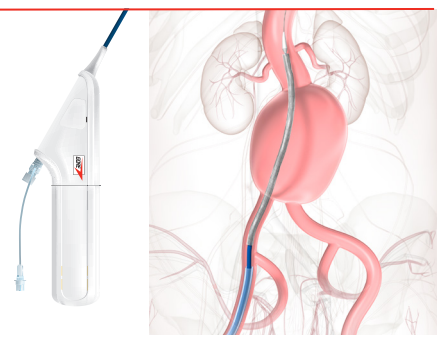
GORE® EXCLUDER®

AAA Endoprosthesis

DEPLOYMENT SEQUENCE

Constrained Trunk-Ipsilateral Leg endoprosthesis

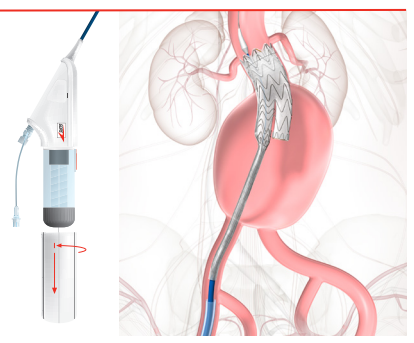
1 Advance constrained Trunk-Ipsilateral Leg to desired location.



Fully deploy trunk to contralateral gate

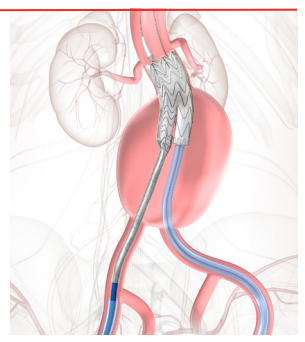
2 Rotate white outer deployment knob counterclockwise and pull in a continuous motion.

Result: Trunk body is at full diameter. Ipsilateral Leg is fully constrained.



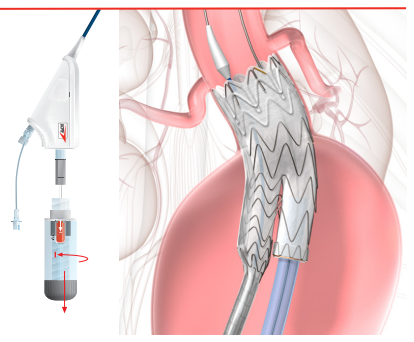
Cannulate contralateral gate

3 Cannulate contralateral gate, then advance introducer sheath into the gate.



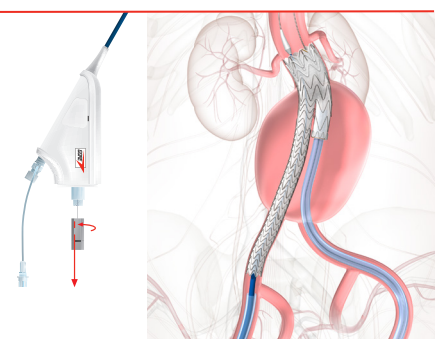
Remove constraining mechanism

4 Pull back and hold red safety tab, rotate transparent knob counterclockwise and pull in a continuous motion.



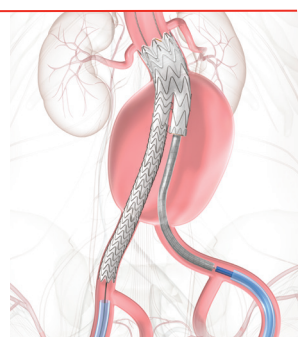
Deploy Ipsilateral Leg

5 Rotate gray deployment knob counterclockwise and pull in a continuous motion.



Advance and deploy Contralateral Leg

6 Insert device over .035 guidewire and deploy with GORE® SIM-PULL Delivery System.

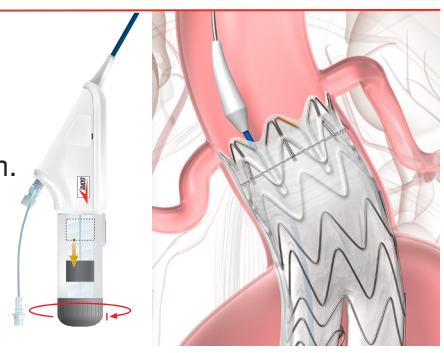


OPTIONAL STEPS

Repositioning for optimizing position

2a Rotate gray constraining dial clockwise to constrain.

When device is in place, rotate gray constraining dial to reopen.



Optional Aortic Extender: Deployment

Insert device over 0.035" guidewire and through sheath. Carefully position, stabilize and deploy. Extender deploys 'hub-to-tip' direction.

WARNINGS:

Do not:

- Rotate trunk delivery catheter beyond 360° when device is fully constrained on catheter.
- Withdraw undeployed endoprosthesis through introducer sheath.
- Attempt to reposition the endoprosthesis while the trunk is at its maximum diameter. Vessel damage or device misplacement may result.
- Use constraining/unconstraining mechanism more than 2 times.

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE: Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac/femoral access; Infrarenal aortic neck treatment diameter range of 19–32 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation ≤ 60°; Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender and Iliac Extender Endoprosthesis.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE® EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and/or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® AAA Endoprosthesis is contraindicated in: patients with known sensitivities or allergies to the device materials; patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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