Hybrid Repair of Arch and Descending Aorta Lesions with The Thoraflex Device and RelayPro TEVAR Device: Technical Tips and Clinical Experience

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Disclosures

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- EXTEND Study
- Sizing Strategies

RelayPro for Thoraflex Hybrid Extension

RelayPro for Thoraflex Hybrid Extension

The Only On-Label Option to extend Thoraflex Hybrid

THORAFLEX HYBRID INSTRUCTION FOR USE

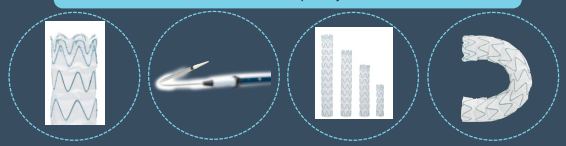
*Due to the indications for use and the device configurations, if the lesion requires use of an extension, only a **RelayPro NBS configuration should be used**.*

Adjunctive devices with barb or hook** features which would be positioned in the overlap region **should not be used

RelayPro for Thoraflex Hybrid Extension

RelayPro Features

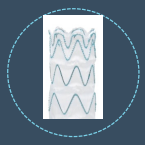
RelayPro is the **ideal** endovascular solution for extending treatment in Thoraflex™ Hybrid patients with more extensive disease, thanks to its **advanced features** designed to ensure a reliable compatibility.



NBS Proximal Configuration | *Low-Profile Delivery System* | *Wide Range Sizes* | *Indications across disease types*

RelayPro for Thoraflex Hybrid Extension

Relay®Pro Features – NBS Proximal Configuration

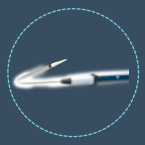


NBS Proximal Configuration

Without any bare stent struts on the proximal end, RelayPro NBS provides **conformability and apposition** with a **precise deployment** while **reducing risks of endoleaks or fabric wear** when used extending the Thoraflex Hybrid

RelayPro for Thoraflex Hybrid Extension

Relay®Pro Features – Low-Profile Delivery System



Low-Profile Delivery System

With a **low-profile delivery system**, RelayPro NBS is **suitable for a broader patient population** with small or complex accesses as well as navigating more easily through compressed true lumens in a dissection

RelayPro for Thoraflex Hybrid Extension

RelayPro Features – Wide Range Sizes

Wide Range Sizes

With the **most extensive standard portfolio** on the market, including both straight and tapered configurations, RelayPro NBS simplifies the selection of the ideal graft to extend ThoraflexHybrid.
The **Upon-Request** platform further expands the options by offering customized lengths and tapers to better match treatment and anatomical requirements

RelayPro for Thoraflex Hybrid Extension

RelayPro Features – Indications across Disease Types

Indications across disease types

With **comprehensive indications** for the descending thoracic aortic diseases including aneurysm, PAUs, dissections, and transections, and **excellent clinical outcomes**, RelayPro NBS provides a robust solution for Thoraflex Hybrid extensions, regardless of the lesion type

EXTEND Study

EXTEND Study

Overview

Coordinating Investigators

Europe
Prof. Martin Czerny

USA
Prof. Joseph Bavaria

Primary Objective

A prospective, multi-center, non-randomized, single arm, global post-market study to evaluate the **Thoraflex Hybrid device on its own and in combination with the RelayPro NBS** in the treatment of aortic disease affecting the aortic arch and descending aorta w or w/o involvement of the ascending aorta

EXTEND Study

Overview

Patients	**200** subjects • minimum of 65 subjects with a RelayPro NBS distal extension • 50% of subjects enrolled must be from the United States (US)
Investigational Sites	***Up to 55 sites*** (in Europe and USA)
Follow-up	**10 years** (from index Thoraflex Hybrid procedure) • Pre-operative, Implant (index and first extension, when applicable), • Post-operative (Discharge/30 Days, 1 year and Annually to 10 years).

