Choosing the right FEVAR for the right patient

Jürgen Falkensammer

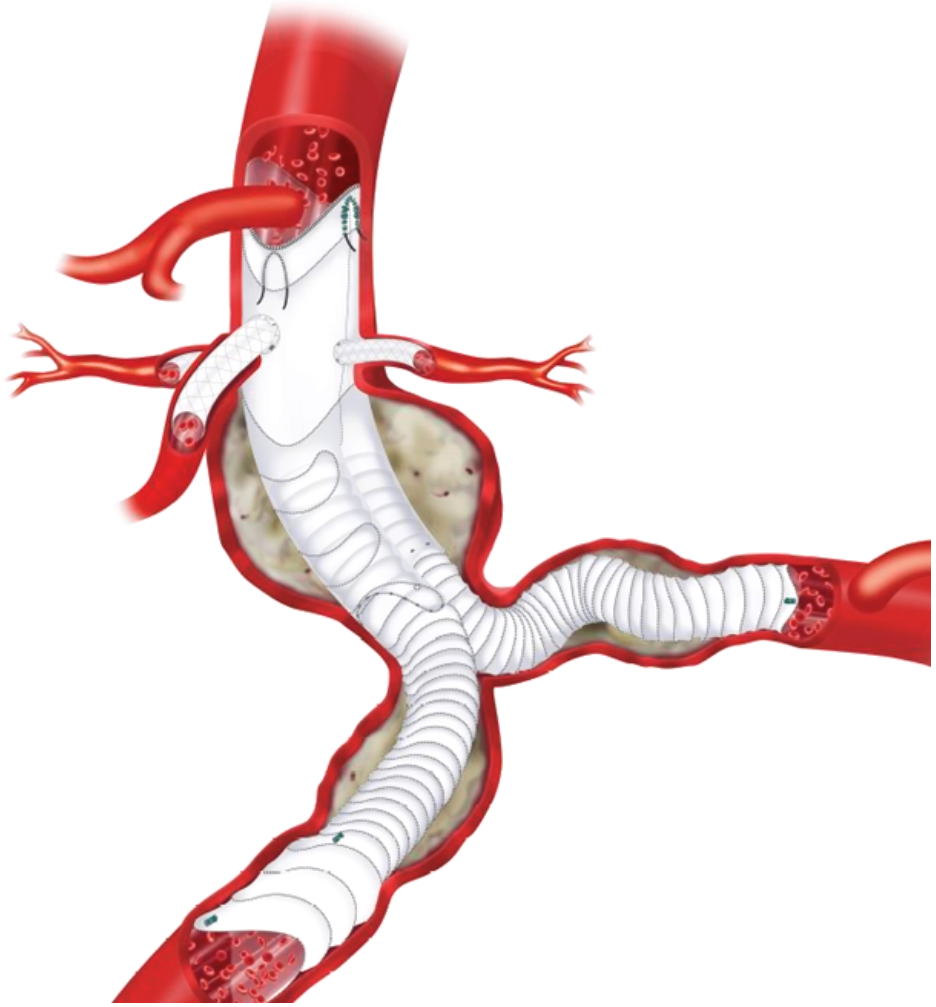
Disclosures

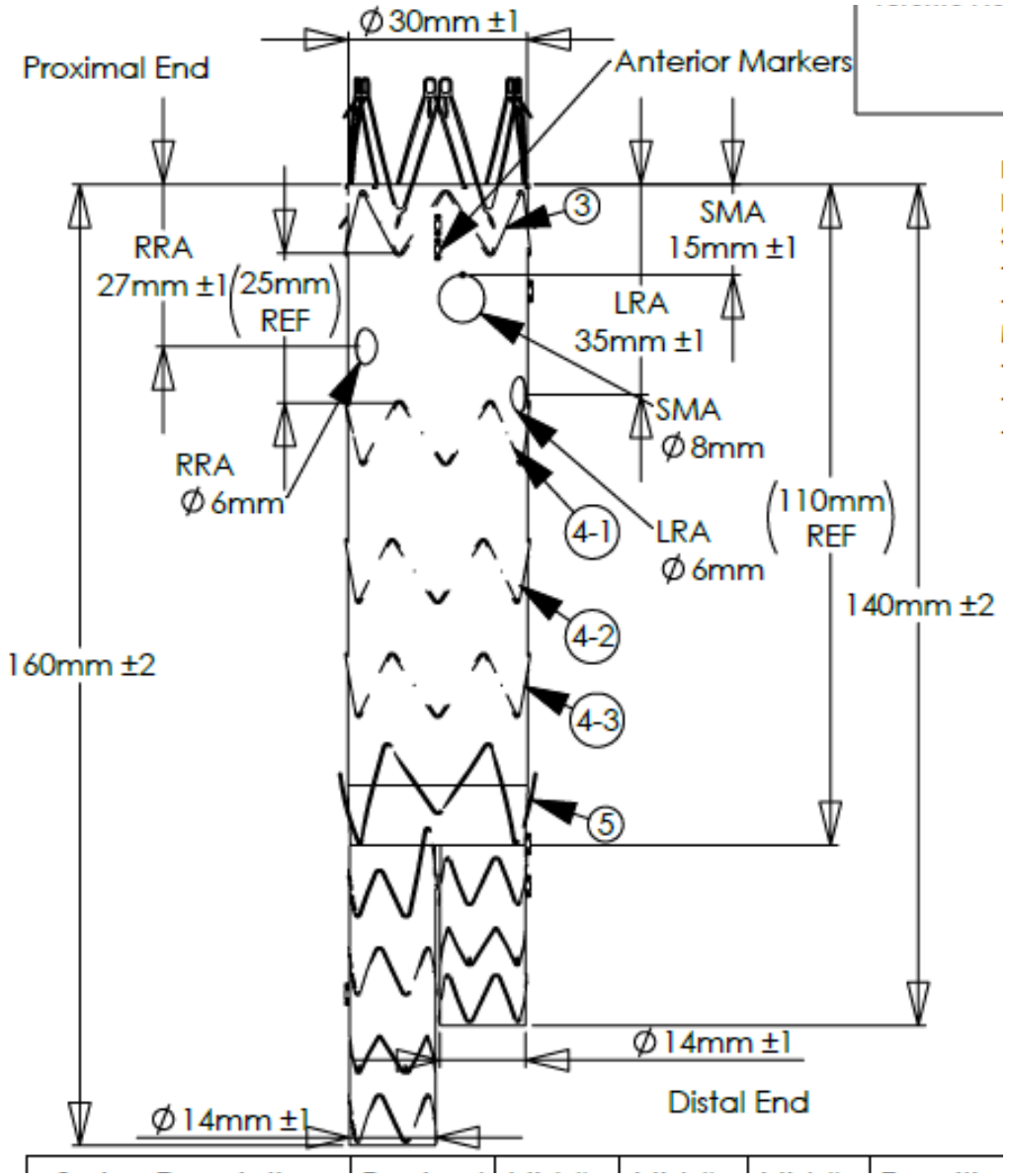
Speaker name: Jürgen Falkensammer

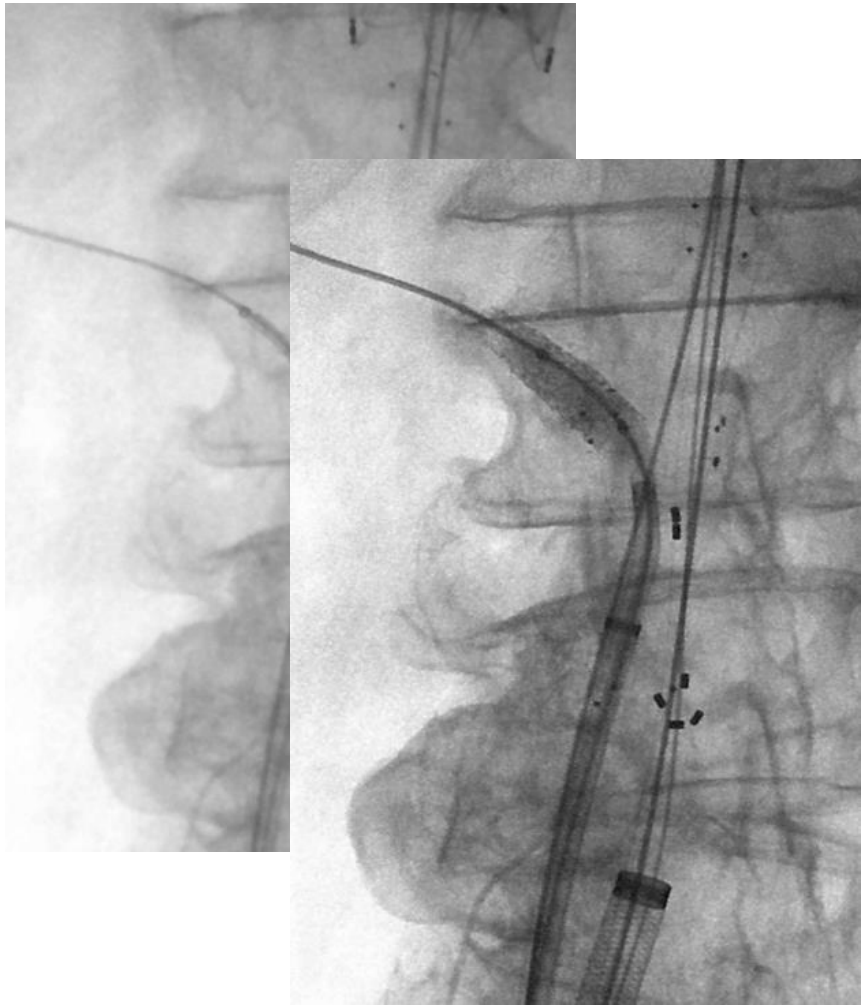
☒ I have the following potential conflicts of interest to report:

