

Repositioning

the Future of EVAR



PERFORMANCE by design



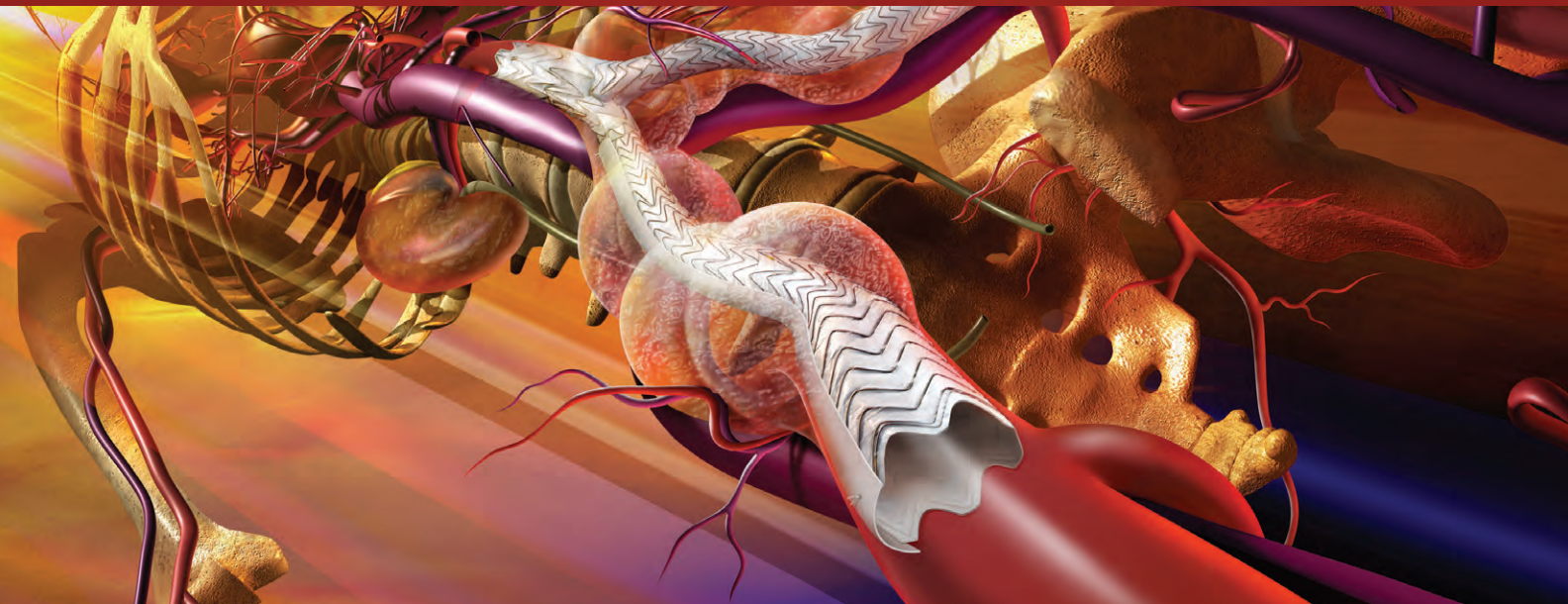
ExcluderC3.com



EXCLUDER®

AAA ENDOPROSTHESIS

Unparalleled Design, Simplicity



The GORE® EXCLUDER® AAA Endoprosthesis is the result of a collaboration between leading EVAR physicians and Gore engineers. With more than 135,000 devices distributed worldwide, the GORE® EXCLUDER® AAA Endoprosthesis is characterized by its low profile, flexible on and off catheter characteristics, active infrarenal fixation and strong clinical data. In addition, the GORE® EXCLUDER® Device is supported by a highly rated clinical support team, a comprehensive educational offering, and Gore's outstanding community awareness programs.

Unparalleled Design

The graft material is expanded polytetrafluoroethylene and fluorinated ethylene propylene (ePTFE and FEP), supported by nitinol (nickel titanium alloy) wire along its external surface. Combined, these elements make a durable, yet flexible stent graft that has stood the test of time.

Nitinol anchors and an ePTFE / FEP sealing cuff are located at the aortic end of the trunk. The sealing cuff is designed to help prevent Type I endoleaks, while the anchors are designed to support that same goal by holding the graft in place.

An ePTFE / FEP sleeve is used to constrain the endoprosthesis on the leading end of the delivery catheter, for low-profile passage and access through narrow and tortuous aortic anatomies. The GORE® C3 Delivery System features a redesigned radiopaque olive with improved visibility under fluoroscopy. The flexibility of the wire / catheter interface facilitates tracking through challenging aortic anatomies.

