by the delivery system as it is advanced to the aneurysm location over a guidewire. As deployment occurs, the stent graft components including the suprarenal stents and anchor pins self-expand due to the superelastic properties of the nitinol stents. Upon deployment, the proximal and distal ends of the Endurant Stent Graft conform to the shape and size of the proximal and distal seal zones due to the radial force of the stents.

1.1 STENT GRAFT COMPONENTS

The particular configuration of an Endurant Stent Graft (Figure 1 and 2) is assembled by selecting from a number of modular stent graft components including in one configuration a bifurcated modular device comprised of two primary components: an aortic-iliac bifurcated component and a contralateral limb component. Additional components which may be used at the discretion of the treating physician include aortic extensions, abdominal tubes, iliac extensions, and aorto-uni-iliac (AUI) stent grafts. After the placement of the bifurcated component, each subsequent component is introduced separately into the vasculature and is mated in vivo to the components already in situ.

All components are composed of metal stents coupled to a fabric graft. The suprarenal stents with anchoring pins adjacent to the crowns are initially formed by laser cutting nitinol tubing. The bifurcated body component includes seal, body, contour, and limb stents formed of nitinol wire. The wire stents are each formed in a ring with opposing ends being joined together in a crimp sleeve. The suprarenal stents are sewn to the multifilament polyester (PET) graft fabric using ultra high molecular weight polyethylene (UHMWPE) suture. The wire formed stents are sewn to the graft fabric using polyester suture.

Radiopaque markers are sewn onto each component of the stent graft to aid in visualization and to facilitate accurate placement of each component. Radiopaque markers are located at the proximal and distal ends of the graft material of each stent graft component, as well as at the location of the bifurcation and contralateral gate of the bifurcated stent graft component to help visualize the edges and locations of the stent grafts. The nitinol stents may also be visualized under fluoroscopy.
Figure 1: Endurant Stent Graft Configurations (Bifurcated, Contralateral Limb, Aortic Extension and Iliac Extension)

Note: Graphic representation not to scale
Above Schematic represents the location of the top Radiopaque markers.

Above Schematic represents the location of the bottom of the Radiopaque markers.

Above Schematic represents the location of the Overlap Marker.

**Figure 2: Endurant Stent Graft Configurations (AUI)**

*Note:* Graphic representation not to scale.
1.1.1 BIFURCATED STENT GRAFT COMPONENT

The proximal section of the bifurcated stent graft component in use is deployed into the proximal neck and upper section of the aneurysm. All stents on the proximal aortic section of the bifurcated component are sewn to the outside of the graft fabric. The proximal stent (suprarenal) of the aortic section is not covered with graft fabric. As such, this bare stent design allows the Endurant Stent Graft to be fixed above the renal arteries without obstructing them with graft fabric. Refer to Figure 3 for a pictorial representation of the proximal configuration. The suprarenal stent has anchoring pins to help fix the stent graft in place. The suprarenal stent is joined to the proximal edge of the graft by ultra high molecular weight polyethylene suture.

![Figure 3: Endurant Bifurcated Stent Graft Component Aortic Proximal Configuration](image)

Note: Graphic representation not to scale

Distally, the aortic section bifurcates into two smaller tubes: an ipsilateral single iliac limb and a contralateral (stub) leg. In the ipsilateral limb of the bifurcated stent graft component, the stents are sewn to the outside of the graft fabric providing a smooth inner lumen. In the contralateral stub leg of the bifurcated stent graft component, the stents are sewn to the inside of the graft fabric providing additional friction for higher disjunction (separation) forces with the contralateral limb component. Refer to Figure 4 for a pictorial representation of the ipsilateral limb distal configuration of the Endurant Bifurcated Stent Graft Component.

![Figure 4: Endurant Bifurcated Stent Graft Limb Distal Configuration](image)

Note: Graphic representation not to scale

The diameters of the available proximal aortic section of the bifurcated stent graft components range from 23 mm to 36 mm, and the covered length of the bifurcated stent graft components range from 120 mm to 170 mm. In use all stent graft components are oversized to fix the stent graft components in place and to provide sealing for the exclusion of the aneurysm. The aortic sections of the bifurcated stent graft components should be over-sized approximately 10% to 20% in relation to the actual measured vessel inner diameter. The available aortic sections sizes are able to be used in aortas with diameters ranging from 19 mm to 32 mm. The dimensions of the ipsilateral distal limb portion of the bifurcated stent graft components range in diameter from 13 mm to 20 mm, which can be used in iliac
arteries with diameters ranging from 10 mm to 18 mm. If a larger range of limb sizes is necessary refer to the iliac extension section 1.1.3.

1.1.2 CONTRALATERAL LIMB COMPONENT

The proximal end of the tube-like contralateral limb component is deployed within the contralateral stub leg of the bifurcated stent graft component, while the contralateral limb component’s distal end is deployed in the contralateral iliac artery. The proximal section of the contralateral limb component uses an open web configuration. The intent of the design is to reduce the risks of endoleaks. The distal diameter of contralateral limb components available range from 10 mm to 28 mm with total lengths ranging from 80 mm to 120 mm. The contralateral limb component should be over-sized approximately 10% to 25% in relation to the vessel inner diameter and can be used in iliac arteries ranging from 8 mm to 25 mm.

1.1.3 ILIAC EXTENSION COMPONENT

In cases in which additional distal length of the stent graft is needed, iliac extension components are available. The iliac extension component has a proximal end open web configuration similar to contralateral limb component. The diameters of available iliac extension components range from 10 mm to 28 mm with a covered length of 80 mm. Similar to the contralateral limb component, the iliac extension component is designed for oversizing of 10% to 25% and can be used in iliac arteries ranging from 8 mm to 25 mm in diameter.

1.1.4 AORTIC EXTENSION COMPONENT

In cases in which additional proximal length of the stent graft is needed, aortic extension components are available. The aortic extension components use the same proximal bare suprarenal stent with anchoring pin design as the proximal stent of the aortic section of the bifurcated component. The diameters of available aortic extension components range from 23 mm to 36 mm with the aortic extension having a covered length of 45 mm. Similar to the bifurcated component, the aortic extension component is designed for oversizing of 10% to 20% and can be used in aortic arteries ranging from 19 mm to 32 mm in diameter.

1.1.5 ABDOMINAL TUBE COMPONENT

In cases in which additional proximal length of the stent graft longer than provided by the Aortic Extension Component is needed, abdominal tube components are available. They are identical to the Aortic Extension Component except that they have a covered length of 70 mm.

1.1.6 AORTO-UNI-ILIAC (AUI) STENT GRAFT COMPONENT

The proximal section of the aorto-uni-iliac stent graft component in use is deployed into the proximal neck and upper section of the aneurysm. All stents on the proximal aortic section of the aorto-uni-iliac component are sewn to the outside of the graft fabric. The proximal stent (suprarenal) of the aortic section is not covered with graft fabric. As such, this bare stent design allows the aorto-uni-iliac stent graft component to be fixed above the renal arteries without obstructing them with graft fabric. Refer to Figure 3 for a pictorial representation of the proximal configuration. The suprarenal stent includes anchoring pins to help fix the AUI stent graft component in place. The suprarenal stent is joined to the proximal edge of the graft by ultra high molecular weight polyethylene suture.
Distally, the proximal aortic section tapers down to a smaller diameter tube. In the distal end of the tapered aorto-uni-iliac component, the stents are sewn to the inside of the graft fabric.

