# INSTRUCTIONS FOR USE FOR:


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English

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**INSTRUCTIONS FOR USE**

# EXCLUDER BIFURCATED ENDOPROSTHESIS

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

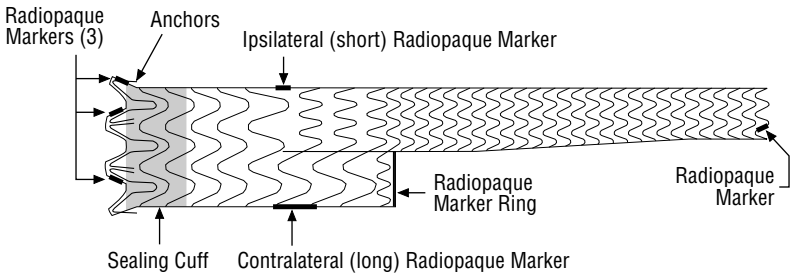
## DESCRIPTION

The EXCLUDER Bifurcated Endoprosthesis (EXCLUDER Endoprosthesis) is a device that provides endovascular treatment of infrarenal abdominal aortic aneurysms (AAA).

The EXCLUDER Endoprosthesis is comprised of two components, the Trunk-Ipsilateral Leg Endoprosthesis (Trunk) (Figure 1) and the Contralateral Leg Endoprosthesis (Figure 2). The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), and is supported by nitinol wire along its external surface. Nitinol anchors and an ePTFE/FEP sealing cuff are located near the aortic end of the trunk. An ePTFE/FEP sleeve is used to constrain the endoprostheses on the leading end of the delivery catheters (Figures 3A, 3B, and 3C).

Deployment of both endoprosthesis components initiates from the leading (aortic) end and proceeds toward the trailing (iliac) end of the delivery catheter. The ePTFE/FEP sleeve remains *in situ* between the endoprosthesis and the vessel wall.

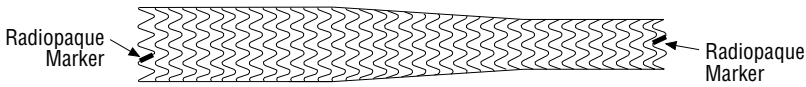
**Figure 1: Trunk-Ipsilateral Leg Endoprosthesis**




**Trunk-Ipsilateral Leg Endoprosthesis Radiopaque Markers**

- Three (3) short markers at the aortic end.
- One (1) long and one (1) short marker at the endoprosthesis bifurcation level. The long marker denotes the contralateral leg side location and orientation.
- One (1) marker ring at the opening of the contralateral leg hole.
- One (1) short marker at the iliac end of the ipsilateral leg.

**Figure 2: Contralateral Leg Endoprosthesis**




**Contralateral Leg Endoprosthesis Radiopaque Markers**

- One (1) marker at each end

**Figure 3A: EXCLUDER Endoprosthesis Delivery Catheter**

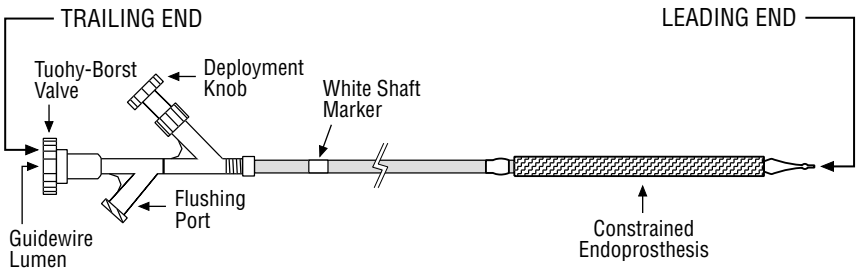


**Figure 3B: Constrained EXCLUDER Endoprosthesis (Trunk-Ipsilateral) on Delivery Catheter with Radiopaque Markers**

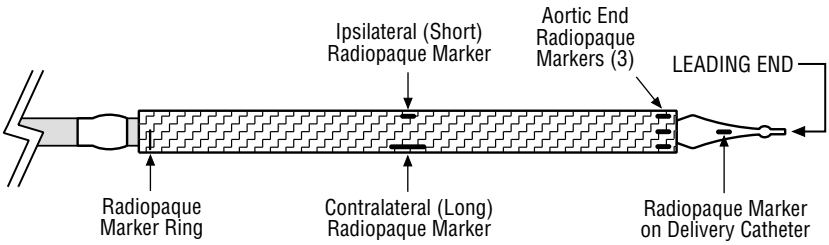
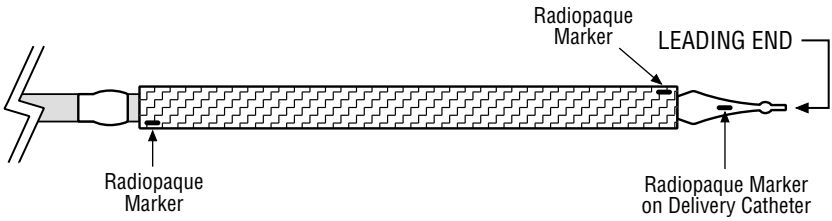



