

Advancing Aortic Technologies
with Purpose™



Our purpose is to develop simple, elegant solutions that address cardiac and vascular surgeons' most difficult challenges in treating patients with diseases of the aorta and to deliver breakthrough technologies of unsurpassed quality that have far-reaching impact.

When the need is aortic, the solution is Artivion

Our intentional focus on the aorta and collaboration with the world's foremost cardiac and vascular surgeons allow us to leverage our combined expertise in the development of new, innovative, life-changing aortic-centric technologies.

NOTE: All products and indications are not available/approved in all markets.

Please contact your local Artivion representative for details.

**Made to fit your patients.
Made to fit you.**



ARTIVION | E-vita® Open Neo
Hybrid Stent Graft System

Product Highlights

Based on over ten years of clinical experience, E-vita Open Neo is the next-generation hybrid graft system for aortic arch and descending thoracic aorta repair with the Frozen Elephant Trunk technique.



ADAPTING TO PATIENT'S DISEASE

- Each disease requires unique technique and oversizing strategies. E-vita Open Neo has been created with three stent graft configurations and dedicated designs of the vascular and stent graft sections.
- The three diameters of the vascular section allow for reproducible anastomosis. The full range of options of the stent graft section provides adequate oversizing for both aneurysms and dissections.¹

CONTROL IN YOUR HANDS

- The new compact delivery system allows easy positioning of the device, and deployment can be performed in a controlled fashion with progressive expansion of the stent graft section.¹



STRAIGHT CONFIGURATION

Island Technique

Collar Anastomosis in Zone 2/3

BRANCHED CONFIGURATION

Sequential Anastomoses

Collar Anastomosis in Zone 1/2/3



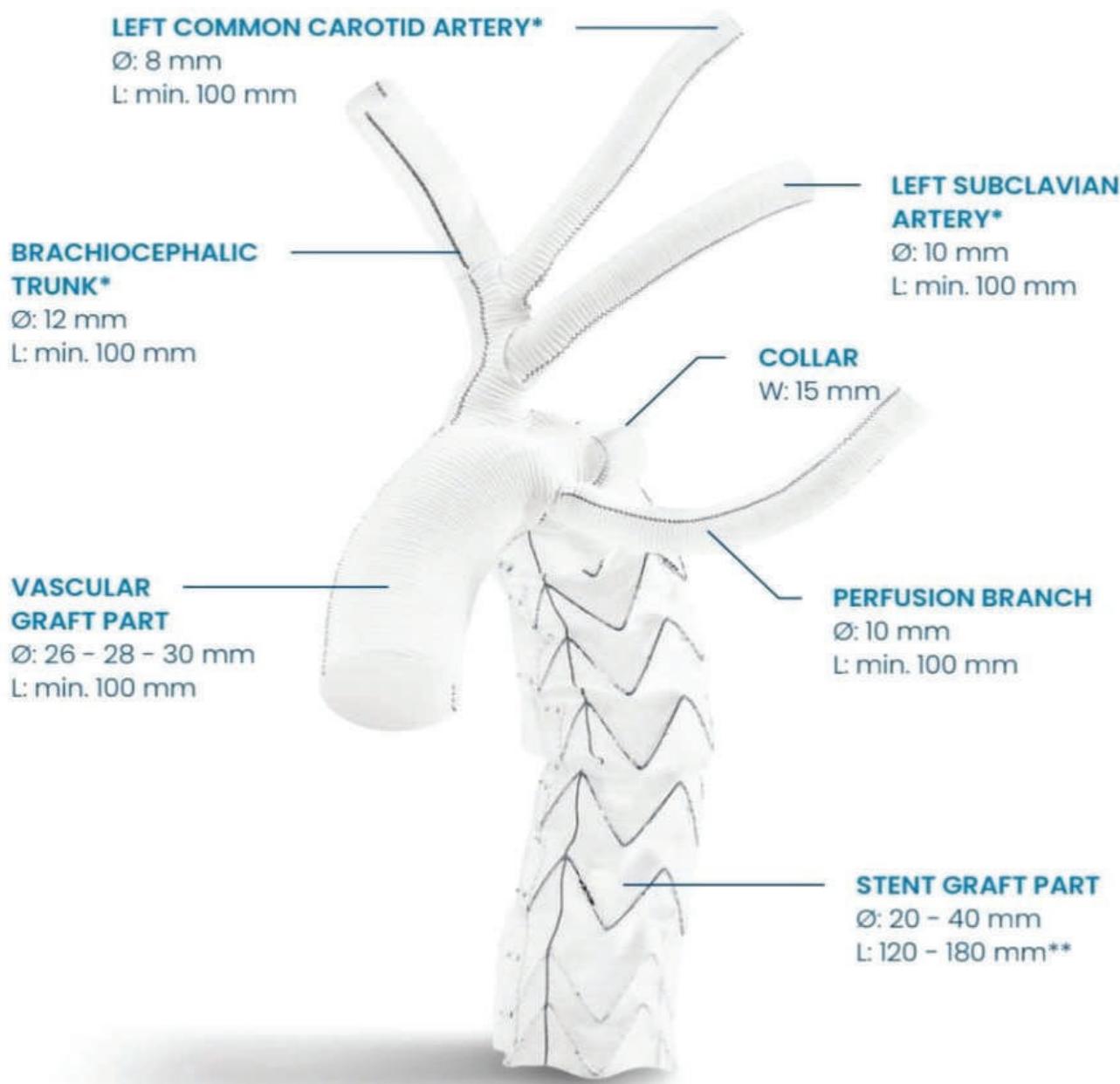
TRIFURCATED CONFIGURATION

Sequential Anastomoses

Collar Anastomosis in Zone 0/1

Made to fit Your Patients. Made to fit You.

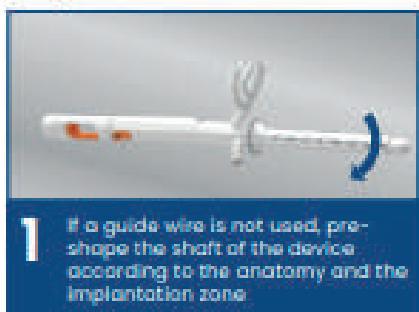
4/8



* branches for supraortic trunks available only on the Branched and Trifurcated configurations
** please refer to the IFU for the specific length of each configuration and diameter

E-vita® Open Neo Implantation Technique

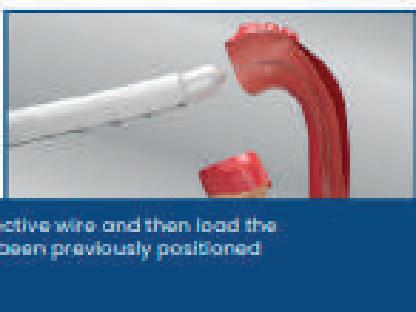
Preparation



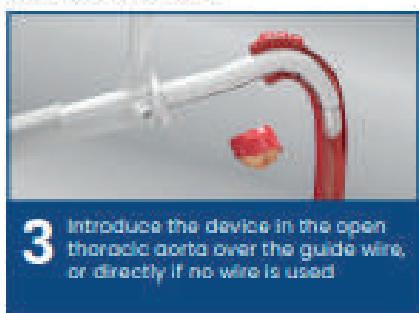
- 1** If a guide wire is not used, pre-shape the shaft of the device according to the anatomy and the implantation zone.



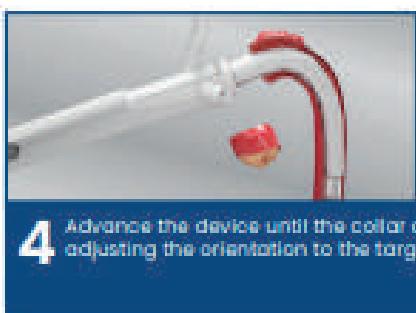
- 2** If a guidewire is used, remove the protective wire and then load the system on the stiff guide wire that has been previously positioned.



