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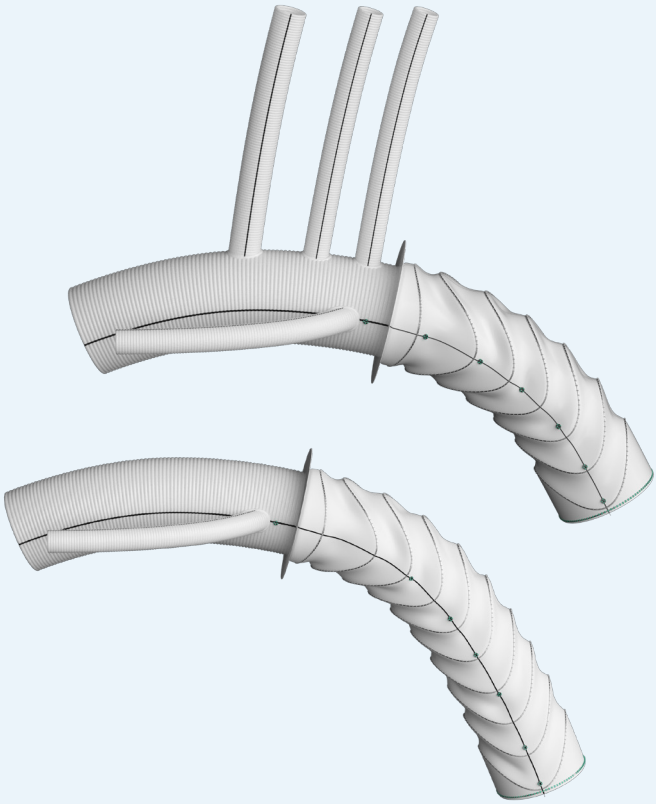
GLOBAL



SIZING GUIDE

Thoraflex™ Hybrid

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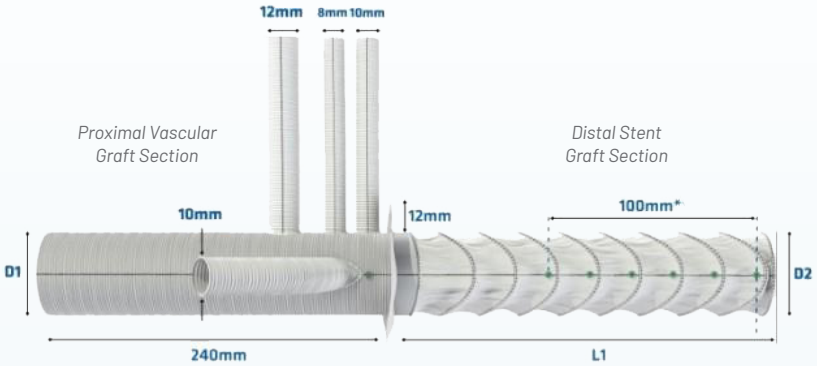
thoraflex™ hybrid

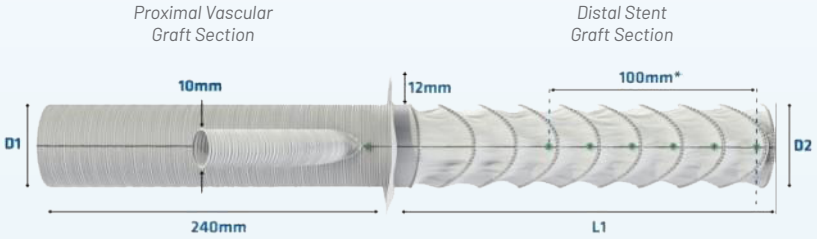
Thoraflex Hybrid Dimensions

Figure 1 Thoraflex Hybrid Plexus Device Dimensions



* Length shown to indicate overall marker positions. The distance between each marker is approximately 20mm but varies from 17.5mm - 22mm depending on the ring stent configuration, which varies with stent section diameter and length.