**Figure 3C: Constrained EXCLUDER Endoprosthesis (Contralateral) on Delivery Catheter with Radiopaque Markers**




## INTENDED USE

The EXCLUDER Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal AAA disease and who have appropriate anatomy.

## CONTRAINDICATIONS

Known contraindications include, but are not limited to:

- Significant thrombus at the arterial implantation sites, specifically proximal aortic neck and distal iliac artery interface
- Severe proximal aortic neck angulation > 60°
- Infrarenal aortic neck < 15 mm in length
- Ilio-femoral access vessel morphology which is not compatible with vascular access techniques, devices and accessories.

## WARNINGS

- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- Do not advance the device outside of the sheath.
- Do not rotate the Trunk or the Contralateral Leg delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage or premature deployment may occur.
- Do not rotate the Trunk delivery catheter beyond 360° to avoid delivery system damage and/or premature deployment.
- Do not rotate the Contralateral Leg delivery catheter during delivery. Catheter breakage or premature deployment may occur.
- Do not attempt to withdraw the undeployed endoprosthesis through the 18 Fr or 12 Fr introducer sheath valve. The sheath and catheter must be removed together.
- Do not attempt to reposition the endoprosthesis after deployment has been initiated. Vessel damage or device misplacement may result.
- Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage may occur.
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Do not cover significant renal or mesenteric arteries (exceptions are inferior mesenteric and ilio-femoral) with the endoprosthesis. Vessel occlusion may occur.
- Do not use delivery catheter for high pressure fluid injections.

## PRECAUTIONS

- Do not resterilize; for single use only.
- Do not use if damaged or if sterile barrier has been compromised.
- Do not use after the “use by” (expiration) date printed on the label.

## ADVERSE EVENTS

Adverse events that may require intervention include, but are not limited to: infection; bleeding at the site of catheter and sheath placement; lymph fistula; local neurologic damage; ilio-femoral vascular access anatomy complications including vascular trauma, occlusion, arteriovenous fistula, thrombosis and/or pseudoaneurysm; trauma to the aortic or ilio-femoral vessel wall, including dissection, perforation, rupture or erosion; fever and localized inflammation; microembolization and macroembolization; bowel ischemia; aortoenteric fistula; acute hepatic failure; renal failure or other renal complications; respiratory complications; congestive heart failure; arrhythmia; myocardial infarction; paraplegia; stroke; incomplete device component deployment; improper endoprosthesis component placement; endoprosthesis component migration; stent fracture; graft material failure or dilatation, erosion, puncture, separation of graft material from stent; endoprosthesis occlusion; endoprosthesis infection; endoleak; continued aneurysm enlargement; aneurysm rupture and death.

## SUMMARY OF CLINICAL STUDIES

### OBJECTIVES

The primary objective of the clinical study was to demonstrate that the EXCLUDER Bifurcated Endoprosthesis is a safe and effective alternative to open surgical repair in the primary treatment of infrarenal abdominal aortic aneurysms. Safety was determined by demonstrating that the EXCLUDER Bifurcated Endoprosthesis subjects would have a total proportion of major adverse events that is less than the subjects treated with open surgical repair as evaluated through one year follow-up. Effectiveness was based on exclusion of the aneurysm including the absence of an endoleak, the absence of aneurysm enlargement (≥ 5 mm), and the absence of major device efficacy adverse events evaluated through one year follow-up. Secondary objectives included an assessment of clinical benefit and quality-of-life measures.

### STUDY DESIGN

This prospective, non-randomized, multi-center clinical study was designed to compare patients treated with endovascular repair to an open surgical repair control group. The control group included patients whose vascular anatomy (proximal aortic neck length, proximal neck angulation, and arterial implantation site condition) may not have been suitable for endovascular AAA repair. The planned ratio of EXCLUDER Bifurcated Endoprostheses to control subjects was approximately 2:1. Follow-up evaluations were scheduled for pre-discharge, 1-month, 3-months (if endoleak at 1-month), 6-months and 12-months. An independent Core Lab facility reviewed CT scans and abdominal x-rays to assess aneurysm diameter changes, device and relative component migration, device integrity (wire and graft) and the presence and type of endoleaks.