The diameters of the available proximal aortic section of the aorto-uni-iliac stent graft components range from 23 mm to 36 mm, and the covered length of the aorto-uni-iliac stent graft component is 105 mm. In use, all stent graft components are oversized to fix the stent graft components in place and to provide sealing for the exclusion of the aneurysm. The aortic sections of the aorto-uni-iliac stent graft components should be over-sized approximately 10% to 20% in relation to the actual measured vessel inner diameter. The available aortic sections sizes are able to be used in aortas with diameters ranging from 19 mm to 32 mm. The diameter of the distal end of the aorto-uni-iliac stent graft component is 14 mm.

1.2 TALENT™ OCCLUDER SYSTEM

The Talent Occluder System is available to be used with Endurant Stent Graft System. The Occluder is typically used in conjunction with the aorto-uni-iliac component and a femoral-femoral bypass in the event that:

- It is not possible to place a bifurcated component due to patient’s anatomy, tortuous anatomy, a significant extension of aneurysmal disease, inability to access the contralateral iliac.
- It is needed to stop retrograde blood flow into the aneurysm sac.
- It is needed for repair.

The Occluder is a tubular stent-graft segment sealed at both ends. The Occluder ensures that the blood flowing through the contralateral iliac artery does not “backflow” into the aneurysm sac, but instead flows from the fem-fem bypass into the patient’s contralateral leg artery. The Occluder Delivery System consists of a dilator used for delivery system insertion, a cartridge preloaded with the Occluder, a sheath for delivering the stent graft to the target location, and a pushrod to advance and help deploy the stent graft. Additional details are available in the Talent Abdominal Stent Graft System Instructions for Use.

1.3 ENDURANT DELIVERY SYSTEM

The Endurant Stent Graft is delivered by the Endurant Delivery System, which facilitates the placement of the various selected stent graft components via the arterial vasculature (e.g., femoral arteries). Using fluoroscopic guidance, the Endurant Delivery System is properly positioned within the patient’s vasculature and a specific stent graft component is deployed.

The Endurant Delivery System is a general title for two specific kinds of Endurant Delivery Systems. Each consists of a single use, disposable catheter with an integrated handle to provide the user with accurate and controlled deployment. The catheter assembly is flexible and compatible with a 0.035” (0.89 mm) guidewire. The two kinds are: (1) Endurant Aortic Delivery Systems and (2) Endurant Iliac Delivery System. The Endurant Aortic Delivery system is for delivering Endurant bifurcated, aortic extension, abdominal tube and aorto-uni-iliac (AUI) stent graft components; and the Endurant Iliac Delivery System for delivering the Endurant contralateral limb and iliac extension stent graft components.

1.3.1 ENDURANT AORTIC DELIVERY SYSTEM
The Endurant Aortic Delivery System (Figure 5-7) is constructed of four concentric single lumen shafts (an outer hydrophilic coated polymer graft cover, a stainless steel spindle-tube shaft, a middle member polymer shaft, and a guidewire lumen containing nitinol inner member). A stent stop is attached to the distal end of the middle member shaft.

Figure 5: Endurant Aortic Delivery System
Note: Graphic representation not to scale

The taper tip detail of the Endurant Aortic Delivery System, is depicted in Figure 6. An atraumatic tapered polymeric tip is attached at the distal end of the inner member to facilitate tracking through tortuous and calcified vessels. A metallic spindle is attached to the distal end of the spindle-tube shaft to prevent axial movement of the suprarenal stent crowns before release. Attached to the proximal end of the polymeric tip is a metallic sleeve that holds the suprarenal stent crowns and anchor pins constrained and on the spindle. The polymeric taper tip, stent stop, and ring marker on the distal end of the graft cover are radiopaque and aid in fluoroscopic visualization. Retraction of the graft cover while the suprarenal stent crowns are held by the spindle and the metallic sleeve of the tapered tip is designed to allow for accurate positioning and partial deployment of the body of the bifurcated stent graft component.
The back-end wheel can be rotated clockwise to advance the inner member attached to taper tip thereby moving the metallic sleeve forward to release the suprarenal stent crowns and adjacent anchor pins from the spindle. After release of the suprarenal stent crowns, the back-end wheel should be rotated counter clockwise to reseat the tip of the delivery system before performing the step of retracting the taper tip to the graft cover through the deployed stent graft component in the process of removing the delivery system from the body.

1.3.2 ENDURANT ILIAC DELIVERY SYSTEM

The Endurant Iliac Delivery System (Figure 8) is constructed of three concentric single lumen shafts (an outer hydrophilic coated polymer graft cover, a middle member polymer shaft, and a guidewire
lumen containing stainless steel inner member). A stent stop is attached to the distal end of the middle member shaft to maintain the position of the contralateral (or other) limb component during deployment. A polymeric, atraumatic tapered tip is attached at the distal end of the inner member to facilitate tracking through tortuous and calcified vessels. The taper tip, stent stop, and ring marker on the distal end of the graft cover are radiopaque and aid in fluoroscopic visualization. The deployment of the self-expanding stent graft components is facilitated by the retraction of the graft cover. Post-deployment of the stent graft component, the tip of the delivery system should be retracted into the graft cover before removing the delivery system from the body.

Figure 8: Endurant Iliac Delivery System
Note: Graphic representation not to scale
2 INDICATIONS FOR USE

The Endurant Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:

- Adequate iliac/femoral access
- Short and angulated proximal neck aneurysms with neck diameters of 19-32 mm
- Iliac diameters of 8-25 mm
- Proximal necks ≥10 mm in length with non-significant calcification, and/or non-significant thrombus with ≤60° infrarenal and ≤45° suprarenal angulation and a vessel diameter approximately 10-20% smaller than the labeled Endurant Stent Graft diameter
- Proximal necks ≥15 mm neck with non-significant calcification, and/or non-significant thrombus with ≤75° infrarenal and ≤60° suprarenal angulation and a vessel diameter approximately 10-20% smaller than the labeled Endurant Stent Graft diameter
- Proximal necks with morphology suitable for endovascular repair
- Distal fixation length of ≥15 mm
- One of the following:
  - Aneurysm diameter > 5 cm; or
  - Aneurysm diameter of 4-5 cm which has also increased in size by 0.5 cm in the last 6 months; or
  - Aneurysm which is at least 1.5 times the diameter of the normal infrarenal aorta.

3 CONTRAINDICATIONS

There are no known contraindications currently associated with the Endurant Stent Graft System.