EXTEND Study

Primary Safety Endpoint

Composite endpoint consisting of the following:

Permanent disabling stroke	**Grade 3 spinal cord ischemia**	**All-cause mortality**
mRS >2 and an increase in at least one mRS category from the individual's pre-stroke baseline, occurring within 30 days of either index procedure or extension and present at 1-year follow-up	(SVS reporting standards) & occurring within 30 days of either index procedure or extension	within 1 year of either procedure

Note: The primary safety endpoint ismeasured at one-year after the index procedure and again at least 8 months after the (first) extension procedure

EXTEND Study

Primary Effectiveness Endpoint

Treatment Success is defined as device technical success (of either procedure) with absence of the following at 1-year

Lesion Related Mortality	**Aortic Rupture**	**Lesion Expansion**	**Secondary Intervention**
defined as all deaths occurring within 30 days of, or, prior to discharge, from either the index procedure or the extension procedure or any revision procedures to treat the original lesion(s) and any other deaths adjudicated by Clinical Events Committee as related or probably related to the lesion(s)	in the treated segment	≥5mm increase from measurement at discharge/within 30 days	to address the following: Stent graft-induced aortic wall injury (SAWI) Fistula Type I or III endoleak Migration Loss of Patency Thromboembolic events Failure of integrity

Note: The primary effectiveness endpoint will be measured at one-year after the index procedure and again at least 8 months after the (first) extension procedure

Sizing Strategies

Sizing Strategies

Overlapping Length

INSTRUCTION FOR USE

The minimum recommended overlap between a Relay®Pro NBS device and a Thoraflex Hybrid is **3 overlapping covered stents** (approximately 50mm).

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Smaller overlap may result in endoleak (with or without component separation)

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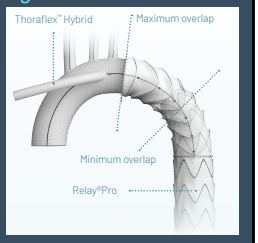
RelayPro NBS **device lengths should be selected accordingly**



Sizing Strategies

Diameter – "Unsupported" Extension

INSTRUCTION FOR USE

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

↓

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 RelayPro NBS device

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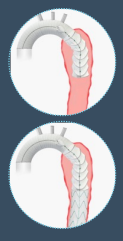
E.g. if a 34mm RelayPro NBS device has been selected for the distal treatment, then the compatible Thoraflex Hybrid device would be 32mm

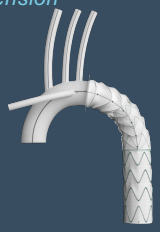


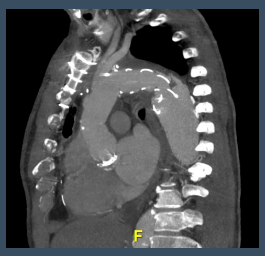
Sizing Strategies

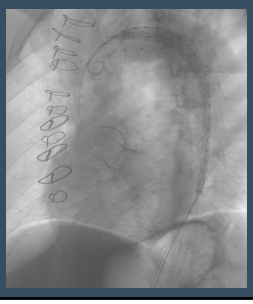
Diameter –"Supported" Extension

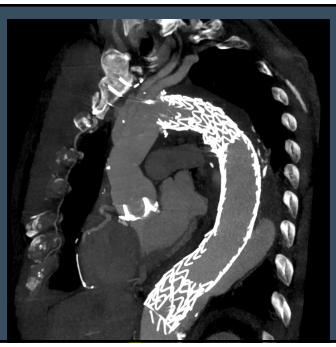
INSTRUCTION FOR USE

For modular, **supported** junctions (i.e. where the Thoraflex Hybrid distal stent graft region is within dissection), a Relay®Pro NBS device with a proximal outer diameter equal to the nominal outer diameter of the in-situ Thoraflex Hybrid must be used









Conclusion

- Thoraflex and Relay PRO when used in conjunction is an excellent option to treat complex aortic pathology
- Attention is needed as to type of proximal stent as well as sizing