

PRODUCT BROCHURE

# Fenestrated TREO®

Advancing Fenestrated Horizons



# The All - Encompassing Next Generation Fenestrated Endograft

#### SYSTEM SPECIFICATIONS

#### Stent

#### Electropolished Nitinol

#### Diameters

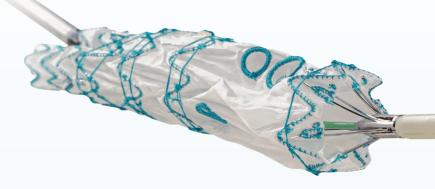
▶ 24mm – 36mm

#### Graft

Woven Polyester

#### **Body Lengths**

▶ 80-100-120-and 140mm



#### PRODUCT INDICATIONS

#### Disease

Complex Aneurysms

#### Regulatory Status

Custom Made Device

#### **Anatomical Region**

 Infrarenal, juxtarenal, pararenal and paravisceral zones

#### AVAILABILITY

**Delivery Time** 

▶ 5 Weeks Delivery Time\*



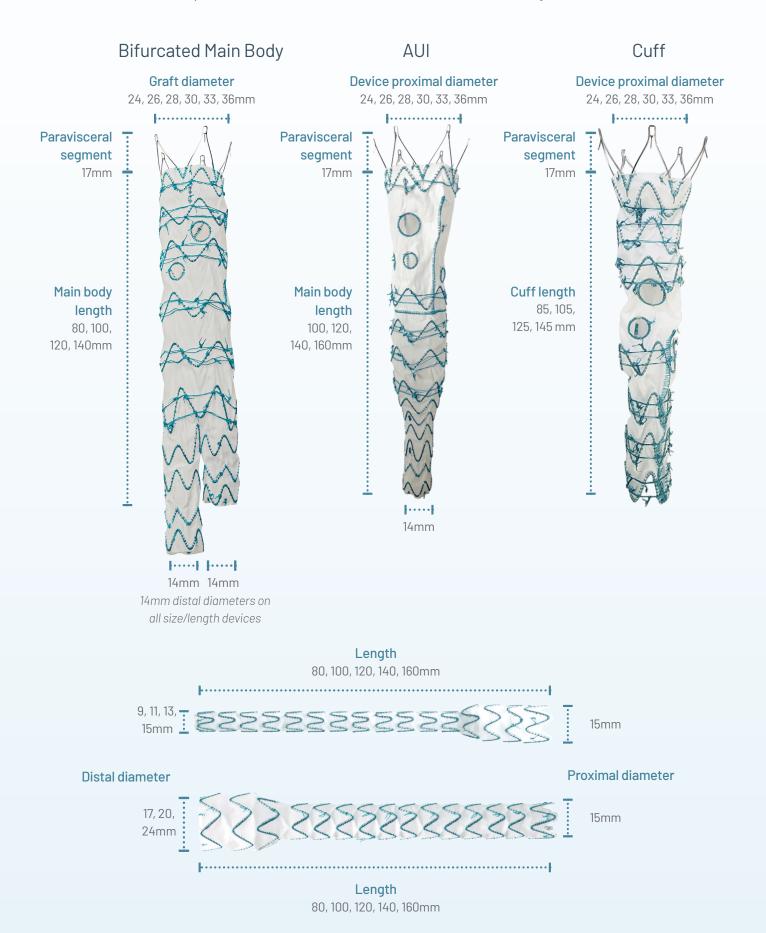
### Fenestrated TREO® Key Features

- ▶ Trimodular System\*\*
- Reliable Staged Expansion
- ► Freedom to Position Fenestrations
- Optimised Stent Configuration
- ▶ Ability to Cannulate from Above
- ▶ Highly Visible Markers
- ▶ Low Profile Delivery System\*\*

# Trimodular System

### 3-Piece System and Unique Limb Taper Design

The Fenestrated TREO platform is based on the standard TREO trimodular system.

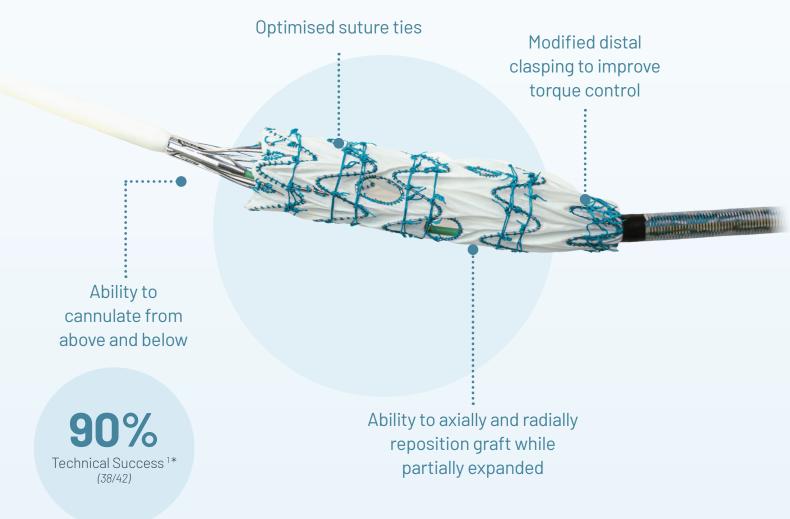


# Reliable staged expansion

### Controlled deployment

"After first deployment, the endograft is still constrained to 20 mm by circular diameter reducing ties, making it easy to maneuver the endograft, and adjust the position of the fenestration before the target branches "1