### DESCRIPTION OF SUBJECTS

Nineteen U.S. sites enrolled 235 EXCLUDER Bifurcated Endoprostheses and 99 control subjects. Given the epidemiology of AAA and surgical repair, males predominated over females (83% compared to 17%). The selection criteria for the study were based on enrolling subjects with the appropriate anatomy for endovascular repair. A total of 31 females were treated with EXCLUDER Bifurcated Endoprostheses and 26 with open surgical repair. For subjects treated with EXCLUDER Bifurcated Endoprostheses, there were no differences between males and females for results through one year for survival, freedom from major adverse events and cumulative adverse events. For open surgical repair subjects, females compared to males as follows: results at one year showed that females had a lower rate of cumulative adverse events (0.4 vs 0.8 with p=0.003), comparable freedom from major adverse events, and a slightly lower survival rate (87% vs 97% with p=0.07).

## RESULTS

Tables 1 and 2 compare the subject characteristics and initial anuerysm diameter of the EXCLUDER Bifurcated Endoprosthesis and open surgical population, respectively.

### Table 1: Comparison of Subject Characteristics

| Characteristic | EXCLUDER Bifurcated Endoprosthesis (N = 235) N | (%) | Control (N = 99) N | (%) | p-Value |
|---|---|---|---|---|---|
| Average Age (range in years) | 73.0 | (48 - 91) | 70.1 | (51 - 87) | 0.002 |
| Gender: | | | | | |
| Male | 204 | 87% | 73 | 74% | |
| Female | 31 | 13% | 26 | 26% | 0.004 |
| Coronary Artery Disease | 145 | 62% | 53 | 54% | 0.165 |
| Arrhythmia | 56 | 24% | 21 | 21% | 0.591 |
| Valvular Heart Disease | 18 | 8% | 7 | 7% | 0.852 |
| Congestive Heart Failure | 22 | 9% | 8 | 8% | 0.708 |
| Stroke | 26 | 11% | 10 | 10% | 0.818 |
| Aneurysm Symptomatic | 11 | 5% | 15 | 15% | < 0.001 |
| Inflammatory AAA | 2 | 1% | 1 | 1% | 1.00 |
| Family History of AAA | 14 | 6% | 9 | 9% | 0.307 |
| Other Concomitant Aneurysms | 18 | 8% | 13 | 13% | 0.116 |
| Peripheral Arterial Occlusive Disease | 38 | 16% | 14 | 14% | 0.640 |
| Prior Vascular Intervention | 26 | 11% | 10 | 10% | 0.796 |
| Long Term Use of Steroids | 8 | 3% | 1 | 1% | 0.290 |
| Thrombotic Event | 17 | 7% | 4 | 4% | 0.332 |
| COPD | 62 | 26% | 25 | 25% | 0.830 |
| Smoking History | 208 | 89% | 84 | 85% | 0.357 |
| Renal Dialysis | 0 | 0% | 0 | 0% | n/a |
| Paraplegia | 0 | 0% | 0 | 0% | n/a |
| Erectile Dysfunction (males only) | 33 | 16% | 10 | 14% | 0.616 |
| Hepatic Dysfunction | 6 | 3% | 1 | 1% | 0.679 |
| Bleeding Disorder | 11 | 5% | 1 | 1% | 0.119 |
| Cancer | 59 | 25% | 19 | 19% | 0.243 |

### Table 2: Aneurysm Diameter Distribution

| Diameter Range | EXCLUDER Bifurcated Endoprosthesis (N = 235) N | (%) | Control (N = 98) N | (%) |
|---|---|---|---|---|
| < 30 mm | 0 | 0% | 0 | 0% |
| 30 - 39 mm | 0 | 0% | 0 | 0% |
| 40 - 49 mm | 61 | 26% | 15 | 15.3% |
| 50 - 59 mm | 109 | 46.4% | 46 | 46.9% |
| 60 - 69 mm | 44 | 18.7% | 21 | 21.4% |
| 70 - 79 mm | 15 | 6.4% | 10 | 10.2% |
| 80 - 89 mm | 4 | 1.7% | 5 | 5.1% |
| ≥ 90 mm | 2 | 0.9% | 1 | 1.0% |

Data gathered in Tables 3-13 were collected by either the Core Lab or the clinical study sites.Table 3 compares the safety and efficacy measures between the EXCLUDER Bifurcated Endoprosthesis and control subjects as reported by the clinical sites through the primary study end point of 12 months.

