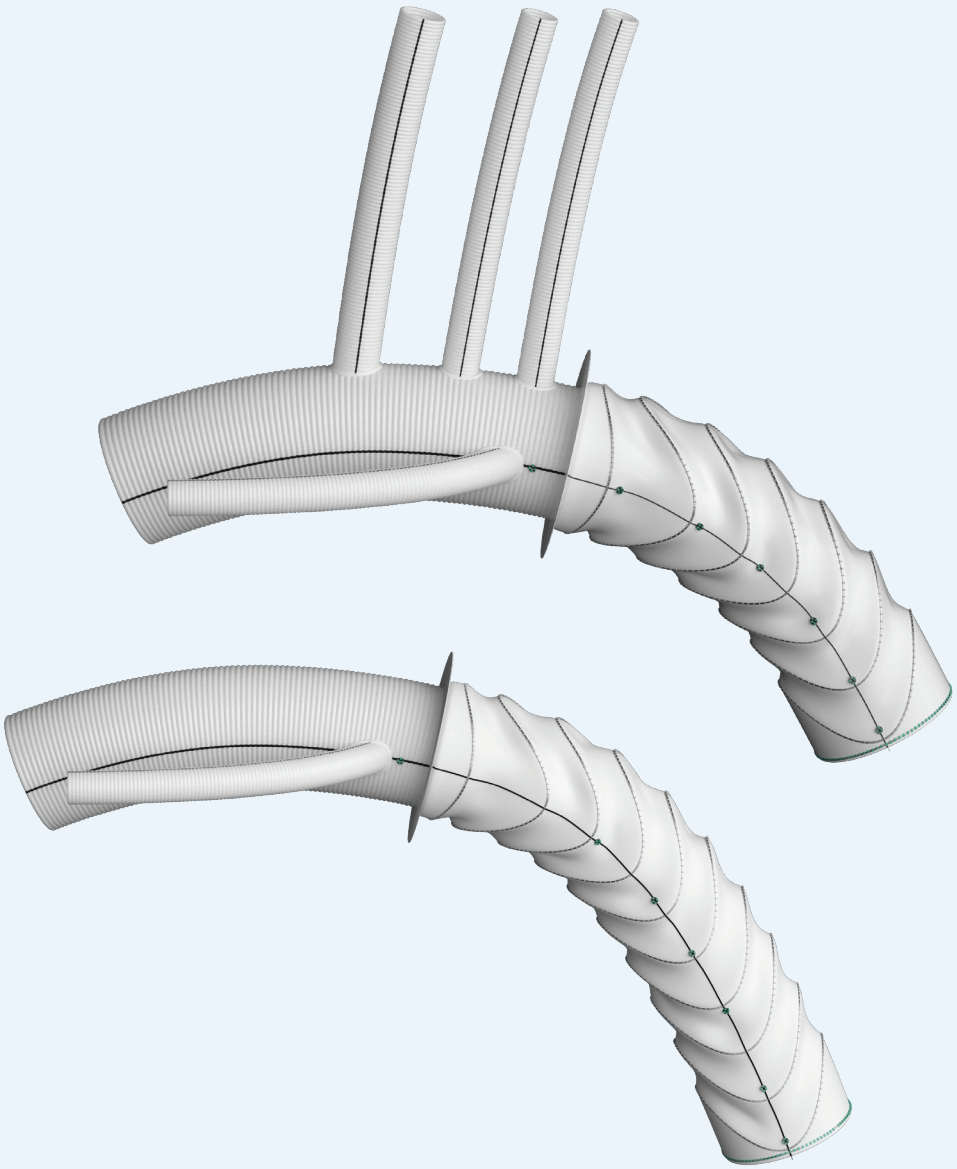
TERUMO AORTIC

USA



PRODUCT BROCHURE

Thoraflex™ Hybrid

Conforming Arch Surgery to the Gold Standard

For more information, visit
terumoaortic.com/thoraflex-hybrid

thoraflex™ hybrid

Gold Standard, Surgical Confidence

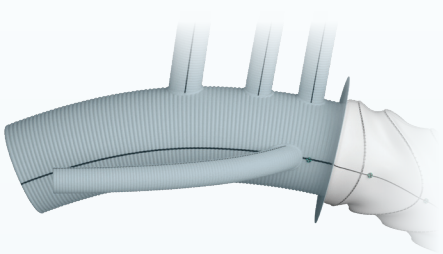
Deliver proven outcomes when treating your patient's complex aortic arch pathology, utilizing innovative Terumo Aortic Hybrid Solutions.

