



E[®]-vita OPEN PLUS
Stent Graft System

THE ULTIMATE IN PERFORMANCE AND QUALITY: STENT GRAFT SYSTEMS FROM JOTEC

JOTEC is an innovation-oriented company that consistently focuses on its core competencies: the development and manufacture of high-quality medical devices for the treatment of aortic and peripheral vascular disease. Working closely with the clinical users, we develop and produce therapeutic solutions that meet the most demanding needs of clinical practice and ensure safe, effective treatment of patients.



The product portfolio comprises:

- Endovascular stent graft systems
- Hybrid stent graft systems
- Peripheral stents
- Conventional vascular grafts
- Interventional accessories including sheaths, guide wires and balloon catheters

E-vita OPEN PLUS

The original: Uniquely effective

Following the launch of the first generation, this hybrid stent graft system has established itself in the treatment of complex thoracic lesions of the aorta. The combination of classical vascular reconstruction and intraluminal aortic stenting significantly simplifies the existing therapeutic procedures.

Trust the original, trust E-vita OPEN PLUS

Many years of clinical data confirm the efficiency and safety of this product and treatment concept. The one-piece implant guarantees a continuous and seamless transition between the woven vascular graft section and the stent graft section. Impregnation or preclotting can be dispensed with thanks to the blood-tight woven polyester fabric¹. The suture collar facilitates a tension-free and flexible anastomosis between the stent graft and the aortic wall. The stent graft configuration also impresses with its high flexibility and optimal radial force, together with excellent anti-kink behaviour and longitudinal stability.

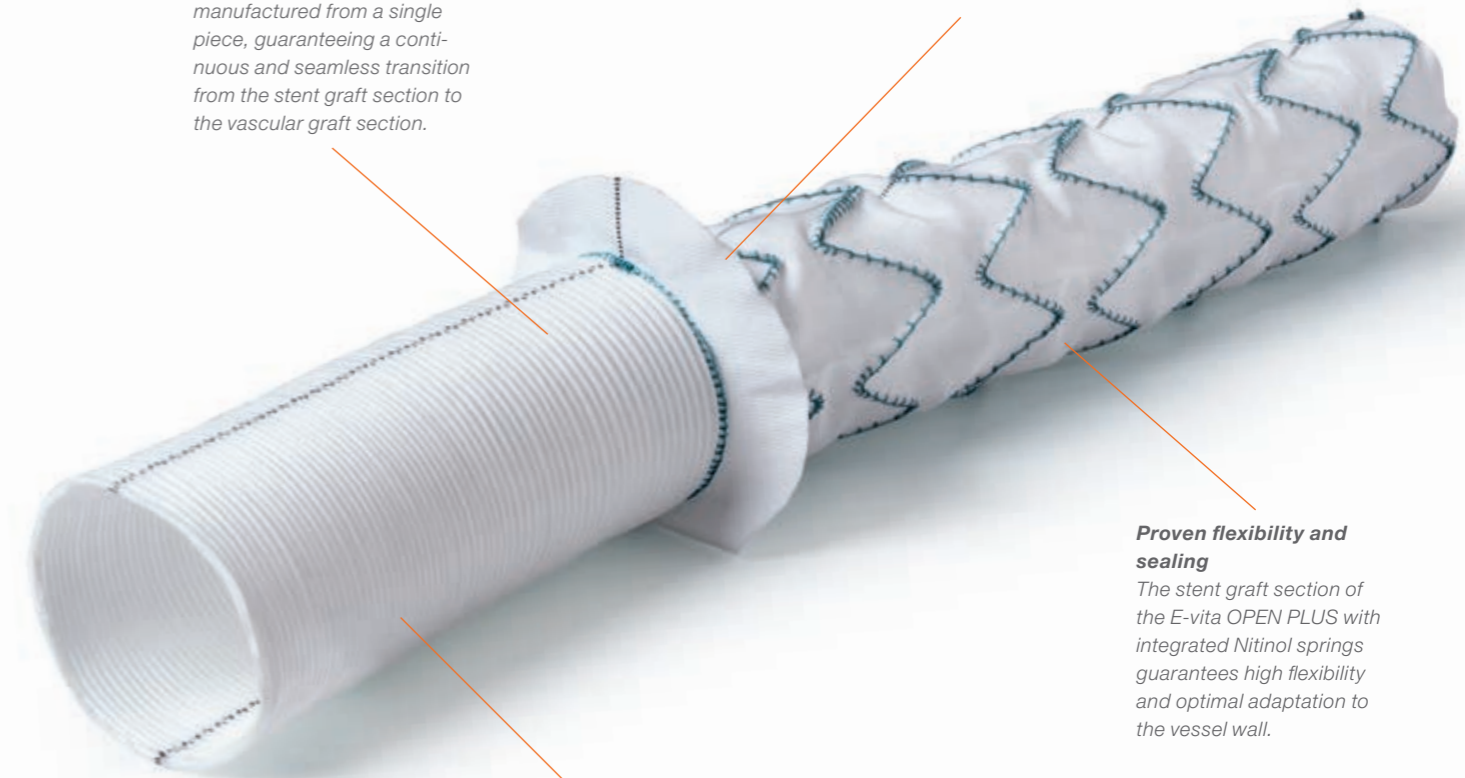
Perfect components for successful treatment