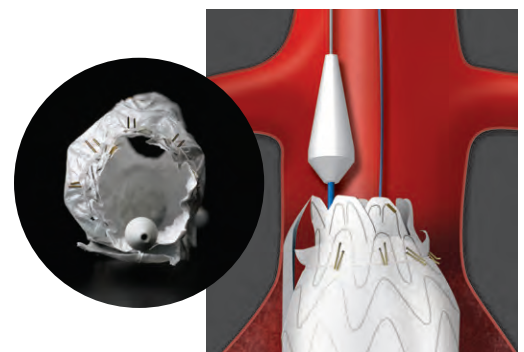
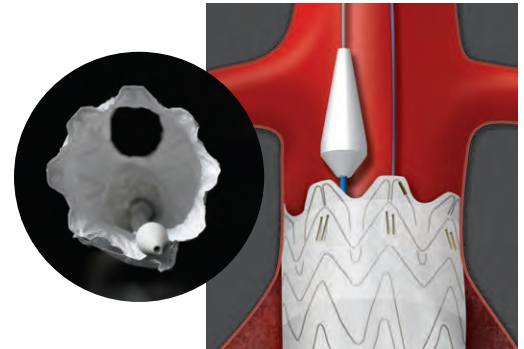




Endograft malpositioning could involve coverage of one or more branch vessels, a compromised infrarenal seal, blocked access to the contralateral gate and / or additional graft components. The GORE® C3 Delivery System offers physicians the control and confidence desired for endograft positioning.

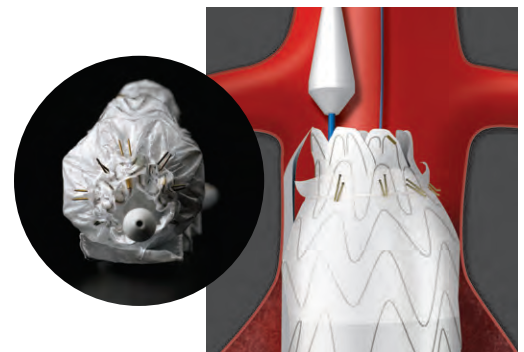
CONTROL

Repositioning with the GORE® C3 Delivery System offers physicians additional opportunities to place the GORE® EXCLUDER® Device Trunk-Ipsilateral Leg where desired during implantation.



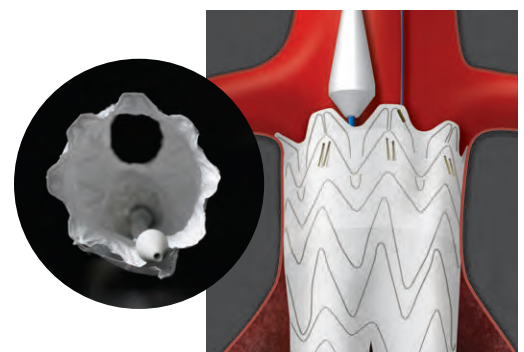
CONFIDENCE

When the landing zone is tight, and a narrow margin for error favors more than one controlled deployment, the repositionable option of the GORE® C3 Delivery System offers physicians a second and third chance to accurately position the device.



CANNULATION ASSISTANCE

The repositioning option of the GORE® C3 Delivery System enables the graft to rotate and move to facilitate contralateral gate access.



Repositioning the Future of EVAR

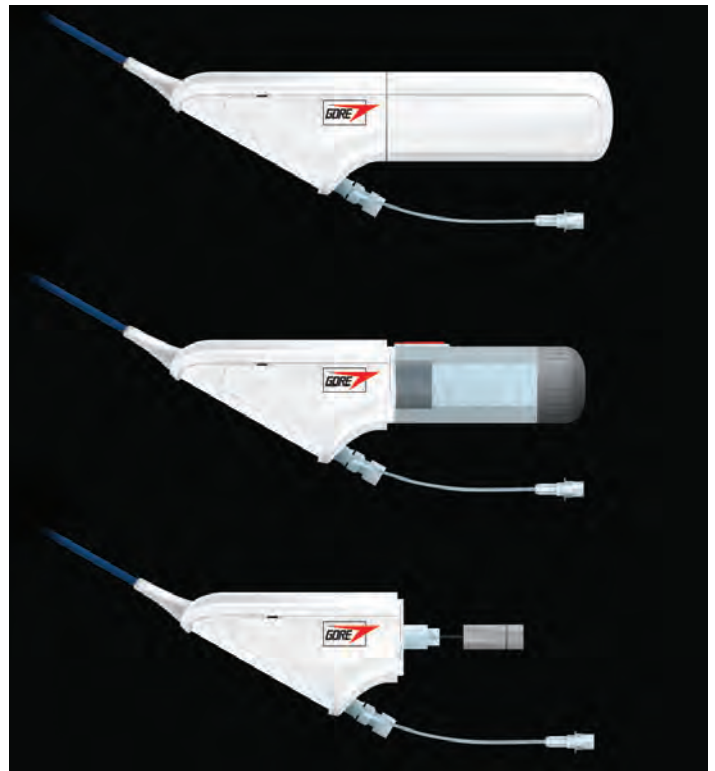


Intuitive Simplicity

The GORE® EXCLUDER® Device has long been known for its elegantly simple delivery and deployment.