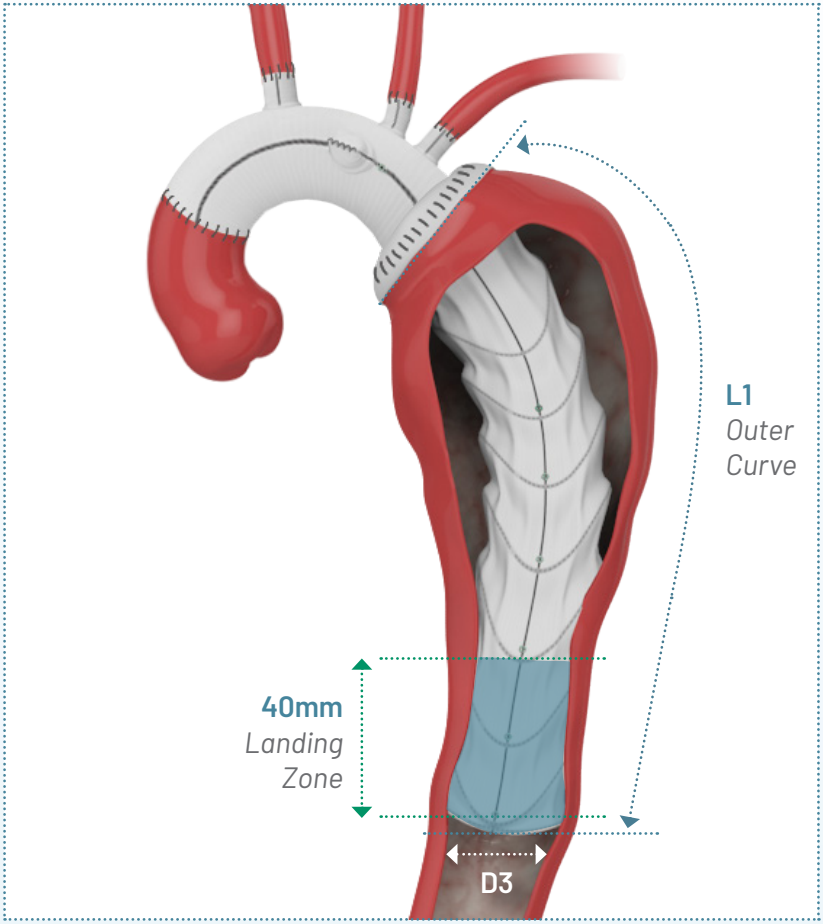
Figure 2 Thoraflex Hybrid Ante-Flo Device Dimensions



* Length shown to indicate overall marker positions. The distance between each marker is approximately 20mm but varies from 17.5mm - 22mm depending on the ring stent configuration, which varies with stent section diameter and length.

Thoraflex Hybrid Sizing

Figure 3 Device Sizing



Stent ring oversizing and landing zone guidelines are applicable to all designs. Some movement of the distal ring of the Thoraflex Hybrid implant may occur following re-perfusion of the thoracic aorta. Excessive aortic tortuosity may result in inability to properly position the stent-graft, or stent-graft kinking with thrombus formation. If balloon modelling is desired (e.g., for endoleak, stent-graft kinking or stenosis), use a compliant balloon equal in size to the largest target vessel's diameter. Balloon inflation should not exceed 1 atm.