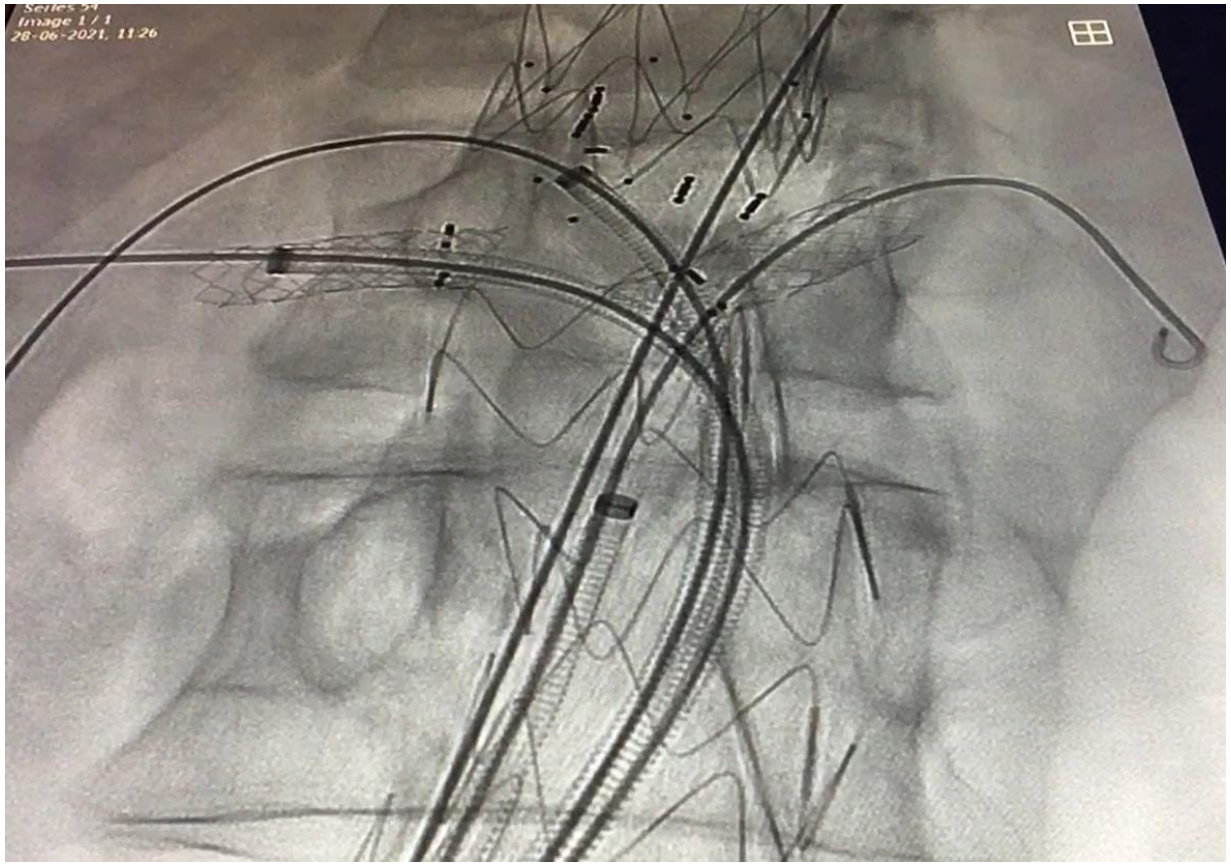
- ☐ Receipt of grants/research support
- ☒ Receipt of honoraria and travel support
- ☐ Participation in a company-sponsored speaker bureau
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company

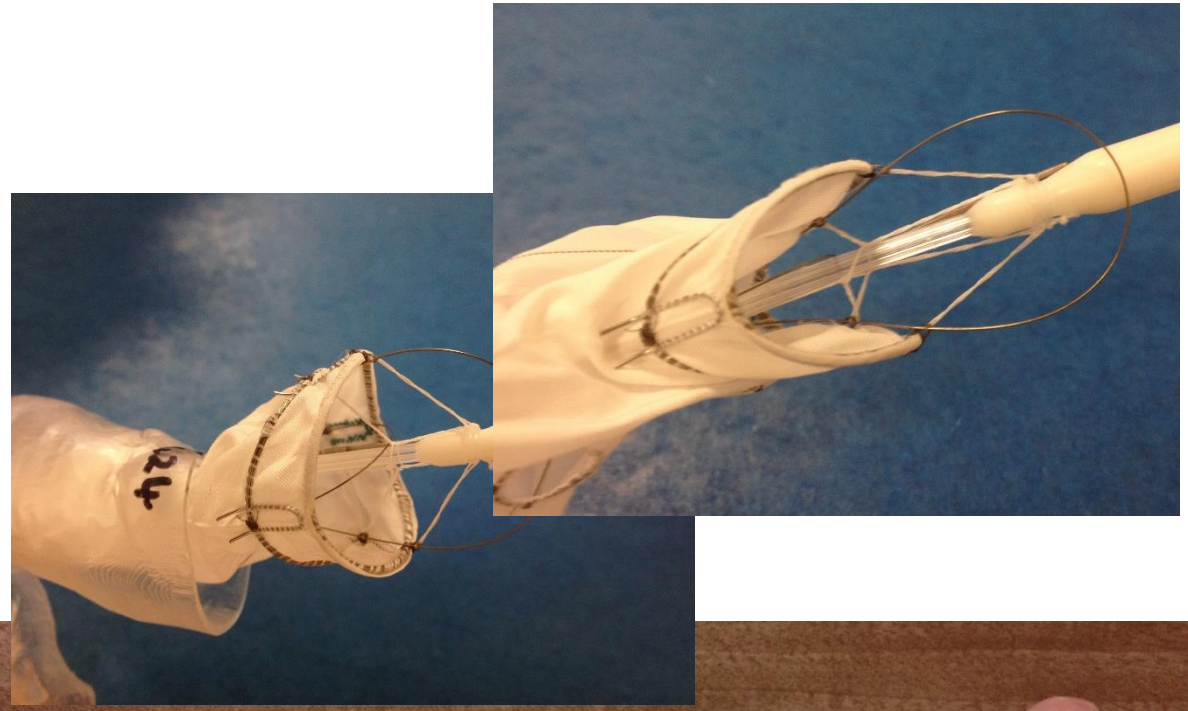
☐ I do not have any potential conflict of interest

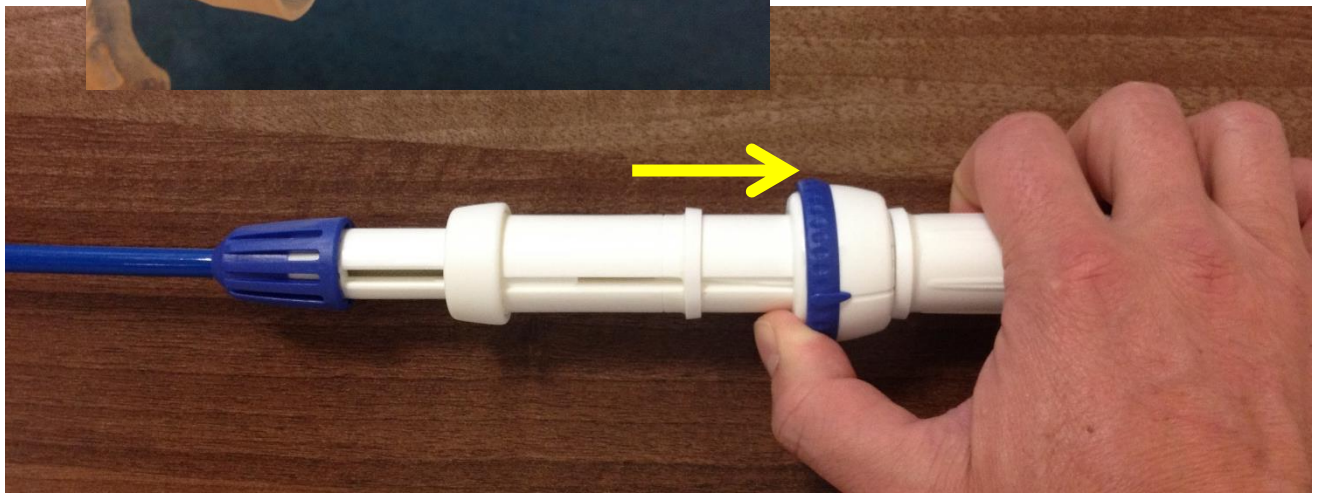


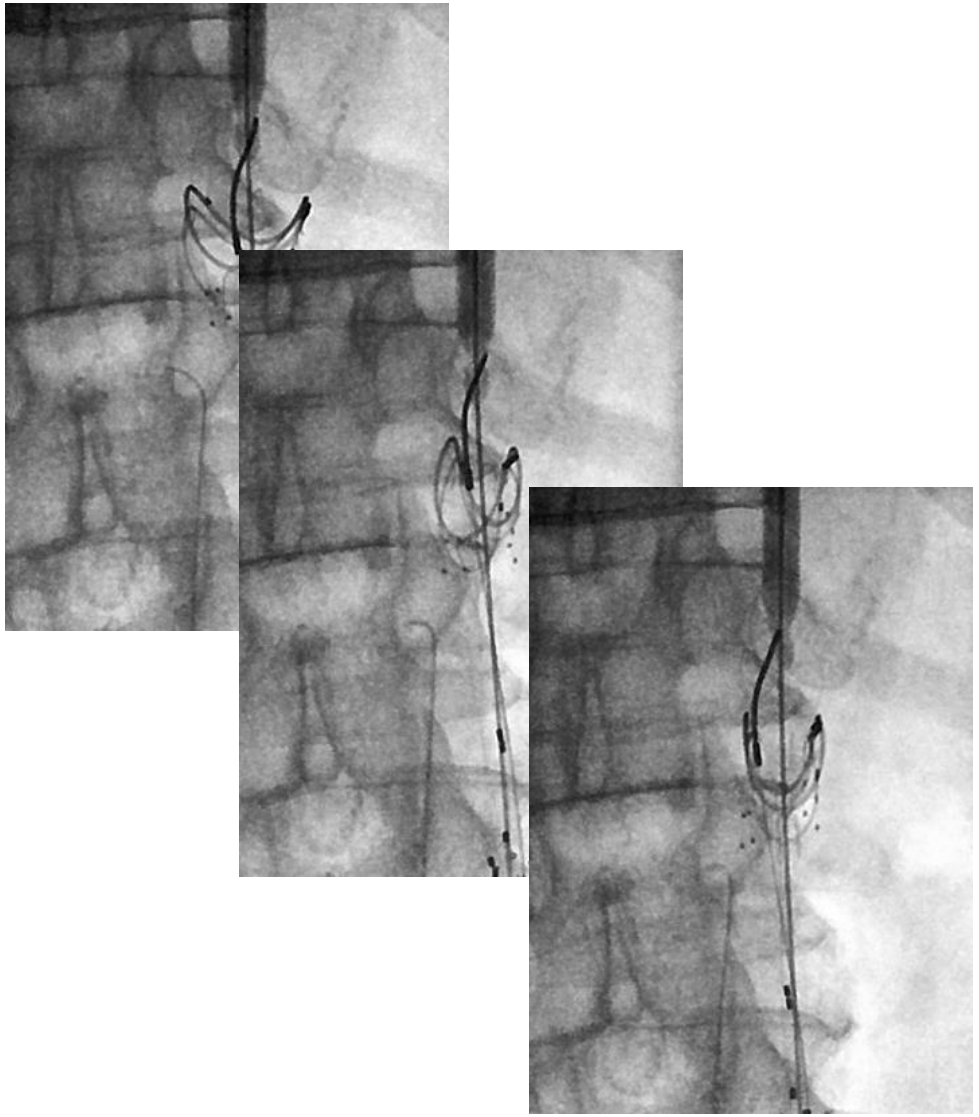

Ø 30mm ±1
Proximal End
Anterior Markers
3
SMA
15mm ±1
RRA
27mm ±1
(25mm
REF)
LRA
35mm ±1
SMA
Ø 8mm
RRA
Ø 6mm
4-1
LRA
Ø 6mm
(110mm
REF)
140mm ±2
160mm ±2
4-2
4-3
5
Ø 14mm ±1
Distal End
Ø 14mm ±1



