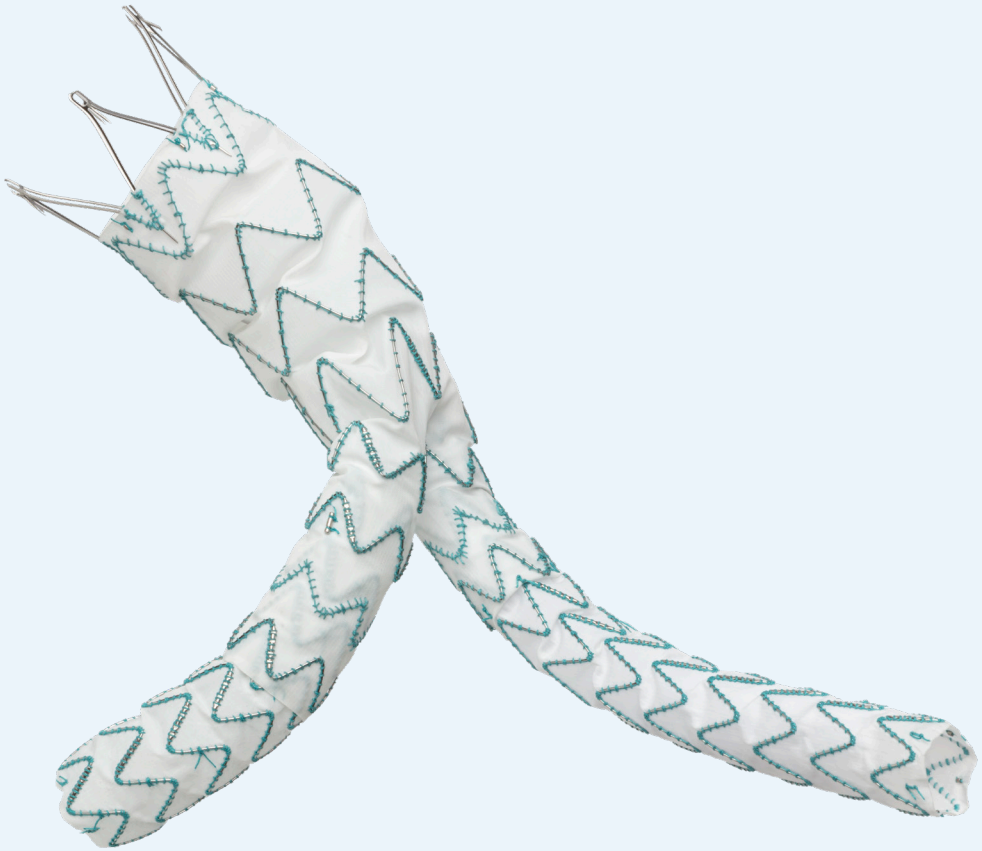
TERUMO AORTIC

USA



PRODUCT BROCHURE

TREO®

Versatile by Design. Fit for any Anatomy.*

*Per IFU.

For more information, visit
terumoaortic.com/treo

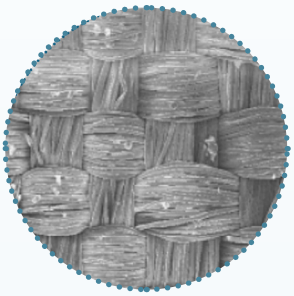
TREO®
ABDOMINAL STENT-GRAFT SYSTEM

Inspiring Confidence with Next-Generation Device Technology

0%
Conversion to open repair through 3 years [1]
(0/150)

0%
Type III/IV Endoleak through 3 years [1]
(0/150)

0%
Rupture through 3 years [1]
(0/150)



Fabric

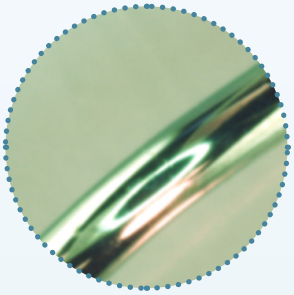
Woven Polyester with an optimized weave pattern

- Low profile
- High strength
- Low permeability

Suture

5-0 braided polyester surgical suture impregnated with PTFE

- High wear resistance
- High tensile strength



Stents

Electropolished Nitinol:

- Super-elastic properties
- Proven fatique endurance
- Suprarenal stent is laser-cut for durability

Radiopaque Markers

- Platinum Iridium (90%-10%)
  - Radiopaque material for enhanced visibility
  - Low profile
  - Galvanic corrosion resistance
- Positioned to aid device placement and easier contralateral gate cannulation

References available on page 15

The NEXT Evolution of EVAR is Here

The TREO® Abdominal Stent-Graft System is indicated for use in the endovascular treatment of patients with infrarenal abdominal aortic and aorto-iliac aneurysms with the following characteristics:

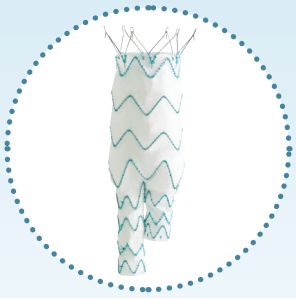
- Adequate iliac or femoral access compatible with the required delivery systems and accessories
- Minimum overall AAA treatment length (proximal landing location to distal landing location) of 13cm
- Minimum overall length from the lowest renal artery to the aortic bifurcation of 9cm