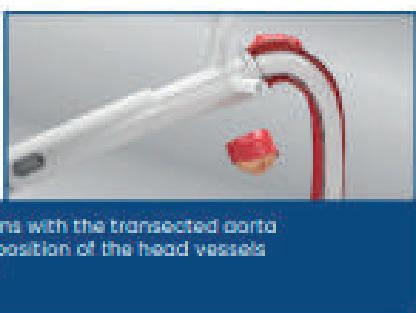
Introduction



- 3** Introduce the device in the open thoracic aorta over the guide wire, or directly if no wire is used.



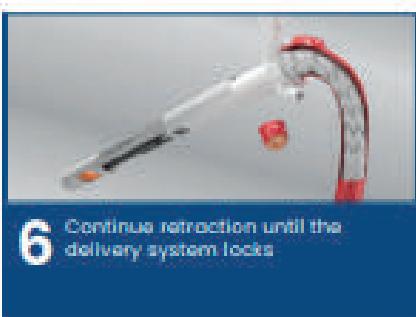
- 4** Advance the device until the collar aligns with the transected aorta, adjusting the orientation to the target position of the head vessels.



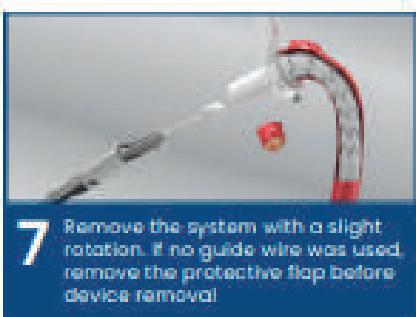
Deployment & Removal



- 5** Press the orange release trigger and pull the release handle straight backwards.



- 6** Continue retraction until the delivery system locks.



- 7** Remove the system with a slight rotation. If no guide wire was used, remove the protective flap before device removal.

Conclusion



- 8** Perform distal anastomosis at the collar. At this point distal body perfusion can begin via the perfusion branch.



- 9** Perform proximal anastomosis and anastomoses of the head vessel (depending on the chosen design).

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Always check instructions for use prior application.

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E-vita® Open Neo
Hybrid Stent Graft System

Sizing Sheet – Aneurysm

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E-vita® Open Neo
Hybrid Stent Graft System

Patient initials

Date of birth

Gender

f

m

Implantation date

Date of Assessment

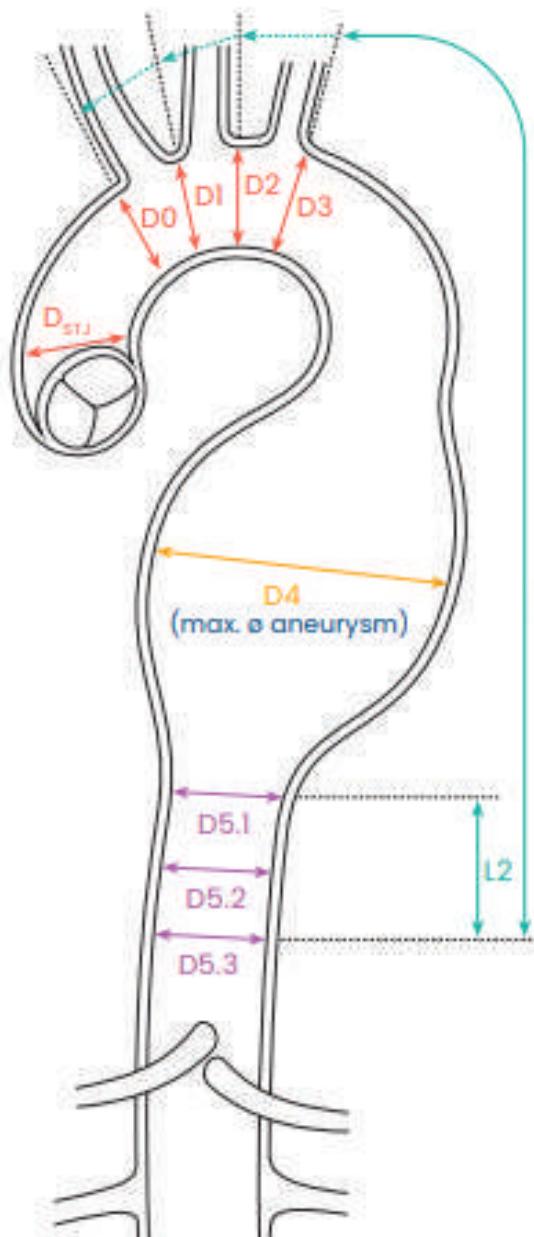
Evaluated by

Hospital/City/Country

Date CT/MRI/Slice thick.

Head vessel diameter [mm]

BCT	LCCA	LSA



Device choice

Device configuration

- straight
- branched
- trifurcated

Zone of collar anastomosis

0 1 2 3

Aortic arch diameter [mm]

D _{STJ} =
D ₀ =
D ₁ =
D ₂ =
D ₃ =

Diameter aneurysm

D ₄ =

Length [mm]

L ₁ =
L ₂ =

L₁ = total outer length
L₂ = > 25, 38, 53 mm according to the diameter of the device. Please refer to the IFU.

Distal sealing zone [mm]

D _{5.1} =
D _{5.2} =
D _{5.3} =

Comments

Ordering Information



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 JOTEC GmbH, Löbenbicker Str. 23, 72379 Hechingen, Germany

JT-SIA-0950200-EN V02 II/2022

Sizing Sheet – Dissection

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E-vita® Open Neo

Hybrid Stent Graft System

Patient initials

Date of birth

Gender

f m

Implantation date

Date of Assessment

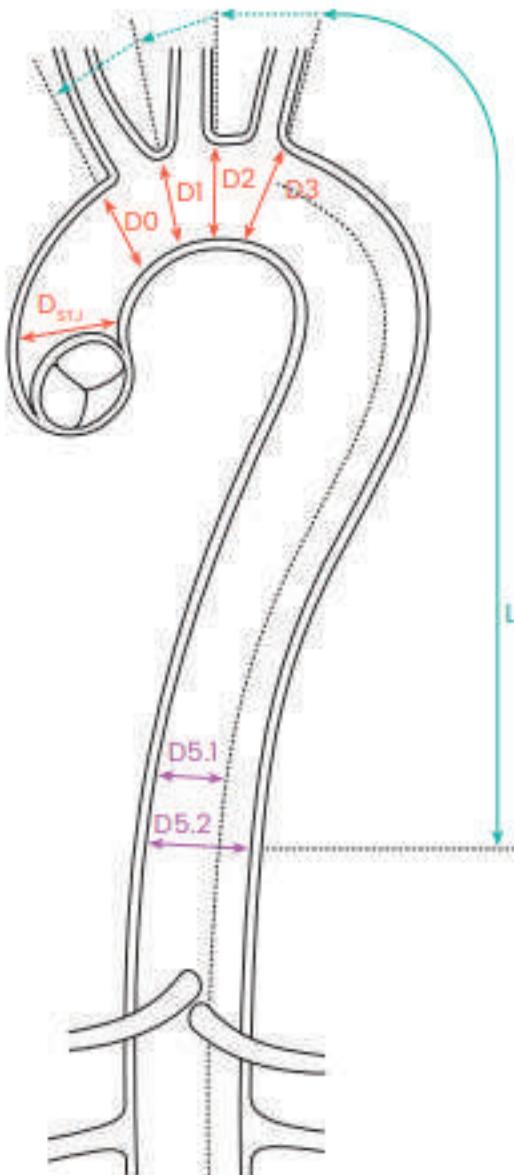
Evaluated by

Hospital/City/Country

Date CT/MRI/Slice thick.