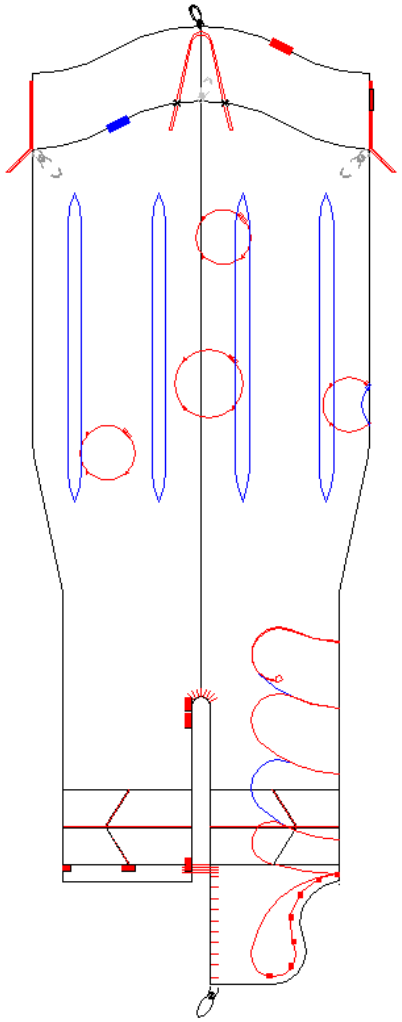

Series 34
Image 1 / 1
28-06-2021, 11:26







f-Anaconda



→ 22.3F delivery system

→ max. length from top to flow divider: 100mm

→ graft diameter: 21.5, 23.5, 25.5, 28, 30.5, 32 & 34 (36) mm

→ max. 5 fenestrations

f-Anaconda

→ 22.3F delivery system

→ max. length from top to flow divider: 100mm

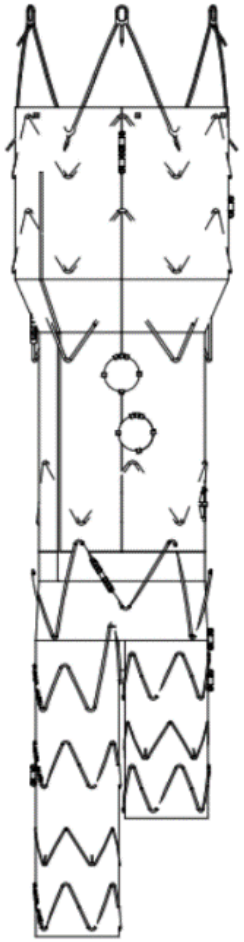
→ graft diameter: 21.5, 23.5, 25.5, 28, 30.5, 32 & 34 (36) mm

→ max. 5 fenestrations

→ up to 60mm of unsupported space for fenestration placement

→ max. angulation 90°

f-Treo



→ 19Fr delivery system

→ max. length from top to flow divider: 120mm

→ graft diameter: 24mm, 26mm, 28mm, 30mm, 33mm and 36mm

→ up to 5 fenestrations

f-Treo

→ 19Fr delivery system

→ max. length from top to flow divider: 120mm

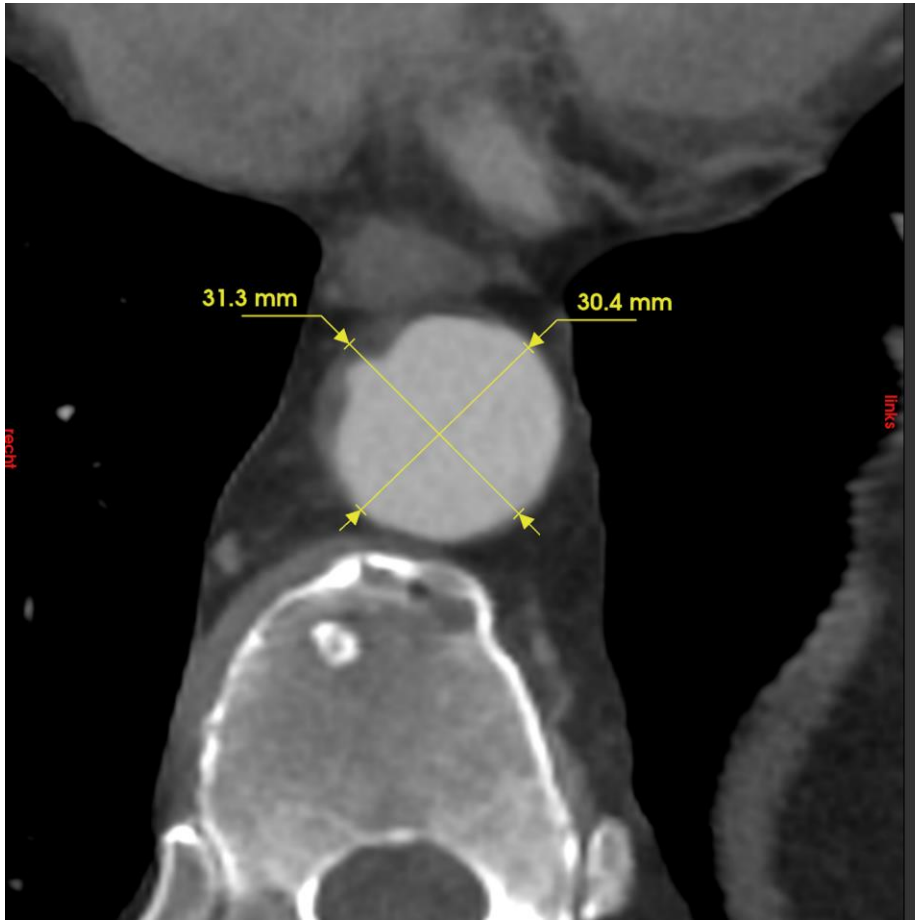
→ graft diameter: 24mm, 26mm, 28mm, 30mm, 33mm and 36mm