4 WARNINGS AND PRECAUTIONS

4.1 GENERAL

- The long term safety and effectiveness of this implant has not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.
- Exercise care in the handling of the device and delivery technique to aid in the prevention of vessel rupture.
- Inappropriate patient selection may contribute to poor Endurant Stent Graft System performance. Refer to Section 2 and Section 6 for specific information regarding patient selection.
- The Endurant Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the Endurant Stent Graft System. Specific training expectations are described in Section 9.1.
- Do not use the Endurant Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies as described in Section 9.9.
Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

4.2 PATIENT SELECTION, TREATMENT, AND FOLLOW-UP

- Do not use the Endurant Stent Graft System in patients that have systemic infection, or are suspected of having systemic infection
- Do not use the Endurant Stent Graft System in patients with sensitivities or allergies to the Endurant Stent Graft System materials. These materials include:
  - Polyester Block Amide (PEBA)
  - Polyether Block Amide (PEBA) with Barium-Sulfate filler
  - Polyamide 12
  - Acrylonitrile-Butadiene-Styrene (ABS) copolymer*
  - Stainless steel
  - Platinum-Iridium alloy
  - Nickel-Cobalt-Chromium-Molybdenum alloy
  - Nickel-Titanium (Nitinol) alloy
  - Ethylene Propylene Rubber*
  - Silicone
  - Polycarbonate
  - Photo-reactive polyvinylpyrrolidone copolymer
  - Platinum-Iridium alloy
  - Platinum
  - Gold
  - Polyester
  - Polyethylene
  * Denotes materials that are a part of the delivery system but do not contact the patient

- The Endurant Stent Graft System does not contain natural rubber latex. However during the manufacturing/assembly process, the Endurant Stent Graft System may have incidental contact with latex containing products (e.g. handling of the Endurant Stent Graft System by operators wearing latex gloves).
- Potential anatomical limitations (e.g. small access vessels) need to be recognized.
- The use of this device requires administration of radiographic agents. Patients with pre-existing renal insufficiency may have an increased risk of renal failure postoperatively.
- Proper use of this device requires accurate fluoroscopic imaging. This device is not recommended for patients whose weight may impede accurate fluoroscopic imaging.
- Regular follow-up including imaging of the device should be performed in accordance with the standard of care of the treating hospital/physician. Patients should be monitored for aneurysm size, occlusion of vessels, pulsatility, migration, leaks, and device integrity.
- Additional treatment including endovascular treatment or surgical conversion should be considered in the following cases:
  - Aneurysm growth > 5 mm (with or without leak) since last follow-up.
  - Change in aneurysm pulsatility (with or without growth or leak).
  - Persistent endoleak with or without aneurysm growth.
  - Stent graft migration resulting in an inadequate seal zone.
  - Decrease in renal function due to renal artery occlusion (migration or poor placement).
In all above mentioned cases, the treating physician should on a case by case basis and in accordance with the standard of care decide an appropriate action.

4.3 CLINICAL USE

- Pre-operative planning for access and placement should be performed before opening the device packaging.
- Carefully inspect the Endurant Stent Graft System packaging and device for damage or defects prior to use. Do not use product if any sign of damage or breach of the sterile barrier is observed. Do not attempt to resterilize the Endurant Delivery System or the Endurant Stent Graft.
- Do not bend or kink the Endurant Delivery System prior to implantation because it may cause deployment difficulties.
- To prevent thrombotic problems, an additional bolus of IV heparin should be administered before inserting the device.
- Do not deploy the Endurant Stent Graft Components in a location that will occlude arteries necessary to supply blood flow to organs or extremities.
- Always use fluoroscopic guidance to advance the Endurant Delivery System. Do not use excessive force to advance or withdraw the Endurant Delivery System when resistance is encountered.
- Do not continue to torque the delivery system without tip response.
- Exercise particular care in areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels. Perform balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system.
- Always monitor the implant procedure under fluoroscopy to detect kinking or alignment problems with the Endurant Stent Graft. If the Endurant Delivery System kinks during insertion, do not attempt to deploy the Endurant Stent Graft. Remove the system and insert a new delivery system.
- Inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent graft.
- The Endurant Stent Graft cannot be replaced or drawn back into the Endurant Delivery System, even if the stent graft is only partially deployed.
- If the graft cover is accidentally withdrawn, the device will prematurely deploy and may be incorrectly positioned.
- Improper placement may result in leakage or occlusion, necessitating surgical removal of the device.
- When using the trigger to rapidly deploy the stent graft, be sure to hold the front grip of the delivery system stationary. Do not rotate the handle during this step.
- If a balloon catheter is used, do not over inflate or inflate outside the graft material. Follow all manufacturer instructions regarding catheter operation.

5 ADVERSE EVENTS

5.1 POTENTIAL ADVERSE EVENTS

Potential risks or adverse events associated with use of the Endurant Stent Graft System are similar to those known to occur with conventional open surgical repair of Abdominal Aortic Aneurysm (AAA).
Such risks may be related to use of the device, the implant procedure, anesthesia, or the attendant equipment and supplies.

A list of potential risks that may occur with use of the Endurant Stent Graft System and its associated procedures are provided in Table 1. The occurrence of adverse events listed in Table 1 may lead to the need for a repeat endovascular intervention and/or open surgical repair.

### Table 1: Potential Risks Associated with Use of the Endurant Stent Graft System

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Potential Risks</th>
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<tbody>
<tr>
<td>Access failure</td>
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<td>• Allergic reaction (to contrast, anti-platelet therapy, stent graft material)</td>
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<td>• Anastomotic false aneurysm</td>
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<td>• Amnesia</td>
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<td>• Anasthesia-related complications</td>
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<td>• Aneurysm expansion</td>
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<td>• Aneurysm rupture</td>
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<td>• Aortic vessel rupture</td>
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<td>• Aortoenteric fistula</td>
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<td>• Arrhythmia</td>
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<td>• Arteriovenous fistula</td>
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<td>• Atelestasis</td>
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<td>• Cerebrovascular accident</td>
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<td>• Change in mental status</td>
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<td>• Coagulopathy</td>
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<td>• Congestive heart failure</td>
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<td>• Contrast toxicity</td>
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<td>• Conversion to surgical repair</td>
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<td>• Damage to the vessel which may require a conversion to open repair</td>
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<td>• Death</td>
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<td>• Dehiscence</td>
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<td>• Deployment failures</td>
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<td>• Device malfunction</td>
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<td>• Dissection, perforation, or rupture of the aortic vessel &amp; surrounding vasculature</td>
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<td>• Embolism</td>
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<td>• Endoleaks</td>
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<td>• Excessive or inappropriate radiation exposure</td>
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<td>• Extrusion/erosion</td>
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<td>• Failure to deliver the stent graft</td>
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<td>• Fem-Fem bypass occlusion</td>
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<td>• Gastrointestinal bleeding</td>
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<td>• Genitourinary complications</td>
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<td>• Hematoma</td>
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<td>• Hypotension/hypertension</td>
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<td>• Infection</td>
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<td>• Intramural hematoma</td>
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<td>• Lower limb edema</td>
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<td>• Loss of stent graft integrity</td>
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<td>• Loss of stent graft patency</td>
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<td>• Lymphocele/lymph fistula</td>
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<td>• Myocardial infarction</td>
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<td>• Neck enlargement (aneurysmal)</td>
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<td>• Neoplasms</td>
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<td>• Pseudoaneurysm</td>
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<td>• Spinal neurological deficit</td>
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<td>• Stenosis</td>
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<td>• Stent graft dilatation</td>
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<td>• Stent graft thrombosis</td>
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<td>• Transient-ischemic attack</td>
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<td>• Vascular trauma</td>
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<td>• Vessel occlusion</td>
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<td>• Wound infection</td>
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6  PATIENT SELECTION AND TREATMENT

6.1  INDIVIDUALIZATION OF TREATMENT

Each Endurant Stent Graft Component must be ordered in a size appropriate to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. The aortic stent graft component should be over-sized approximately 10% to 20% from the vessel inner diameter, and the Endurant stent graft components cover aortic diameters ranging from 19 mm to 32 mm. The recommended overall length of multiple deployed *in situ* assembled modular components of the Endurant Stent Graft System should extend from the lowest renal artery to just above the internal iliac (hypogastric) artery bifurcation. 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 not certain. Using this approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

Medtronic Vascular may consult with physicians 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 previously described in Section 4.3 should be carefully considered for each patient before use of the Endurant Stent Graft System.