Proximal aortic landing zone with:
Infrarenal landing neck length of ≥15mm
Suprarenal neck angle of ≤ 45 degrees
Infrarenal neck angle of ≤ 60 degrees
Aortic neck diameters ≥17mm and ≤32mm

Distal iliac landing zone with:
An inside diameter of 8mm - 13mm and a length of ≥10mm
An inside diameter of >13mm - 20mm and a length of ≥15mm

100%
Technical Success
(at index procedure)[2]
(150/150)

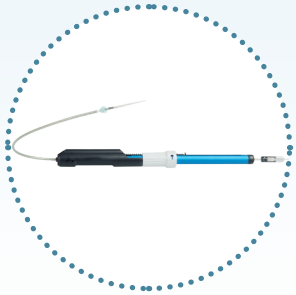
100%
Freedom from aneurysm related mortality through 3 years[1]
(150/150)



TREO Key Features

Graft features

- Multiple size options
- Flexible graft design
- Dual active fixation
- Optimized proximal seal
- Lock stent technology



Delivery system features

- Low profile delivery system
- Controlled, precise graft delivery
- Leave behind sheath
- Protective proximal clasp

References available on page 15

More Choices, More Possibilities

Multiple size options for planning and treatment versatility.

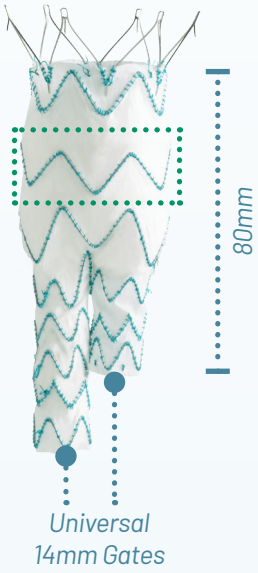
90%
of procedures utilize 3 pieces [2]

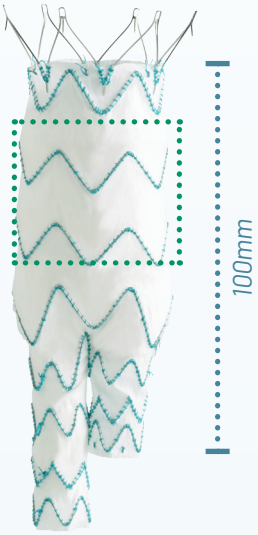
True three-piece modular design with a wide variety of sizes, lengths and tapers

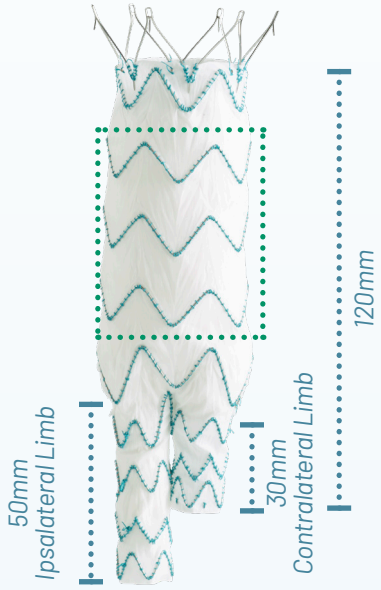
TREO offers
29,400
unique treatment options

20mm - 36mm Diameters

Main Bodies





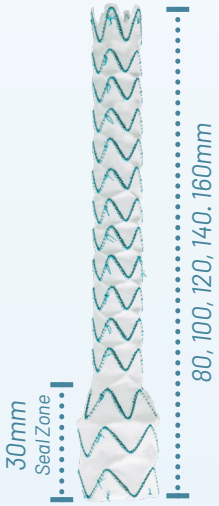


Cuff

Taper Late
15mm

9, 11, 13, 15mm

Flare Late
15mm

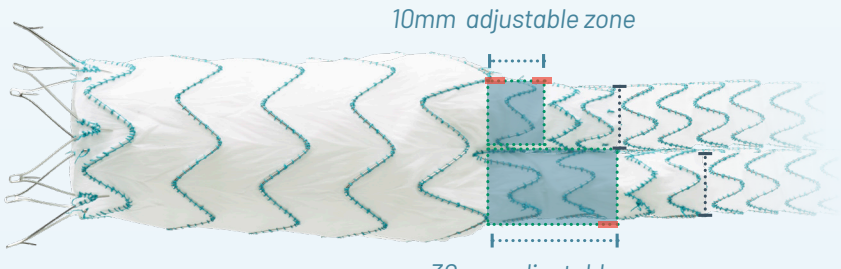


17, 20, 24mm

Optimized Limb Tapering Design

- Limbs taper late in smaller diameters
- Limbs flare late in larger diameters
- In-situ adjustable limb landing zones

Resulting in expanded treatment options, particularly in tight/ narrow aortic bifurcations.