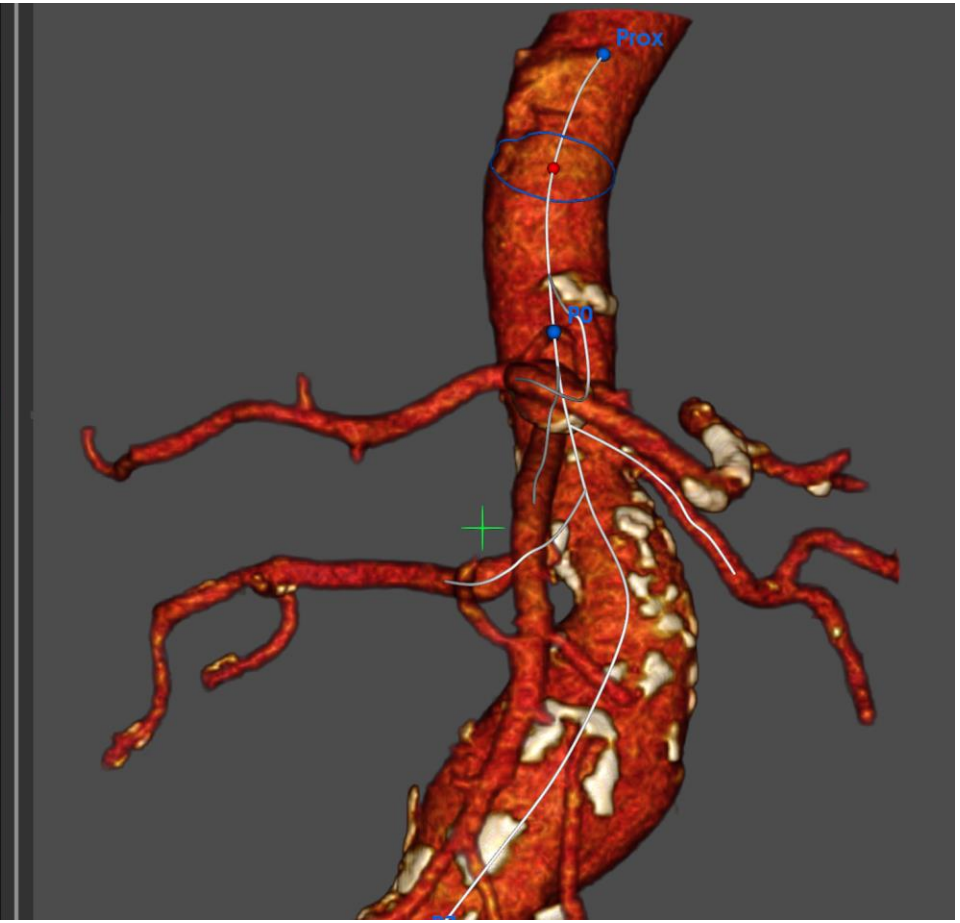
→ up to 5 fenestrations

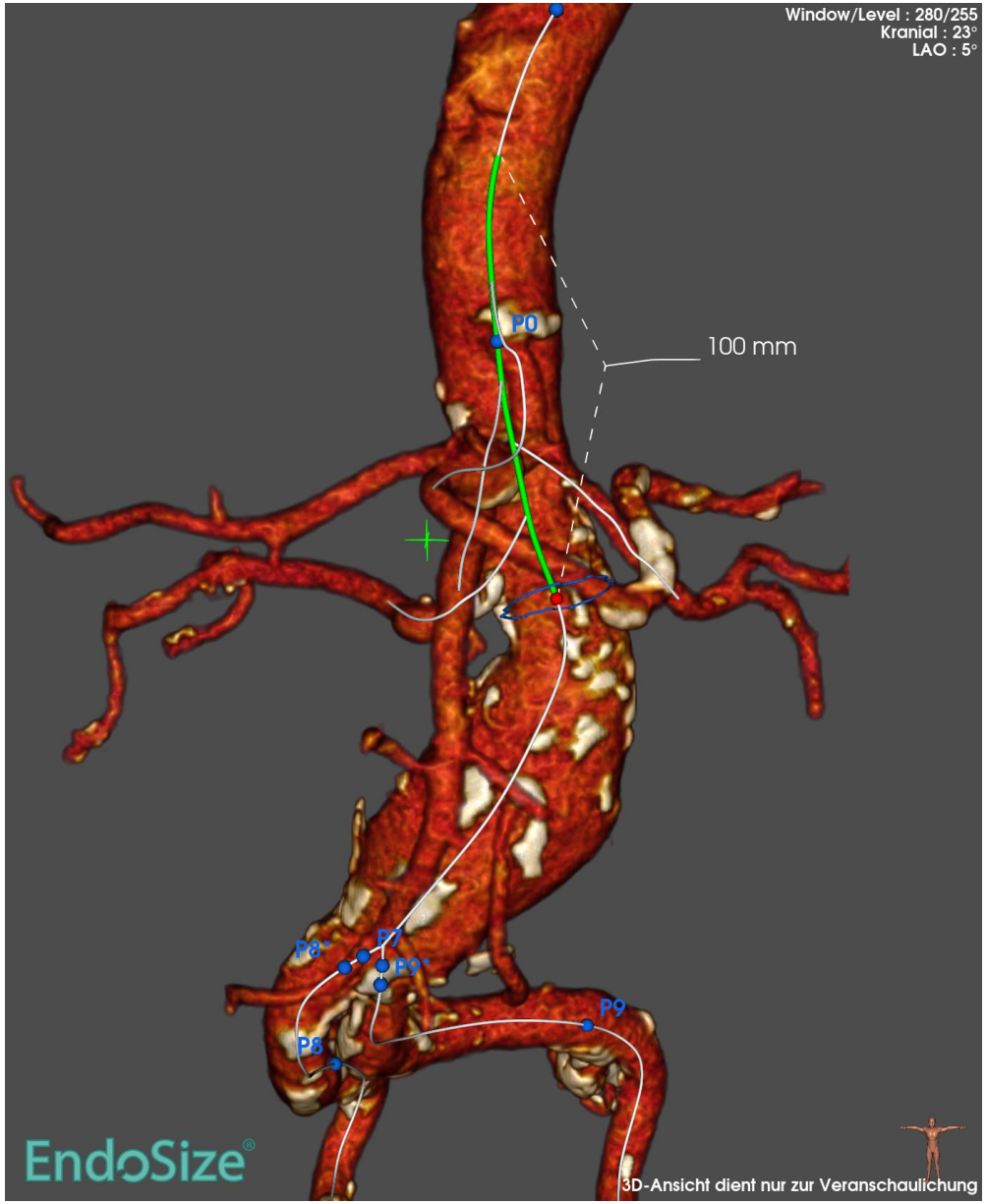
→ up to 40mm of free space between springs for fenestration placement

→ max. angulation? 70°?

Case





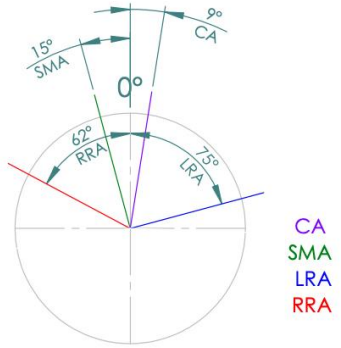

Window/Level : 280/255
Kranial : 23°
LAO : 5°
P0
100 mm
P8*
P7
P9*
P9
P8
EndoSize®
3D-Ansicht dient nur zur Veranschaulichung

L1	Bottom of CA to top of SMA ostium	14
L2	Bottom of the CA to the proposed centre of the SMA fenestration	19
L3	Bottom of the CA to the bottom of the SMA ostium	23
L5	Bottom of the CA to the proposed centre of the LRA fenestration	31
L6	Bottom of the CA to the proposed centre of the RRA fenestration	50
	Proximal Sealing Diameter	31
	Proximal Sealing Ring Size	CFD36
	Oversize	16.13%

Artery	Angle (°)	Ø Vessel (mm)	Ø Fenestration (mm)
Celiac	9	8	8
Superior Mesenteric	-15	8	8
Left Renal	75	6.5	7
Right Renal	-62	7.5	7

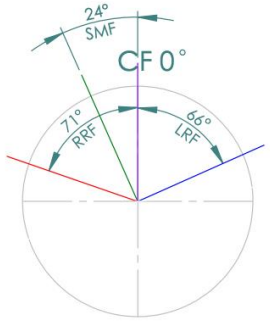
For joined bodies, the horizontal positions are based on the proximal ring diameter on the scheme image. These will be modified for the distal body diameter on the graft. Joining ring above CA fenestration.

Proximal body size - CFD36
Distal body size - CFD30

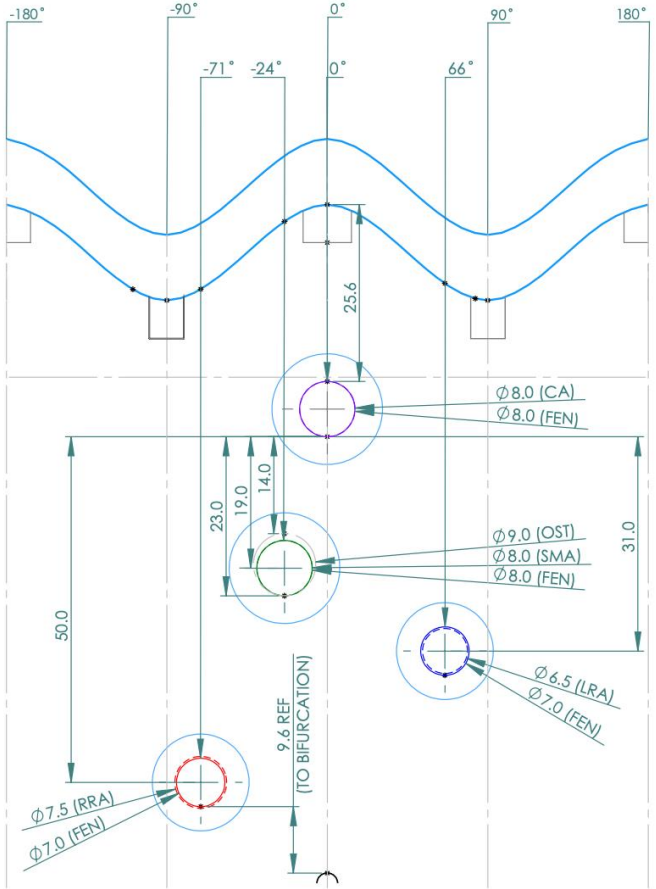


PATIENT MEASUREMENTS

CA
SMA
LRA
RRA



DEVICE MEASUREMENTS (CA)



OVERSIZE POSITION

fenestrated anaconda
device scheme Custom AAA Stent Graft System

PAT 4544-B1

TERUMO Aortic

Bifurcated Device
4 Fenestrations
Mid-ring Removed
Pleated
Peak to Bifurcation: 100 mm
Contralateral Flare Removed
Legs Lateral

Not to scale
All dimensions in mm unless otherwise stated

ISSUE	DATE	CHECKED BY	DESCRIPTION	ENGINEER
1	14 FEB 2024	AS014	1st Issue	SM015

NOTES:
1- All components are attached to the fabric using suture (H)
2- Three (3) apexes for each spring may present a tolerance of ± 2mm.
3- 2 proximal apexes of spring B1 are left unsewn. See view A & B.
4- One apex of spring D is offset as shown in drawing (use sewing template as needed for reference only).
5- Spring B1 is sewn INTERNAL.

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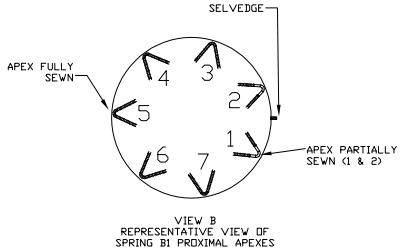
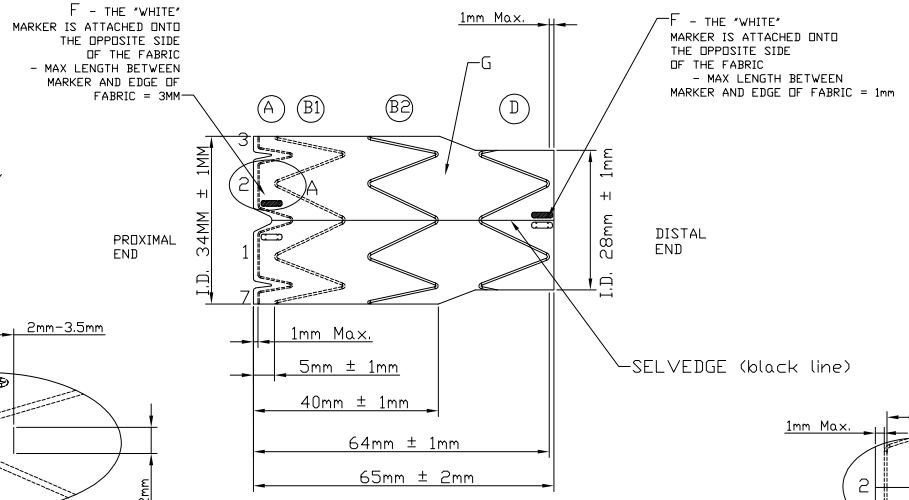
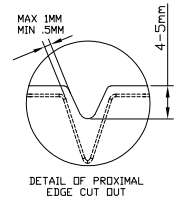
TERUMO AORTIC
Email: custommade@terumoaortic.com