Pathology

Acute	<input type="checkbox"/>
Subacute	<input type="checkbox"/>
Chronic	<input type="checkbox"/>
Dissection ends at:	



Head vessel diameter [mm]

BCT	LCCA	LSA

Dissected

Device choice

Device configuration

- straight
- branched
- trifurcated

Comments

Ordering Information



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JT-SID-0951200-EN V02 II/2022

E-vita® Open Neo

Hybrid Stent Graft System

Ordering Information (all measurements are in mm)

Straight



Catalog Number	Ø Vascular Graft Part	Ø Stent Graft Part	Length Stent Graft Part
95H02620L120-C01	26	20	120
95H02624L120-C01	26	24	120
95H02624L175-C01	26	24	175
95H02626L120-C01	26	26	120
95H02628L120-C01	26	28	120
95H02628L180-C01	26	28	180
95H03030L120-C01	30	30	120
95H03030L180-C01	30	30	180
95H03033L180-C01	30	33	180
95H03033L180-C01	30	33	180
95H03036L120-C01	30	36	120
95H03036L180-C01	30	36	180
95H03040L120-C01	30	40	120
95H03040L180-C01	30	40	180

Branched



Catalog Number	Ø Vascular Graft Part	Ø Stent Graft Part	Length Stent Graft Part
95H02622L120-C02	26	22	120
95H02624L120-C02	26	24	120
95H02624L175-C02	26	24	175
95H02626L120-C02	26	26	120
95H02626L180-C02	26	26	180
95H02628L120-C02	26	28	120
95H02628L180-C02	26	28	180
95H03030L120-C02	30	30	120
95H03030L180-C02	30	30	180
95H03033L120-C02	30	33	120
95H03033L180-C02	30	33	180
95H03036L120-C02	30	36	120
95H03036L180-C02	30	36	180
95H03040L120-C02	30	40	120
95H03040L180-C02	30	40	180

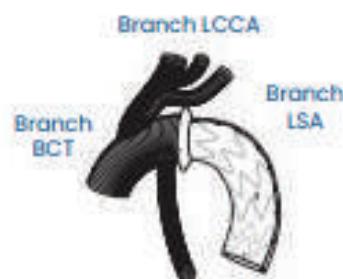
Trifurcated



Catalog Number	Ø Vascular Graft Part	Ø Stent Graft Part	Length Stent Graft Part
95H02624L175-C03	26	24	175
95H02626L180-C03	26	26	180
95H02628L180-C03	26	28	180
95H03030L180-C03	30	30	180
95H03033L180-C03	30	33	180
95H03036L180-C03	30	36	180
95H03040L180-C03	30	40	180

Sizes in italics are available on demand

Vascular Graft Part Length (without tension): 100mm on every configuration and size
Perfusion Branch: diameter of 10mm and length without tension of minimum 100mm on every configuration and size



Branch Specifications

	Ø	Length
Branch BCT	12 mm	min. 100 mm
Branch LCCA	8 mm	min. 100 mm
Branch LSA	10 mm	min. 100 mm

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JT-RS-0950200-EN v02 05/2022

Woven Vascular Prostheses



ARTIVION | FlowWeave Bioseal

FlowWeave Bioseal

- Specific weaving techniques for high burst resistance and low dilatation^{1,2}
- Different internal and external surface structures enable blood flow optimization
- Aldhyde and isocyanate free Bioseal impregnation using dehydrothermal crosslinked collagen guarantees primary sealing of the blood in the prosthesis³
- Concentric crimping and the guide line allow precise positioning of the prosthesis
- Soft and supple texture for easy handling

ORDERING INFORMATION

Catalogue No.	Ø (mm)	Length (cm)
455T1508	8	15
455T3008	8	30
455T1510	10	15
455T3010	10	30
455T1512	12	15
455T3012	12	30
455T1520	20	15
455T3020	20	30
455T1522	22	15
455T3022	22	30
455T1524	24	15
455T3024	24	30
455T1526	26	15

Catalogue No.	Ø (mm)	Length (cm)
455T2026	26	30
455T1528	28	15
455T3028	28	30
455T1530	30	15
455T3030	30	30
455T1532	32	15
455T3032	32	30
455T1534	34	15
455T3034	34	30



Length
30 cm

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References:

1. 2010 C. Weisheit, et al. Study of CrystoSeal, Inc., Internal Threaded and Braided stents. *J Biomed Mater Res Part A*, Vol. 91, No. 1, pp. 1-10, 2010.
 2. Weisheit C.-A. [Study on the issue of optimization of textile implants]. - [Dissertation thesis, 2010]. Würzburg.
 3. Finsen Viking J., et al. and Manner, M. E. - Clinical Experience with a Collagen Impregnated Braided Dacron Vascular Graft. *J Am Coll Cardiol*. 1993; 22(3):639-645.
- Artivion, FlowWeave Bioseal is indicated in arterial and venous vascular applications. The primary indication for Artivion Bioseal is vascular replacement for the total end-to-end occlusion, although it can also be used in peripheral vascular applications involving vessel diameters of at least 8 mm.

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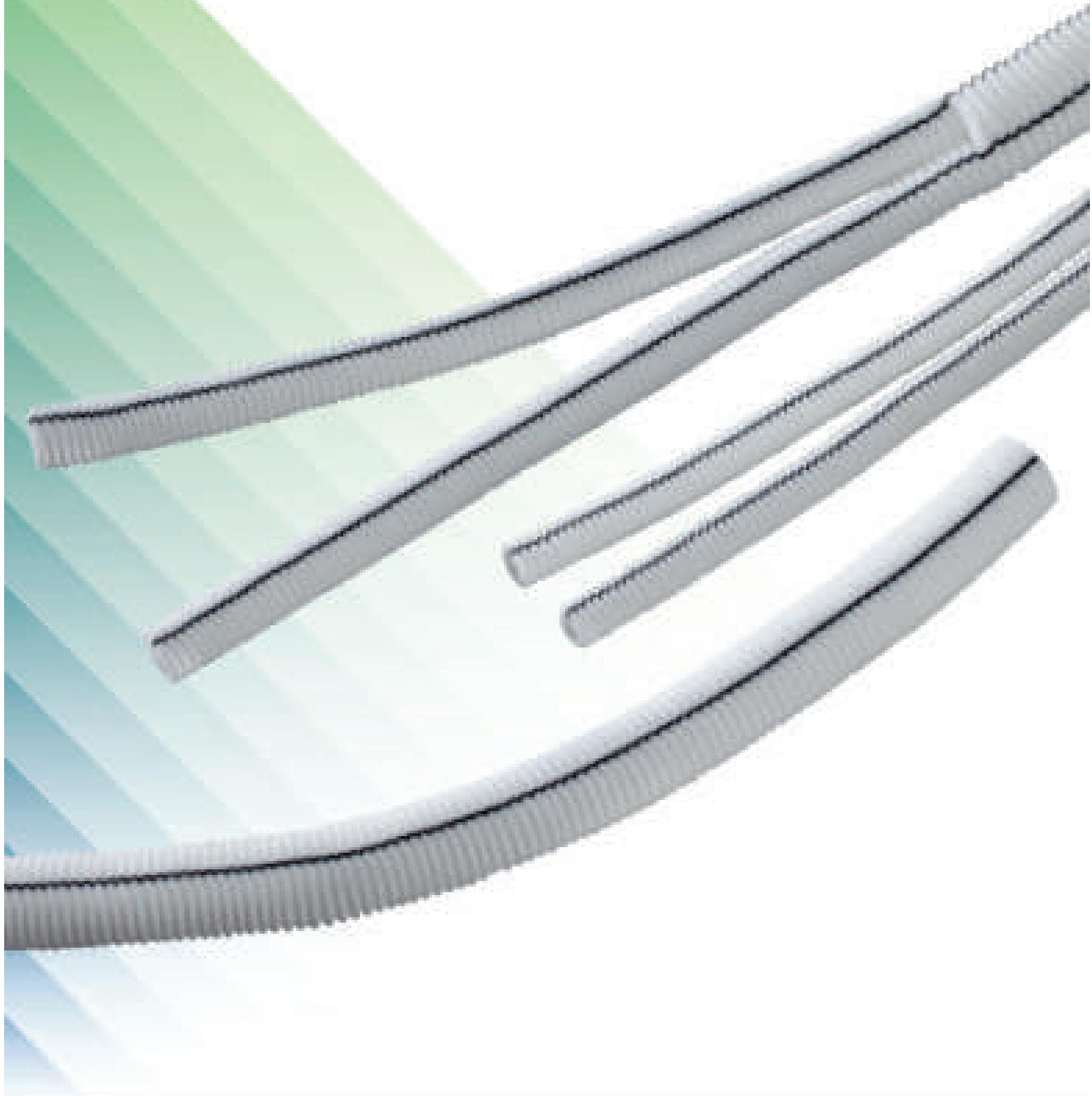
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E-mail: info@artivion.com