"The use of the TREO stent graft also allows for in situ limb length flexibility. Both ipsilateral and contralateral gates have 1 to 3 cm of docking overlap, allowing for treatment of a more continuous range of patient anatomies and accurate targeting of the distal landing zone." [1]

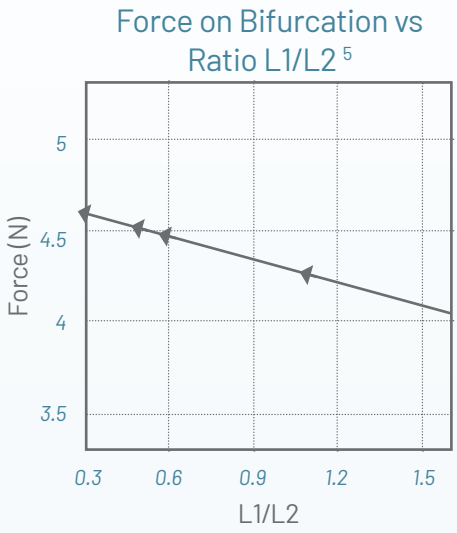
References available on page 15

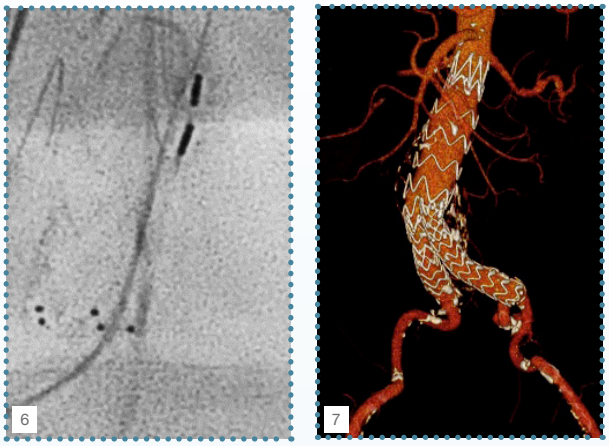
TREO®

Provides the Ideal Platform for Both Present and Future EVAR Needs

Long main bodies provide:

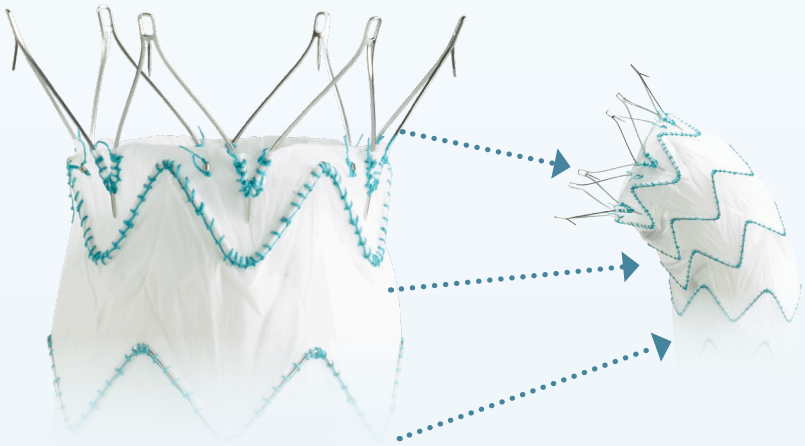
- Lower displacement forces and increased endograft stability during the cardiac cycle [3, 5]
- Endograft closer to aortoiliac bifurcation makes it easier and faster to cannulate contralateral gate [4]





Ease of gate cannulation with long main body

TREO's long main body's ability to sit close to aortoiliac bifurcation, along with limb lock mechanism, may reduce the risk of both proximal and distal migration. [5]



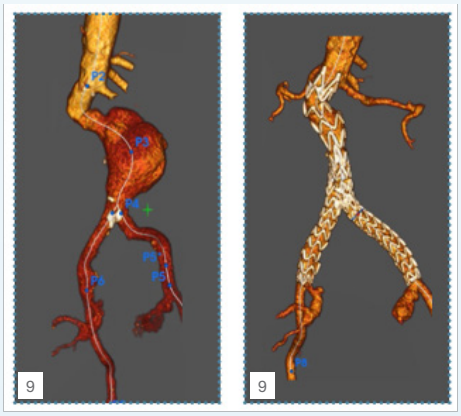
Highly flexible design for challenging, angulated anatomy

- Z-Stent Configuration
- Space between stents

73%
Of patients with hostile neck anatomy [8*]
(27/37)

92%
Overall survival rate after 5 years [8*]
(34/37)

100%
Freedrom from aortic related mortality through 5 years [8*]
(37/37)



* TREO indications differ in the US vs outside US; refer to US IFU for complete indications.
References available on page 15.