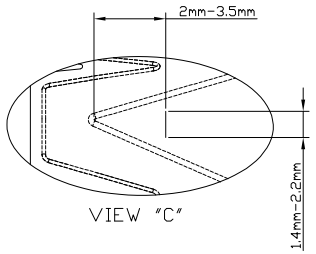
Physician Approval:

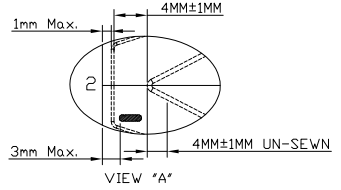
Date: Nov 11 2018

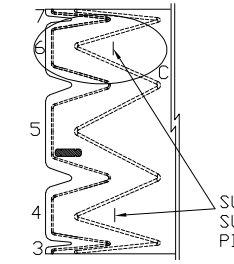












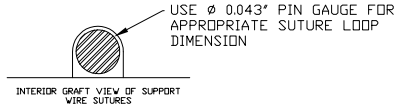


FIGURE I

INTRODUCER FR: 23FR
INTRODUCER LENGTH: 60CM
CUSTOM FEATURE(S): LARGE CONSTRAINING SLEEVE

ITEM I.D.	DESCRIPTION	PART NUMBER	QTY
A	34MM CROWN SPRING	2822-0579-07	1
B1-B2	34MM NBS PROXIMAL SPRING	2822-0575-07	2
D	28MM DISTAL SPRING	2822-0257-00	1
F	CYLINDRICAL MARKER	2822-0557	4
G	34MMX120MM FABRIC	2822-0625-07	1
H	5-0 SUTURE	2822-0315	8

	Name	Date
DRAWN	YT	11-08-18

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN MILLIMETERS TOLERANCES: N/A

MATERIAL: see individual component

FINISH: N/A

TERUMO Aortic

TITLE: 34MM/28MM X 65MM CUSTOM STENT GRAFT ASSEMBLY

SIZE: A | DWG NO.: 2833-0372-PAT 2024 | ECN

SCALE | SHEET


Window/Level : 280/255
Kranial : 15°
LAO : 2°
Prox
P0
110 mm
P8*
P7
P9*
P9
P8
EndoSize®
3D-Ansicht dient nur zur Veranschaulichung

Custom Solutions

Custom Device Design Approval Record

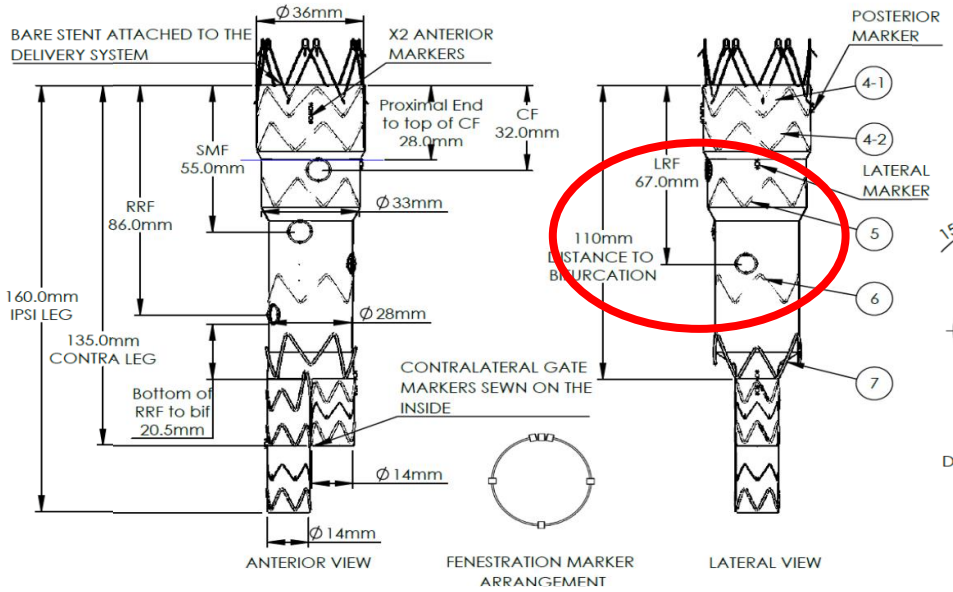
CP#: 05925
Document#: Form – 0514
Rev: A

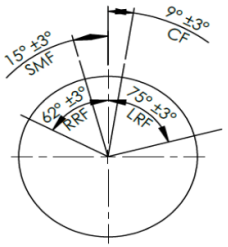
TERUMO Aortic

Case Identifier	Catalogue No.	Patient ID	Clinician	Engineer	Planner	Issue	Issue Date
PAT 4544-B1	28BC36B13514S196	RM221250	Dr. J Falkensammer	Arwa Hussein	Jamie Clucas	1	27 February 2024

Device Parameters

Device Type	Delivery System	Introducer OD & Length	IFU Reference
Fenestrated TREO	Fenestrated TREO	19Fr/60cm	LSPEC-2844-8507 Rev D





DEVICE MEASUREMENTS

SPRING DESCRIPTION	PROXIMAL	PROXIMAL	MIDDLE	MIDDLE	TRANSITION
SPRING NUMBER	4-1	4-2	5	6	7
CONSTRAINED TO SIZE [±2mm]	24	24	22	18	18

Patient Parameters

	Bottom of CA to middle of vessel (mm)	Vessel Diameter (mm)	Fenestration Diameter (mm)
CA	-	8	8
SMA	19	8	8
LRA	31	6.5	7
RRA	50	7.5	7

Notes:

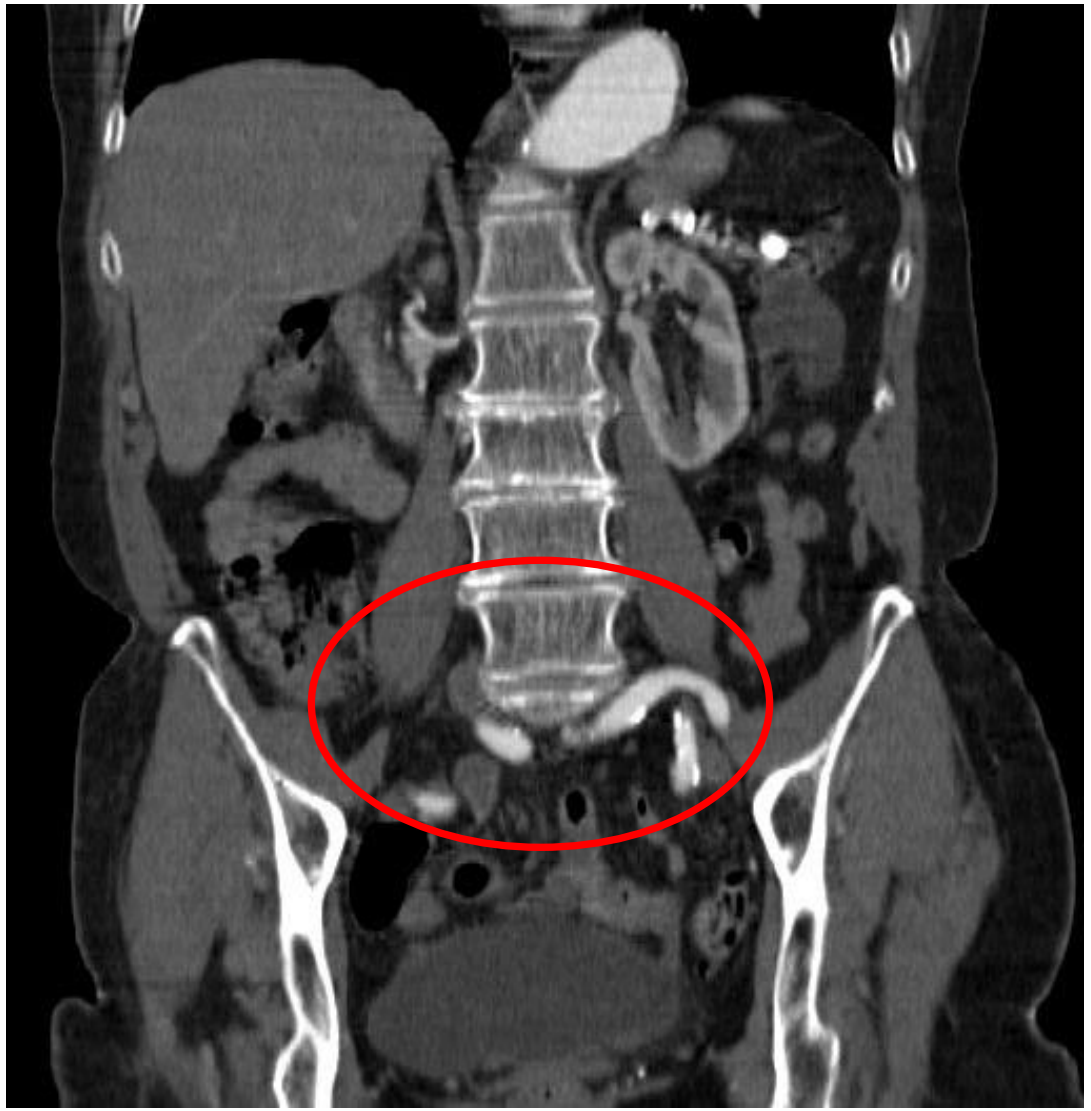
- Access Side - Right
- Legs in lateral orientation
- Lowest fenestration to bifurcation 20.5mm
- Distal markers at distal edge of contralateral leg
- Maximum and minimum overlap markers on lateral edge of each distal docking zone

Comments

Main body length reduced to 110mm.
Fabric landing 28mm above the CA.
Ipsilateral limb length increased to 50mm.
Contralateral limb length increased to 25mm.
CA MAL compression