Patient selection factors to be assessed should include:

- Patient’s age and life expectancy
- Co-morbidities (e.g. cardiac, pulmonary or renal insufficiency prior to surgery)
- Patient morphologic suitability for endovascular repair

**NOTE:** Due to the nature of the design and the flexibility of the Endurant Stent Graft System, the overall length of each stent graft component may be shorter when deployed than expected due to compression during deployment or tortuous anatomy.

**CAUTION:** Vessel over-distension and damage may be caused by excessive oversizing of the stent graft in relation to the diameter of the blood vessel.

**CAUTION:** Insufficient oversizing may increase the risk of endoleaks.

6.2  SPECIFIC PATIENT POPULATIONS

The safety and effectiveness of the Endurant Stent Graft System for the treatment of the abdominal aortic aneurysms (AAA) has not been evaluated in patients:

- With aneurysms pending rupture
- With connective tissue disorder
- With hypercoagulability
- With mesenteric artery occlusive disease
- With ilio-femoral, thoracic or inflammatory aneurysms
- With juxtarenal AAA
- With pararenal AAA
- With suprarenal or thoraco-abdominal aneurysms
• Who are morbidly obese
• Pregnant or nursing
• Less than 18 years old
• With less than one year life expectancy

7  PATIENT COUNSELING INFORMATION

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

• Risks and benefits related to open surgical repair.
• Risks and benefits related to endovascular repair.
• Differences between endovascular repair and surgical repair.
• Possibility that subsequent endovascular or open surgical repair of the aneurysm may be required.
• The long-term safety and effectiveness of 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.
• Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should be monitored closely.

Medtronic Vascular recommends that the physician disclose to the patient (in written form) all risks associated with treatment using the Endurant Stent Graft System. Details regarding risks occurring after implantation of the device are contained in the Patient Information sheet. Please follow EVAR protocol required from each treating institution.

8  HOW SUPPLIED

The Endurant Stent Graft System Components are available in the sizes described in Tables 2- 6.

<table>
<thead>
<tr>
<th>Table 2: Sizing Chart - Bifurcated Stent Graft Component</th>
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<tbody>
<tr>
<td>OD (Fr.)</td>
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<tr>
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<td>20</td>
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<tr>
<td>36x16</td>
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<td>32x20</td>
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<td>120, 145, 170</td>
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<td>23x16</td>
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<td>23x13</td>
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<td>19-20</td>
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<table>
<thead>
<tr>
<th>Table 3: Sizing Chart – Aorto-Uni-Iliac Stent Graft Component</th>
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<td>OD (Fr.)</td>
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<td>32x14</td>
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<td>28x14</td>
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<td>18</td>
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<tr>
<td>23x14</td>
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</tbody>
</table>
### Table 4: Sizing Chart – Aortic Extension & Abdominal Tube Components

<table>
<thead>
<tr>
<th>OD (Fr.)</th>
<th>Proximal x Distal Diameter (mm x mm)</th>
<th>Covered Length (mm)</th>
<th>Vessel Treated (mm)</th>
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<tbody>
<tr>
<td>20</td>
<td>36x36</td>
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<td>32x32</td>
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<td>25x25</td>
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<td>23x23</td>
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<td>21-22</td>
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</table>

### Table 5: Sizing Chart – Contralateral Limb Component

<table>
<thead>
<tr>
<th>OD (Fr.)</th>
<th>Proximal x Distal Diameter (mm x mm)</th>
<th>Covered Length (mm)</th>
<th>Vessel Treated (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>16x28</td>
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<td>23-25</td>
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<td>16x24</td>
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<td></td>
<td>16x20</td>
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<td>15-18</td>
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<tr>
<td>14</td>
<td>16x16</td>
<td>80, 95, 120</td>
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<td></td>
<td>16x13</td>
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<td>12-14</td>
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<td></td>
<td>16x10</td>
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<td>10-11</td>
</tr>
</tbody>
</table>

### Table 6: Sizing Chart – Iliac Extension Component

<table>
<thead>
<tr>
<th>OD (Fr.)</th>
<th>Proximal x Distal Diameter (mm x mm)</th>
<th>Covered Length (mm)</th>
<th>Vessel Treated (mm)</th>
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<td>18</td>
<td>28x28</td>
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<td>8-9</td>
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</table>

### 8.1 STERILITY

Each Endurant Stent Graft Component (bifurcated, contralateral limb, aortic extension, abdominal tube, iliac extension, and AUI) is individually contained within an Endurant Delivery System. The Endurant Delivery System is sterilized using E-beam and are supplied sterile for single use only.

- Do not reuse or attempt to resterilize.
- Do not use if package is opened or damaged.

### 8.2 CONTENTS

- One (1) Endurant Stent Graft System
- One (1) Instructions for Use

### 8.3 STORAGE

Store at room temperature in a dark, dry place.
9 CLINICIAN USE INFORMATION

9.1 PHYSICIAN TRAINING PROGRAM

CAUTION: The Endurant Stent Graft System should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.

The recommended skill/knowledge requirements for physicians using the Endurant Stent Graft System are outlined below:

Patient Selection:

- Knowledge of the natural history of abdominal aortic aneurysms (AAA) and co-morbidities associated with AAA repair.
- Knowledge of radiographic image interpretation, device selection, and sizing.

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

- Femoral cutdown, arterial bypass, arteriotomy, and repair
- Percutaneous access and closure techniques
- Non-selective and selective guidewire and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

9.2 INSPECTION PRIOR TO USE

Inspect the device and packaging to verify that no damage or defects exist. Do not use product after the “Use By” date on the package. If the device is damaged or the integrity of the sterilization barrier has been compromised, do not use the product and contact your Medtronic Vascular representative for return information.

9.3 MATERIALS REQUIRED (NOT INCLUDED IN STENT GRAFT SYSTEM PACKAGING)

At the time of surgery have available:

- Additional Endurant Stent Graft Systems (bifurcated, contralateral limb, aortic extension, abdominal tube, iliac extension, and aortic extension components) of various lengths and diameters to customize the implant to fit the anatomy of the individual patient.
- Fluoroscope with digital angiography capabilities (C-arm or fixed unit). Fluoroscopic imaging and the ability to record and recall all imaging.
• Assorted guidewires of adequate length. In addition to guidewires used for accessing the vessel, 0.035 inch (0.89 mm) diameter guidewires or equivalents must be used to maximally support the Endurant Delivery System into the aortic vasculature.
• Heparinized saline solution.