The study design is based on one-year safety and effectiveness outcomes. Subject follow-up is continuing and two-year data are also presented.

### Table 3: Principal Safety and Efficacy Results

| Outcome Measures | EXCLUDER Bifurcated Endoprosthesis (N = 235) N | (%) | Control (N=99) N | (%) | p-Value |
|---|---|---|---|---|---|
| Early (≤ 30 day) Mortality | 3 | 1% | 0 | 0% | p = 0.56 |
| Early (≤ 30 day) Adverse Events | 32 | 14% | 56 | 57% | p < 0.0001 |
| Early Conversion | 0 | 0% | 0 | 0% | n/a |
| Late Conversion | 0 | 0% | 0 | 0% | n/a |
| Rupture | 0 | 0% | 0 | 0% | n/a |

Three conversions have occurred > 24 months postoperative due to aneurysm enlargement and proximal neck aneurysm enlargement.

Tables 4-11 describe results of the EXCLUDER Bifurcated Endoprosthesis subjects as reported by the Core Lab. Device performance factors analyzed by the Core Lab included device integrity (Table 4), device patency (Table 5), migration (Tables 6 and 7), and anuerysm exclusion (Tables 8-11). For device performance factors, more than one incident can occur to one subject and incidents are not necessarily viewed at every time point for one subject. Device integrity encompasses the structural findings of the wire-form via abdominal x-ray images at the corresponding follow-up timepoints.

### Table 4: Device Integrity Assessment by Abdominal X-ray Imaging Data

| Device Integrity: KUB | Discharge (N = 171) N | (%) | 6 Months (N = 156) N | (%) | 12 Months (N = 140) N | (%) | 24 Months (N = 117) N | (%) |
|---|---|---|---|---|---|---|---|---|
| Subjects Free from Device Integrity Issues | 145 | 85% | 129 | 83% | 120 | 86% | 110 | 94% |
| Subjects with ≥ 1 Device Integrity Issue | 26 | 15% | 27 | 17% | 20 | 14% | 7 | 6% |
| - Fracture | 1 | 0.6% | 0 | 0% | 0 | 0% | 0 | 0% |
| - Kink | 22 | 13% | 18 | 12% | 16 | 11% | 4 | 3% |
| - Compression | 4 | 2% | 9 | 6% | 4 | 3% | 3 | 3% |

### Table 5: Occlusion or Narrowing of the Flow Channel by CT Imaging Data

| Occlusion / Narrowing | 1 Month (N = 212) N | (%) | 6 Months (N = 193) N | (%) | 12 Months (N = 185) N | (%) | 24 Months (N = 148) N | (%) |
|---|---|---|---|---|---|---|---|---|
| EXCLUDER Bifurcated Endoprosthesis | 3 | 1.5% | 0 | 0% | 2 | 1.1% | 2 | 1.4% |

### Table 6: CT Findings – Trunk Migration

| CT - Trunk Migration | 6 Months (N = 171) N | (%) | 12 Months (N = 175) N | (%) | 24 Months (N = 144) N | (%) |
|---|---|---|---|---|---|---|
| Trunk Migration | 5 | 3.0% | 4 | 2.3% | 2 | 1.4% |

### Table 7: Abdominal X-ray Findings – Component Migration

| Abdominal X-ray - Component Migration | 6 Months (N = 139) N | (%) | 12 Months (N = 139) N | (%) | 24 Months (N = 122) N | (%) |
|---|---|---|---|---|---|---|
| Component Migration | 2 | 1.4% | 1 | 1.0% | 1 | 1.0% |

### Table 8: Endoleak Status According to Evaluation Interval

| Type of Endoleak[1,2] | Evaluation Interval | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 Month (N = 180) | | 6 Months (N = 177) | | 12 Months (N = 156) | | 24 Months (N = 119) | |
| | N | (%) | N | (%) | N | (%) | N | (%) |
| Type I | 7 | 4% | 3 | 2% | 2 | 1% | 3 | 3% |
| Type II | 21 | 12% | 19 | 11% | 19 | 12% | 16 | 13% |
| Type III | 0 | 0% | 0 | 0% | 0 | 0% | 0 | 0% |
| Type IV | 0 | 0% | 0 | 0% | 0 | 0% | 0 | 0% |
| Indeterminate | 11 | 6% | 14 | 7% | 6 | 4% | 5 | 4% |
| Total | 39 | 22% | 36 | 20% | 27 | 17% | 24 | 20% |