Selection criteria

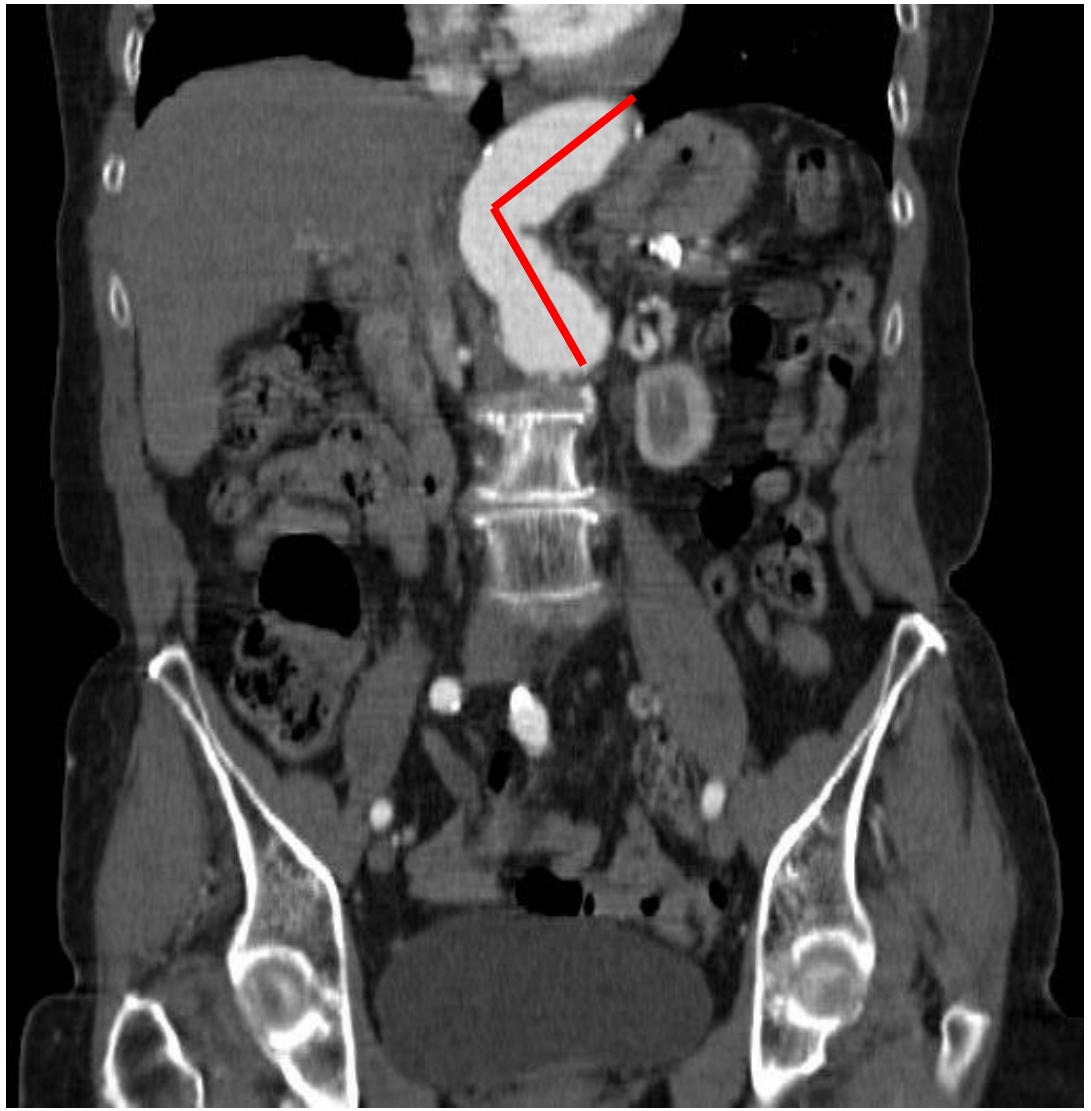
→ suitability (narrow or kinked) access vessels



Selection criteria

→ suitability (narrow or kinked) access vessels

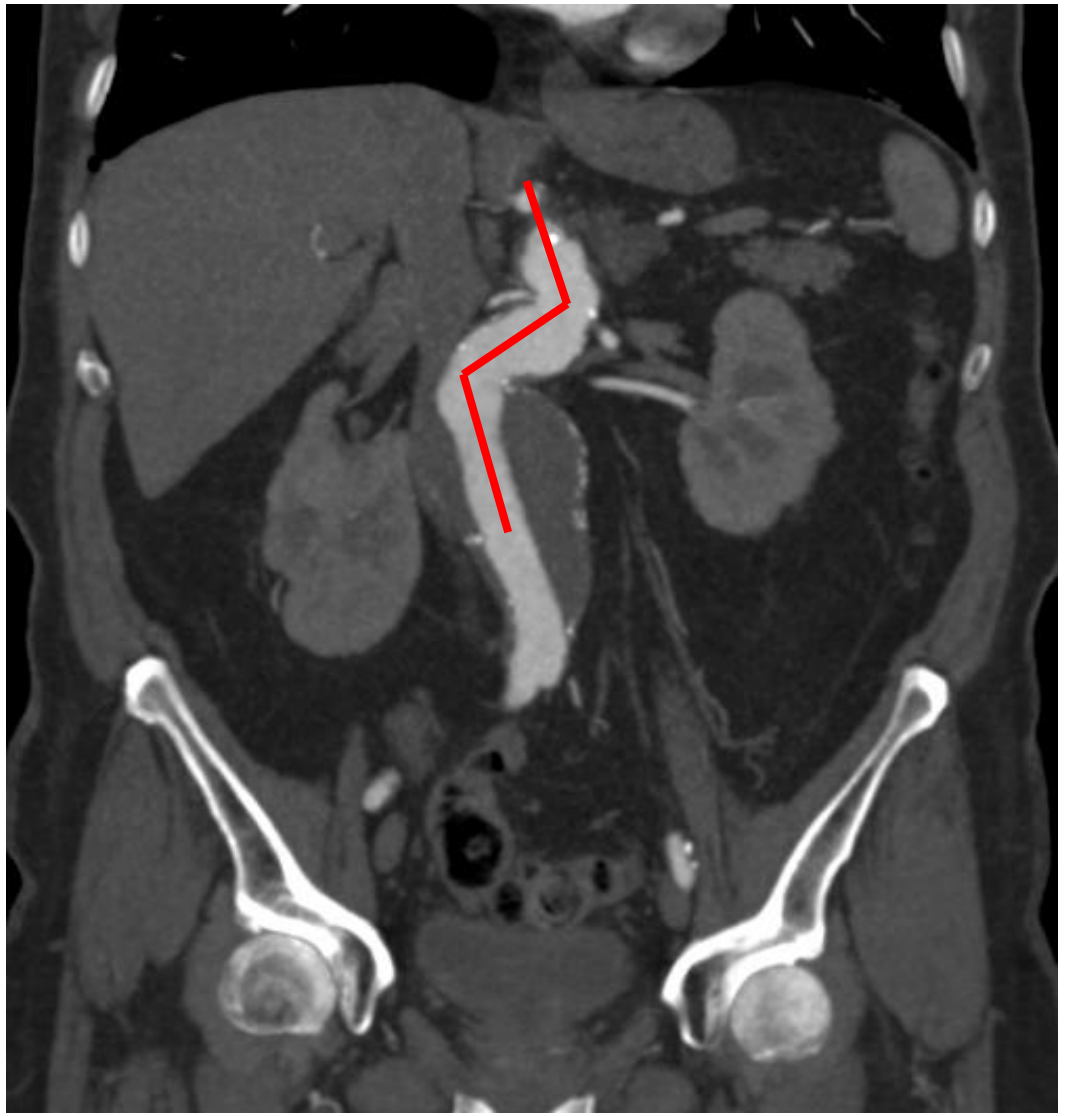
→ angulation of the aneurysm neck (supra-



Selection criteria

→ suitability (narrow or kinked) access vessels

→ angulation of the aneurysm neck (supra- and infrarenal)



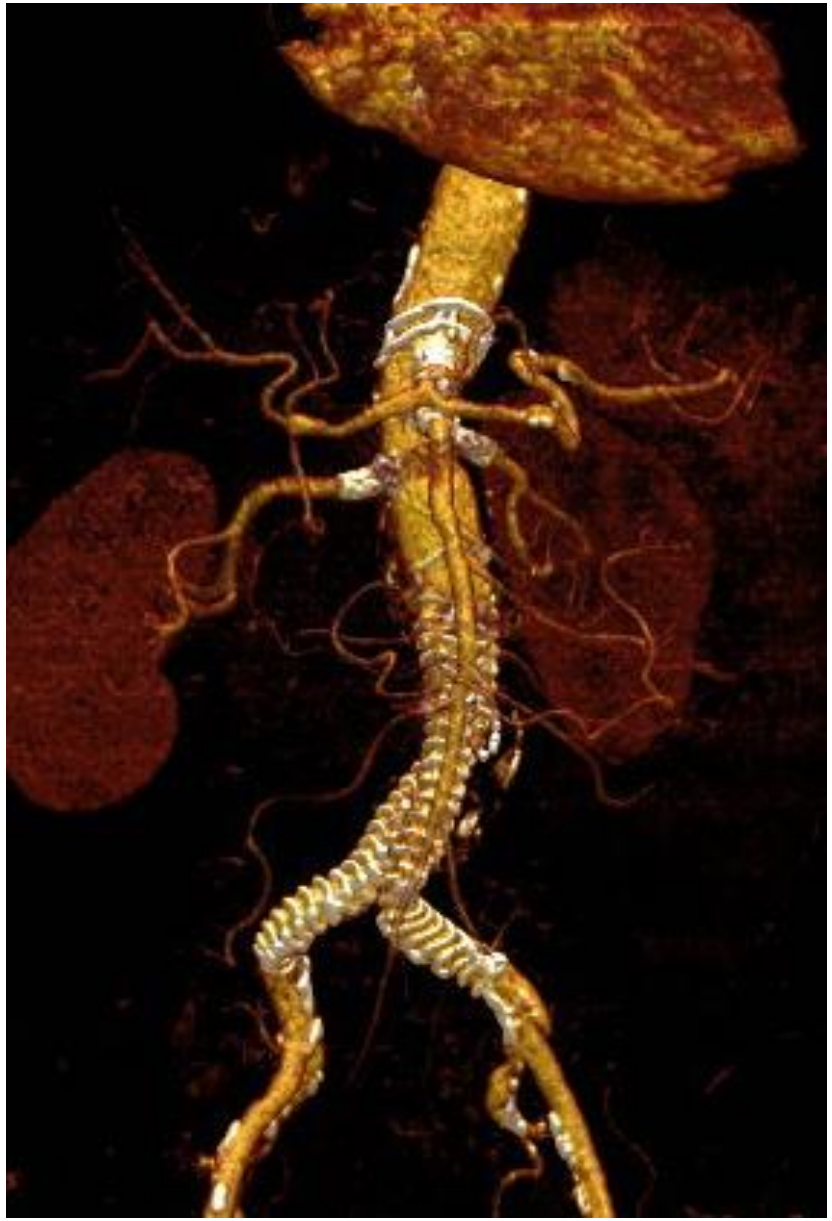
Selection criteria

→ suitability (narrow or kinked) access vessels

→ angulation of the aneurysm neck (supra- and infrarenal)