Vessel diameter in the visceral area	Graft diameter	Constrained graft diameter
19-21mm	24mm	16mm
21-23mm	26mm	16mm
23-25mm	28mm	18mm
25-27mm	30mm	19mm
27-30mm	33mm	22mm
30-32mm	36mm	24mm

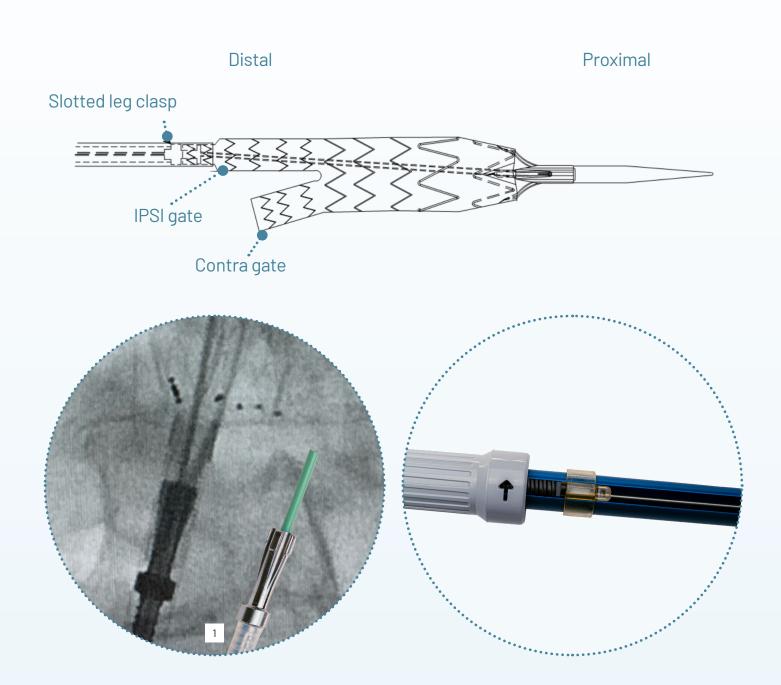


<sup>\*</sup>Technical success was defined as successful endovascular implantation of the stent graft with preservation of antegrade flow to the target vessels, and absence of type 1 or 2 endoleak (EL) at the first postoperative computed tomography angiography

<sup>1.</sup> Yeung et al. (2024). Endovascular Repair of Juxtarenal and Pararenal Abdominal Aortic Aneurysms Using a Novel Low-Profile Fenestrated Custom-Made Endograft: Technical Details and Short-Term Outcomes. Journal of Endovascular Therapy.

# Excellent Torque Control with Distal Leg Clasp

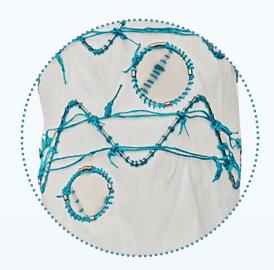
- Provides improved proximal and distal control of the device
- ▶ Improves cranial/caudal movements of the device before ipsilateral leg deployment
- Prevents premature deployment of the ipsilateral leg



### Freedom to Position Fenestrations

### Accommodating a Variety of Anatomies

- Up to 5 Fenestrations
- Freedom to position stents and fenestrations as required
- Cannulation from above possible
- Reinforced Fenestrations with Nitinol rings
- Radiopaque marker for improved visualisation and alignment accuracy
- 3mm minimum space requirement between fenestrations
- Fenestration sizes up to 12mm
- Staged expansion using optimized circumferential reduction ties maintain fenestration alignment with the target vessel



"Fenestration position and main body design can be widely customised according to specific preoperative anatomy. " 2

64% Patients treated with a device with 4 fenestrations 1 (27/42)



# Optimised Stent Configuration

### Designed for Flexibility

- ▶ Fully configurable support positioning for optimal fenestration placement
- Main body can allow up to 40mm of free space between stents for fenestration placement
- Additional sealing stents can be added to provide a longer proximal sealing zone



O%
Type la Endoleak
at the first CT scan¹
(0/42)



Fully supported main body



Partially supported main body

<sup>&</sup>quot;The design includes an option for an unsupported part at the visceral and renal level in the main body of the endograft, enhancing flexibility at the fenestrations. It could diminish limitations in positioning of fenestrations, especially if the patients received a previous aortic repair."