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Knitted Vascular Prostheses



ARTIVION | FlowNit Bioseal

FlowNit Bioseal

Knitted vascular prostheses:

- Specific knitting techniques for high burst resistance and low dilatation¹
- Aldehyde and isocyanate free BIOSEAL impregnation using dehydrothermal crosslinked collagen guarantees primary sealing of the blood in the prosthesis²
- Concentric crimping and the guide line allow precise positioning of the prosthesis
- Soft and supple texture for easy handling

Ordering Information

Straight prostheses:

Catalogue No.	Ø (mm)	Length (cm)
388116001	8	10
388116004	8	30
388116009	8	60
388116011	11	15
388116007	11	30
388116007	11	60
388116010	11	10
388116008	12	30
388116008	12	10
388116009	12	60
388116012	12	100
388116013	14	15
388116013	14	30
388116013	14	60
388116014	16	15
388116014	16	30
388116014	16	60
388116015	18	15
388116015	18	30
388116015	18	60
388116016	20	15
388116016	20	30
388116016	20	60
388116017	22	15
388116017	22	30
388116017	22	60
388116018	24	15
388116018	24	30
388116018	24	60
388116019	26	15
388116019	26	30
388116019	26	60
388116020	28	15
388116020	28	30
388116020	28	60

Straight prostheses:

Catalogue No.	Ø (mm)	Length (cm)
388116021	12	10
388116030	12	30
388116030	12	60
388116031	14	10
388116031	14	30
388116031	14	60
388116032	16	10
388116032	16	30
388116032	16	60
388116033	18	10
388116033	18	30
388116033	18	60
388116034	20	10
388116034	20	30
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388116035	22	10
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388116036	24	10
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388116036	24	60
388116037	26	10
388116037	26	30
388116037	26	60
388116038	28	10
388116038	28	30
388116038	28	60
388116039	30	10
388116039	30	30
388116039	30	60
388116040	32	10
388116040	32	30
388116040	32	60

Bifurcated prostheses:

Catalogue No.	Ø (mm)	Length (cm)
388116041	12x12	10
388116047	12x12	30
388116047	12x12	60
388116049	14x14	10
388116049	14x14	30
388116049	14x14	60
388116050	16x16	10
388116050	16x16	30
388116050	16x16	60
388116051	20x20	10
388116051	20x20	30
388116051	20x20	60
388116052	24x24	10
388116052	24x24	30
388116052	24x24	60



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References:

1. JOTEC® Standard, substituent of Copaxone, Inc., Infra-red spectrometric test method

2. Bent C-M. [Study on the issue of expansion of textile implants] - (Unpublished thesis). JOTEC® Standard

3. French F, J.-L. and Boumez M. H. Clinical experience with Collagen impregnated Knotted Dacron Vascular Graft. Ann of Vascular Surg 1991; 5(5): 499-505

In addition to FlowNit®, Bioseal is indicated in systemic bypasses with stent vascular prostheses. FlowNit® BIOSEAL is prepared by knotted for vascular replacement in the arterial system and can be used to reconstruct vascular occlusions by using several different types of collateral vessels.

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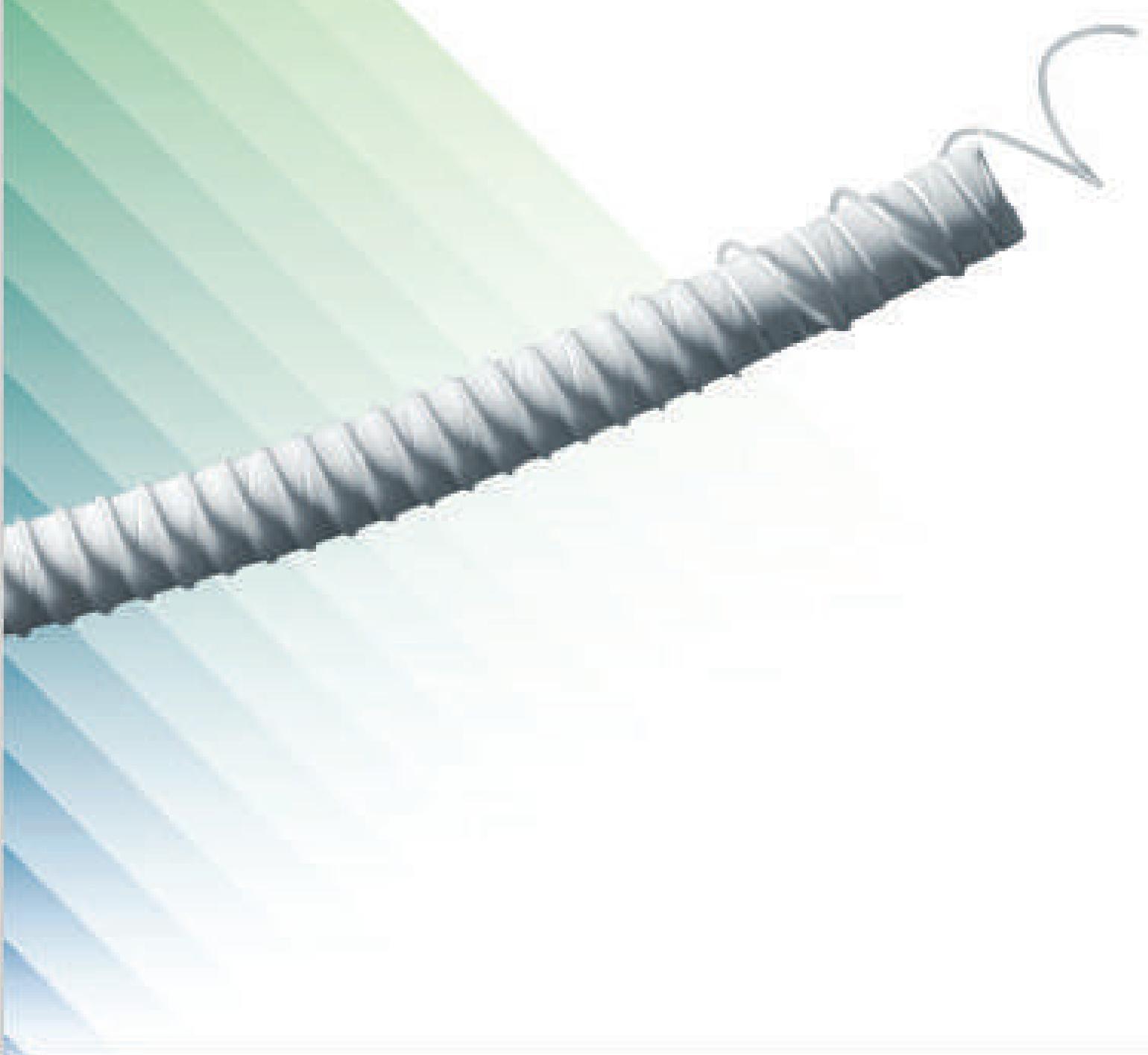
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10-00-1240003-00010000