Enhanced Proximal Fixation and Sealing: Optimal Outcomes

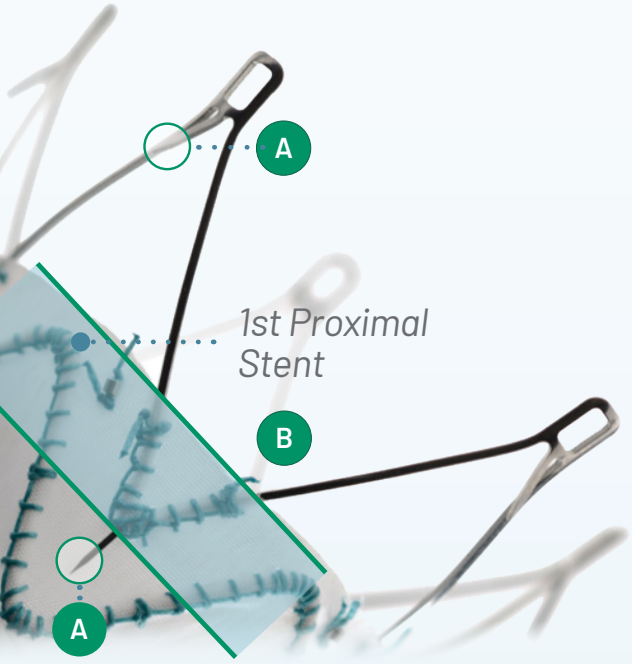
TREO is the only EVAR graft with both suprarenal and infrarenal active fixation and long, overlapping stents for an optimized proximal seal.

A SUPRARENAL & INFRARENAL FIXATION

- Two levels of fixation increase migration resistance.

B IMPROVED PROXIMAL SEAL ZONE

- Long overlapping proximal stents and seal stent sewn on the inside of graft pushes fabric against the aortic wall and increases vessel contact points for a confident seal and low type 1a endoleak rate.



0.8%
Type 1a endoleak at 1 year [1]
(1/144)

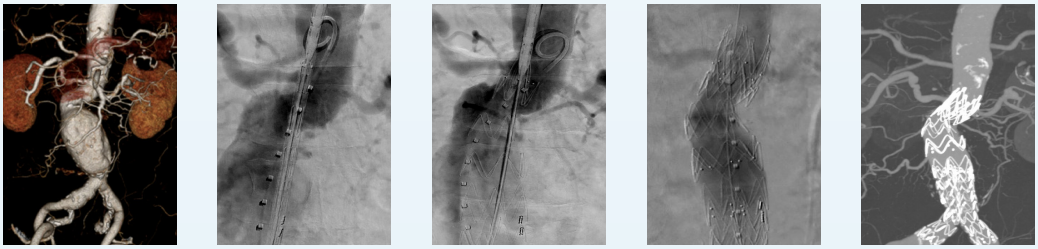
0%
Migration through 3 years [1]
(0/150)

Overlapped Proximal End Configuration

- 3 seal points per apex

20mm-28mm Diameters	30mm-36mm Diameters
5 Peak Design = 15 seal points	6 Peak Design = 18 seal points

Before — During — After



Images provided courtesy of Neal Cayne, MD

"Infrarenal barbs provide additional fixation and contribute to migration resistance in large, angulated necks." [4]

