

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

- ▶ Infraarenal, 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**

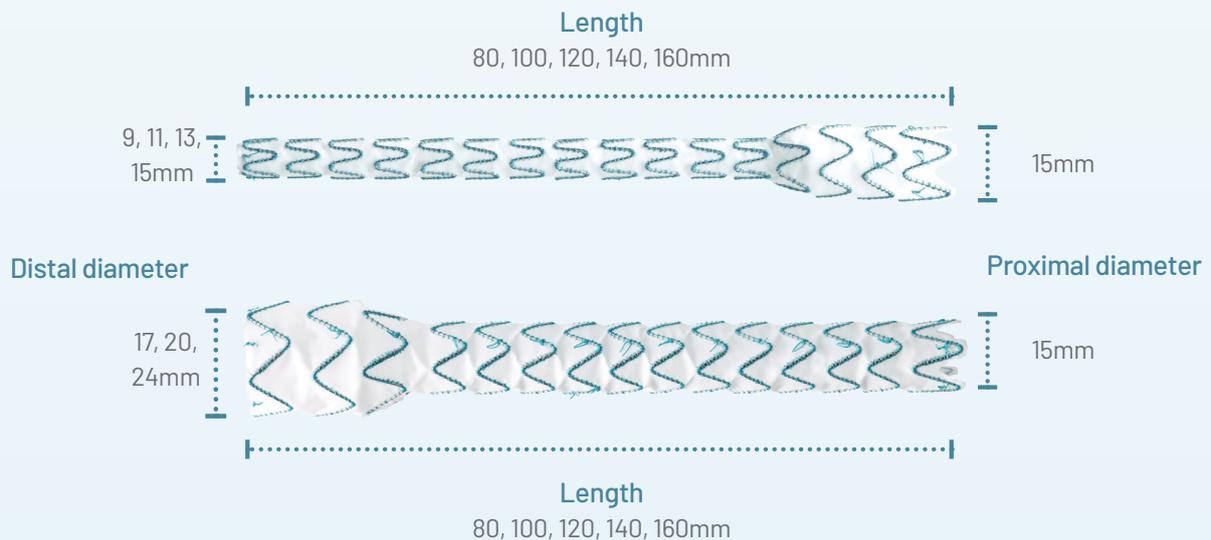