10+
Years of Clinical data

8.1%
30 day mortality rate [4]
Acute Thoracic Aortic Syndrome
(5/62 Patients)

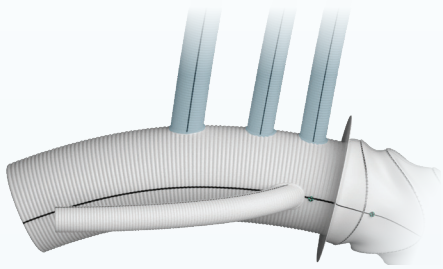
100%
Gelatin Sealed
Gelweave™ surgical graft and polyester stent graft

5%
30 Day Mortality Rate [4]
(Total 9/181 patients)



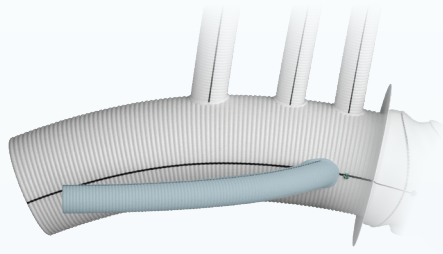
Polyester Graft

- Gelatin sealed *(hydrolysis <14 days)*
- Effective & easy suturing [1]
- Easy to handle [1]
- Gelatin: lower thrombogenic potential [2] *(than unsealed polyester grafts)*
- High resistance to dilation *at 2 years* [3]



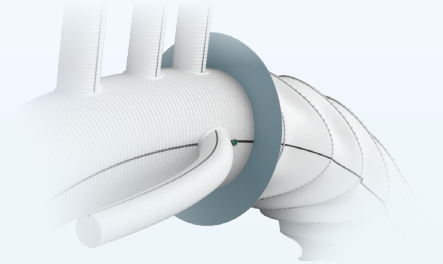
Supra-Aortic Branches

- Plexus design
- Replacement of dissected vessels
- 12/8/10mm or 10/8/8mm



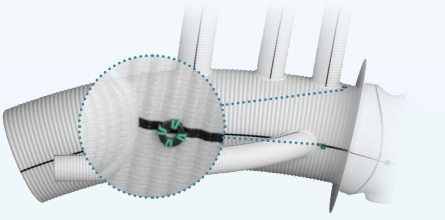
Antegrade Perfusion Branch

- Facilitates organ perfusion and rewarming [5]



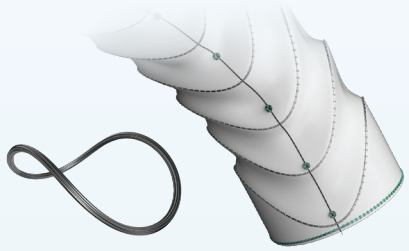
Pre-attached Collar

- Easier/safer Anastomosis [5]
- Reduced Haemodynamic traction [5]



Tantalum Radiopaque Markers

- Stent: Endovascular extension markers (20mm increments)
- Graft: 2x branch markers



