



**PHYSICIAN**  
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## ACCESS SITES

- In most cases, bilateral groin access to the common femoral arteries is required.

## DIAGNOSTIC DEVICES USED

### SHEATH SIZES

Sheath sizes are used as necessary for individual endograft introduction. Some devices employ an integral sheath and others utilize a separate introducer sheath. Profiles for sheaths range from 12 F to 24 F for the gamut of AAA stent grafts.

### FLUSH DIAGNOSTIC CATHETERS

Preferred catheters are 5-F angiographic pigtail, with 1-cm graduated markers of 20 cm total length. The total catheter length is predicated on the segment of the aorta to be treated. In the abdomen, 60 cm to 80 cm is usual.

### SELECTIVE DIAGNOSTIC CATHETERS

Depending on iliac and aortic tortuosity and the proximity or involvement of various branch vessels in association with the aortic pathology (aneurysm, dissection, etc.), a wide spectrum of preformed catheter shapes may be helpful in conjunction with stent graft procedures. Typical selective catheter shapes that may be necessary to safely negotiate difficult iliac anatomy or large aneurysms include vertebral/angled tip, Cobra, multipurpose, and internal mammary. In AAA endografts, a special procedural challenge involves the catheterization of

the contralateral leg hole or opposite aperture for iliac limb extension in multicomponent bifurcated devices. The catheters listed above may be beneficial in the process of attempting to retrogradely catheterize the contralateral leg hole of the aortic component via the aneurysm sac. In addition, back-seeking catheter shapes are often valuable for difficult retrograde approaches and are the primary choice selected for up-and-over antegrade catheterizations from the ipsilateral limb through the contralateral opening for the iliac limb. These catheters may be 4 F or 5 F.

### DIAGNOSTIC GUIDEWIRES

As previously discussed, the selection of basic working guidewires is often based on personal experience and operator preference. Many types of wires with or without torque control features can be used to facilitate initial positioning of the pigtail catheter proximal to the aortic pathology. Commonly employed guidewires are either .035 inch or .038 inch in diameter. Bentson, Teflon LLT, and Starter are basic nontorque wires. The angled Glidewire is one example of a routinely used steerable guidewire that may be helpful in negotiating challenging tortuous vascular anatomy.

## INTERVENTIONAL DEVICES USED

### INTERVENTIONAL GUIDEWIRES

In AAA interventions, endografts are typically advanced over stiff or ultrastiff, .035-inch or .038-inch highly supportive guidewires to straighten tortuous anatomy and facilitate device tracking to the target. Examples of these wires that are commonly included in stent graft procedures include Lunderquist, straight or precurved, Amplatz, Meier BU.

### BALLOONS

Postdeployment ballooning of stent graft prostheses at the attachment sites of AAA devices is a common practice and often prescribed by endograft manufacturers. Occlusion type, compliant balloons capable of expansion through a range of diameters and large-diameter PTA balloons for AAA devices exclusively are both applicable for securing device expansion.

# ABDOMINAL AORTIC INTERVENTIONS

## ENDOGRAFTS

AAA may be single-component bifurcated or multicomponent bifurcated. Development of fenestrated and branched AAA products is expected.

## OTHER DEVICES

Of note, multicomponent, bifurcated AAA devices may require catheterization of the contralateral leg hole via an antegrade approach up-and-over from an ipsilateral iliac/aortic component route. In these cases, it will necessary to use a vascular snare device to grab the wire within the aneurysm sac or contralateral iliac artery after it has been threaded across the graft bifurcation and through the aperture for placing the contralateral iliac limb. Once the snare has captured the guidewire, it is withdrawn from the contralateral arterial access to allow insertion of the contralateral iliac component.

In addition, one other potentially valuable adjunct to

AAA procedures is intravascular ultrasound. This technology can provide important planning or confirmatory anatomical information, including precise neck diameter measurements, extent of branch vessel involvement in cases of aortic dissection, and lengths between aortic branches and aortic disease. Some centers use intravascular ultrasound routinely for endograft procedures, whereas the majority of investigators have it available to use in selective cases when the aortic pathology is not routine.

## IMAGING

Multi-slice CT or MR imaging with three-dimensional, multi-planar display. Supplemental intravascular ultrasound or catheter angiography in selected cases.