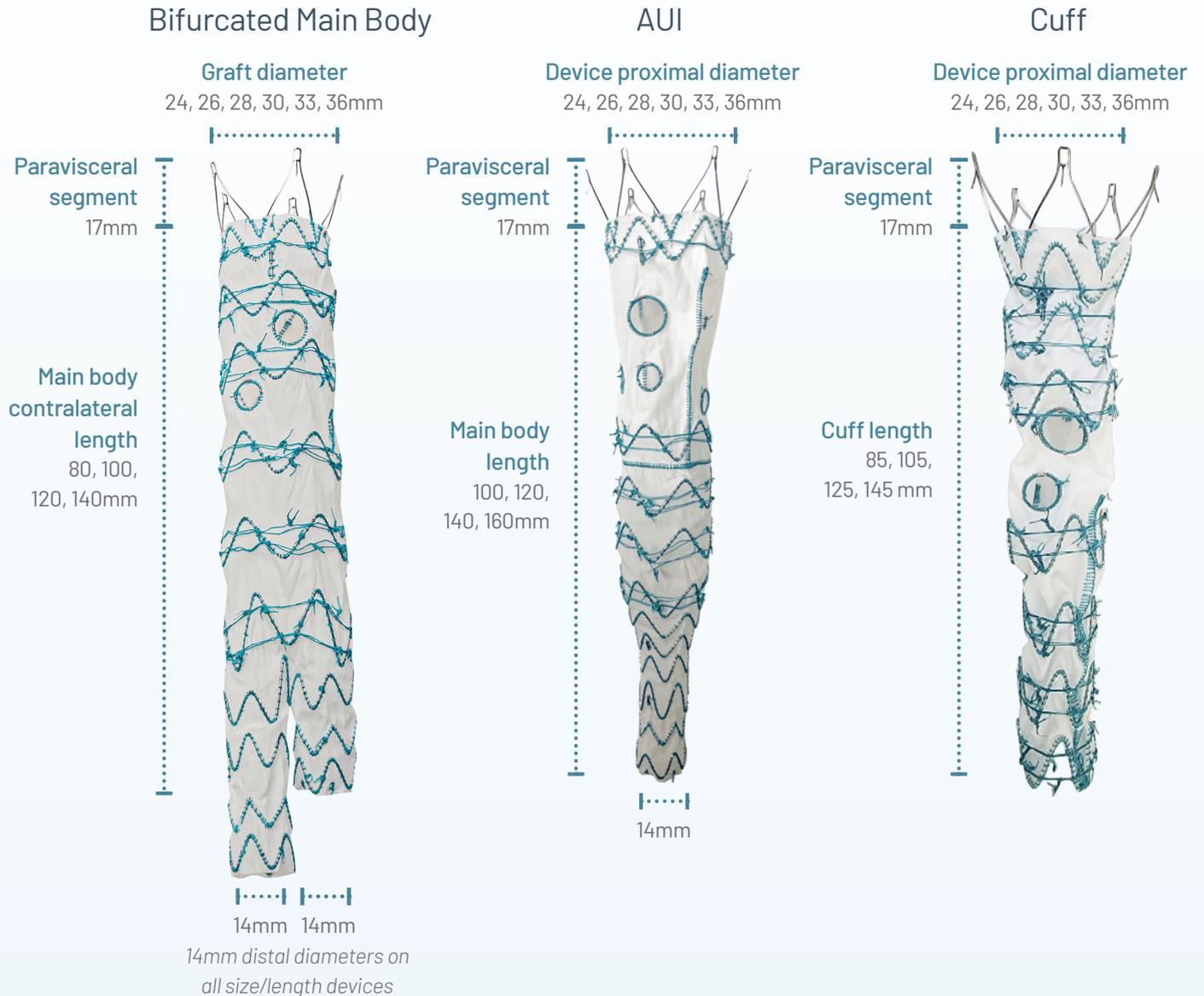
*Delivery time given as an estimate only. Please check current delivery times with your representative.