Peripheral Treatment with ePTFE



FlowLine Bipore

- Bipore design with two different fibril lengths for low thrombogenicity
- An additional ePTFE wrap for enhanced suture retention and high burst strength
- Unique guideline indicates diameter and wall thickness of the graft
- Helical reinforcement for increased resistance against kinking and compression
- Excellent and pliable handling and suture behaviour
- Simple and easy removal of the spiral reinforcement

Ordering Information

Length (cm)	Diameter (mm)	Thin Wall Reinforced		Standard Wall Reinforced	
		Catalogue No.	Catalogue No.	Catalogue No.	Catalogue No.
10	5	10TW1005N	10TW1005S	10SW2005N	—
20	6	10TW2006N	—	10SW2007N	—
30	7	10TW3007N	—	10SW4005N	—
20	8	10TW2008N	—	10SW5006N	10SW5006S
40	5	10TW4005N	10TW4005S	10SW5007N	10SW5007S
40	6	10TW4006N	—	10SW5008N	10SW5008S
50	6	10TW5006N	10TW5006S	10SW7005N	10SW7005S
50	7	10TW5007N	10TW5007S	10SW8006N	10SW8006S
50	8	10TW5008N	10TW5008S	10SW8007N	10SW8007S
70	6	10TW7006N	10TW7006S	10SW8008N	10SW8008S
80	6	10TW8006N	10TW8006S	—	—
80	7	10TW8007N	10TW8007S	—	—
80	8	10TW8008N	10TW8008S	—	—

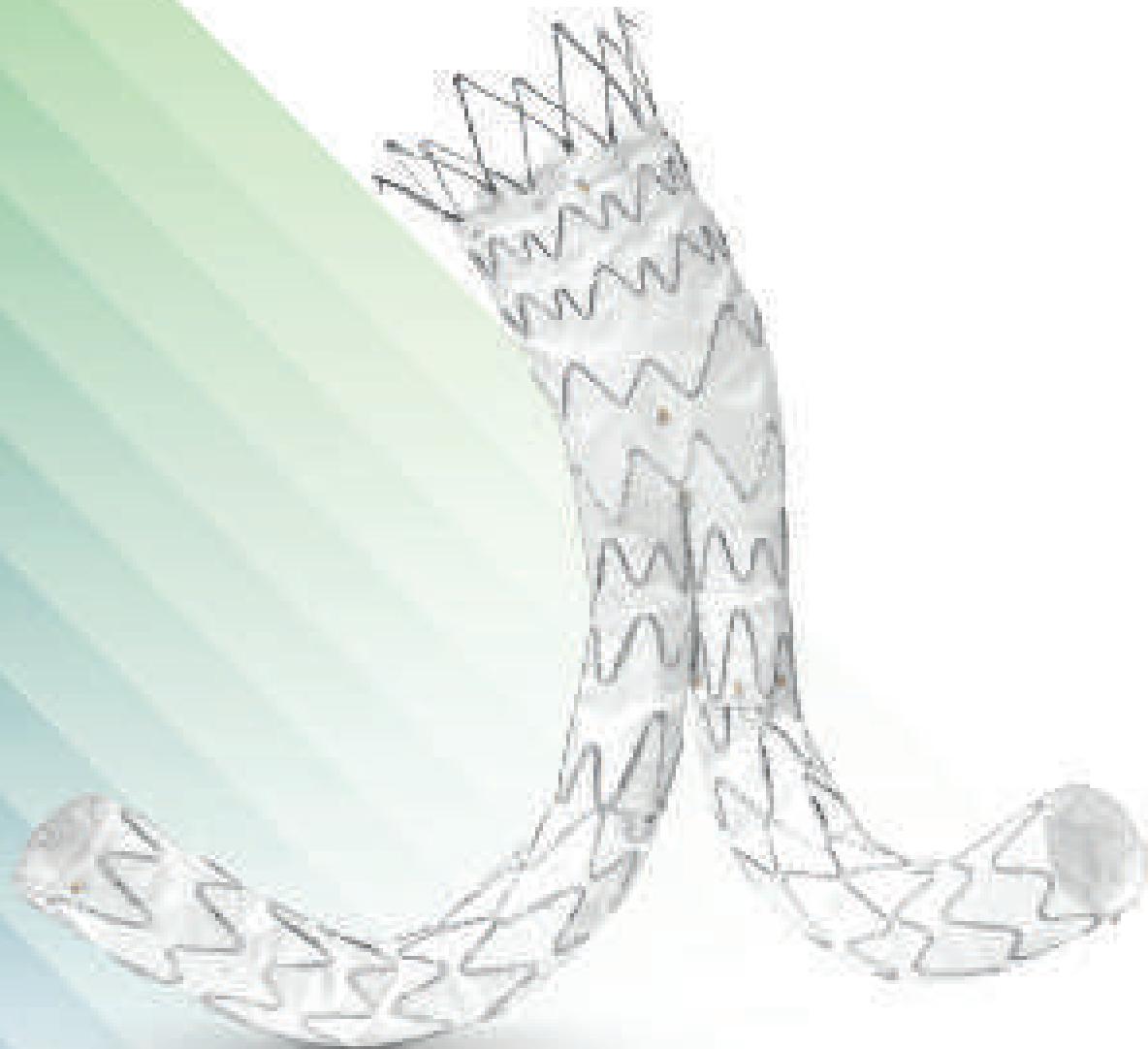
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Every Day. Every Case.



ARTIVION

E-tegra™
Stent Graft System

Ordering Information

E-tegra Stent Graft System

01 Main Body

Catalog Number	Proximal ID (mm)	Distal ID (mm)	Total Length (mm)	Covered Length (mm)	OD Delivery System (mm)
ETM-110001-000	14	10	200	150	20
ETM-110001-100	14	10	210	160	20
ETM-110001-110	14	10	220	170	20
ETM-110001-120	14	10	230	180	20
ETM-110001-130	14	10	240	190	20
ETM-110001-140	14	10	250	200	20
ETM-110001-150	15	11	200	150	20
ETM-110001-160	15	11	210	160	20
ETM-110001-170	15	11	220	170	20
ETM-110001-180	15	11	230	180	20
ETM-110001-190	15	11	240	190	20
ETM-110001-200	15	11	250	200	20

Special sizes on demand only:

ETM-110001-005	10	8	200	150	20
ETM-110001-010	10	8	210	160	20
ETM-110001-015	10	8	220	170	20
ETM-110001-020	10	8	230	180	20
ETM-110001-025	10	8	240	190	20
ETM-110001-030	10	8	250	200	20

02 Contralateral Leg

Catalog Number	Proximal ID (mm)	Distal ID (mm)	Mobile Length (mm)	Fixed Length (mm)	OD Delivery System (mm)
ETC-110001-000	14	10	100	100	20
ETC-110001-100	14	10	110	90	20
ETC-110001-110	14	10	120	80	20
ETC-110001-120	14	10	130	70	20
ETC-110001-130	14	10	140	60	20
ETC-110001-140	14	10	150	50	20
ETC-110001-150	15	11	100	100	20
ETC-110001-160	15	11	110	90	20
ETC-110001-170	15	11	120	80	20
ETC-110001-180	15	11	130	70	20
ETC-110001-190	15	11	140	60	20
ETC-110001-200	15	11	150	50	20