## CONTRAST RECOMMENDATIONS

Non-ionic, iso-osmolar contrast media ■

### Indications

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

- Adequate iliac/femoral access
- Infrarenal nonaneurysmal neck length of greater than 1 cm at the proximal and distal ends of the aneurysm and an inner vessel diameter approximately 10–20% smaller than the labeled device diameter
- Morphology suitable for endovascular repair
- One of the following:
  - (1) Aneurysm diameter of >5 cm
  - (2) Aneurysm diameter of 4–5 cm which has also increased in size by 0.5 cm in the last 6 months
  - (3) Aneurysm which is twice the diameter of the normal infrarenal aorta.

### Contraindications

There are no known contraindications currently associated with this device.

### Warnings and Precautions

The AneuRx Stent Graft is intended to prevent rupture of abdominal aortic aneurysms. However, this risk is not completely eliminated. Based on reports received for patients enrolled in all phases of the clinical study, through August 1, 2001, ruptures have occurred in 2/1193 patients (0.167%) during the operative period; in 3/1193 patients (0.251%) within 30 days of the treatment; and in 10/1193 patients (0.838%) greater than 30 days after treatment. The one-year freedom-from-rupture rate for patients enrolled in all phases of the clinical study is 99.5%; the two-year freedom-from-rupture rate is 98.6%; and the three-year freedom-from-rupture rate is 98.5%; and the four-year freedom-from-rupture rate is 98.5%.

The long-term safety and effectiveness of this implant have 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 and delivery technique to aid in the prevention of vessel rupture. If an AneuRx Stent Graft is placed with less than one centimeter length of non-aneurysmal tissue at the proximal or distal end attachment sites, there is potential for leaking or migration due to inadequate apposition of the stent graft.

Inappropriate patient selection may contribute to poor device performance. Preliminary data indicate that patients with an aortic neck angle >45 degrees may have a higher likelihood of suboptimal outcomes compared to patients with an aortic neck angle <45 degrees. The same data indicate that patients with an aortic seal length of <15 mm and an iliac seal length of <25 mm may also have a higher likelihood of suboptimal outcomes.

This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device.

Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies.

The results of the clinical studies indicated that patients who experience an unsuccessful endovascular repair attempt, and as a result undergo conversion to surgical abdominal aortic aneurysm (AAA) repair, are likely to have

increased complications arising from both procedures (i.e., cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues and mortality).

The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms have 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 thoracoabdominal aneurysms
- Who are morbidly obese
- Pregnant or nursing
- Less than 18 years old
- With less than one-year life expectancy.

Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

### Patient Selection, Treatment and Follow-up

Do not use this device in patients having an active systemic infection. Do not use this device in patients with sensitivities or allergies to the device materials. The materials include: polyethylene-terephthalate (PET), nickel, titanium, tantalum, stainless steel, polyether-esterblock-copolymer (Hytrell), polyetherblockamide (Pebax), polyetheretherketone (PEEK), platinum, ethyl cyanoacrylate, polymethyl-methacrylate and hydroquinone.

The results of the clinical study indi-

cate that women treated with this device may have a higher mortality rate as compared to their male counterparts.

The use of this device requires administration of radiographic agents. Patients with preexisting 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 exceeds 350 lbs (150 kg) or whose weight may impede accurate fluoroscopic imaging.

Regular follow-up including imaging of the device should be performed every 3 to 6 months for patients in the enhanced surveillance group and at least every 6 to 12 months for patients in the routine surveillance group (see IFU for patient follow-up recommendations).

During the recommended follow-up imaging schedule, patients should be monitored for aneurysm size, occlusion of vessels, change in pulsatility, migration, leaks and device integrity.

Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:

- Aneurysm growth >5 mm (with or without aneurysm pulsatility (with or without growth or leak))
- Persistent endoleak with or without aneurysm growth
- Stent graft migration resulting in an inadequate seal zone.

The results of the clinical study indicate that subjects experiencing reduced blood flow through the graft limbs and/or leaks may be required to undergo secondary interventions or minor surgical procedures.

MRI may be used on the stent graft only if the patient has no other MRI contraindications. ©2005 Medtronic, a Division of Johnson & Johnson. All rights reserved. 4002066903611 stat 12/05