**Based on TREO Abdominal Stent-Graft System

Trimodular System

3-Piece System and Unique Limb Taper Design

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

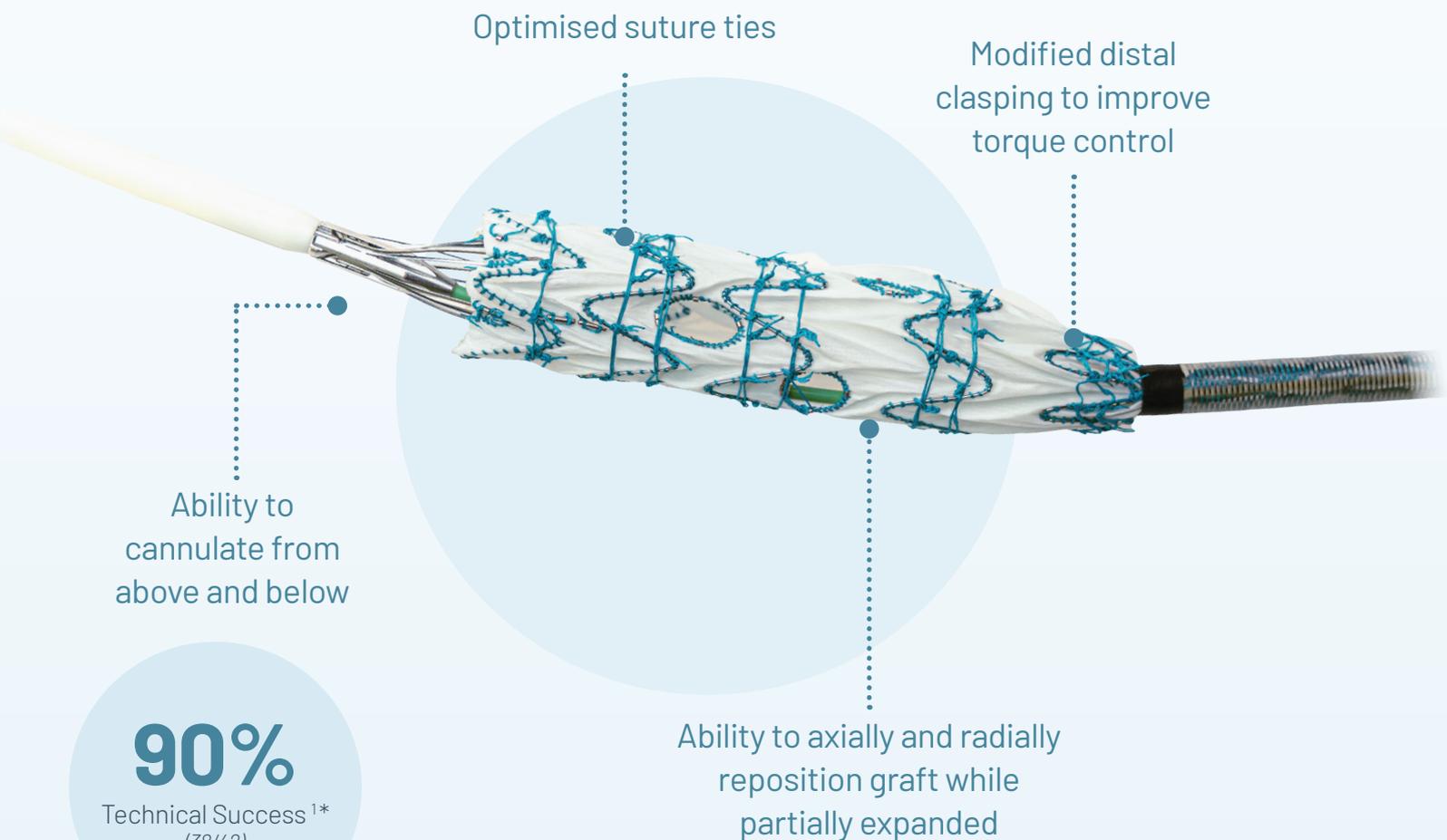


Reliable staged expansion

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

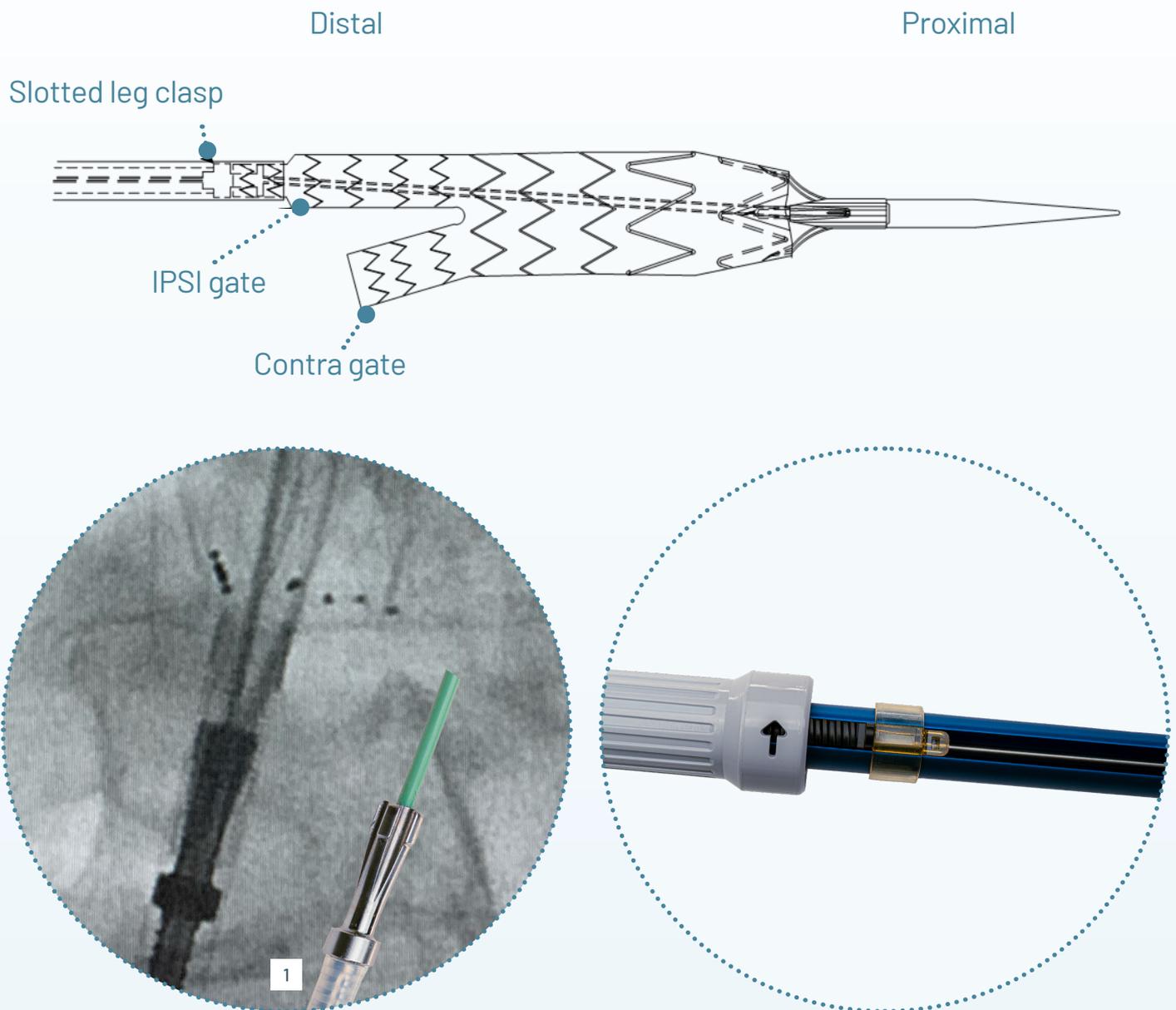
Vessel diameter in the visceral area	Graft diameter	Constrained graft diameter
20mm	24mm	16mm
20mm	26mm	16mm
22mm	28mm	18mm
23mm	30mm	19mm
26mm	33mm	22mm
28mm	36mm	24mm



*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

Excellent Torque Control with Distal Leg Clasp

