INSTRUCTIONS FOR USE FOR:

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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.

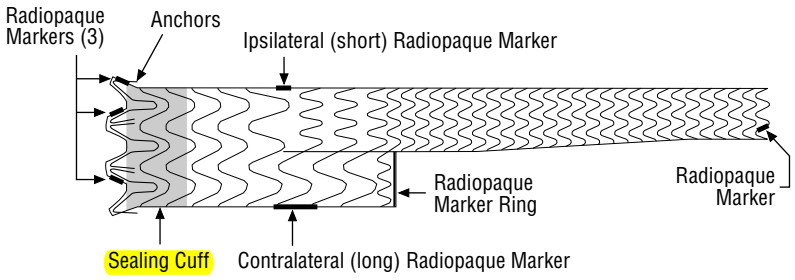
DESCRIPTION

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.

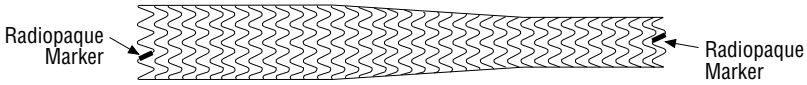
Figure 1: Trunk-Ipsilateral Leg Endoprosthesis



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

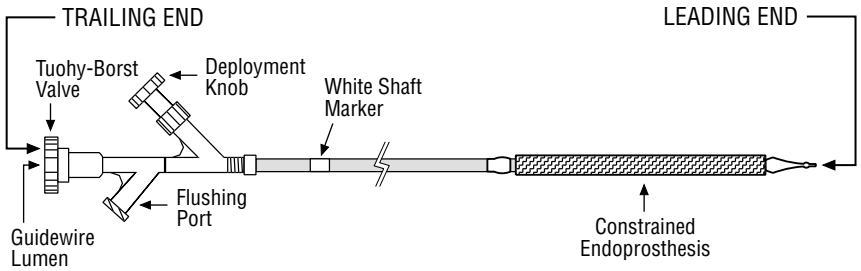


Figure 3B: Constrained EXCLUDER Endoprosthesis (Trunk-Ipsilateral) on Delivery Catheter with Radiopaque Markers

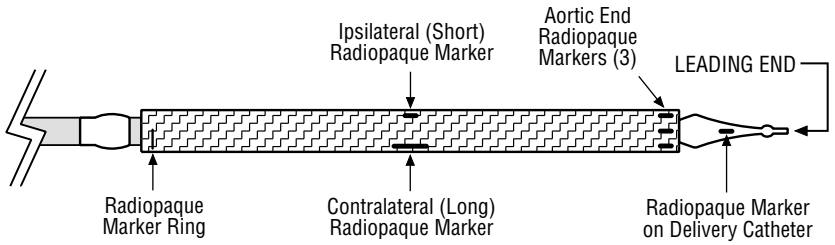
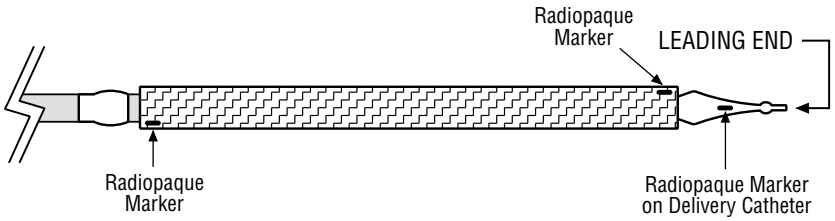


Figure 3C: Constrained EXCLUDER Endoprosthesis (Contralateral) on Delivery Catheter with Radiopaque Markers



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.

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