The GORE® C3 Delivery System enables the graft to be repositioned, but also helps maintain physician focus on the patient's anatomy and the stent-graft, rather than on a complex delivery handle and cumbersome deployment process.

This simple three-stage deployment employs a series of three familiar 90° counter-clockwise rotations and pulls to deploy the graft. The nested design of these deployment knobs aids in ensuring an intuitively straightforward sequence.



GORE® C3 Delivery System Handle



Unparalleled Principles of Design

SEAL VS. FIXATION

“Seal is the apposition of the outer surface of the endograft to the luminal surface of the aorta to exclude the aneurysm sac from systemic pressure. The amount of seal achieved is determined by the length of the proximal neck and the position of the endograft. Fixation is the counterforce that prevents migration of the endograft and helps maintain seal.”¹ All devices, supra and infrarenal, must exclude the aneurysm by means of an infrarenal seal, “...there is no substitute for seal.”¹

INFRARENAL BY CHOICE

“A critical review of the literature has shown that: ...suprarenal fixation does not increase seal and has not been shown to increase the applicability of EVAR to aneurysms with shorter necks without compromising results. Furthermore, there is no evidence to suggest that suprarenal fixation is more effective than active infrarenal fixation in the prevention of migration.”¹ Suprarenal devices:

- may affect the flow dynamics into the renals
- often require more procedural steps to deploy a top stent
- usually have more complicated delivery systems to achieve this
- are limited in their ability to seal by suprarenal angulation of the aorta
- may offer challenges to surgical conversion that infrarenal grafts do not

Why complicate EVAR? Stay put, stay patent, stay infrarenal.

FLEXIBLE BY DESIGN

The main body and limbs of the GORE® EXCLUDER® AAA Endoprosthesis are designed to provide flexibility and long-term conformability for challenging patient anatomies. The GORE® EXCLUDER® AAA Device has a unique combination of:

- advanced fully supporting sinusoidal stent design
- ultra smooth ePTFE graft material
- sutureless attachment between the stent and graft

This combination enables these components to track through tortuous anatomy while on catheter and adapt to the patient’s anatomy once deployed.

¹Minion DJ. Neck, seal, and fixation. *Endovascular Today* 2009;8(1)Supplement:3-6.

Trunk-Ipsilateral Leg Endoprosthesis

ORIGINAL DELIVERY SYSTEM CATALOGUE NUMBER	GORE® C3 DELIVERY SYSTEM CATALOGUE NUMBER	INTENDED AORTIC INNER DIAMETER (mm)	AORTIC ENDOPROSTHESIS DIAMETER (mm)	INTENDED ILIAC INNER DIAMETER (mm)	ILIAC ENDOPROSTHESIS DIAMETER (mm)	OVERALL DEVICE LENGTH (cm)	RECOMMENDED SHEATH SIZE (Fr)
PXT231212	RMT231212	19–21	23	10–11	12	12	18
PXT231214	RMT231214	19–21	23	10–11	12	14	18
PXT231216	RMT231216	19–21	23	10–11	12	16	18
PXT231218	RMT231218	19–21	23	10–11	12	18	18
PXT231412	RMT231412	19–21	23	12–13.5	14.5	12	18
PXT231414	RMT231414	19–21	23	12–13.5	14.5	14	18
PXT231416	RMT231416	19–21	23	12–13.5	14.5	16	18
PXT231418	RMT231418	19–21	23	12–13.5	14.5	18	18
PXT261212	RMT261212	22–23	26	10–11	12	12	18
PXT261214	RMT261214	22–23	26	10–11	12	14	18
PXT261216	RMT261216	22–23	26	10–11	12	16	18
PXT261218	RMT261218	22–23	26	10–11	12	18	18
PXT261412	RMT261412	22–23	26	12–13.5	14.5	12	18
PXT261414	RMT261414	22–23	26	12–13.5	14.5	14	18
PXT261416	RMT261416	22–23	26	12–13.5	14.5	16	18
PXT261418	RMT261418	22–23	26	12–13.5	14.5	18	18
PXT281212	RMT281212	24–26	28.5	10–11	12	12	18
PXT281214	RMT281214	24–26	28.5	10–11	12	14	18
PXT281216	RMT281216	24–26	28.5	10–11	12	16	18
PXT281218	RMT281218	24–26	28.5	10–11	12	18	18
PXT281412	RMT281412	24–26	28.5	12–13.5	14.5	12	18
PXT281414	RMT281414	24–26	28.5	12–13.5	14.5	14	18
PXT281416	RMT281416	24–26	28.5	12–13.5	14.5	16	18
PXT281418	RMT281418	24–26	28.5	12–13.5	14.5	18	18
PXT311413	RMT311413	27–29	31	12–13.5	14.5	13	20
PXT311415	RMT311415	27–29	31	12–13.5	14.5	15	20
PXT311417	RMT311417	27–29	31	12–13.5	14.5	17	20