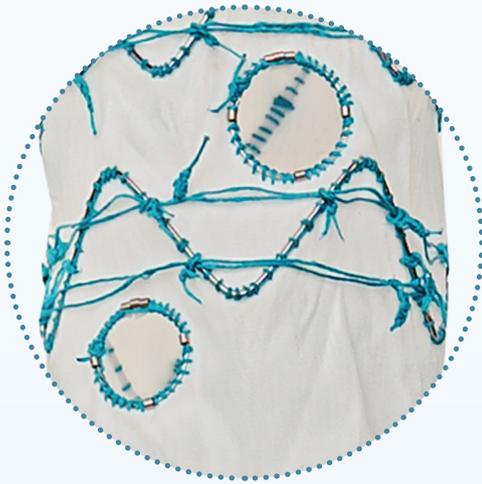
- ▶ Provides proximal and distal control of the device
- ▶ Improves cranial/caudal movements of the device before ipsilateral leg deployment
- ▶ Prevents premature deployment of the ipsilateral leg



Freedom to Position Fenestrations

Accommodating a Variety of Anatomies

- ▶ **Up to 6 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
fenestrations¹
(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

17%

Patients treated with a
previous aortic repair¹
(7/42)

0%

Type Ia Endoleak
at the first CT scan¹
(0/42)