Sizing Chart - Aneurysm

Table 1 Thoraflex Hybrid Aneurysm sizing chart

Catalogue No. (Plexus Design)	Catalogue No. (Ante-Flo Design)	D1 Graft ID (mm)	D2 Stent Graft OD (mm)	D3 Descending Landing Zone Vessel ID (mm)	Branch Configuration IA, LCC, LSA (mm)	L1* Stent Graft Nominal Length (mm)
THP2224x100E	THA2224x100E	22	24	19-21	10,8,8	100
THP2426x100E	THA2426x100E	24	26	20-22	10,8,8	100
THP2628x100E	THA2628x100E	26	28	22-24	12,8,10	100
THP2830x100E	THA2830x100E	28	30	24-26	12,8,10	100
THP3032x100E	THA3032x100E	30	32	25-27	12,8,10	100
THP3034x100E	THA3034x100E	30	34	27-29	12,8,10	100
THP3036x100E	THA3036x100E	30	36	29-31	12,8,10	100
THP3038x100E	THA3038x100E	30	38	30-33	12,8,10	100
THP3040x100E	THA3040x100E	30	40	32-34	12,8,10	100
THP3240x100E	THA3240x100E	32	40	32-34	12,8,10	100
THP2224x150E	THA2224x150E	22	24	19-21	10,8,8	150
THP2426x150E	THA2426x150E	24	26	20-22	10,8,8	150
THP2628x150E	THA2628x150E	26	28	22-24	12,8,10	150
THP2830x150E	THA2830x150E	28	30	24-26	12,8,10	150
THP3032x150E	THA3032x150E	30	32	25-27	12,8,10	150
THP3034x150E	THA3034x150E	30	34	27-29	12,8,10	150
THP3036x150E	THA3036x150E	30	36	29-31	12,8,10	150
THP3038x150E	THA3038x150E	30	38	30-33	12,8,10	150
THP3040x150E	THA3040x150E	30	40	32-34	12,8,10	150
THP3240x150E	THA3240x150E	32	40	32-34	12,8,10	150

* Nominal Length Quoted.

This is the recommended sizing for the Thoraflex Hybrid implant for aneurysm treatment, when landed distally in healthy vessel of the descending thoracic aorta. The Thoraflex Hybrid aneurysm sizing chart incorporates a suitable oversize of ring stent diameter to aortic diameter. Aortic diameter is based on inner vessel diameter (ID) measurements therefore no further oversize is required. If outside vessel diameters (OD) are measured, then an allowance for the vessel wall thickness must be made before using the sizing chart for device selection. Based on testing that has been performed it is recommended that a 40mm distal landing zone length is used and will provide optimum sealing within healthy vessel (Table 1, Figure 1, Figure 2, Figure 3).

NOTE: The diameter of the sheath measures 10mm.

Sizing Chart - Dissection

Table 2 Thoraflex Hybrid Dissection sizing chart

Catalogue No. (Plexus Design)	Catalogue No. (Ante-Flo Design)	D1 Graft ID (mm)	D2 Stent Graft OD (mm)	D3 Descending Landing Zone Vessel ID (mm)	Branch Configuration IA, LCC, LSA (mm)	L1* Stent Graft Nominal Length (mm)
THP2224x100E	THA2224x100E	22	24	20-22.5	10,8,8	100
THP2426x100E	THA2426x100E	24	26	21.5-24.5	10,8,8	100
THP2628x100E	THA2628x100E	26	28	23.5-26.5	12,8,10	100
THP2830x100E	THA2830x100E	28	30	25-28.5	12,8,10	100
THP3032x100E	THA3032x100E	30	32	26.5-30	12,8,10	100
THP3034x100E	THA3034x100E	30	34	28.5-32	12,8,10	100
THP3036x100E	THA3036x100E	30	36	30-34	12,8,10	100
THP3038x100E	THA3038x100E	30	38	32-36	12,8,10	100
THP3040x100E	THA3040x100E	30	40	34-38	12,8,10	100
THP3240x100E	THA3240x100E	32	40	34-38	12,8,10	100
THP2224x150E	THA2224x150E	22	24	20-22.5	10,8,8	150
THP2426x150E	THA2426x150E	24	26	21.5-24.5	10,8,8	150
THP2628x150E	THA2628x150E	26	28	23.5-26.5	12,8,10	150
THP2830x150E	THA2830x150E	28	30	25-28.5	12,8,10	150
THP3032x150E	THA3032x150E	30	32	26.5-30	12,8,10	150
THP3034x150E	THA3034x150E	30	34	28.5-32	12,8,10	150
THP3036x150E	THA3036x150E	30	36	30-34	12,8,10	150
THP3038x150E	THA3038x150E	30	38	32-36	12,8,10	150
THP3040x150E	THA3040x150E	30	40	34-38	12,8,10	150
THP3240x150E	THA3240x150E	32	40	34-38	12,8,10	150