Contralateral Leg Endoprosthesis

CATALOGUE NUMBER	INTENDED ILIAC INNER DIAMETER (mm)	ILIAC ENDOPROSTHESIS DIAMETER (mm)	CONTRALATERAL LEG LENGTH (cm)	RECOMMENDED SHEATH SIZE (Fr)
PXC121000	10–11	12	10	12
PXC121200	10–11	12	12	12
PXC121400	10–11	12	14	12
PXC141000	12–13.5	14.5	10	12
PXC141200	12–13.5	14.5	12	12
PXC141400	12–13.5	14.5	14	12
PXC161000*	13.5–14.5	16	9.5	18
PXC161200*	13.5–14.5	16	11.5	18
PXC161400*	13.5–14.5	16	13.5	18
PXC181000*	14.5–16.5	18	9.5	18
PXC181200*	14.5–16.5	18	11.5	18
PXC181400*	14.5–16.5	18	13.5	18
PXC201000*	16.5–18.5	20	9.5	18
PXC201200*	16.5–18.5	20	11.5	18
PXC201400*	16.5–18.5	20	13.5	18
PXC231000*	18.5–21.5	23	10	18
PXC231200*	18.5–21.5	23	12	18
PXC231400*	18.5–21.5	23	14	18
PXC271000*	21.5–25.0	27	10	18
PXC271200*	21.5–25.0	27	12	18
PXC271400*	21.5–25.0	27	14	18

Iliac Extender Endoprosthesis

CATALOGUE NUMBER	INTENDED ILIAC INNER DIAMETER (mm)	ENDOPROSTHESIS DIAMETER (mm)	ENDOPROSTHESIS LENGTH (cm)	RECOMMENDED SHEATH SIZE (Fr)
PXL161007	8–9	10	7	12
PXL161207	10–11	12	7	12
PXL161407	12–13.5	14.5	7	12

Aortic Extender Endoprosthesis

CATALOGUE NUMBER	INTENDED AORTIC INNER DIAMETER (mm)	ENDOPROSTHESIS DIAMETER (mm)	ENDOPROSTHESIS LENGTH (cm)	RECOMMENDED SHEATH SIZE (Fr)
PXA230300	19–21	23	3.3	18
PXA260300	22–23	26	3.3	18
PXA280300	24–26	28.5	3.3	18
PXA320400	27–29	32	4.5	20

* PLEASE NOTE: All large diameter Contralateral Leg Endoprostheses (16, 18, 20, 23, 27 mm) can be used as Iliac Extenders.