Fully supported main body



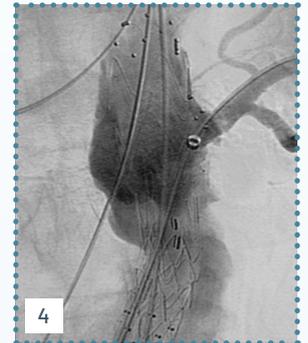
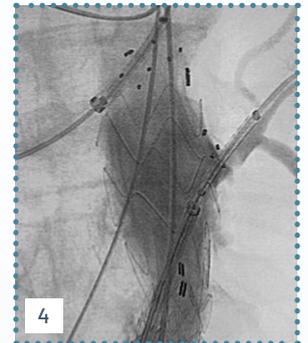
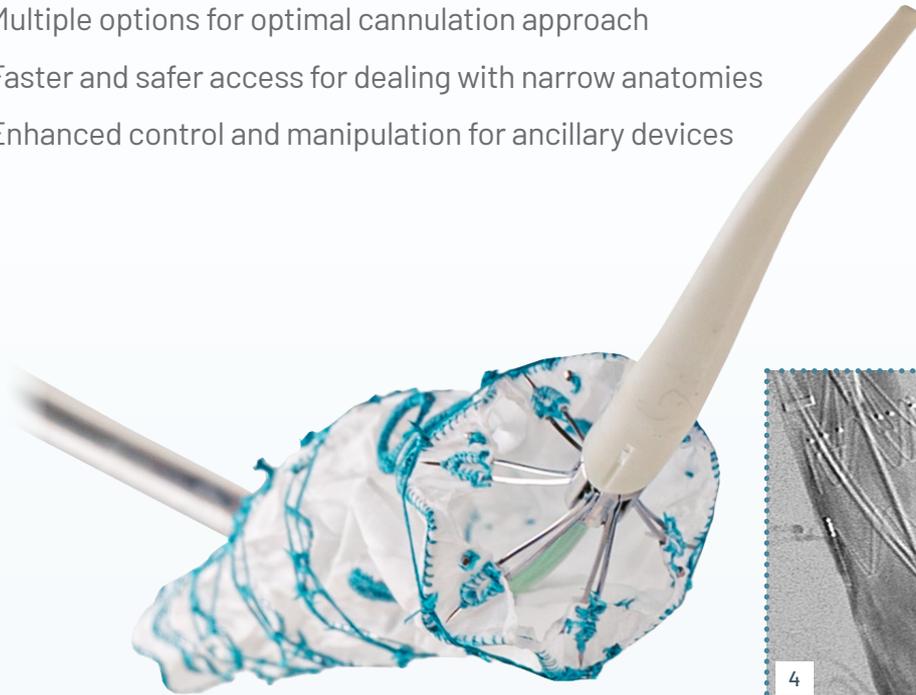
Partially supported main body

“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.”¹

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

Anterior Markers

Fenestration Markers

3 Markers

1 Marker

1 Marker

1 Marker

Posterior Marker

Lateral Marker

99%

Target Vessel
Cannulation Success¹

(148/149)

98%

Target Vessel Patency*¹

During follow-up**

(146/149)

¹The 3 occluded target vessels were in one patient with a previously diagnosed coagulation disorder
²Median follow-up was 101 (2-620) days

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.”¹

19 Fr

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



Reducing ties
Reducing ties mechanism allows graft repositioning until completely opened

Proximal clasp
The clasp mechanism keeps control of deployment and allows precise placement with cranial and caudal adjustment before the bare stent is released

Precise delivery system
The mechanical deployment provides controlled and stable stent-graft deployment

Introducer sheath
60cm low profile sheath with hydrophilic coating and flexible tip for easier navigation

81%
Patients treated with a Percutaneous Approach¹
(34/42)