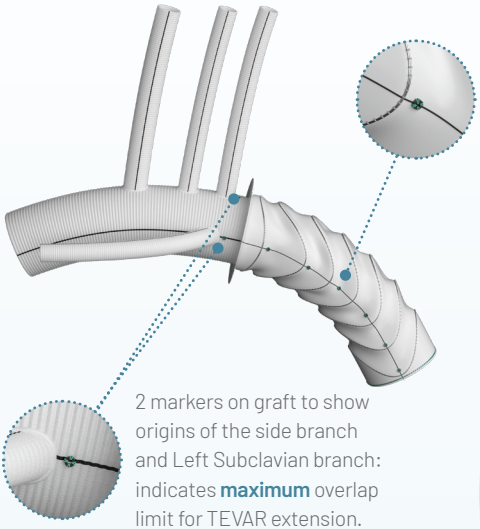
* Nominal Length Quoted.

This section describes the recommended sizing for the Thoraflex Hybrid implant for dissection treatment, when landed distally in dissected vessel of the descending thoracic aorta. When oversizing in a dissection clinical judgement must be used on an individual patient basis, using the Thoraflex Hybrid dissection sizing chart (Table 2) as a guideline. The Thoraflex Hybrid dissection sizing chart incorporates a suitable oversize of ring stent diameter to aortic diameter. It is recommended that a minimum 40mm distal landing zone length is used.

NOTE: The diameter of the sheath measures 10mm.

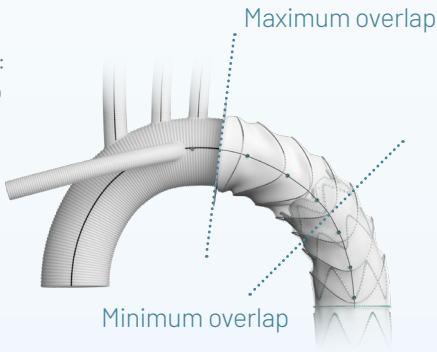
2nd Stage Extension

Figure 4 Thoraflex Hybrid Radiopaque Markers



Stent graft markers positioned 20mm apart. Minimum overlap for Relay® Pro NBS TEVAR extension is 3 covered stents or 50mm (per IFU).

2 markers on graft to show origins of the side branch and Left Subclavian branch: indicates **maximum** overlap limit for TEVAR extension.



Due to the indications for use and the device configurations, if the lesion requires use of an extension, **only a Relay NBS configuration should be used**. Adjunctive devices with barb or hook features which would be positioned in the overlap region should not be used.

The implantation procedure for Relay NBS devices should follow the manufacturer's IFU, describing an endovascular retrograde implantation approach. Compatibility of extension devices deployed from the antegrade approach has not been assessed, as this approach is not indicated in the IFU.

The minimum recommended overlap between a Relay NBS device and a Thoraflex Hybrid implant is three overlapping covered stents (approximately 50mm). Smaller overlap may result in endoleak (with or without component separation).

2nd Stage Extension

Figure 5 Thoraflex Hybrid Distal Stent within the Aneurysm

Thoraflex Hybrid is indicated to be extended using a Relay NBS device to exclude aneurysms longer than the standard Thoraflex Hybrid device. In these cases the distal stent graft of the Thoraflex Hybrid will be within the aneurysm sac and there will be no distal seal until the Relay NBS device has been implanted.

Sizing of the Thoraflex Hybrid device should be based on the complete treatment and take into account the size of the distal landing zone of the compatible Relay NBS device, e.g. if a 34mm Relay NBS device has been selected for the distal treatment then the compatible Thoraflex Hybrid device would be 32mm – see Section 17.2 for further information on extension device sizing.

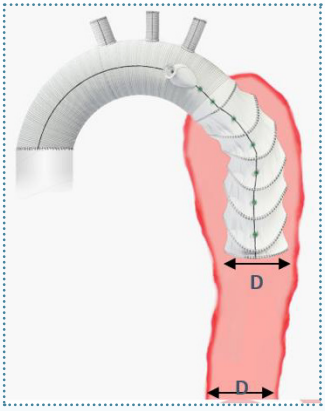
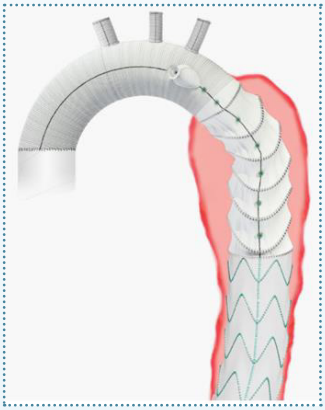