9.4 MATERIALS RECOMMENDED (NOT INCLUDED IN STENT GRAFT SYSTEM PACKAGING)

At the time of surgery have available:

• An appropriately sized introducer sheath to provide an adequate conduit for the Endurant Delivery System to be used.
• Sterile introducer sheaths for introduction into femoral arteries during road mapping or further diagnostic imaging.
• Power Injector for angiographic contrast studies.
• Assorted balloon catheters to potentially dilate blood vessels prior to insertion of the Endurant Delivery System.
• Compliant balloon catheters for stent graft expansion following implantation.
• Suitable introducer sheath for compliant balloon.
• Radiopaque contrast media.
• Sterile silicone lubricant or sterile mineral oil.
• Interventional snare devices.
• Curved guidewire.

9.5 MRI INFORMATION

Nonclinical testing has demonstrated that the Endurant Stent Graft is MR Conditional. It can be scanned safely in both 1.5 Tesla and 3.0 Tesla magnetic resonance (MR) systems under the following conditions.

9.5.1 MRI SYSTEM, 1.5 TESLA

• Static magnetic field of 1.5 Tesla
• Spatial gradient field of 1000 Gauss/cm
• Maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning (or the maximum SAR allowed by the MR System, whichever is less).

In nonclinical testing, the Endurant Stent Graft produced a temperature rise of less than 0.30° C when normalized to the local specific absorption rate (SAR) for 15 minutes of MR scanning in a 64 MHz whole body transmit coil, which corresponds to a static field of 1.5 Tesla.

9.5.2 MRI SYSTEM, 3.0 TESLA

• Static magnetic field of 3.0 Tesla
• Spatial gradient field of 1000 Gauss/cm
• Maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning (or the maximum SAR allowed by the MR System, whichever is less).
In nonclinical testing, the Endurant Stent Graft produced a temperature rise of less than 0.60°C when normalized to the local specific absorption rate (SAR) for 15 minutes of MR scanning in a 3.0 Tesla Siemens TrioTim MR scanner.

**9.5.3 IMAGE ARTIFACT (1.5 TESLA AND 3.0 TESLA SYSTEMS)**

Magnetic resonance image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. The image artifact extends approximately 5 and 8 mm from the device, both inside and outside the device lumen when scanned in nonclinical testing using the sequence: spin echo and gradient echo, respectively, in a 3.0 Tesla Siemens TrioTim (VB 13 Software) MR system with a whole body coil.

Patients with an Endurant Stent Graft Component for the abdominal aortic or aorto-iliac aneurysm may safely undergo MRI for Normal Mode and First Level Controlled Operating Mode of the MR System, as defined in IEC Standard 60601-2-33.

**9.6 VASCULAR ACCESS AND THE PREPARATION OF THE ENDURANT STENT GRAFT SYSTEM**

Correct sizing of the aorta and iliac vessels must be determined before implantation of the Endurant Stent Graft Components using spiral computer aided tomography (CT) as well as angiograms of both the iliacs and aorta. These images should be available for review during the procedure.

Vascular instruments and other surgical supplies needed to perform surgical cutdowns and to catheterize access vessels should also be available.

To reduce the risk of thromboembolism, it is recommended that the patient be heparinized for the duration of the procedure.

**CAUTION:** Do not retract the graft cover of the Endurant Delivery System until the system is accurately placed within the vasculature and ready for deployment.

**CAUTION:** Never advance or retract equipment from the vasculature without the use of fluoroscopy.

**9.6.1 VASCULAR ACCESS**

Following aseptic procedure, perform a vascular access at the femoral arteries. Place a guidewire in the ipsilateral femoral artery and advance it above the renal arteries. From the contralateral side femoral artery, place a second guidewire directed to the abdominal aorta. Over this second guidewire, place an angiography catheter above the renal arteries. Consider taking an angiogram.

**NOTE:** There is a possibility that an additional incision might be necessary to access the common iliac artery.

**9.6.2 PREPARATION**

Prior to insertion, it is advisable to view each delivery system under fluoroscopy to visualize the radiopaque markers on the stent graft component. The radiopaque markers indicate the position of the
proximal and distal edges of the graft material and some additional guide markers on graft material. For a bifurcated component turn the graft cover to align the radiopaque marker on the stub leg with the patient's contralateral iliac artery. Flush the guidewire lumen with heparinized saline.

9.7 DELIVERY PROCEDURE ENDURANT STENT GRAFT SYSTEM

Medtronic Vascular recommends using an appropriate caliber introducer sheath to perform diagnostic tests.

WARNING: NEVER ADVANCE THE OBTURATOR WITHOUT FIRST HAVING PLACED A GUIDEWIRE. NEVER ADVANCE AN INTRODUCER SHEATH BEFORE THE OBTURATOR IS FULLY INSERTED.

WARNING: TO PREVENT THROMBOTIC PROBLEMS, A SECOND BOLUS OF IV HEPARIN IS RECOMMENDED BEFORE INSERTING THE DEVICE.

9.7.1 INTRODUCTION OF BIFURCATED STENT GRAFT COMPONENT

Wet the graft cover of the delivery system to activate the hydrophilic coating. Slowly insert the Endurant Aortic Delivery System containing a bifurcated stent graft component. Advance over the guidewire so that the proximal most stent and the radiopaque markers are visualized in the target proximal aortic neck. Refer to Figure 9.

Inject contrast media into the abdominal aorta and mark the position of the target location, either on the imaging screen or on the patient's body. Adjust the position of the bifurcated stent graft component such that the top edge of the graft fabric is just below the lowest renal artery. The edge of the graft fabric is 0.5 to 1.0 mm above the top edge of the proximal radiopaque markers (1.0 – 1.5 mm above the center of proximal radiopaque markers).

NOTE: If the top edge of the graft fabric is to be placed very close to the renal arteries, contrast media may be injected to identify the location of the lower renal artery and verify the position before fully deploying device. Once the proximal position has been identified, do not move the patient or imaging equipment. The angiographic catheter can be removed prior to deployment. However, if the angiographic catheter is not removed until after the deployment, ensure that the tip is straightened (pigtail catheter) with a guidewire before removal so that the stent graft is not pulled down.

CAUTION: When aligning the position of an Endurant Stent Graft System Component, be sure the fluoroscope is angled perpendicularly to the center line of the infrarenal aorta to avoid parallax or other source of visualization error. Some cranial caudal angulation of the I-I tube may be necessary to achieve this, especially if there is anterior angulation of the aneurysm neck.
Figure 9: Introduce the Endurant Aortic Delivery System
Note: Graphic representation not to scale

9.7.2 CONFIRM POSITION

Ensure that the distal portion of the contralateral stub leg is above the aortic bifurcation and within the aneurysmal sac, and not within the iliac vessel. Rotate the handle until the radiopaque marker on the distal-most stent of the contralateral stub leg is aligned with the contralateral iliac artery. In this orientation, the cylindrical radiopaque marker on the distal most stent of the contralateral gate will be oriented to the side. When attempting to rotate the system, if a tip response is not observed, do not continue to torque the delivery system. Pull back the system and re-position until the intended position is achieved.
9.7.3 DEPLOYING THE PROXIMAL END OF BIFURCATED COMPONENT

With one hand on the front grip, hold the Endurant Aortic Delivery System stationary. Next, slowly withdraw the graft cover with the other hand by rotating the slider counter-clockwise (in the direction of the arrow on the slider), until two to three of the covered stents have been fully deployed as depicted in Figure 10.

Use angiography to verify the position of the stent graft in relation to the renal arteries.

If needed, gently push the entire delivery system proximally or distally until the proximal end of the graft material is even with the distal edge of the lowest renal artery.