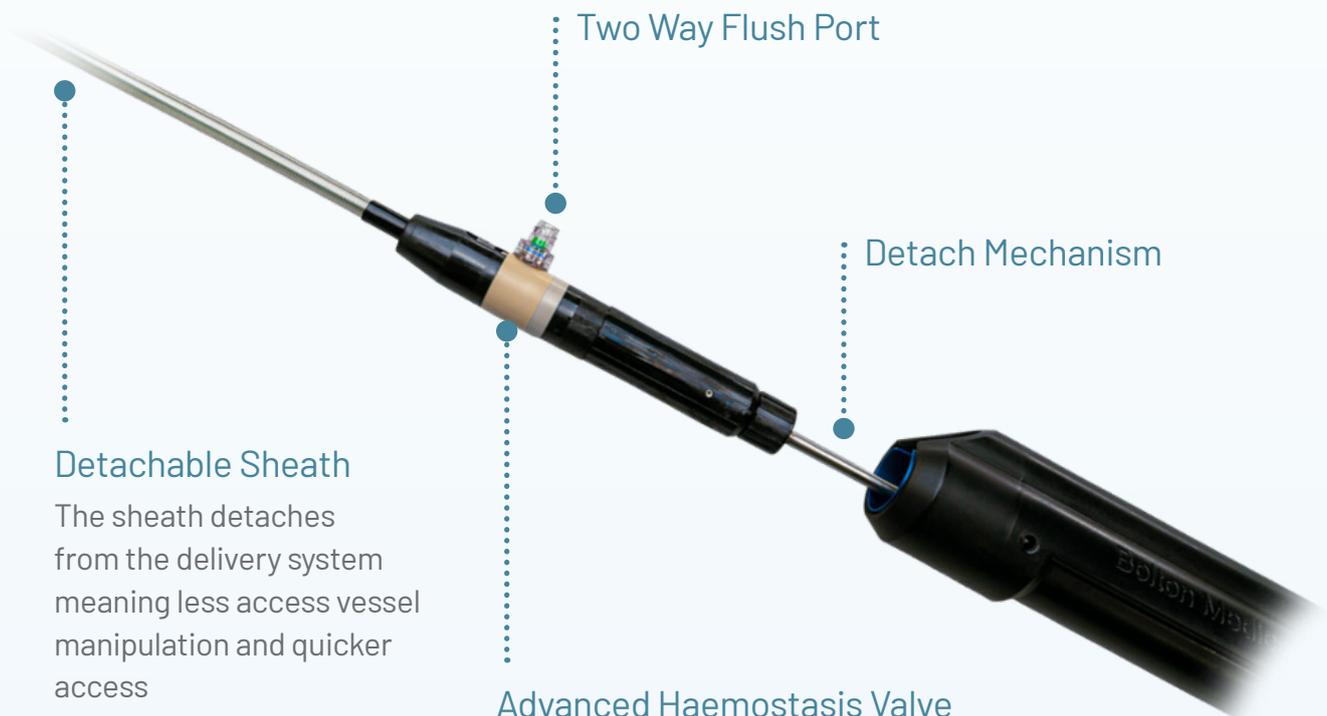
*Based on TREO Abdominal Stent-Graft System

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



Detachable Sheath

The sheath detaches from the delivery system meaning less access vessel manipulation and quicker access

Two Way Flush Port

Detach Mechanism

Advanced Haemostasis Valve

Double valve mechanisms, one passive and one active with 10 different positions, secures hemostasis

*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



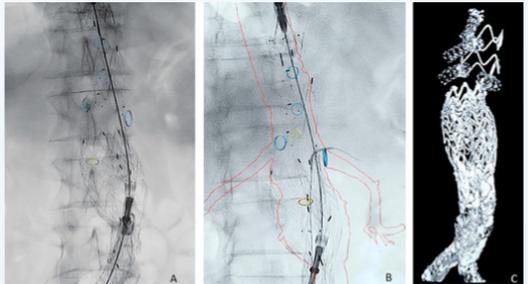
Short-term Results

Target Vessel Cannulation Success [^]	Patients treated with a Percutaneous Approach	Technical Success*	Type Ia Endoleak At the first post-op CT scan	Type Ib Endoleak At the first post-op CT scan
99%	81%	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 Ia and Ib Endoleak	Sac Shrinkage***	Target Vessel Patency**** [^]
0%	55%	98%
(0/11)	(6/11)	(146/149)



[^]Target Vessel Cannulation Success and Target Vesel Patency data is based on total number of vessels

“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 [...]”

*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

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

*** Sac Shrinkage>5mm

**** The 3 occluded target vessels were in one patient with a previously diagnosed coagulation disorder

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