One-piece

The E-vita OPEN PLUS hybrid stent graft system is manufactured from a single piece, guaranteeing a continuous and seamless transition from the stent graft section to the vascular graft section.

Easy suturing, better retention

The ideally dimensioned flexible suture collar facilitates secure anastomosis of the stent graft section with the aortic wall and offsets differences in diameter.



Primarily blood-tight

The woven polyester is primarily blood-tight¹ and does not require any additional coating or preclotting, making for a simpler procedure.

Proven flexibility and sealing

The stent graft section of the E-vita OPEN PLUS with integrated Nitinol springs guarantees high flexibility and optimal adaptation to the vessel wall.

THE ULTIMATE IN HANDLING: THE JOTEC DELIVERY SYSTEM

The E-vita OPEN PLUS delivery system excels with its proven Squeeze-to-Release by offering outstanding and controlled handling. The operations during use are optimally matched to the needs of the user:

- Atraumatic vascular access thanks to the inflatable and deflatable balloon tip
- Optimal handling thanks to the short delivery system
- Exact placement of the product thanks to the separate positioning aid
- Maximum flexibility thanks to the reinforced catheter material
- Extremely precise release thanks to the patented JOTEC Squeeze-to-Release

Control centre

The ergonomically shaped control handle secures the position of the delivery system during the procedure.

Discover simplicity

The Squeeze-to-Release is activated simply by sliding the switch. The following options are available: „Park position“ (P), „Release“ (D for Drive) and „Neutral position“ (N). Sliding the switch to D opens the lever mechanism. The stent graft is gradually released by gently moving the lever up and down. In the neutral position the handle can be moved continuously to release the stent graft.



Pole position

The positioning aid enables precise positioning of the E-vita OPEN PLUS. The distal ring on the positioning aid marks the transition from the stent graft section to the vascular graft section and helps to avoid possible incorrect placement.



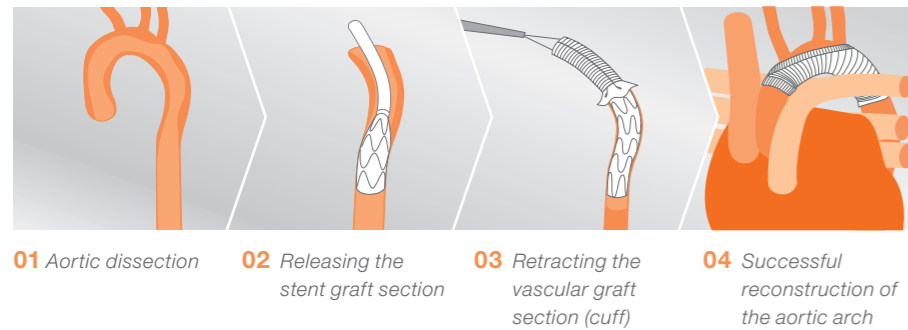
Smooth passage

The inflatable and deflatable balloon tip ensures a smooth transition from the tip to the textile sheath and thus a gentle vascular access.

OPTIMIZED FROZEN ELEPHANT TRUNK: TWO IN ONE

The combination of surgical and endovascular treatment allows a one-stage aortic reconstruction, where two surgical procedures would otherwise be required.

The stentgraft section of E-vita OPEN PLUS treats the surgically inaccessible part of the thoracic aorta. The woven vascular graft section allows secure fixation and serves as a link to the classical vascular reconstruction of the aortic arch.