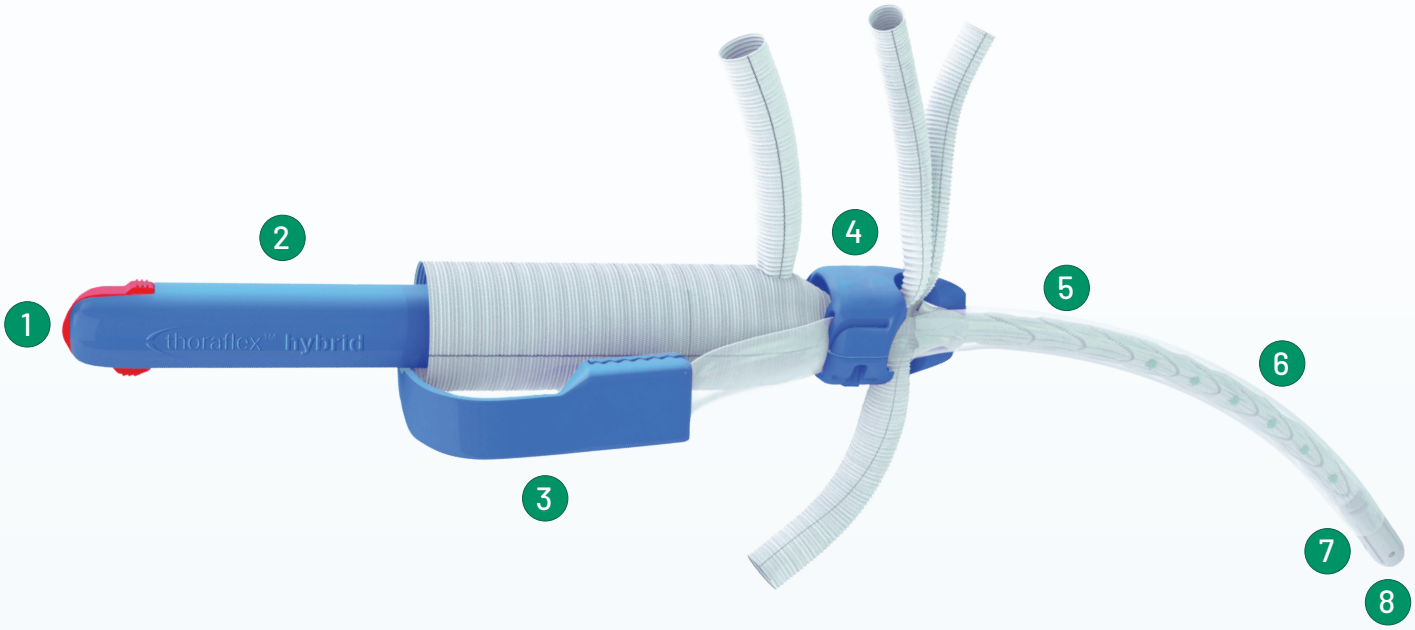
Independent Ring-Stent Design

- Anatomic Conformability [6]
- Minimizes risk of intimal injury [6]
- Induces downstream remodelling [7]
- Structural support for **Gelatin Sealed** endovascular fabric

1. Adachi *et al*. (1996) 'Clinical Experience of a New Gelatin Impregnated Woven Dacron Graft.' *Japan Journal of Artificial Organs*, 25 (1), pp214-219.
2. Drury *et al*. (1987) 'Experimental and Clinical Experience with a Gelatin Impregnated Dacron Prosthesis.' *Annals of Vascular Surgery*, 1, pp542-547.
3. Mattens *et al*. (1999) 'Gelseal® Versus Gelweave® Dacron Prosthetic Grafts in the Descending Thoracic Aorta: A Two-Year Computed Tomography Scan Follow-Up Study.' *Cardiovascular Surgery*, 7 (4), pp432- 435.

Flexible & Compact Delivery System

Intuitive design with enhanced deployment performance for accurate positioning.



1 RELEASE WIRE CLIP

- Designed to detach graft from delivery system

2 HANDLE

- Control during deployment
- Visualization of operating field

3 STRAP HANDLE

- Attached to sheath
- Pull to start graft deployment

4 SHEATH SPLITTER

- Atraumatic blades (top/bottom)
- Rapid release suture system

5 PTFE SHEATH (30F)

- Peelable/Splittable Sheath
- Split-Lines to facilitate deployment

6 MALLEABLE SHAFT

- Adaptable to patient anatomy
- Can be reshaped

7 ATRAUMATIC TIP

- 30F diameter (10mm)

8 (2X) 0.035" GUIDEWIRE ACCESS PORTS

- Delivery system introduction
- Accurate placement of stent

"Thanks to the malleable shaft, the stented part can be shaped to conform to the isthmus and descending aorta anatomy. This makes the device less traumatic on the descending aortic wall and easier to introduce into the aorta..." [5]

4. Results from Thoraflex Hybrid Post-Market Study (THOR) - NCT03414866 (unpublished).
5. Ruggieri *et al*. (2015) 'Multibranched hybrid device for frozen elephant trunk: what does it change?' *Journal of Thoracic & Cardiovascular Surgery*, 15 (1), 253-255.
6. Ma *et al*. (2015) 'Open Stented Grafts for Frozen Elephant Trunk Technique: Technical Aspects and Current Outcomes.' *AORTA*, 3 (4), pp122-135.
7. Berger *et al.* (2018) 'True-lumen and false-lumen diameter changes in the downstream aorta after frozen elephant trunk implantation.' *European Journal of Cardiothoracic Surgery*, 54, pp375–381.

Versatility in Treatment

Plexus and Ante-Flo™ designs enable a choice of surgical techniques and widen the treatable patient population.