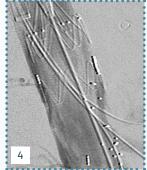
### Ability to Cannulate from Above

### Easy Visceral Vessel Cannulation

- Multiple options for optimal cannulation approach
- ▶ Faster and safer access for dealing with narrow anatomies
- Enhanced control and manipulation for ancillary devices









# Highly Visible Markers

### Visibility for Precise and Accurate Deployment





<sup>\*</sup>The 3 occluded target vessels were in one patient with a previously diagnosed coagulation disorder \*\*Median follow-up was 101 (2-620) days

<sup>1.</sup> Yeung et al. (2024). Endovascular Repair of Juxtarenal and Pararenal Abdominal Aortic Aneurysms Using a Novel Low-Profile Fenestrated Custom-Made Endograft: Technical Details and Short-Term Outcomes. Journal of Endovascular Therapy.

<sup>4.</sup> Images courtesy of Peter Bungay

<sup>5.</sup> Image courtesy of Giovanni Pratesi

# Low Profile Delivery System\*

### **Enabling Percutaneous Access**

"This device could offer easier iliac access and navigation, which in turn could result in a more controlled deployment for accurate placement."

19Fr

Main Body	Leg Extension		
24 - 36mm	9 to 15mm	17 - 24mm	
19Fr(OD)	13Fr(OD)	14Fr(OD)	

### 60cm low profile sheath Reducing ties with hydrophillic coating Reducing ties mechanism allows graft and flexible tip for easier repositioning until completely opened navigation Proximal clasping The clasp mechanism keeps control of deployment and Precise delivery system allows precise placement The mechanical deployment with cranial and caudal provides controlled and stable adjustment before the bare stent-graft deployment stent is released

77%
Patients treated with a Percutaneous Approach 1 (34/42)

\*Based on TREO Abdominal Stent-Graft System

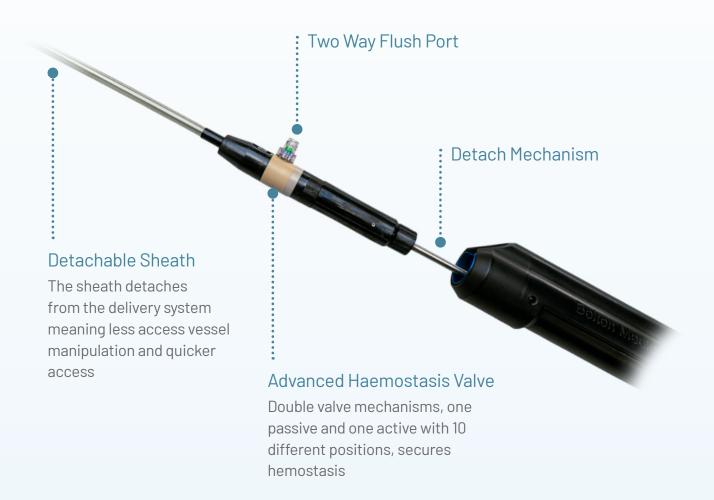
Introducer sheath

# Low Profile Delivery System\*

### Leave-Behind Sheath

Fenestrated TREO shares the same detachable sheath mechanism as the standard TREO delivery system:

"The leave-behind sheath can act as a conduit for leg extensions, reducing the procedure time and protecting the access vessel intima from the tracking of a second device." 3



\*Based on TREO Abdominal Stent-Graft System

# Endovascular Repair of Juxtarenal and Pararenal Abdominal Aortic Aneurysms Using a Novel Low-Profile Fenestrated Custom-Made Endograft: Technical Details and Short-Term Outcomes

Yeung, Nederhoed, Tran, Di Gregorio, Pratesi, Bastianon, Melani, Riambau, Bloemert-Tuin,. Hazenberg, van Herwaarden, Balm, Lely, van der Meijs, Blankensteijn, Hoksbergen, and Jongkind

#### Background







#### Short-term Results

Target Vessel Cannulation Success^	Patients treated with a Percutaneous Approach	Technical Success*	Type la Endoleak At the first post-op CT scan	Type Ib Endoleak At the first post-op CT scan
99%	<b>77</b> %	90%	0%	2.4%
(148/149)	(34/42)	(38/42)	(0/42)	(1/42)

### Long-term Results

• Follow up data available in 11 patients (11/42; 26.2%) at median 361 days (82 - 620)\*\*

Type la and lb Endoleak	Sac Shrinkage***	Target Vessel Patency****^	
0%	<b>55</b> %	98%	
(0/11)	(6/11)	(146/149)	







<sup>^</sup>Target Vessel Cannulation Success and Target Vesel Patency data is based on total number of vessels

<sup>&</sup>quot;The results of these first experiences using the custom-made fenestrated TREO®[...] are promising. In this study, there was a high success rate for the cannulation of the target vessels and placement of the bridging stents through the fenestrations (99%). There was a low short-term mortality and morbidity rate in these patients of which 17% had previous AAA repair[...]"

<sup>\*</sup>Technical success was defined as successful endovascular implantation of the stent graft with preservation of antegrade flow to the target vessels, and absence of type 1 or 2 endoleak (EL) at the first postoperative computed tomography angiography

<sup>\*\* 11</sup> patients received more than 1 CTA during a median follow-up of 361 days (82-620) in the outpatient clinic

<sup>\*\*\*</sup> Sac Shrinkage>5mm

<sup>\*\*\*\*</sup> The 3 occluded target vessels were in one patient with a previously diagnosed coagulation disorder

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