### Table 9: Change in Aneurysm Size by Interval

| Change in Aneurysm Size | 1 Month to 6 Months (N = 182) | | 1 Month to 12 Months (N = 181) | | 1 Month to 24 Months (N = 146) | |
|---|---|---|---|---|---|---|
| | N | (%) | N | (%) | N | (%) |
| Decrease | 18 | 10% | 26 | 14% | 28 | 19% |
| No Change | 159 | 87% | 142 | 78% | 97 | 67% |
| Increase | 5 | 3% | 13 | 7% | 21 | 14% |

### Table 10: Maximum Aneurysm Diameter and Endoleaks at 12 Months

| Aneurysm Change from 1 to 12 Months* | N | Endoleak at 12 Months* | | p-Value |
|---|---|---|---|---|
| | | N | (%) | |
| Increase (≥ 5 mm) | 10 | 4 | 40% | |
| No Change | 118 | 19 | 16% | |
| Decrease (≤ 5 mm) | 18 | 2 | 11% | |
| Total | 146 | 25 | 17% | 0.12 |

* Only includes subjects with interpretable films (endoleak) and measurements of aneurysm change from 1 to 12 months.

### Table 11: Maximum Aneurysm Diameter and Endoleaks at 24 Months

| Aneurysm Change from 1 to 24 Months* | N | Endoleak at 24 Months* | | p-Value |
|---|---|---|---|---|
| | | N | (%) | |
| Increase (≥ 5 mm) | 15 | 7 | 47% | |
| No Change | 74 | 10 | 14% | |
| Decrease (≤ 5 mm) | 23 | 2 | 9% | |
| Total | 112 | 19 | 17% | 0.004 |

* Only includes subjects with interpretable films (endoleak) and measurements of aneurysm change from 1 month to 24 months.

Secondary interventions within the first and second year each were performed in 6% of the EXCLUDER Bifurcated Endoprostheses subjects as shown in Table 12. All interventions were catheter-based. Subjects may have a single intervention for an endoleak and an aneurysm enlargement.

### Table 12: Interventions for Endoleak and Aneurysm Size Increases

| Intervention | Post-procedure to 12 Months (N = 235) | | > 12 Months to 24 Months (N = 203) | |
|---|---|---|---|---|
| | N | (%) | N | (%) |
| Number of Subjects with ≥ 1 Intervention | 15 | 6% | 12 | 6% |
| Treat an Endoleak: | | | | |
| Embolization | 16 | 7% | 8 | 4% |
| Ligation | 1 | 0% | 0 | 0% |
| Conversion to open repair | 0 | 0% | 2* | 1% |
| Treat an Aneurysm Increase: | | | | |
| Embolization | 0 | 0% | 5 | 3% |
| Ligation | 1 | 0% | 0 | 0% |
| Conversion to open repair | 0 | 0% | 3* | 1% |

* Total of three conversions

As described in Table 13, treatment of AAA with EXCLUDER Bifurcated Endoprosthesis compared to the control group demonstrated significant benefits in recovery and quality of life measures.

**Table 13: Secondary Outcomes by Treatment Group**

| Secondary Outcomes | EXCLUDER Bifurcated Endoprosthesis | Control | p-Value |
|---|---|---|---|
| Blood Loss (ml)<br>Mean (range) | 310<br>(50 - 2160) | 1590<br>(100 - 7000) | < 0.0001 |
| Procedure Transfusion (%) | 14% | 89% | < 0.0001 |
| Procedure Time (minutes)<br>Mean (range) | 144<br>(51 - 320) | 196<br>(67 - 420) | < 0.0001 |
| ICU Stay (%) | 24% | 87% | < 0.0001 |
| Hospital Length of Stay (days)<br>Mean (range) | 2<br>(1 - 11) | 9.8<br>(3 - 114) | < 0.0001 |
| Time to First Oral Intake (days)<br>Mean (range) | 0.5<br>(0 - 2.1) | 2.6<br>(0.07 - 9.5) | < 0.0001 |
| Time to Ambulation (days)<br>Mean (range) | 1.0<br>(0 - 5.0) | 2.6<br>(0 - 18) | < 0.0001 |

## CONCLUSIONS FROM CLINICAL STUDIES

As compared to conventional open surgery, the clinical benefits of the EXCLUDER Bifurcated Endoprosthesis are a lower rate of major complications, reduced blood loss and blood replacement volume, reduced need for an ICU stay, shorter hospitalization and faster return to normal activities. The risks include procedure- and/or device-related phenomenon, which include but are not limited to endoleaks and increase in aneurysm size.