**NOTE:** In the unlikely event of delivery system failure that results in partial stent graft deployment due to graft cover severance, the “handle disassembly” technique may permit the successful deployment of the stent graft. Refer to Section 9.8.

**CAUTION:** Do not rotate the graft cover during deployment.

**CAUTION:** If the graft cover is accidentally withdrawn, the stent graft component will prematurely deploy and may be incorrectly positioned.

**WARNING:** FAILURE TO PROPERLY ALIGN THE RADIOPAQUE MARKERS MAY RESULT IN IMPROPER DEPLOYMENT OF THE STENT GRAFT COMPONENT.

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Figure 10: Deploy the Proximal End of Bifurcated Component

Note: Graphic representation not to scale
9.7.4 DEPLOY THE CONTRALATERAL STUB LEG OF BIFURCATED COMPONENT

While continuing to hold the Endurant Aortic Delivery System stationary with one hand on the front grip, slowly rotate the slider counter-clockwise until the graft cover has withdrawn to the point that the contralateral stub leg has been released from the delivery sheath as depicted in Figure 11.

Figure 11: Deploy the Contralateral Leg
Note: Graphic representation not to scale
9.7.5 RELEASE PROXIMAL END OF SUPRARENAL STENT CROWNS AND ANCHOR PINS

Use angiography to verify the position of the bifurcated stent graft component in relation to the renal arteries.

Continue to hold the Endurant Aortic Delivery System stationary with one hand on the front grip. With the other hand, rotate the back-end wheel clockwise, moving the taper tip and metallic sleeve forward to release the proximal end of the suprarenal stent as depicted in Figure 12. Observe the release of the crowns and anchor pins at the proximal end of the suprarenal stent under fluoroscopy and continue turning the back-end wheel until all parts of the suprarenal stent are completely clear from the spindle of the delivery system. Confirm that the spindle has fully separated from the crowns of the suprarenal stent.

NOTE: In the unlikely event that the proximal end of the suprarenal stent cannot be released, refer to Section 9.8 for bail-out techniques.

NOTE: It is recommended that the angiographic catheter be pulled down prior to release of the suprarenal stent to prevent the anchor pins from binding the catheter shaft against the aorta.

CAUTION: When treating highly tortuous anatomy, in the unlikely event that the back-end wheel separates during the rotation of the wheel, reassemble the wheel. A bail-out technique may be required. Refer to Section 9.8 for bail-out techniques.

CAUTION: Make sure to stop rotating the back-end wheel when you reach the top of the back-end screw gear.
Figure 12: Release the Proximal End of Suprarenal Stent

Note: Graphic representation not to scale
9.7.6 DEPLOY DISTAL END OF BIFURCATED COMPONENT

There are two methods to deploy the distal end of the Bifurcated Component.

Either continue to rotate the slider counter-clockwise or while holding the front grip of the delivery system stationary, use your thumb to pull the trigger on the slider and pull the slider back all the way to finish deploying graft. Withdraw the graft cover until the distal stent of the ipsilateral iliac component is completely deployed as depicted in Figure 13.

NOTE: Retract the graft cover past the flexible stent stop tip (approximately 10 mm) to ensure the graft cover edge does not disturb the graft position during forward advancement of the delivery system for tip recapture.

CAUTION: When using the trigger to rapidly deploy the stent graft, be sure to hold the delivery system stationary. Do not rotate the delivery system during this step.

Figure 13: Deploy the Distal End of Bifurcated Component
Note: Graphic representation not to scale
9.7.7 RECAPTURE SPINDLE WITHIN SLEEVE OF THE TAPER TIP

Continue to hold the Endurant Aortic Delivery System with one hand on the front grip. Confirm the spindle has fully separated from the crowns of the suprarenal stent, gently torque the delivery system if it has not. Gently torque and push the entire delivery system proximally approximately 3 cm so that the taper tip and spindle are completely clear of the suprarenal stent. With the other hand, rotate the back-end wheel counter-clockwise capturing the spindle in the taper tip as depicted in Figure 14. Observe the capture of the spindle within the sleeve of the taper tip under fluoroscopy. Continue turning the back-end wheel counter-clockwise until the spindle has been completely captured and the back-end wheel is at the bottom of the back-end screw gear.

NOTE: Ensure that the ipsilateral limb is fully deployed before advancing the delivery system.

NOTE: Ensure that the suprarenal stent is fully disengaged from the spindle before pushing the Delivery System forward.

NOTE: If the spindle catches on the suprarenal stent during advancement, completely advance the back-end wheel clockwise. Using a gentle in-and-out motion with the delivery system, rotate the delivery system until the spindle slips past the suprarenal stent. Then continue with the withdrawal instructions.

CAUTION: The spindle must be recaptured within the taper tip sleeve in order to prevent complications.

CAUTION: Make sure to stop rotating the back-end wheel when you reach the bottom of the back-end screw gear.

WARNING: FAILURE TO ADEQUATELY ADVANCE THE DELIVERY SYSTEM TO RECAPTURE THE SPINDLE CAN RESULT IN THE TRAPPING OF A SUPRARRENAL CROWN WITHIN THE TAPER TIP SLEEVE AND RESULT IN AN ALTERATION OF THE PROXIMAL LANDING ZONE UPON ATTEMPTED WITHDRAWAL.
9.7.8 DELIVERY SYSTEM REMOVAL

Continue to hold the Endurant Aortic Delivery System with one hand on the front grip and the other hand on the slider. Gently torque and withdraw the delivery system until the spindle is retracted into the fabric portion of the stent graft. Pull back the slider trigger and hold the slider stationary while bringing the front grip to the slider as depicted in Figure 15. Use continual fluoroscopy and watch the top of the Bifurcated Stent Graft Component while slowly pulling back the taper tip into the graft cover of the delivery system.

Gently remove the delivery system using fluoroscopy to ensure that the stent graft component does not move during the withdrawal.

NOTE: Maintain vessel access until all stent graft components are in place.
Figure 15: Remove the Endurant Aortic Delivery System

Note: Graphic representation not to scale
9.7.9 CONTRALATERAL LIMB STENT GRAFT COMPONENT DEPLOYMENT

Prepare the Endurant Stent Graft System using the procedure described in Section 9.6.2.

On the patient’s contralateral side, insert a guidewire through the contralateral leg and the aortic neck portion of the previously placed bifurcated stent graft component.

Wet the graft cover of delivery system to activate the hydrophilic coating. Place the Endurant Iliac Delivery System containing a contralateral limb over the guidewire and into the contralateral leg of the deployed bifurcated stent graft component.

Insert the contralateral limb component into the contralateral stub leg of the bifurcated stent graft component. The proximal radiopaque marker of the contralateral limb component should be aligned to the radiopaque marker at the bifurcation of the bifurcated graft component. Ensure that there is a three stent overlap as depicted in Figure 16.

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**Figure 16: Introduce the Endurant Iliac Delivery System**

*Note: Graphic representation not to scale*
With one hand on the front grip, hold the Endurant Iliac Delivery System stationary. Then, slowly withdraw the graft cover with the other hand by rotating the slider counter-clockwise. At any point, use your thumb to pull the trigger on the slider and pull the slider back all the way to finish deploying stent graft component as depicted in Figure 17. Remove Endurant Iliac Delivery System in the same method as referenced in Section 9.7.8.