Figure 6 Thoraflex Hybrid Extended with a Relay NBS Stent-Graft

Once a suitable Relay NBS device has been selected to treat D3 (e.g. a 34mm device) then a compatible Thoraflex Hybrid device can be chosen with a relevant D2 (e.g. 32mm)

In these cases where the Thoraflex Hybrid does not create a complete distal seal, using larger devices than required will increase the complexity of sizing the extension device and may additionally increase the risk of thrombus generation until completion of the therapy



Sizing Chart – 2nd Stage Aneurysm

Relay NBS device lengths should be selected accordingly. For modular, unsupported junctions (i.e. where the Thoraflex Hybrid distal stent graft region is within an aneurysm sac), a Relay NBS device with a proximal outer diameter 2mm greater than the nominal outer diameter of the in-situ Thoraflex Hybrid must be used (Table 3).

In these cases the distal stent graft of the Thoraflex Hybrid will be in the aneurysm sac and there will be no distal seal until the Relay NBS device is implanted. This may increase the risk of thrombus generation until completion of the therapy. Sizing of the Thoraflex Hybrid device should be based on the complete treatment and take into account the size of the distal landing zone of the compatible Relay NBS device, e.g. if a 34mm Relay NBS device has been selected for the distal treatment then the compatible Thoraflex Hybrid device would be 32mm.

Table 3 Thoraflex Hybrid implant with Relay NBS extension device – Unsupported junction sizing chart

Catalogue No. (Plexus Design)	Catalogue No. (Ante-Flo Design)	Thoraflex Hybrid Stent Graft OD (mm)	Relay NBS Stent Graft Proximal OD (mm)
THP2224X100E	THA2224X100E	24	26
THP2426X100E	THA2426X100E	26	28
THP2628X100E	THA2628X100E	28	30
THP2830X100E	THA2830X100E	30	32
THP3032X100E	THA3032X100E	32	34
THP3034X100E	THA3034X100E	34	36
THP3036X100E	THA3036X100E	36	38
THP3038X100E	THA3038X100E	38	40
THP3040X100E	THA3040X100E	40	42
THP3240X100E	THA3240X100E	40	42
THP2224X150E	THA2224X150E	24	26
THP2426X150E	THA2426X150E	26	28
THP2628X150E	THA2628X150E	28	30
THP2830X150E	THA2830X150E	30	32
THP3032X150E	THA3032X150E	32	34
THP3034X150E	THA3034X150E	34	36
THP3036X150E	THA3036X150E	36	38
THP3038X150E	THA3038X150E	38	40
THP3040X150E	THA3040X150E	40	42
THP3240X150E	THA3240X150E	40	42

In cases of aneurysm, extension procedures should be planned and performed to ensure that the combined devices take the outer curve between the proximal anastomosis above the aneurysm and the distal neck below the aneurysm. This is consistent with the existing guidance for planning and implantation of Thoraflex Hybrid. When extending Thoraflex Hybrid with a Relay NBS device, the distal end of the Relay NBS should be landed in healthy vessel within the descending thoracic aorta according to the Relay NBS distal sizing chart (Table 5).

NOTE: This sizing follows the Relay NBS IFU.

Sizing Chart – 2nd Stage Dissection

For modular, supported junctions (i.e. where the Thoraflex Hybrid distal stent graft region is within dissection), a Relay NBS device with a proximal outer diameter equal to the nominal outer diameter of the in-situ Thoraflex Hybrid must be used (Table 4). Sizing outside these guidelines may result in endoleak, migration, stent-graft separation, infolding or device damage.