1 White GH, May J, Waugh RC, et al. Type II and type IV endoleak: Toward a complete definition of blood flow in the sac after endoluminal AAA repair. J Endovasc Surg 5:305-309, 1998.

2 White GH, Yu W, May J, et al. Endoleak as a complication of endoluminal grafting of abdominal aortic aneurysms: Classification, incidence, diagnosis and management. J Endovasc Surg 4:152-168, 1997.

## INDIVIDUALIZATION OF TREATMENT

These endoprostheses have not been studied in the following patient populations: traumatic, ruptured, or mycotic aneurysms; pseudoaneurysms resulting from previous graft or stent-graft placement; pregnant females; genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndromes); concomitant thoracic aortic or thoracoabdominal aneurysms.

## HOW SUPPLIED

The EXCLUDER Endoprosthesis is preloaded on a delivery catheter and supplied sterile and non-pyrogenic.

## STORAGE AND HANDLING

Store in a cool dry place.

## RECOMMENDED MATERIALS

- 0.035" (0.89 mm) 'super-stiff' guidewire, 145 cm or longer
- 18 Fr x 30 cm and 12 Fr x 30 cm introducer sheaths (Tables 13 and 14)
- Large diameter, low pressure aortic balloon (Monitor balloon volumes and pressures as recommended in balloon catheter Instructions for Use)
- Percutaneous transluminal angioplasty (PTA) balloons (Table 14)
- Angiographic radiopaque marker catheter
- Contrast media
- Syringe
- Heparin and heparinized saline

### Table 14: Trunk-Ipsilateral Leg Endoprosthesis Sizing Guide*

| Intended Aortic Vessel Diameter (mm) | Aortic Endoprosthesis Diameter[1] (mm) | Intended Iliac Vessel Diameter (mm) | Iliac Endoprosthesis Diameter[2] (mm) | Overall Device Lengths (cm) | Recommended Introducer Sheath (Fr x cm) |
|---|---|---|---|---|---|
| 19 - 21 | 23 | 10 - 11 | 12 | 14, 16, 18 | 18 x 30 |
| | | 12 - 13.5 | 14.5 | | |
| 22 - 23 | 26 | 10 - 11 | 12 | 14, 16, 18 | 18 x 30 |
| | | 12 - 13.5 | 14.5 | | |
| 24 - 26.5 | 28.5 | 10 - 11 | 12 | 14, 16, 18 | 18 x 30 |
| | | 12 - 13.5 | 14.5 | | |

[1] Recommended endoprosthesis oversizing relative to the aortic vessel is approximately 10-21% and 7-25% for the iliac vessel.

[2] Recommended angioplasty balloon size is 12 mm and 14 mm respectively

* Note: All dimensions are nominal

### Table 15: Contralateral Leg Endoprosthesis Sizing Guide*

| Intended Iliac Vessel Diameter (mm) | Iliac Endoprosthesis Diameter[1] (mm) | Overall Device Lengths (cm) | Recommended Contralateral Introducer Sheath (Fr x cm) | Recommended Angioplasty Balloon Size (mm) |
|---|---|---|---|---|
| 10 - 11 | 12 | 10, 14, 16 | 12 x 30 | 12 x 40 |
| 12 -13.5 | 14.5 | 10, 14, 16 | 12 x 30 | 14 x 40 |

[1] Recommended endoprosthesis oversizing relative to the vessel is approximately 7-25%

* Note: All dimensions are nominal

## DIRECTIONS FOR USE

### Pre-Treatment Planning

- Determine accurate size of anatomy and proper size of Trunk-Ipsilateral and Contralateral Endoprosthesis (Tables 14 and 15).
- Use high resolution, non-contrast and contrast enhanced computerized tomography (CT) at ≤ 3 mm acquisition and reconstruction collimation.
- Use multiple view, digital subtraction angiography with a radiopaque marker catheter or spiral CT multi-planar reconstruction.
- For angiography, use correct imaging angulation (cranial-caudal, lateral-oblique) to accurately identify origin of branch vessel anatomy.
- Consider breath-hold technique to optimize digital subtraction angiography image quality.