Offering Plexus & Ante-Flo Configurations

- Thoraflex™ Hybrid Plexus configuration facilitates individual arch vessel reconstruction [8]
- Thoraflex™ Hybrid Ante-Flo™ configuration facilitates the island technique [9]

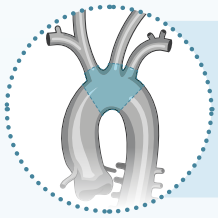
Thoraflex™ Hybrid is designed for the open surgical repair of aneurysms and/or dissections in the aortic arch and descending aorta with or without involvement of the ascending aorta.

100%
False Lumen Thrombosis
(within 2 years) [10]
at the level of the stent graft

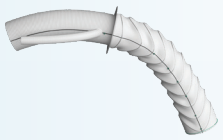
1
Single-Stage Operation Potential for the Patient [11]

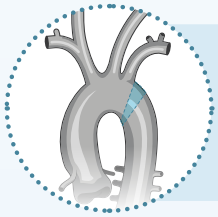
Global Regulatory Approvals
EU (2012), US (2022), Japan (2023)

40
Size Options
Multiple configurations offer optimal outcomes to a wider patient population

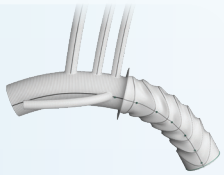


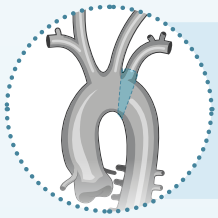
Island/En Bloc
Re-implantation of SAT
SAT = Supra-Aortic Trunk



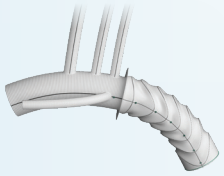


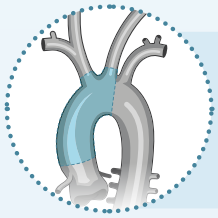
Zone 3
Standard technique



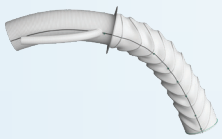


Zone 2
Distal LSA anastomosis
LSA = Left Subclavian Artery





Zone 0/1
Proximal anastomosis



8. Di Marco *et al*. (2017) 'The frozen elephant trunk technique: European Association for Cardio-Thoracic Surgery Position and Bologna experience.' *Korean Journal Thoracic & Cardiovascular Surgery*, 50, pp1-7.
9. Coselli *et al.* (2024) 'Total aortic arch replacement using a frozen elephant trunk device: Results of a 1-year US multicenter trial', *The Journal of Thoracic and Cardiovascular Surgery- Adult Aorta*, 167 (5) pp1-12.
10. Shrestha *et al*. (2016) 'Total aortic arch replacement with a novel 4-branched frozen elephant trunk prosthesis: single-centre results of the first 100 patients.' *Journal of Thoracic & Cardiovascular Surgery*, 152 (1), pp148-159.

Thinking Ahead

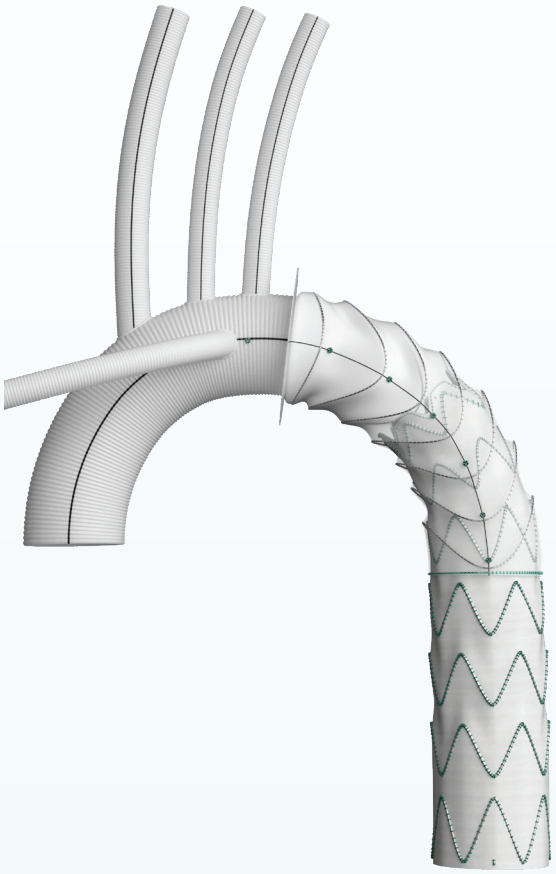
With up to 33% FET repairs needing a future downstream intervention,[12] utilizing Relay®Pro in conjunction with Thoraflex™ Hybrid is indicated for on-label distal endovascular repair.