03 Iliac Extension

Catalog Number	Proximal ID (mm)	Distal ID (mm)	Mobile Length (mm)	Fixed Length (mm)	OD Delivery System (mm)
ETI-110001-000	14	10	100	100	20
ETI-110001-100	14	10	110	90	20
ETI-110001-110	14	10	120	80	20
ETI-110001-120	14	10	130	70	20
ETI-110001-130	14	10	140	60	20
ETI-110001-140	15	11	100	100	20
ETI-110001-150	15	11	110	90	20
ETI-110001-160	15	11	120	80	20
ETI-110001-170	15	11	130	70	20
ETI-110001-180	15	11	140	60	20
ETI-110001-190	15	11	150	50	20

04 Aortic Extension

Catalog Number	Proximal ID (mm)	Distal ID (mm)	Covered Length (mm)	OD Delivery System (mm)
ETA-110001-000	14	10	100	20
ETA-110001-100	14	10	110	20
ETA-110001-110	14	10	120	20
ETA-110001-120	14	10	130	20
ETA-110001-130	14	10	140	20

05 Aorta-Uni-Iliac

ETU-110001	14	10	100	20
ETU-110001	14	10	110	20
ETU-110001	14	10	120	20
ETU-110001	14	10	130	20
ETU-110001	15	11	100	20

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Hypogastric Artery Matters



ARTIVION

E-iliac®
Stent Graft System

Ordering Information

E-iliac Stent Graft System

01 Aorto-iliac Aneurysms

Ordering Number	Proximal D (mm)	Distal D (mm)	Total Length (mm)	Proximal Length (mm)	Distal Length (mm)	OD Delivery System (mm)
1000000000000000000	10	10	300	100	200	100.00
1000000000000000001	10	12	300	100	200	100.00
1000000000000000002	10	14	300	100	200	100.00

Special sizes on demand only

Ordering Number	Proximal D (mm)	Distal D (mm)	Total Length (mm)	Proximal Length (mm)	Distal Length (mm)	OD Delivery System (mm)
1000000000000000003	10	10	300	100	200	100.00
1000000000000000004	10	12	300	100	200	100.00
1000000000000000005	10	14	300	100	200	100.00

02 Isolated Iliac Aneurysms

Ordering Number	Proximal D (mm)	Distal D (mm)	Total Length (mm)	Proximal Length (mm)	Distal Length (mm)	OD Delivery System (mm)
1000000000000000006	10	10	300	100	200	100.00
1000000000000000007	10	12	300	100	200	100.00
1000000000000000008	10	14	300	100	200	100.00
1000000000000000009	10	16	300	100	200	100.00
1000000000000000010	10	18	300	100	200	100.00

Special sizes on demand only

Ordering Number	Proximal D (mm)	Distal D (mm)	Total Length (mm)	Proximal Length (mm)	Distal Length (mm)	OD Delivery System (mm)
1000000000000000011	10	12	300	100	200	100.00
1000000000000000012	10	14	300	100	200	100.00
1000000000000000013	10	16	300	100	200	100.00
1000000000000000014	10	18	300	100	200	100.00
1000000000000000015	10	20	300	100	200	100.00

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Making the Revolutionary Routine.

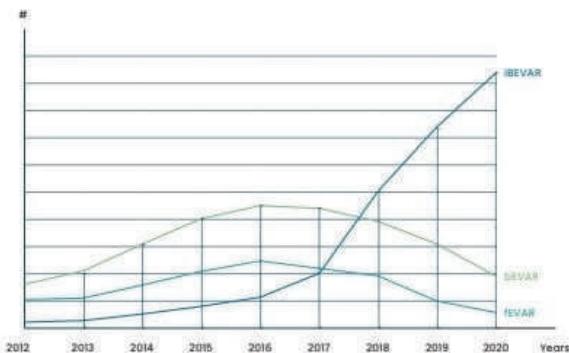


ARTIVION | E-nside™ TAAA
Multibranched Stent Graft System

Innovation at its Core.

Thoracoabdominal aortic aneurysms (TAAA) are still a major challenge for vascular physicians to deal with. Since the first customised branched endograft that was implanted in 2001, the technology has been evolving to treat patients with varied anatomies and complex pathologies. For the past 9 years E-xtra DESIGN ENGINEERING service has provided physicians with patient specific solutions for complex endovascular thoracoabdominal repairs; with more than 2200 projects for complex TAAA pathologies (and over 5000 customised solutions overall) made available for the treating physicians, a deep understanding of endovascular thoracoabdominal repair was developed.

E-inside TAAA is the result of years of experience in facing the challenges of the TAAA space and was born to respond to the unmet needs and challenges still present in this space.

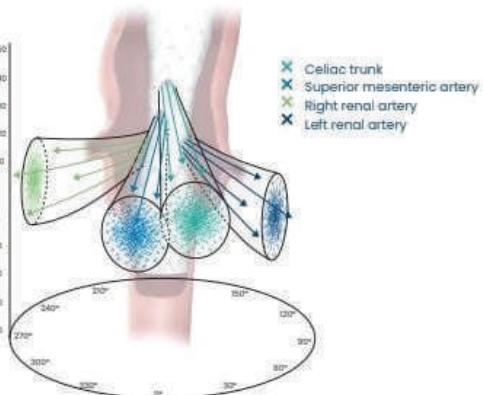


E-inside TAAA is the first **PRE-CANNULATED**, inner branch based, off-the-shelf solution for thoracoabdominal aneurysms accessible on the market.

Being available as an **OFF-THE-SHELF**, it's designed to treat both elective and emergency cases with a consistent approach.

The inner branch technology (**iBEVAR**) that E-inside TAAA is based on enables the treatment of varied anatomies with a **CONSISTENT APPROACH**. Internal tunnels can be used in narrow, kinked anatomies¹ as well as large, dilated aneurysms.²

Pre-cannulation is designed to **MINIMIZE** fluoroscopy and implantation **TIME** as well as contrast media necessary to finalize the procedure.



Distances and angles of CT, RRA and LRA in relation to SMA derived from over 300 CT scans analysed to maximise the applicability of the device.

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Making the Revolutionary Routine.

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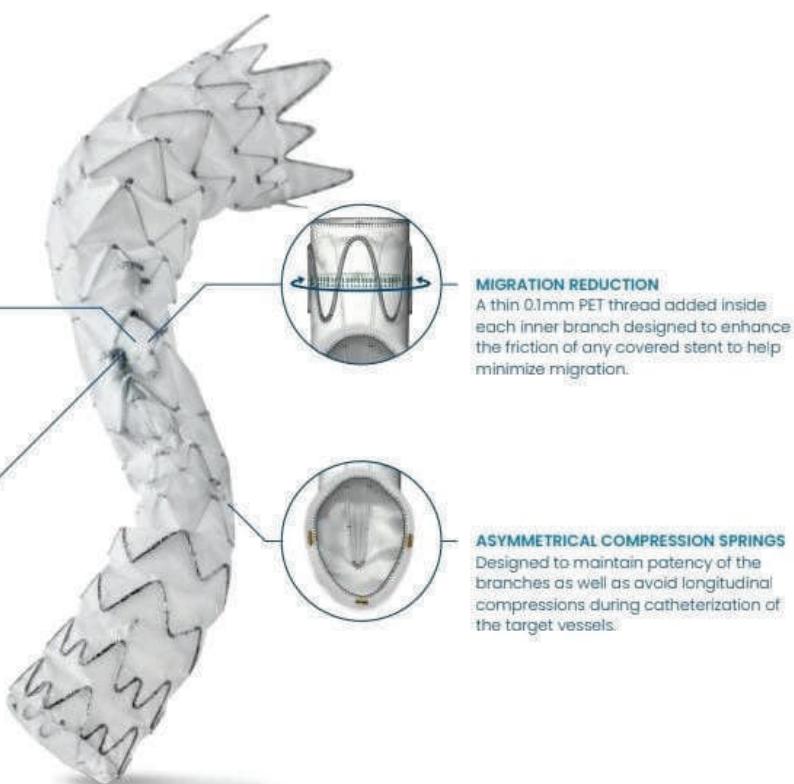
Different Anatomies. A Consistent Approach.