→ suitability of proximal landing zone

→ distance between CT and distal RA

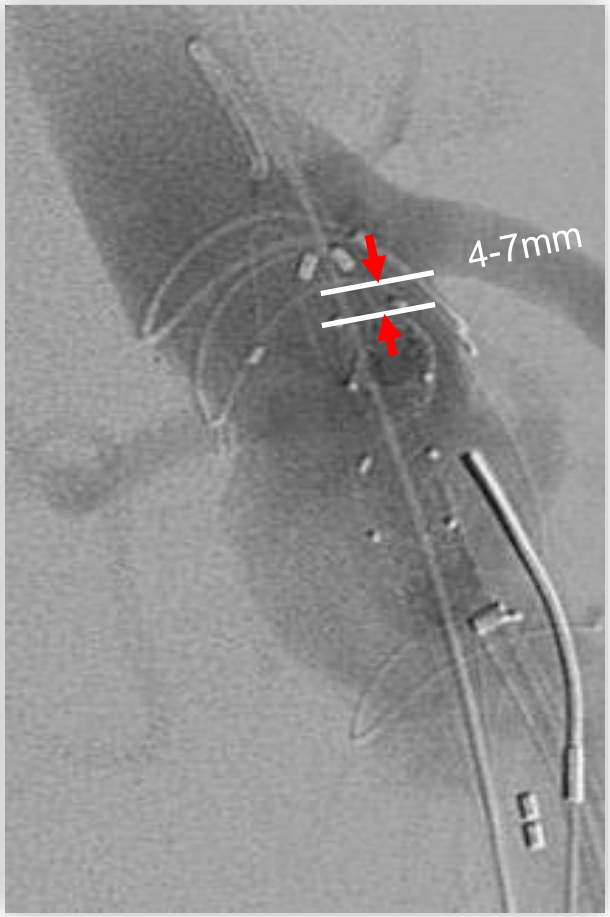


BARMHERZIGE BRÜDER
KONVENTHOSPITAL LINZ

Thank you !

Ordens klinikum Linz
Barmherzige Schwestern Elisabethinen

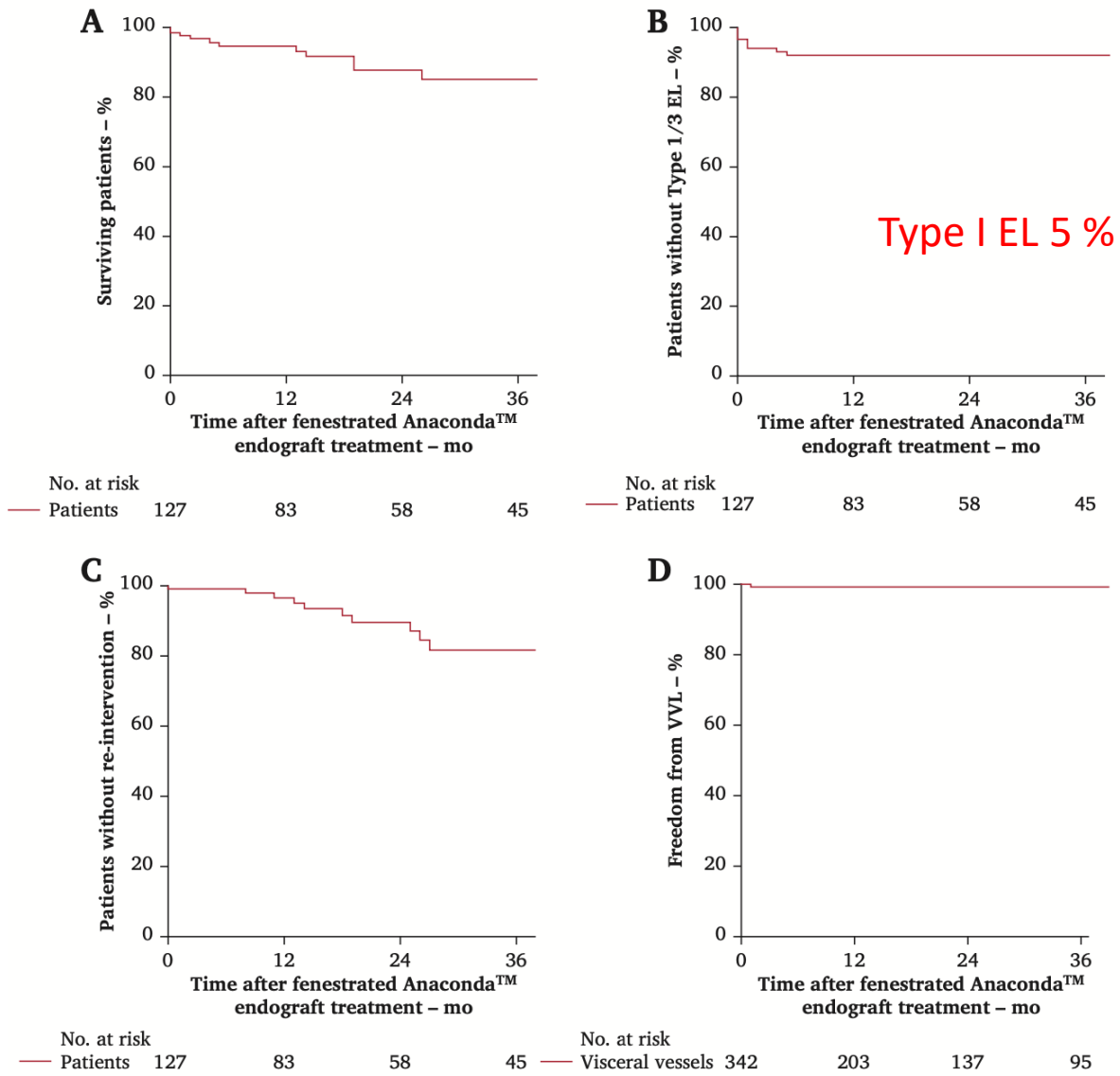
SPITALS PARTNER
Brüder. Schwestern. Linz

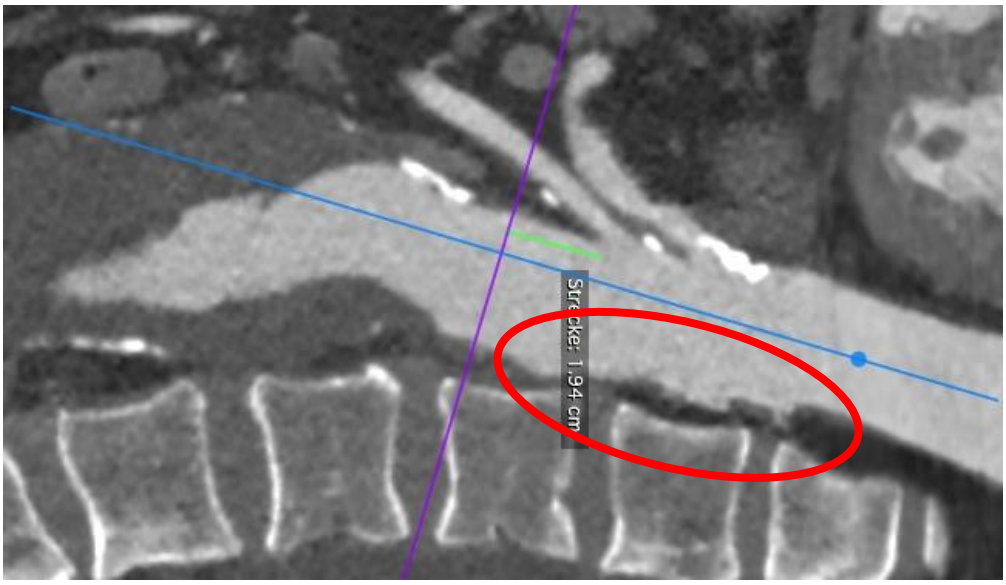

4-7mm

The Italian Multicentre Registry of Fenestrated Anaconda™ Endografts for Complex Abdominal Aortic Aneurysms Repair

Rodolfo Pini [a,*], Jacopo Giordano [a], Michelangelo Ferri [b], Bruno Palmieri [c], Marco Solcia [c], Stefano Michelagnoli [d], Emiliano Chisci [d], Franco Fadda Gian [e], Pierluigi Cappiello [f], Francesco Talarico [g], Silvio Licata [h], Paolo Frigatti [i], Sonia Ronchey [j], Nicola Mangialardi [j], Carlo Pratesi [k], Mauro Salvini [l], Domenico Milite [m], Fabio Pilon [m], Reinhold Perkmann [n], Carlo Stringari [n], Raffaele Pulli [o], Gianluca Faggioli [a], Mauro Gargiulo [a]

Objective: The aim was to describe the outcomes of the Anaconda™ Fenestrated endograft Italian r
complex aortic aneurysms (AAAs), unsuitable for standard endovascular aneurysm repair (EVAR).
Methods: Between 2012 and 2018 patients with a proximal neck unsuitable for standard EVAR, treated
fenestrated Anaconda™ endograft, were prospectively enrolled in a dedicated database. Endpoints wer
operative technical success (TS) and evaluation of type Ia/b or 3 endoleaks (T1/3 EL), target visceral v
(TVV) occlusion, re-interventions, and AAA related mortality at 30 days, six months, and later follow up.
Results: One hundred twenty seven patients (74 ± 7 years, American Society Anesthesiology (ASA) II/III/IV: 12/85/30) were included in the study in 49 Italian Vascular Surgery Units (83 juxta/para-renal AAA, 13 type IV thoraco-abdominal AAA, 16 T1aEL post EVAR, and 15 short neck AAA). Configurations with one, two, three, and four fenestrations were used in 5, 56, 39, and 27 cases, respectively, for a total of 342 visceral vessels. One hundred and eight (85%) bifurcated and 19 (15%) tube endografts were implanted. In 35% (44/127) of cases the endograft was repositioned during the procedure, and 37% (128/342) of TVV were cannulated from brachial access. TS was 87% (111/127): five T1EL, six T3EL (between fenestration and vessel stent), and six loss of visceral vessels (one patient with a Type Ia EL had also a TVV loss) occurred. Thirty day mortality was 4% (5/127). Two of the five T1EL resolved spontaneously at 30 days. The overall median follow up was 21 ± 16 months; one T1EL (5%) occurred at six months and one T3EL (4%) at the three year follow up. Another two (3%) TVV occlusions occurred at six months and five (3%) at three years. The re-intervention rate at the 30 days, six months, and three year follow up was 5%, 7%, and 18 ± 5%, respectively.
Conclusion: The fenestrated Anaconda™ endograft is effective in the treatment of complex AAA. Some structure properties, such as the re-positionability and the possibility of cannulation from above, are specific characteristics helpful for the treatment of some complex anatomies.