Relay®Pro offers the ideal endovascular solution to treat FET patients with more extensive disease, by virtue of:

- NBS (non-bare stent) configuration
- Low profile delivery system

Use of Relay®Pro subject to local regulatory approval

CT Image courtesy of Marco Di Eusanio;
Lancisi Cardiovascular Center Ancona, Italy



"Downstream TEVAR following the FET procedure is associated with excellent clinical outcomes. We thus maintain that staging thoracic aortic repair - FET and secondary TEVAR - is a very successful and safe strategy..." [13]

DISCOVER MORE
Features and Benefits of Thoraflex™ Hybrid

Features and Benefits:

terumoaortic.com/features-benefits

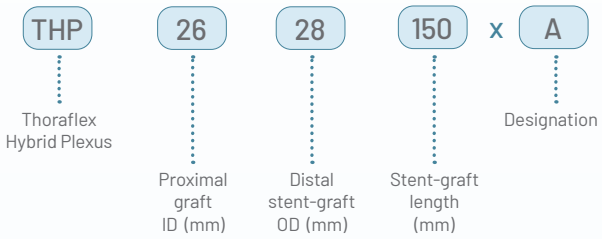
Discover how each of the key features and benefits are integrated into every one of our products to ensure the highest quality and performance possible.

- DURABILITY & RELIABILITY
- SAFETY & EFFICACY
- ADAPTABILITY & VERSATILITY
- FLEXIBILITY
- PRECISION
- DESIGN

11. Mariscalco et al (2019), "Reflection from UK Aortic Group: Frozen Elephant Trunk Technique as Optimal Solution in Type A Acute Aortic Dissection." Seminars in Thoracic Surgery 31, pp686–690.
12. Kreibich *et al.* (2020) 'Aortic reinterventions after the frozen elephant trunk procedure.' *The Journal of Thoracic and Cardiovascular Surgery*', 159 (2), pp392-399.
13. Kreibich *et al.* (2022) 'Downstream thoracic endovascular aortic repair following zone 2, 100mm stent graft frozen elephant trunk implantation.' *Interactive CardioVascular and Thoracic Surgery*, 34 (6), pp1141-1146.

Plexus Product Ordering Information

Catalogue Number Explanation



100mm Stent Length

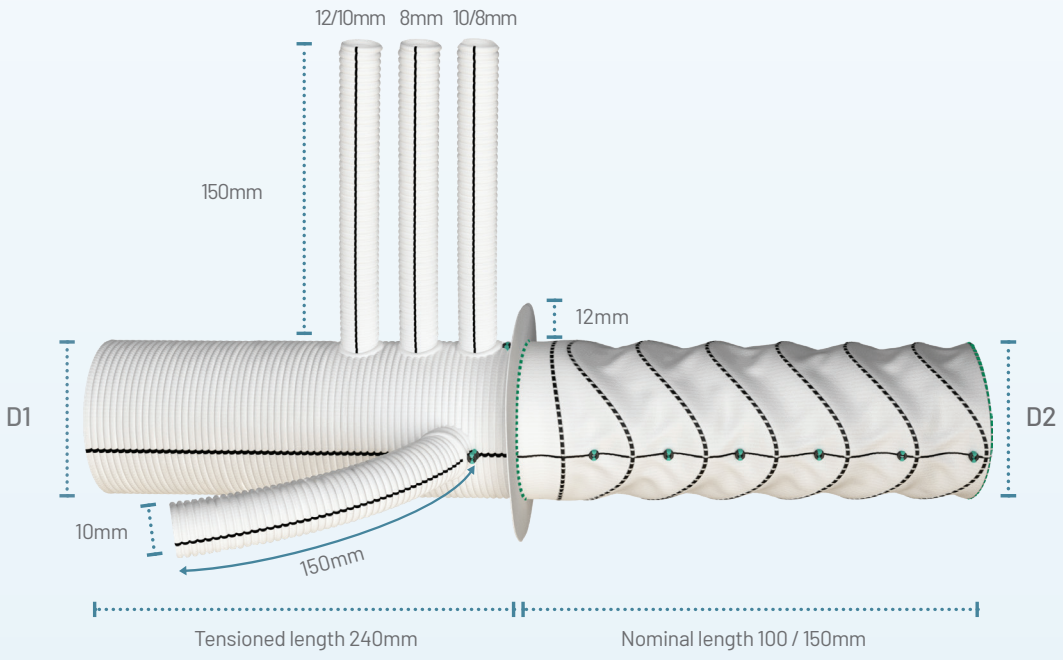
Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THP2224 x 100A*	22	24
THP2426 x 100A*	24	26
THP2628 x 100A	26	28
THP2830 x 100A	28	30
THP3032 x 100A	30	32
THP3034 x 100A	30	34
THP3036 x 100A	30	36
THP3038 x 100A	30	38
THP3040 x 100A	30	40
THP3240 x 100A	32	40