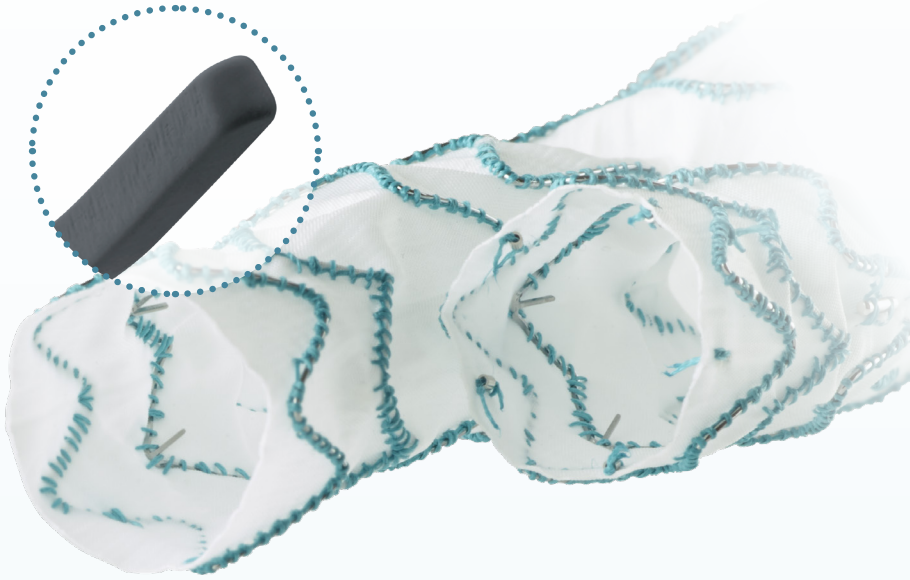
References available on page 15

Unique Limb Lock Stent Technology

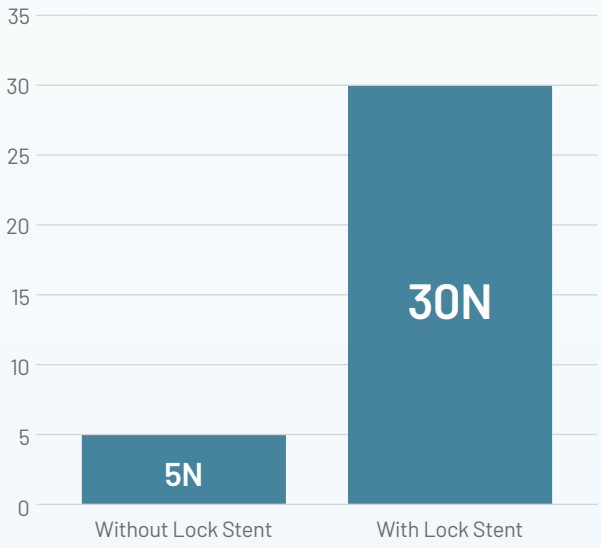
Designed to prevent limb disconnection and Type III endoleaks.

Rounded Barbs

inside main body gates are designed to securely engage with limb stents. The lock stent barbs are dulled to ensure compatibility with balloons.[10]

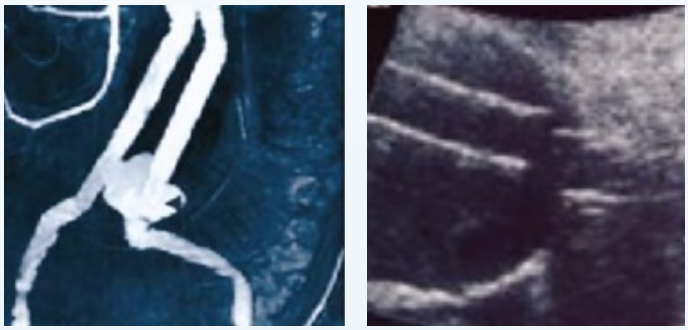


Lock Stent Technology increases pull out force resistance by **6 times** [11]



0%

Type III endoleak through 3 years [1]
(0/150)



Example: Type III/DisconnectionEL [12]

"Dual active proximal fixation and rounded barbs at the limb docking sites have been shown to multiply the migration and detachment pullout forces and might mitigate the development of Type I and III endoleaks respectively." [1]

References available on page 15

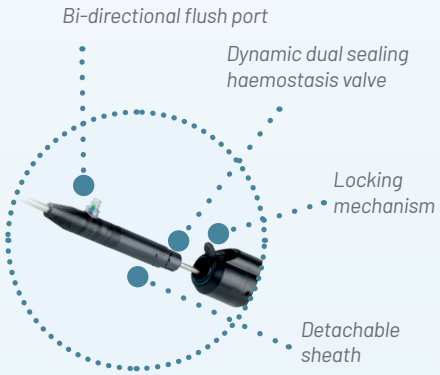
Intuitive Mechanical Advantage for Controlled and Precise Device Deployment

A Low-Profile delivery system & Leave Behind Sheath are designed to enable percutaneous access and fewer sheath exchanges, facilitating a reduction in:

- Access Vessel Trauma and complications [13,14]
- Procedural time, hospital length of stay and cost [13,14]
- Patient post-operative pain [14]

1 INTRODUCER AND LEAVE BEHIND SHEATH

- Low profile introducer and detachable, leave-behind sheath (18/19 Fr OD) with hydrophilic coating and Flexible tip for easier navigation



2 PROXIMAL CLASPING

- Proximal clasp allows for safe graft re-positioning and delivery system removal

3 PRECISE DELIVERY SYSTEM

- The mechanical deployment provides controlled and stable stent-graft deployment

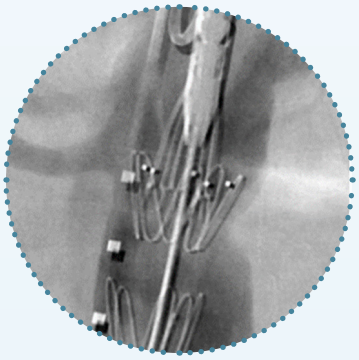
4 PROXIMAL CLASP RELEASE

WATCH
TREO Deployment

References available on page 15

95%
TREO Percutaneous access [15]
(305/321)

Main Body Delivery System		Leg Extension Delivery System	
20 - 28mm	30 - 36mm	9 - 15mm	17 - 24mm
18Fr (OD)	19Fr (OD)	13Fr (OD)	14Fr (OD)



Highly visible proximal markers allow accurate alignment with lowest renal artery

"The device may be repositioned until the proximal clasp is released reducing the risk of proximal misdeployment and improving the accuracy of landing the device below the renal arteries" [10]

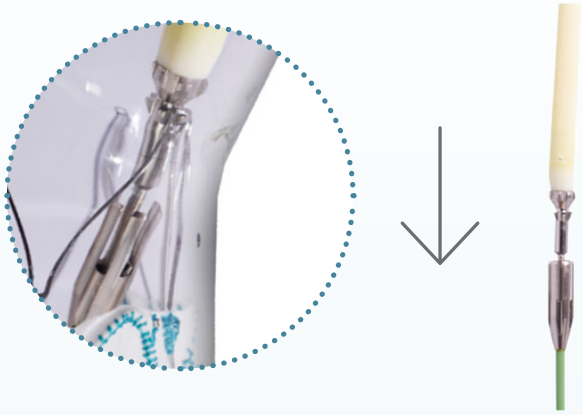
References available on page 15

Optimized Design for Patient Safety and Procedural Success

Proximal clasp allows for safe graft re-positioning and delivery system removal.