### Anatomical Requirements

- For Trunk-Ipsilateral Leg Endoprosthesis: Proximal aortic neck angulation ≤ 60° with minimal thrombus and/or calcification.
- Proximal aortic neck length ≥ 15mm.
- Non-aneurysmal iliac artery length ≥ 10 mm
- For Contralateral Leg Endoprosthesis: Non-aneurysmal iliac artery length ≥ 10 mm
- Ilio-femoral access vessel morphology should be compatible with vascular access techniques, devices and accessories.

### Arterial Access and Angiography

1. Following standard practices, access the intended contralateral side via a percutaneous diagnostic sheath, and perform marker catheter digital subtraction angiography (AP, oblique and lateral views as necessary) to confirm the correct device component sizing, and deployment locations. Consider breath-hold technique to optimize image quality. Leave marker catheter in place at the level of the renal arteries.
2. Following standard practices, perform percutaneous access and/or surgical exposure of the vessels selected to receive the Trunk-Ipsilateral and Contralateral side introducer sheaths.
3. Following the manufacturer's instructions for use, advance an 0.035" (0.89 mm) 'super-stiff' guidewire, or acceptable equivalent to the level of the renal arteries.
4. Following the manufacturer's instructions for use, prepare and advance the 18 Fr diameter x 30 cm length, introducer sheath/dilator over the guidewire, through the ilio-femoral anatomy, aortic aneurysm and up to the level of the proximal aortic neck according to standard practice.
5. Administer heparin according to standard practice.
6. Use standard heparinized saline, pressure flush system technique to prevent thrombus formation in the introducer sheaths.
7. Use an accurate radiopaque patient marking method to assure accurate device positioning and deployment locations.

### Catheter Preparation

1. Use new, sterile gloves and minimize handling the endoprosthesis portion of the delivery catheters.
2. Remove the appropriately sized Trunk-Ipsilateral and Contralateral Leg delivery catheters from their packaging and examine for possible damage.
3. Remove protective packaging mandrel and packaging sheath(s) from the leading end of the delivery catheters (Figure 3A).
4. Flush with heparinized saline through the flushing port on the trailing end of the delivery catheter (Figure 3A).
5. Follow the manufacturer's recommended method for size selection, preparation and use of aortic and iliac dilation balloons. Carefully inflate the balloon to avoid complications.

### Trunk-Ipsilateral Leg Endoprosthesis Positioning and Deployment

1. Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
2. Advance the Trunk delivery catheter over a 0.035" (0.89 mm) 'super-stiff' guidewire, through the 18 Fr x 30 cm long introducer sheath into the aorta to the approximate level of intended positioning. **Warning: The catheter should not be rotated while the endoprosthesis is within the introducer sheath to avoid premature deployment.**
3. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (Figure 3A).
4. Magnify and center the fluoroscopic image on the proximal trunk. Reposition and rotate the Trunk-Ipsilateral delivery catheter as necessary to properly position the proximal device marker as well as orient the long contralateral, and short ipsilateral radiopaque markers and device position on the appropriate side of the anatomy. Maximize the separation between these two markers to achieve maximum lateral positioning of the iliac legs of the device. The long marker should be oriented toward the contralateral side (Figure 1).
5. It is recommended to view and confirm the distal position of the iliac end of the device relative to the internal iliac artery to ensure accurate and desired deployment position of the distal aspect of device.
6. If clinically acceptable, lower the patient's blood pressure to 60-70 mm Hg during Trunk deployment and aortic balloon inflation to decrease blood flow and reduce the risk of endoprosthesis movement.
7. Maintain a contralateral access side sheath, catheter or guidewire in position across the distal, native bifurcation to protect and ensure that contralateral access is maintained into the aneurysm sac and contralateral leg hole of the device during Trunk-Ipsilateral component deployment.

8. Re-center and magnify the image on the proximal Trunk of the device to assure final desired position of proximal device relative to anatomy. Stabilize the Trunk delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
9. Loosen the deployment knob. Confirm final device position and orientation and deploy the Trunk using a steady and continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side arm. Deployment initiates from the leading end toward the trailing end. **Warning: Once deployment is initiated, do not attempt to reposition the endoprosthesis.**
10. Use fluoroscopic guidance during the withdrawal of the delivery catheter to assure safe removal from, and to avoid catching on, the endoprosthesis.
11. Position the aortic balloon inside the proximal region of the trunk. Avoid balloon contact with the flow splitter which is aligned with the long and short radiopaque markers. Inflate and deflate the balloon quickly with dilute contrast solution to seat the aortic end of the endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of aortic and iliac dilation balloons, carefully monitoring both volume and pressure to avoid complications.
12. Use fluoroscopic guidance to ensure the balloon is completely deflated and is safely removed from the endoprosthesis.
13. Advance and inflate the appropriate size PTA balloon catheter to seat the iliac end of the endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of PTA balloons. Carefully inflate the balloon to avoid complication.