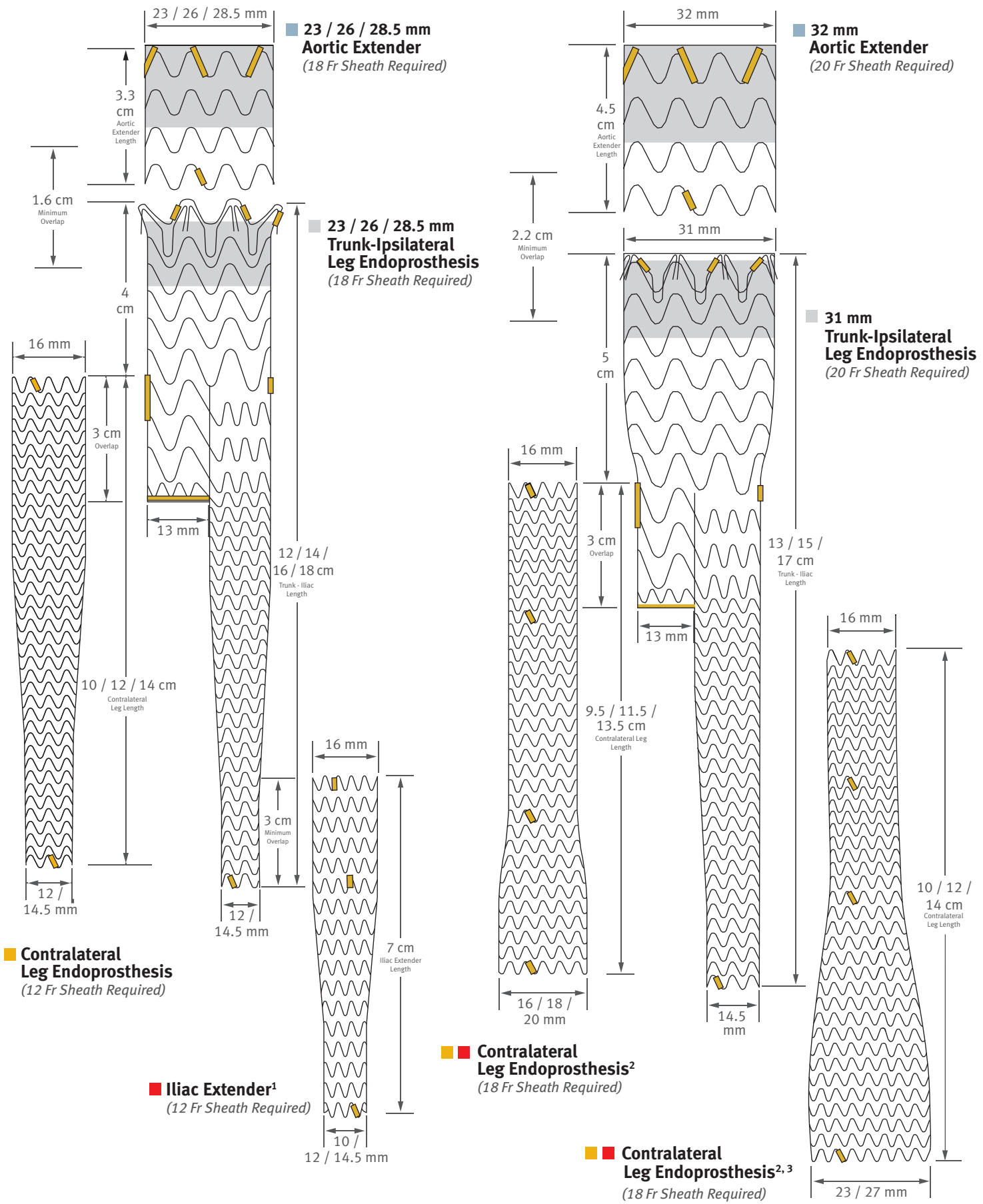
GORE® DrySeal Sheath

CATALOGUE NUMBER	SHEATH SIZE (Fr)
SDV1228	12
SDV1828	18
SDV2028	20

All sheaths are 28 cm in length.

GORE® Tri-Lobe Balloon Catheter

CATALOGUE NUMBER	INNER VESSEL DIAMETER (mm)
BCM1634	16–34



**23 and 27 mm
Contralateral Legs
NOW AVAILABLE**

- Trunk-Ipsilateral
- Contralateral Leg
- Iliac Extender
- Aortic Extender

¹ Traditional sizes of Iliac Extender (10, 12, 14.5 mm) are not compatible with large diameter (16, 18, 20, 23, 27 mm) Contralateral Leg Endoprostheses.
² All large diameter Contralateral Leg Endoprostheses (16, 18, 20, 23, 27 mm) can be used as Iliac Extenders.
³ The 27 mm x 10 cm Contralateral Leg Endoprosthesis does not have a radiopaque marker 6 cm above the distal end.

Service with Integrity

For more than 35 years, Gore has collaborated with and supported physicians specializing in vascular therapies. Gore continues that tradition today with our corporate initiatives and field-based associates, who bring value to physicians beyond the innovative design of our products.

Service through Case Support

Pre-case planning and procedural support are focused on patient care.

Service through Physician Education

Gore's Medical Mastery Series is a commitment to create environments such as Fellows Workshops and Advanced Symposia, where physicians can learn best practices from each other through discussion, case observation and hands-on work with our cutting-edge simulator technology.

Service through Community Education

In collaboration with physicians, Gore created an industry leading program to educate community physicians and patients about AAA risk factors, symptoms, screening and therapies for cardiovascular disease.



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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 – 29 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation $\leq 60^\circ$; Iliac artery treatment diameter range of 8 – 25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** 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 and patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. Rx ONLY