**NOTE:** In the unlikely event of delivery system failure and concurrent partial stent graft component deployment due to graft cover severance, the “handle disassembly” technique may permit the successful deployment of the stent graft component. Refer to Section 9.8.

**CAUTION:** Do not rotate the delivery system during deployment.

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Figure 17: Deploy the Contralateral Limb Component

*Note:* Graphic representation not to scale
9.7.10 AORTIC OR ILIAC EXTENSION COMPONENTS

In the event that an aortic extension component needs to be used, ensure that there is a minimum three stent overlap between the aortic extension component and the bifurcated component. Follow the bifurcated component deployment steps, except rotate the handle to open the extension component entirely before releasing the proximal end of the suprarenal stent of the aortic component.

In the event that an iliac extension component needs to be used, ensure that there is a minimum three stent overlap between the iliac extension component and the component it is inserted into. Follow the contralateral limb component deployment steps described in Section 9.7.9.

9.7.11 ABDOMINAL TUBE COMPONENT

In the event that an abdominal tube component needs to be used, follow the bifurcated component deployment steps with the following exception. Rotate the handle to open the tube component entirely before releasing the proximal end of the suprarenal stent of the tube component.

9.7.12 AUI COMPONENT

Follow the bifurcated component deployment steps, except rotate the handle to open the AUI component graft covered section entirely before releasing the proximal end of the suprarenal stent of the AUI component. Follow the steps described in Sections 9.7.6 – 9.7.8 to remove the delivery system.

In the event that a distal component is required, use the contralateral limb component as the AUI distal extension. Place the delivery system over the existing guidewire, and follow the contralateral limb component deployment steps described in Section 9.7.9. To ensure proper docking, align the proximal radiopaque markers of the contralateral limb component with the AUI component radiopaque marker at the third stent of the distal section.

An occluder may be used to block flow through the contralateral iliac artery. Refer to Section 9.7.13 – Occluder Deployment, and the Talent Abdominal Stent Graft System Instructions for Use.

9.7.13 OCCLUDER DEPLOYMENT

The Talent Occluder System is available to be used with Endurant Stent Graft System and is typically used in conjunction with the AUI component. The Occluder is closed at both ends to stop retrograde blood flow into the aneurysm sac.

For details on use and implantation of the Occluder, refer to the appropriate sections of the “Talent Abdominal Stent Graft System Instructions for Use.”

9.7.14 SMOOTHING STENT GRAFT FABRIC AND MODELING THE ASSEMBLED STENT GRAFT COMPONENTS

The Reliant™ Stent Graft Balloon Catheter is packaged separately. This compliant balloon can be used to assist in stent graft implantation by modeling the covered portion of the stent graft components and to remove wrinkles and folds from the graft material as needed. Use the Reliant Stent Graft Balloon Catheter to model the proximal and distal seal zones as well as any overlapping connection (or junction) areas between the components of the Endurant Stent Graft System. Sub-optimal expansion of the self-
expanding Stent Graft components may also be improved by use of the Reliant Stent Graft Balloon Catheter.

Follow the Reliant Stent Graft Balloon Catheter IFU for specific insertion instructions.

NOTE: The Reliant Balloon is recommended for use with the Endurant Stent Graft System. Data is not available for use with other balloons for remodeling stent grafts.

CAUTION: Over inflation of balloon can cause graft tears and/or vessel dissection or rupture.

WARNING: WHEN EXPANDING A VASCULAR PROSTHESIS, THERE IS AN INCREASED RISK OF VESSEL INJURY AND/OR RUPTURE, AND POSSIBLE PATIENT DEATH, IF THE BALLOON’S PROXIMAL AND DISTAL RADIOPAQUE MARKERS ARE NOT COMPLETELY WITHIN THE COVERED (GRAFT FABRIC) PORTION OF THE PROSTHESIS.

WARNING: DO NOT USE THE RELIANT STENT GRAFT BALLOON CATHETER IN THE TREATMENT OF DISSECTIONS.
9.7.15 Seal Entry Sites

Remove the introducer and the guidewire. Repair the entry site with standard closure technique.

9.7.16 Procedure Completion

At the completion of the procedure, perform angiography to assess the Endurant Stent Graft components for proximal and distal endoleaks and to verify position of the implanted stent graft components in relation to the aneurysm and renal arteries. Leaks at the attachment or connection sites should be treated using the balloon to remodel the stent graft components against the vessel wall. Major leaks that cannot be corrected by re-balloonning may be treated by adding Endurant Aortic or Iliac Extension Components to the previously placed stent graft components.

CAUTION: Any leak left untreated during the implantation procedure must be carefully monitored after implantation.
9.8 BAIL OUT TECHNIQUES

9.8.1 SCREW GEAR HANDLE DISASSEMBLY

In the unlikely event of delivery system failure and concomitant partial stent graft component deployment due to graft cover severance, a “screw gear handle disassembly” technique may permit the successful deployment of the stent graft. See the instructions below.

- Pull back the trigger and fully retract the slider.
- Stabilize the delivery system.
- Insert the tips of a pair of hemostats into each of the screw gear handle disassembly ports on the front grip.
- Disengage the front grip from the screw gear by pressing the tips of the hemostats into the handle disassembly ports and simultaneously advancing the front grip away from the screw gear.
- Advance the front grip until it fully clears the screw gear.
- Separate the screw gear halves in order to identify the location of graft cover severance.
- Manually retract the graft cover with your fingers or with hemostats until the stent graft is fully deployed.
- Follow the standard instruction for use for tip capture section deployment and delivery system removal.

9.8.2 BALLOONING

In the unlikely event of delivery system failure and the captured proximal end of crowns and anchoring pins of the suprarenal stent cannot be deployed while the back-end wheel section still works (the stent graft component being deployed moves together with taper tip when turning the back-end wheel), a “ballooning” technique may permit the successful deployment of the captured proximal end of crowns and anchoring pins of the suprarenal stent. See the instructions below.

- Use a compliant or semi-compliant balloon (recommend Reliant Balloon).
- Insert the balloon and move it to the bifurcated (or other anchor pin containing) stent graft component aortic (or equivalent) section.
- Inflate the balloon inside the stent graft component aortic section to the vessel size to stabilize the stent graft.
- Follow the standard instruction for use for tip capture deployment and delivery system removal.

9.8.3 BACK END HANDLE DISASSEMBLY

In the unlikely event of delivery system failure and concomitant no or partial deployment of the proximal end of crowns and anchoring pins of the suprarenal stent due to back-end wheel failure, a “back end handle disassembly” technique will permit the successful deployment of the proximal end of crowns and anchoring pins of the suprarenal stent. See the instructions below.

- Separate the wheel halves.
- Insert the tips of hemostats into each of the rear handle disassembly ports.
• Disengage the rear handle by pressing the tips of the hemostats into the handle disassembly ports and simultaneously retracting the rear handle from the delivery system.
• Stabilize the delivery system.
• Manually push up the back-end T-tube to deploy the tip captured crowns and anchoring pins of the suprarenal stent.
• Manually pull back the back-end T-tube to recapture the taper tip after the deployment.
• Follow the standard instruction for use for delivery system removal.
• Hold the back-end wheel component so that it remains retracted and the taper tip recaptured during delivery system removal.