### Contralateral Endoprosthesis Positioning and Deployment

1. Use fluoroscopic visualization for all guidewire, sheath and device catheter manipulations.
2. Following manufacturer's instructions for use, advance a 0.035" (0.89 mm) 'superstiff' guidewire into the contralateral leg hole of the Trunk according to standard practice.
3. Verify that the guidewire is within the contralateral leg hole of the Trunk by rotating a formed pigtail catheter within the Trunk, or by standard practice used to verify guidewire location.
4. Following manufacturer's instructions for use, introduce the 12 Fr x 30 cm long contralateral introducer sheath and dilator. Advance the sheath over the guidewire and through the contralateral leg hole of the Trunk.
5. Advance the prepped Contralateral Endoprosthesis delivery catheter to the level of the long radiopaque marker (Figure 1). **Warning: Do not attempt to rotate the Contralateral Leg Endoprosthesis catheter at any point to avoid catheter breakage or premature deployment.**
6. Align the radiopaque marker at the proximal end of the Contralateral Leg Endoprosthesis with the long contralateral radiopaque marker on the Trunk-Ipsilateral Leg Endoprosthesis.
7. While maintaining the delivery catheter in position, withdraw the introducer sheath back to the white shaft marker on the delivery catheter (Figure 3A).
8. Stabilize the Contralateral Leg Endoprosthesis delivery catheter at the level of entry into the introducer sheath and stabilize the sheath relative to the patient's access site.
9. Loosen the deployment knob. Confirm final device position. Deploy the Contralateral Leg Endoprosthesis by using a steady, continuous pull of the deployment knob to release the endoprosthesis. Pull the deployment knob straight out from the catheter side-arm. Deployment initiates from the leading (aortic) end toward the trailing (iliac) end. **Warning: Once deployment is initiated, do not attempt to reposition the endoprosthesis.**
10. Use fluoroscopic guidance during withdrawal of the delivery catheter to assure safe removal from the endoprosthesis.
11. Following manufacturer's instructions for use, advance and inflate a 14 mm PTA balloon catheter to seat the proximal end of the Contralateral Leg Endoprosthesis within the contralateral leg hole overlap region. Follow the manufacturer's recommended method for size selection, preparation and use of aortic and iliac dilation balloons, carefully monitoring both volume and pressure to avoid complications.
12. Following manufacturer's instructions for use, advance and inflate the appropriate size PTA balloon to seat the iliac end of the Contralateral Leg Endoprosthesis. Follow the manufacturer's recommended method for size selection, preparation and use of PTA balloons. Carefully inflate the balloon to avoid complications.

### Completion of the Procedure

1. Perform extended imaging angiography to confirm exclusion of the aneurysm. Consider breath-hold technique to optimize digital subtraction angiography image quality. Consider use of EXCLUDER Endoprosthesis Extender components as necessary.
2. Close arterial access according to standard practice.
3. Follow-up patients as necessary to provide proper surveillance of the long-term performance of the endoprosthesis, procedure and status of the aneurysm. Annual CT's and various views of x-rays may be used for such surveillance.
4. The EXCLUDER Bifurcated Endoprosthesis has been determined to be MR safe. That is, the EXCLUDER Bifurcated Endoprosthesis when present in a patient or other individual undergoing an MRI procedure or in the MR environment at 1.5 Tesla or less will not present an additional hazard or risk, but may affect image quality depending on the pulse sequence that is used and the imaging area of interest evaluated.
   Safety information for magnetic resonance imaging (MRI) procedures (i.e., imaging, angiography, functional imaging, and spectroscopy) pertains to the use of shielded MRI systems with static magnetic fields of 1.5 Tesla or less, gradient magnetic fields of 20 Tesla/second or less, and a whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 30 minutes of imaging. The effects of performing MRI procedures using MR systems with static magnetic fields greater than 1.5 Tesla and other conditions have not been determined.

### DEFINITIONS

Use By

Attention, See Instructions for Use

Do Not Reuse

REF Catalogue Number

LOT Batch Code

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

10LS1887.00.FDA03

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