Infrarenal barbs are obscured in graft fabric "valleys" prior to final clasp release

Suprarenal barbs are completely covered allowing graft to be safely repositioned until clasp is released



Proximal Clasp Simple Caudal Removal

Easily withdraw delivery system without added steps or risk of entanglement

- Proximal clasp prevents barb engagement with vessel wall until released

100%
Technical Success [2]
(at index procedure; 150/150)

0%
Conversions to open repair through 3 Years [1]
(0/150)

References available on page 15

Sac Regression: The Ultimate Indicator of EVAR Success

Not only sac expansion, but any failure for the sac to regress is associated with higher long-term mortality. [18]

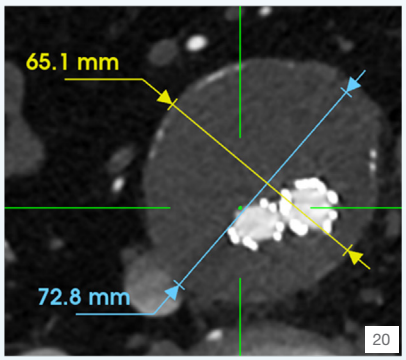
73%
of patients with hostile neck anatomy.[8]
(27/37)

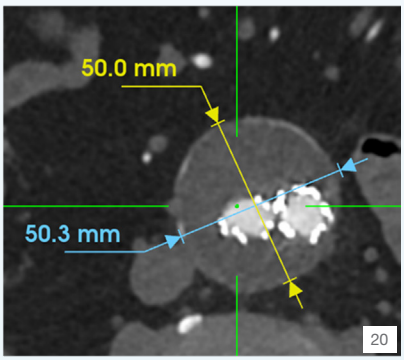
TREO consistently shows durable high Sac Regression and low sac expansion rates across multiple studies

TREO Aneurysm sac changes @ 1 year and 5 years

	IDE [1] (1&5 years)	MARONE, et al [8*] (5 years)	Feasibility Study [17] (1&5 years)	RATIONALE* [4] (1 year)	US PAS^ [15] (1 year)	EVAR VQI Multi Manuf. [18] (TREO not incl)(1 year)
	n=136	*n=31*	*n=28*	*n=202*	*n=226*	*n=14,817*
Decrease	46%	71%	54%	54%	46%	40%
Stable	54%	29%	46%	43%	50%	35%
Increase	0%	0%	0%	3%	4%	**25%**
Decrease @5 Years	**61%** [19] *N=70*	**71%**	**81%** *(17/21)*			

^ TREO US PAS is an all-comers study, follow-up on-going





EVAR Success: Sac Regression

- **32% aneurysm size reduction (23mm) at 1 Year**
- Without usage of adjunctive devices

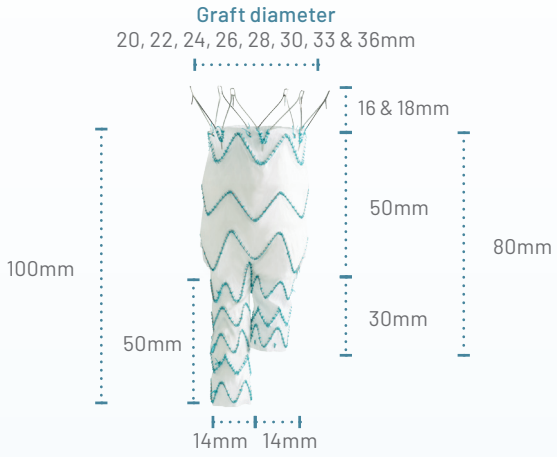
Long main body optimizes sac regression

"The proximity of the distal end of the stent graft to the iliac bifurcation might promote sac regression, provide greater resistance to migration, and counter endograft shortening resulting from aortoiliac tortuosity." [1]

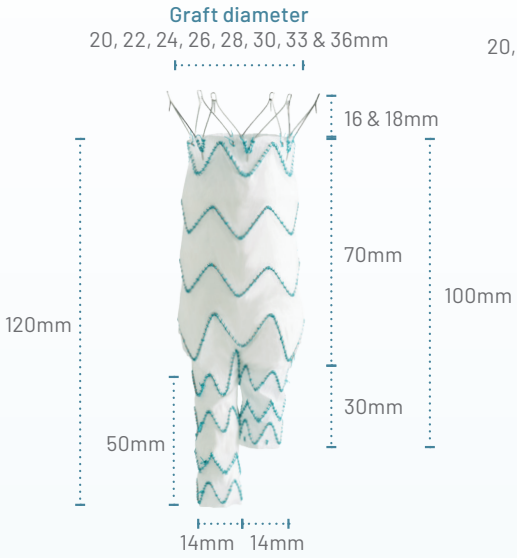
* TREO indications differ in the US vs outside US; refer to US IFU for complete indications.
References available on page 15.