9.8.4 SNARE THE TAPER TIP

In the unlikely event of delivery system failure and concomitant no or partial deployment of the proximal end of crowns and anchoring pins of the suprarenal stent due to back-end wheel failure, and a “back end handle disassembly” technique in Section 9.8.3 cannot give successful deployment of the proximal end of crowns and anchoring pins of the suprarenal stent due to the excessively high deployment force, a “snare the taper tip” technique may permit the successful deployment of the proximal end of crowns and anchoring pins of the suprarenal stent. See the instructions below.

• Use a snare device.
• Advance the snare device to the delivery system taper tip section through upper torso access, i.e. brachial.
• Utilize fluoroscopy to snare the edge of the delivery system taper tip.
• Stabilize the delivery system, especially the back end section.
• Pull the snare device to separate the suprarenal stent from the tip capture.
• Manually pull back the back-end T-tube to recapture the taper tip after the deployment.
• Follow the standard instruction for use for delivery system removal.
• Ensure that the back-end T-tube remains retracted and the taper tip recaptured during delivery system removal.
9.9 FOLLOW-UP IMAGING RECOMMENDATIONS

9.9.1 GENERAL

Current imaging of stent graft patients includes abdominal X-ray and spiral CT, with and without contrast medium. Alternative imaging modalities such as color Doppler ultrasound and magnetic resonance imaging should be used in patients with impaired renal function or intolerance to contrast media.

Imaging should be decided based upon the physician’s clinical assessment of the patient pre- and post-implantation of the stent graft.

9.9.2 X-RAY

Abdominal X-rays should be used to assess the presence of stent graft fracture. Posterior/anterior (PA) and lateral images are recommended for visualization of the stent graft. Ensure that all components of the device are captured on images for device assessment.

9.9.3 SPIRAL CT WITH CONTRAST

- Spiral CT with contrast medium should be used to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, stent graft patency, AAA size, occlusion of branch vessels, and endoleak (including source and type if present). The preferred imaging study uses 3-5 mm collimation, 2-3 mm reformat intervals, with coverage from the celiac artery to the external iliac or femoral arteries during “arterial phase” contrast. For calcifications or areas where metal artifacts may be misinterpreted as endoleak, a non-contrast CT scan should be performed first, using thicker collimation (10 mm) to avoid tube overheating. In aneurysms that are not shrinking but have no apparent endoleak or fixation problems, a delayed or “venous phase” scan may be performed immediately following the “arterial phase” scan. The delayed “venous phase” scan may also be performed with thicker collimation (10 mm) if tube overheating is a concern. This is referred to as the “three-phase” technique. It is recommended that the full electronic data set be archived in case specialized evaluation is needed later (volume measurements, three-dimensional reconstruction and/or computer aided measurement software). If the aneurysm is not shrinking by more than 5 mm within the first year, volume measurements may be obtained as a more sensitive indicator of AAA size using commercial software.

9.9.4 SPIRAL CT WITHOUT CONTRAST

For patients with impaired renal function, a spiral CT without contrast may be considered to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, occlusion of vessels, and size of the AAA with diameter and volume measurements. For aneurysms that are not clearly shrinking, an adjunctive color Doppler ultrasound may be considered to evaluate a possible endoleak (including source and type, if present).
9.9.5 MRI OR MRA

Patients with impaired renal function, i.e. renal insufficiency, may also be considered for magnetic resonance imaging or angiography (MRI, MRA) in facilities that have expertise in this area. Artifact may occur related to the stent, and care should be used to insure adequate imaging of the outer aneurysm wall to assess AAA size. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed. If there are difficulties imaging a possible endoleak, color Doppler ultrasound may be considered.

9.9.6 DUPLEX COLOR DOPPLER ULTRASOUND

Duplex Color Doppler Ultrasound (CDUS) may be used to assess AAA size, exclusion of the aneurysm and endoleak type. This may be an alternative imaging modality for patients with impaired renal function in a facility with adequate technologist skill and training. An ICAVL approved vascular laboratory is strongly preferred. This test should be performed in conjunction with the multiview abdominal X-ray since the X-rays better assess stent graft integrity. Other adjunctive tests may include spiral CT (without contrast in case of impaired renal function) to aid assessment of stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, and size of the AAA with diameter and volume measurements.

<table>
<thead>
<tr>
<th>Imaging Test</th>
<th>Year 1</th>
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</thead>
<tbody>
<tr>
<td>Spiral CT with contrast</td>
<td>30 Day Follow Up</td>
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<tr>
<td>X</td>
<td>X</td>
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<tr>
<td>Abdominal X-rays</td>
<td>X</td>
</tr>
<tr>
<td>Duplex Color Doppler Ultrasound or MRA</td>
<td>X</td>
</tr>
</tbody>
</table>

*Spiral CT evaluation may include “three phase technique,” volume studies, 3-D reconstruction or computer-aided measurements.

**Duplex or MRA may be used in patients with renal failure or contrast intolerance.
9.9.7 SUPPLEMENTAL IMAGING RECOMMENDATIONS

NOTE: Additional radiological imaging may be necessary to further evaluate the stent graft in situ based on findings revealed by one of the surveillance programs. The following recommendations may be considered:

- If there is evidence of poor position of the stent graft, severe angulation, kinking or migration of the stent graft on abdominal X-rays, a spiral CT, and/or CDUS should be performed to assess aneurysm size and the presence or absence of an endoleak.
- If a new endoleak or increase in AAA size is observed by spiral CT, adjunctive studies such as CDUS, 3-D reconstruction or angiographic assessment of the stent graft and native vasculature may be helpful in further evaluating any changes of the stent graft or aneurysm.
- If a new endoleak or increase in AAA size is observed by CDUS, a spiral CT with contrast might be helpful in further evaluating the stent graft and the aneurysm.
- Spiral CT without contrast, MRI or MRA may be considered in select patients that cannot tolerate contrast media or have renal function impairment. For centers with appropriate expertise, gadolinium or CO₂ angiography can be considered in patients with renal function impairment requiring angiographic assessment.

9.9.8 TREATMENT CONSIDERATIONS

Additional endovascular repair or open surgical aneurysm repair should be considered for patients with evidence of suboptimal stent graft fixation, proximal endoleak, distal endoleak, junction endoleak, unknown origin of persistent perigraft flow, or increase in AAA size > 5mm.

9.9.9 PATIENT INFORMATION

Patient follow-up should be individualized to meet patient specific needs. However, imaging should be scheduled based on the physician’s clinical assessment of the patient pre- and post-discharge.
EXPLANATION OF SYMBOLS

Explanation of symbols that may appear on product labeling

Contents: One (1) Endurant Stent Graft System, one (1) Instructions for Use

Do not use if package is damaged

Non-pyrogenic

Pull tab to open

Store at room temperature in a dark, dry place

MR Conditional
11 DISCLAIMER OF WARRANTY

ALTHOUGH THE MEDTRONIC VASCULAR ENDURANT STENT GRAFT AND DELIVERY SYSTEM, HEREAFTER REFERRED TO AS THE ‘PRODUCT’, HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC, INC., MEDTRONIC VASCULAR, INC. AND THEIR RESPECTIVE AFFILIATES, (COLLECTIVELY “MEDTRONIC”) HAVE NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, 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. MEDTRONIC 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 MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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