Thoracoabdominal aneurysms are a complex disease and unique to each patient's anatomy. A consistent approach can be a powerful tool to simplify this variability. Inner branch technology (iBEVAR) has the potential to bring greater predictability to both decision making and treatment. Inner branch technology (iBEVAR) is designed to introduce benefits such as:

ENLARGED, ELLIPTICAL OUTLETS
Re-designed oval-shaped outlets to allow for greater flexibility of the covered stents.

CT/SMA: $\alpha = 50^\circ$
RRA/LRA: $\beta = 70^\circ$

FIXATION SEAM
The proximal fixation of the inner branches allows longitudinal stability and support during cannulation of the target vessels.



Making the Revolutionary Routine.

3/5

Ordering Information

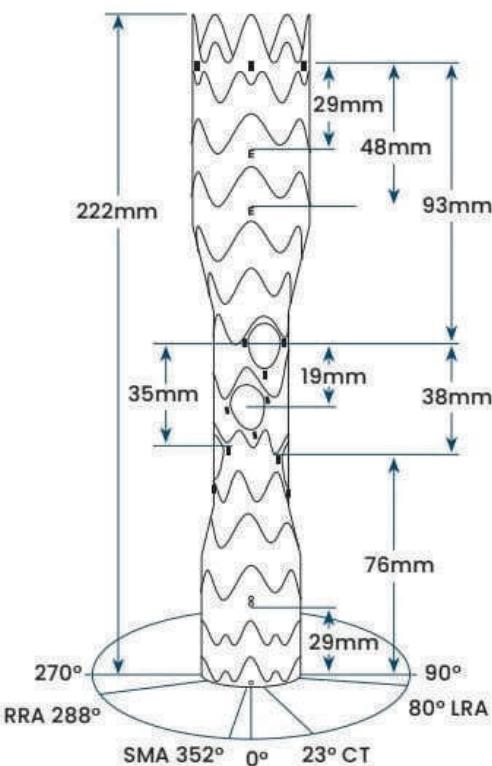
E-inside TAAA Multibranch Stent Graft System

Catalog Number	Ø Proximal (mm)	Ø Central (mm)	Ø Distal (mm)	Total Length (mm)	Ø Branch CT/SMA (mm)	Ø Branch LRA/RRA (mm)	OD delivery system (mm)
65MU33262I-4B8866-00	33	24	26	222	8	6	8.2
65MU33302I-4B8866-00	33	24	30	222	8	6	8.2
65MU38262I-4B8866-00	38	24	26	222	8	6	8.2
65MU38302I-4B8866-00	38	24	30	222	8	6	8.2

Oversizing Guidelines

Ø Distal Thoracic stent graft (mm)	Ø Proximal E-inside TAAA stent graft (mm)	Minimum length of landing zone (mm)
34		
33		
32		
31		
30	38	30
29		
28		
27		

Ø Infrarenal aorta (mm)	Ø Distal E-inside TAAA stent graft (mm)	Minimum length of landing zone (mm)
21		
22		
23		
24		
25	26	30
26		
27		



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1. M. Youssef et. al (2018) - A Multicenter Experience With a New Fenestrated-Branched Device for Endovascular Repair of Thoracoabdominal Aortic Aneurysms, Journal of endovascular therapy, DOI: 10.1177/1526602817752147 2. A.Katsaryris et.al (2018) - Early Experience with the Use of Inner Branches in Endovascular Repair of Complex Abdominal and Thoraco- abdominal Aortic Aneurysms, European Journal of vascular and endovascular surgery, DOI: 10.1016/j.ejvs.2018.01.024 3. V. Bilman, T. Cambiaghi, A. Grandi, N. Carta, G. Melissano, R. Chiesa, L. Bertoglio (2020) - Anatomical feasibility of a new off-the-shelf inner branch stent graft (E-inside) for endovascular treatment of thoraco-abdominal aneurysms, European Journal of Cardio-Thoracic Surgery, Volume 58, Issue 6, Pages 1296-1303, https://doi.org/10.1093/ejcts/ezaa276

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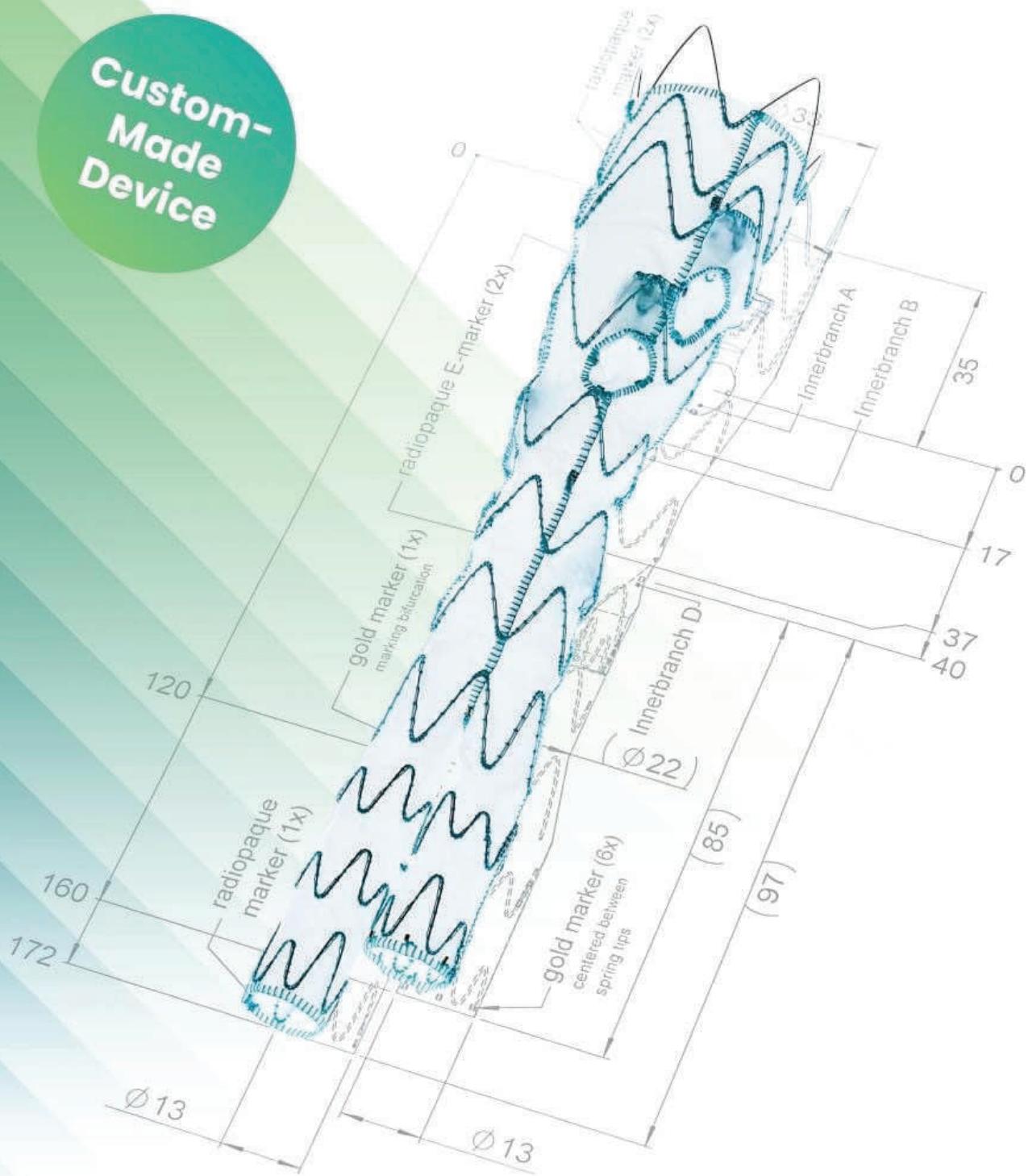
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JT-BR-0650200-EN V03 05/2022