TREO Sizing

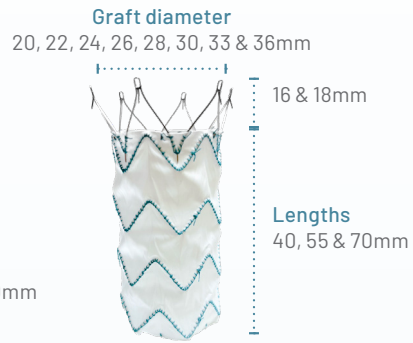
Bifurcate



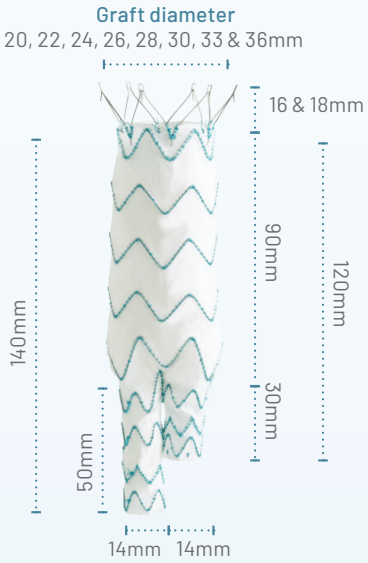
Bifurcate



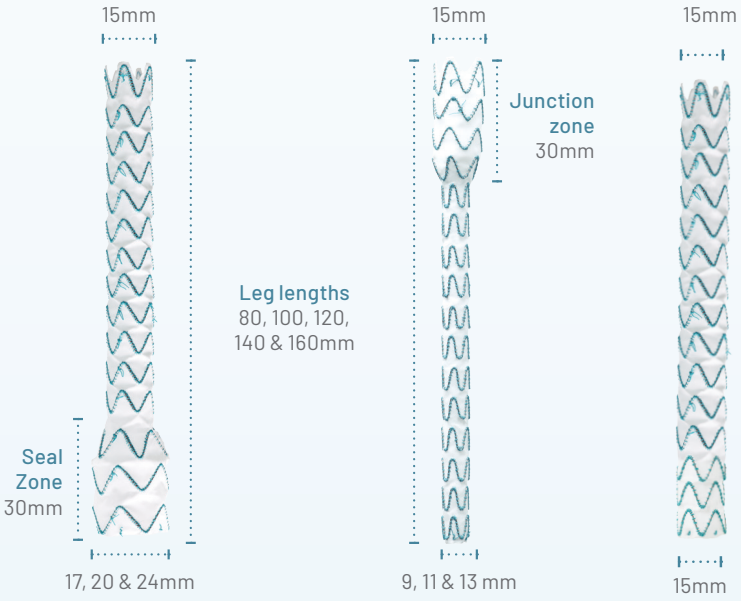
Cuff



Bifurcate



Leg Extension



References available on page 15

TREO Product Ordering Information

28	X2	20	080	S
Product Id.	Device Type	Diameter	Device Covered Length	Product Id.

Device Type Key

X=
B = Bifurcate
L = Leg Extension
C = Cuff
S = Straight Extension

Main Body Bifurcate Stent-Graft

Aortic Outer Diameter (proximal neck angle < 60°)	Proximal Landing Zone Minimum Length (neck angle 60°)	Proximal Diameter	Contralateral Length	Profile OD	MTO^	Catalogue Number
17-18	10	20	80	18 Fr		28-B2-20-080U
	10	20	100	18 Fr	•	28-B2-20-100U
	10	20	120	18 Fr	•	28-B2-20-120U
18-19	10	22	80	18 Fr		28-B2-22-080U
	10	22	100	18 Fr		28-B2-22-100U
	10	22	120	18 Fr	•	28-B2-22-120U
19-21	10	24	80	18 Fr		28-B2-24-080U
	10	24	100	18 Fr		28-B2-24-100U
	10	24	120	18 Fr	•	28-B2-24-120U
21-23	10	26	80	18 Fr		28-B2-26-080U
	10	26	100	18 Fr		28-B2-26-100U
	10	26	120	18 Fr		28-B2-26-120U
23-25	10	28	80	18 Fr		28-B2-28-080U
	10	28	100	18 Fr		28-B2-28-100U
	10	28	120	18 Fr		28-B2-28-120U
25-27	10	30	80	19 Fr		28-B2-30-080U
	10	30	100	19 Fr		28-B2-30-100U
	10	30	120	19 Fr		28-B2-30-120U
27-30	10	33	80	19 Fr		28-B2-33-080U
	10	33	100	19 Fr		28-B2-33-100U
	10	33	120	19 Fr		28-B2-33-120U
30-32	10	36	80	19 Fr		28-B2-36-080U
	10	36	100	19 Fr		28-B2-36-100U
	10	36	120	19 Fr		28-B2-36-120U