Table 4 Thoraflex Hybrid implant with Relay NBS extension device – Supported junction sizing chart

Catalogue No. (Plexus Design)	Catalogue No. (Ante-Flo Design)	Thoraflex Hybrid Stent Graft OD (mm)	Relay NBS Stent Graft Proximal OD (mm)
THP2224X100E	THA2224X100E	24	24
THP2426X100E	THA2426X100E	26	26
THP2628X100E	THA2628X100E	28	28
THP2830X100E	THA2830X100E	30	30
THP3032X100E	THA3032X100E	32	32
THP3034X100E	THA3034X100E	34	34
THP3036X100E	THA3036X100E	36	36
THP3038X100E	THA3038X100E	38	38
THP3040X100E	THA3040X100E	40	40
THP3240X100E	THA3240X100E	40	40
THP2224X150E	THA2224X150E	24	24
THP2426X150E	THA2426X150E	26	26
THP2628X150E	THA2628X150E	28	28
THP2830X150E	THA2830X150E	30	30
THP3032X150E	THA3032X150E	32	32
THP3034X150E	THA3034X150E	34	34
THP3036X150E	THA3036X150E	36	36
THP3038X150E	THA3038X150E	38	38
THP3040X150E	THA3040X150E	40	40
THP3240X150E	THA3240X150E	40	40

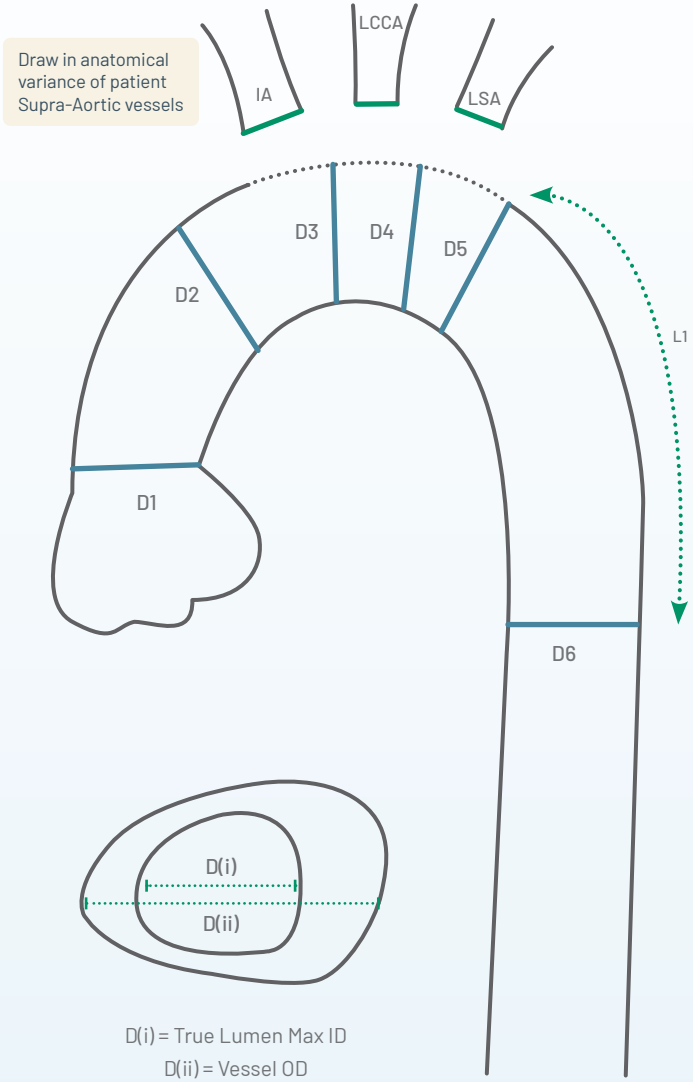
Table 5 Relay NBS extension device - distal sizing chart

Relay NBS Stent Graft Distal OD (mm)	Descending landing zone vessel ID (mm)	Distal landing zone length (mm)
24	20-21	25
26	22-23	
28	24-25	
30	26-27	
32	28-29	
34	30-31	
36	32-33	
38	34	
40	35-36	30
42	37-38	

Sizing Notes

IA: Innominate Artery
LCCA: Left Common Carotid Artery
LSA: Left Subclavian Artery

Draw in anatomical variance of patient Supra-Aortic vessels



D(i) = True Lumen Max ID
D(ii) = Vessel OD

Notes

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