Designed for Patient-Specific Anatomies

Custom-
Made
Device



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E-xtra Design MultiBranch
Stent Graft System

Meeting the Need with a Custom-Made Solution

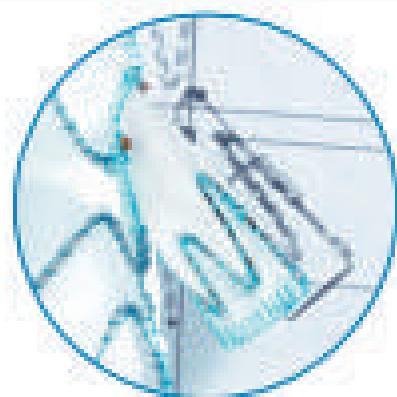
Thoracoabdominal aortic aneurysms (TAAA) are still a major challenge for vascular physicians to deal with. Since the first customised branched endograft that was implanted in 2001, the technology has been evolving to treat patients with varied anatomies and complex pathologies. For more than two decades, E-xtra Design Engineering service has provided physicians with patient-specific solutions for complex endovascular thoracoabdominal repairs.

The E-xtra Design MultiBranch Stent Graft System is indicated for the endovascular treatment of patients with:

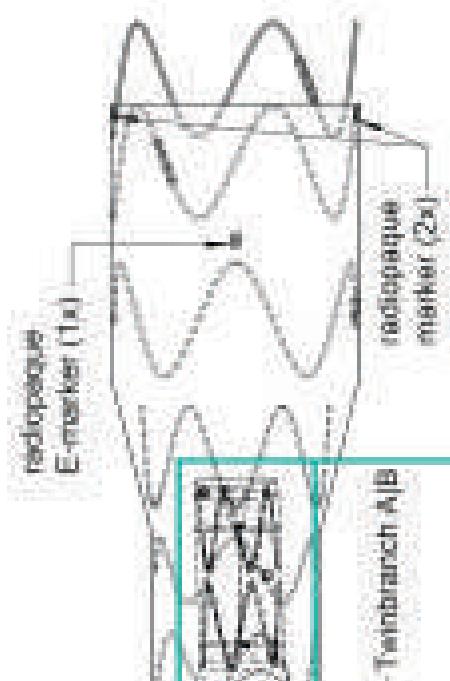
- Type I, II, III, IV or V thoracoabdominal aneurysms
- Supra-, para- or juxtarenal abdominal aortic aneurysms
- Dissections extending to the thoracoabdominal aorta

Dimensions	Description
Main lumen	
Diameters	Proximal: 28 – 40 mm Median: 16 – 26 mm Distal: <ul style="list-style-type: none">• Bifurcated shape: 10, 13 mm• Tube shape: 16 – 40 mm
Minimum and maximum covered length (mm)	105 ≤ L ≤ 235 mm
Features	
Design	<ul style="list-style-type: none">• Outer branches• Inner branches• Semi branches• Twin branches• Scallops• Combination of the above mentioned features
Number	2 to 5 features
Dimensions	Diameters, lengths, widths and orientations are patient-specific

Full Range of Solutions for You



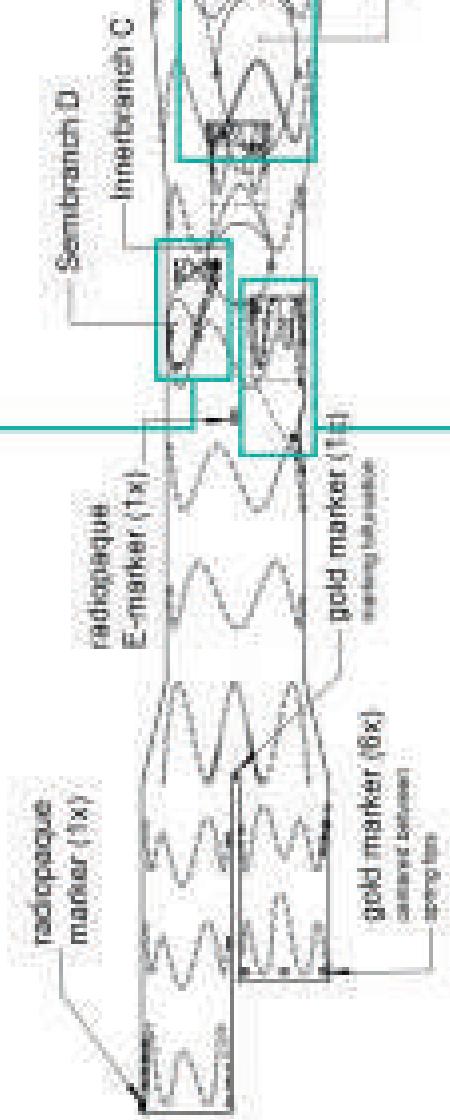
Outer branch



Twin branch



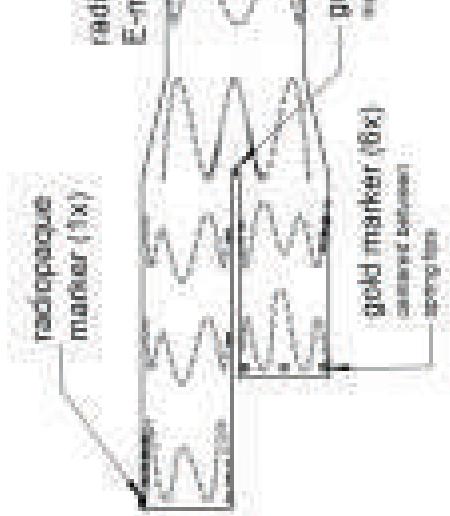
Semi branch



Inner branch



Scallop



Integrated bifurcation

Proven Device through Clinical Evidence

Objectives

Evaluate clinical and technical success as well as safety and feasibility of the **E-xtra Design MultiBranch Stent Graft System**, when used for the treatment of TAAA.

General Study Information

- Observational, prospective, multicenter study
- PCI: Prof. Schelzig, Düsseldorf, Germany
- 44 patients with thoracoabdominal aneurysm were treated
- 8 centers (7 DE, 1 ES)
- 3 years Follow-Up planned
- CoreLab: Dr. Kerezsy, Passau, Germany

Primary Endpoints	N (%) (ITT*=44)
All cause mortality at 30 days	0 (0 %)
Primary technical success	42** (95.5 %)
Reintervention at 30 days (Restoration of renal artery patency)	1 (2.3 %)

* Intent-To-Treat (ITT): defined as all subjects enrolled in the study who attended the procedure

** 2 Patent treated branch vessels 24h after the index procedure

First Interim Results (4-6 weeks Follow-Up)

Results	Other Custom-Made + Standard Multibranched Devices ^{1,2}	CONNECT PMCF Study ³
Early Mortality	3.7 - 8.8 %	0 %
Primary patency	96.6 - 97.3 %	98.1 %
Paraplegia	3.8 - 5 %	4.8 %
Paraparesis	Transient paraparesis: 11.4 % Permanent paraparesis: 2.2 %	2.4 %

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1. Fernandez, C. C. et al. Standard off-the-shelf versus custom-made multibranched thoracoabdominal aortic stent grafts. J Vasc Surg 63, 1208-1215, doi:10.1016/j.jvs.2015.11.035 (2016). 2. Hu, Z. et al. Multibranched Stent-Grafts for the Treatment of Thoracoabdominal Aortic Aneurysms: A Systematic Review and Meta-analysis. J Endovasc Ther 23, 626-633, doi:10.1177/1526602816647723 (2016). 3. Data on file at JOTEC GmbH.

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