150mm Stent Length

Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THP2224 x 150A*	22	24
THP2426 x 150A*	24	26
THP2628 x 150A	26	28
THP2830 x 150A	28	30
THP3032 x 150A	30	32
THP3034 x 150A	30	34
THP3036 x 150A	30	36
THP3038 x 150A	30	38
THP3040 x 150A	30	40
THP3240 x 150A	32	40

* The branches on THP2224x100A, THP2426x100A, THP2224x150A and THP2426x150A are as follows: 10mm, 8mm & 8mm.
(All other sizes have standard branch diameter configurations: 12mm, 8mm & 10mm)

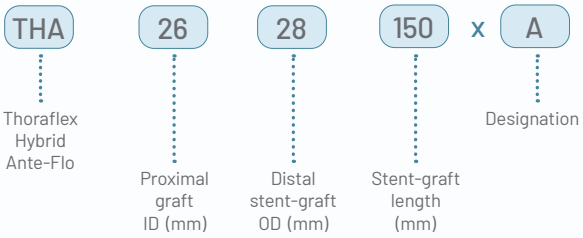
Stent-graft nominal length 100mm / 150mm



Note: drawing not to scale

Ante-Flo™ Product Ordering Information

Catalogue Number Explanation



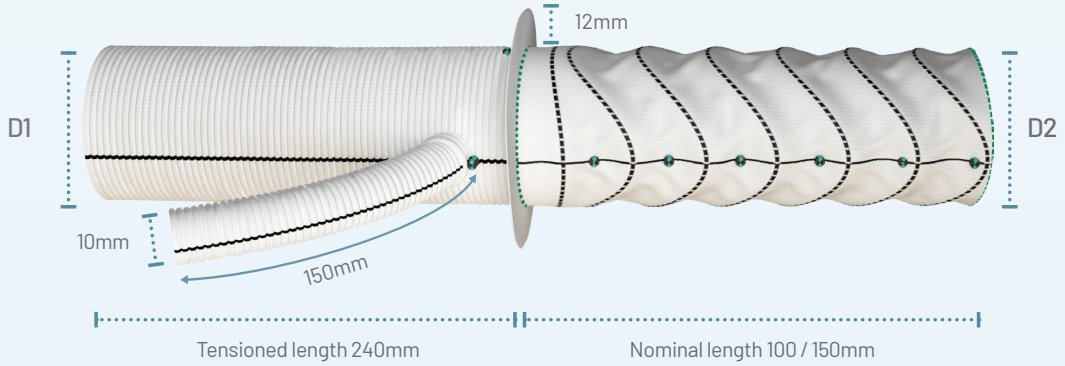
100mm Stent Length

Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THA2224 x 100A	22	24
THA2426 x 100A	24	26
THA2628 x 100A	26	28
THA2830 x 100A	28	30
THA3032 x 100A	30	32
THA3034 x 100A	30	34
THA3036 x 100A	30	36
THA3038 x 100A	30	38
THA3040 x 100A	30	40
THA3240 x 100A	32	40

150mm Stent Length

Catalogue Number	Graft ID - D1 (mm)	Stent-graft OD - D2 (mm)
THA2224 x 150A	22	24
THA2426 x 150A	24	26
THA2628 x 150A	26	28
THA2830 x 150A	28	30
THA3032 x 150A	30	32
THA3034 x 150A	30	34
THA3036 x 150A	30	36
THA3038 x 150A	30	38
THA3040 x 150A	30	40
THA3240 x 150A	32	40

Stent-graft nominal length 100mm / 150mm



Note: drawing not to scale

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TERUMO AORTIC

View IFU at eifu.terumoaortic.com for more information on use, indications, contraindications and warnings/precautions.

Product availability subject to local regulatory approval.

PM-08429

For distributor information, visit terumoaortic.com/contact

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