Straight Extension Stent-Graft#

Iliac Outer Diameter	Iliac Landing Zone Minimum Length	Straight Extension Distal Diameter	Covered Length	Profile OD	Catalogue Number
8	10	9	80	13 Fr	28-S2-09-080U
9	10	11	80	13 Fr	28-S2-11-080U
10-11	10	13	80	13 Fr	28-S2-13-080U

Leg Extension Stent-Graft

Iliac Outer Diameter	Iliac Landing Zone Minimum Length	Leg Extension Distal Diameter	Covered Length	Profile OD	MTO^	Catalogue Number
8	10	9	80	13 Fr	•	28-L2-09-080U
	10	9	100	13 Fr	•	28-L2-09-100U
	10	9	120	13 Fr		28-L2-09-120U
	10	9	140	13 Fr		28-L2-09-140U
	10	9	160	13 Fr		28-L2-09-160U
9	10	11	80	13 Fr		28-L2-11-080U
	10	11	100	13 Fr		28-L2-11-100U
	10	11	120	13 Fr		28-L2-11-120U
	10	11	140	13 Fr		28-L2-11-140U
	10	11	160	13 Fr		28-L2-11-160U
10-11	10	13	80	13 Fr		28-L2-13-080U
	10	13	100	13 Fr		28-L2-13-100U
	10	13	120	13 Fr		28-L2-13-120U
	10	13	140	13 Fr		28-L2-13-140U
	10	13	160	13 Fr		28-L2-13-160U
12-13	10	15	80	13 Fr		28-L2-15-080U
	10	15	100	13 Fr		28-L2-15-100U
	10	15	120	13 Fr		28-L2-15-120U
	10	15	140	13 Fr		28-L2-15-140U
	10	15	160	13 Fr		28-L2-15-160U
14-15	15	17	80	14 Fr		28-L2-17-080U
	15	17	100	14 Fr		28-L2-17-100U
	15	17	120	14 Fr		28-L2-17-120U
	15	17	140	14 Fr		28-L2-17-140U
	15	17	160	14 Fr		28-L2-17-160U
16-17	15	20	80	14 Fr		28-L2-20-080U
	15	20	100	14 Fr		28-L2-20-100U
	15	20	120	14 Fr		28-L2-20-120U
	15	20	140	14 Fr		28-L2-20-140U
	15	20	160	14 Fr		28-L2-20-160U
18-20	15	24	80	14 Fr		28-L2-24-080U
	15	24	100	14 Fr		28-L2-24-100U
	15	24	120	14 Fr		28-L2-24-120U
	15	24	140	14 Fr		28-L2-24-140U
	15	24	160	14 Fr		28-L2-24-160U

Proximal aortic landing zone with:

- Infrarenal landing neck length of ≥15mm
- Suprarenal neck angle of ≤ 45 degrees
- Infrarenal neck angle of ≤ 60 degrees
- Aortic neck diameters ≥17mm and ≤32mm

Distal iliac landing zone with:

- an inside diameter of 8mm – 13mm and a length of ≥ 10mm or
- an inside diameter of >13mm – 20mm and a length of ≥ 15mm

Straight Extension Stent-Grafts indicated for use only with previously implanted Leg Extension Stent-Grafts with the same distal diameter.
^ Made To Order devices are not kept in stock. They will be built upon receipt of Purchase Order and are subject to extended lead times.

TREO Product Ordering Information

Proximal Cuff Extension Stent-Graft

Aortic Outer Diameter (proximal neck angle < 60°)	Proximal Landing Zone Minimum Length (neck angle 60°)	Proximal and DiUtal Diameter	Covered Length	Profile	MTO^	Catalogue Number
17-18	10	20	40	18 Fr	•	28-C2-20-040U
	10	20	55	18 Fr	•	28-C2-20-055U
	10	20	70	18 Fr		28-C2-20-070U
18-19	10	22	40	18 Fr		28-C2-22-040U
	10	22	55	18 Fr	•	28-C2-22-055U
	10	22	70	18 Fr		28-C2-22-070U
19-21	10	24	40	18 Fr		28-C2-24-040U
	10	24	55	18 Fr	•	28-C2-24-055U
	10	24	70	18 Fr		28-C2-24-070U
21-23	10	26	40	18 Fr		28-C2-26-040U
	10	26	55	18 Fr	•	28-C2-26-055U
	10	26	70	18 Fr		28-C2-26-070U
23-25	10	28	40	18 Fr		28-C2-28-040U
	10	28	55	18 Fr	•	28-C2-28-055U
	10	28	70	18 Fr		28-C2-28-070U
25-27	10	30	40	19 Fr		28-C2-30-040U
	10	30	55	19 Fr	•	28-C2-30-055U
	10	30	70	19 Fr		28-C2-30-070U
27-30	10	33	40	19 Fr		28-C2-33-040U
	10	33	55	19 Fr	•	28-C2-33-055U
	10	33	70	19 Fr		28-C2-33-070U
30-32	10	36	40	19 Fr		28-C2-36-040U
	10	36	55	19 Fr	•	28-C2-36-055U
	10	36	70	19 Fr		28-C2-36-070U

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DESIGN

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