The following indications can be treated in a single procedure with E-vita OPEN PLUS:

- Acute aortic dissections Stanford type A
- Complex aortic dissections Stanford type B
- Extensive aortic aneurysms
- Chronic extensive aortic dissections

The ultimate in experience thanks to daily clinical use:

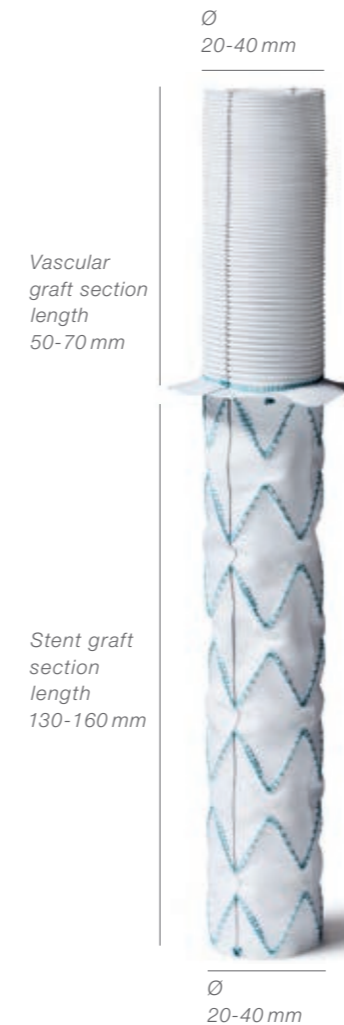
The product design and the clinical use have been described in numerous scientific publications, all of which confirm the unique advantage of the E-vita OPEN PLUS hybrid stent graft in connection with the Frozen Elephant Trunk procedure.

The international E-vita OPEN PLUS Registry with over 400 patients testifies to the excellent therapeutic success that has been achieved in this study. Worldwide, over 3,000 patients have been successfully treated to date with E-vita OPEN PLUS.

Since December 2013 the use of E-vita OPEN PLUS has been recommended by the UK agency NICE (National Institute for Health and Care Excellence) for the treatment of complex thoracic lesions of the aorta.

Results with E-vita OPEN PLUS demonstrate the following:

- Patient avoids the need for a second procedure ^{2,3,4,5,6}
- Efficient and appropriate option for acute and chronic thoracic lesions of the aorta ^{3,4,5}
- Very low rates for morbidity, mortality and postoperative complications compared to the traditional 2-stage procedure ^{2,3,4}
- No proximal endoleaks ^{2,6}
- Reduces surgical trauma, making it a possible therapeutic option for older patients ⁷
- Promotes regression of the false lumen in aortic dissections ^{2,3}



The ultimate in effectiveness – E-vita OPEN PLUS

Since the product portfolio comprises a large number of product configurations, the appropriate E-vita OPEN PLUS hybrid stent graft can be selected to match the specific vascular anatomy of the individual patient.

Configurations

Catalogue number	Length of stent graft (mm)	Length of graft (mm)	Ø graft (mm)	Ø proximal (mm)	Ø distal (mm)
71AC2020S13-PL-CO	130	50	20	20	20
71AC2222S13-PL-CO	130	50	22	22	22
71AC2424S13-PL-CO	130	50	24	24	24
71AC2828S13-PL-CO	130	50	28	28	28
71AC3030S13-PL-CO	130	50	30	30	30
71AC3333S13-PL-CO	130	50	33	33	33
71AC3636S13-PL-CO	130	50	36	36	36
71AC4040S13-PL-CO	130	50	40	40	40
71AC2424S15-PL-CO	150	70	24	24	24
71AC2828S15-PL-CO	150	70	28	28	28
71AC3030S15-PL-CO	150	70	30	30	30
71AC3333S16-PL-CO	160	70	33	33	33
71AC3636S16-PL-CO	160	70	36	36	36
71AC4040S16-PL-CO	160	70	40	40	40

References:

- ¹ Tsagakis, K et al; Impermeability to Blood of the E-vita OPEN PLUS Hybrid Stent-Graft; J ENDOVASC THER 2010;17:340-348
- ² Mestres, Carlos-A. et al; One-stage repair in complex multisegmental thoracic aneurysmal disease: results of a multicentre study; Eur J Cardio-Thorac Surg 2013; 1-7
- ³ Jakob, H and Tsagakis, K; International E-vita open registry; Ann Cardiothorac Surg 2013;2(3):296-299
- ⁴ Di Eusanio, M. et al; Frozen elephant trunk surgery – the Bologna's experience; Ann Cardiothorac Surg 2013;2(5):597-605
- ⁵ Tsagakis, K. et al; Overall Essen's experience with the E-vita open hybrid stent graft system and evolution of the surgical technique; Ann Cardiothorac Surg 2013;2(5):612-620
- ⁶ Jakob, H.; Fascillated surgical strategy in total arch replacement and descending aorta stent grafting with the E-vita open hybrid prosthesis; Ann Cardiothorac Surg 2013;2(5):663-664
- ⁷ Herold U. et al; Neue Entwicklungen in der Aorten Chirurgie; Herz 2006; 31; 434-42

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