A
Surviving patients – %
100
80
60
40
20
0
0
12
24
36
Time after fenestrated Anaconda™ endograft treatment – mo
No. at risk
Patients 127 83 58 45
B
Patients without Type 1/3 EL – %
Type I EL 5 %
C
Patients without re-intervention – %
D
Freedom from VVL – %
No. at risk
Visceral vessels 342 203 137 95



NOTES:
1- All components are attached to the fabric using suture (H)
2- Three (3) apexes for each spring may present a tolerance of ± 2mm.
3- 2 proximal apexes of spring B1 are left unsewn. See view A & B.
4- One apex of spring D is offset as shown in drawing (use sewing template as needed for reference only).
5- Spring B1 is sewn INTERNAL.

The manufacturing of custom devices will only commence upon the receipt of a physician prescription and a physician approved device drawing by Terumo Aortic.

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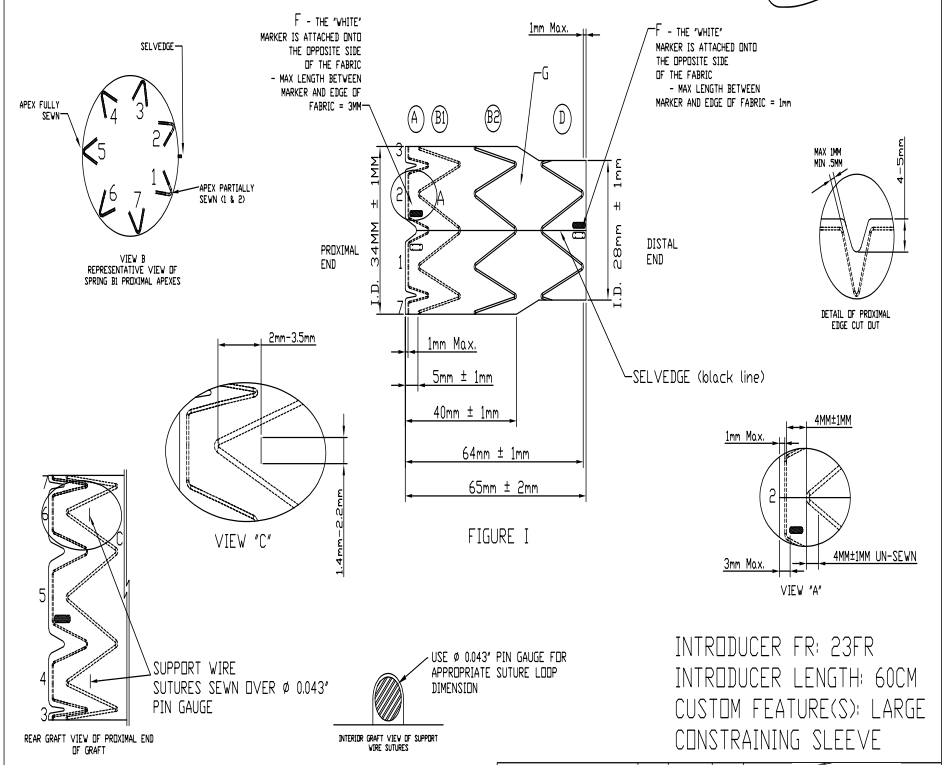
Physician Approval:

Date: Nov 11 2024



INTRODUCER FR: 23FR
INTRODUCER LENGTH: 60CM
CUSTOM FEATURE(S): LARGE CONSTRAINING SLEEVE

ITEM I.D.	DESCRIPTION	PART NUMBER	QTY
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D	28MM DISTAL SPRING	2822-0257-00	1
F	CYLINDRICAL MARKER	2822-0557	4
G	34MMX120MM FABRIC	2822-0625-07	1
H	5-0 SUTURE	2822-0315	8

	Name	Date
DRAWN	YT	11-08-18

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN MILLIMETERS TOLERANCES: N/A

MATERIAL: see individual component

FINISH: N/A

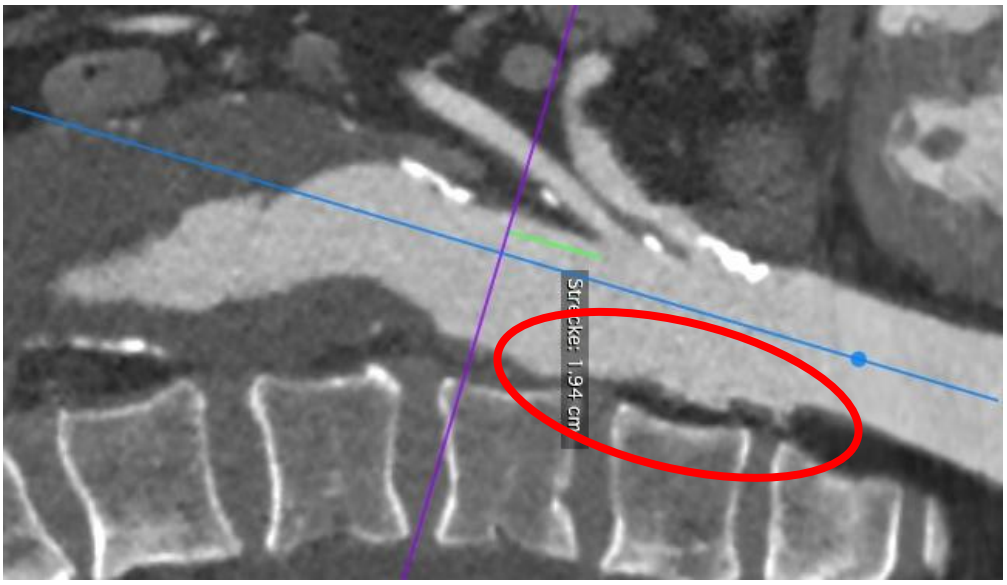
TERUMO Aortic

TITLE: 34MM/28MM X 65MM CUSTOM STENT GRAFT ASSEMBLY

SIZE: A | DWG NO.: 2833-0372-PAT 2024

ECN

SCALE | SHEET



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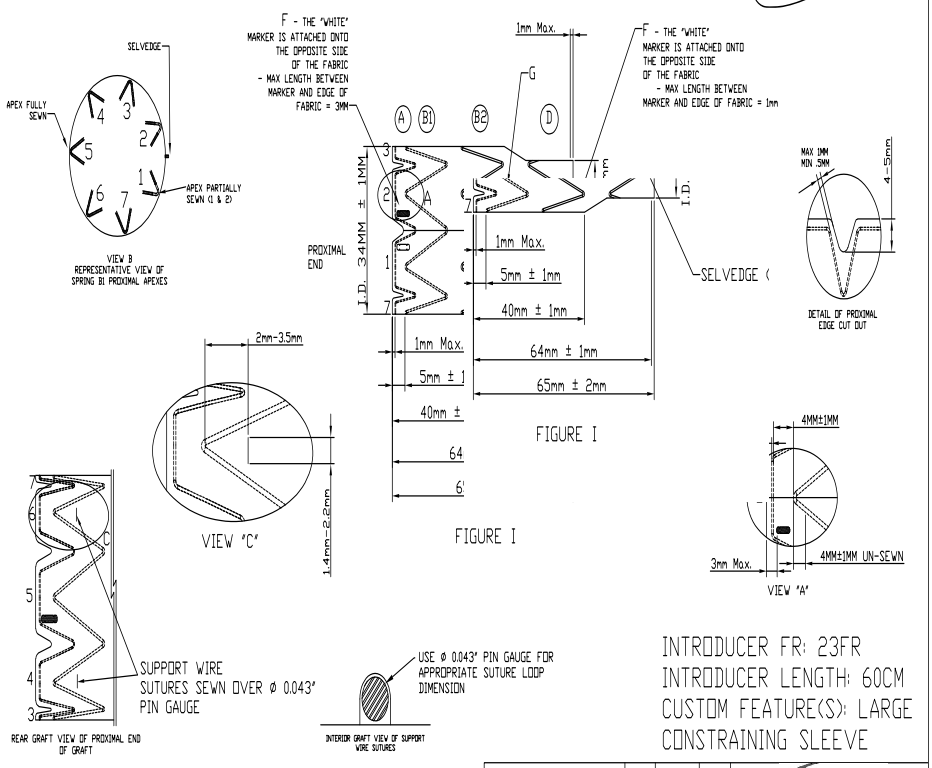
Physician Approval:

Date: Nov 11 2024



INTRODUCER FR: 23FR
INTRODUCER LENGTH: 60CM
CUSTOM FEATURE(S): LARGE CONSTRAINING SLEEVE

ITEM I.D.	DESCRIPTION	PART NUMBER	QTY
A	34MM CROWN SPRING	2822-0579-07	1
B1-B2	34MM NBS PROXIMAL SPRING	2822-0575-07	2
D	28MM DISTAL SPRING	2822-0257-00	1
F	CYLINDRICAL MARKER	2822-0557	4
G	34MMX120MM FABRIC	2822-0625-07	1
H	5-0 SUTURE	2822-0315	8

	Name	Date
DRAWN	YT	11-08-18

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN MILLIMETERS TOLERANCES: N/A

MATERIAL: see individual component

FINISH: N/A

TERUMO Aortic

TITLE: 34MM/28MM X 65MM CUSTOM STENT GRAFT ASSEMBLY

SIZE: A | DWG NO.: 2833-0372-PAT 2024

ECN

SCALE | SHEET