Update on the Terumo Aortic Relay thoracic stent-graft system for TEVAR: how important is stiffness of the device in determining ease of deployment and outcomes: why relay is superior

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• Background
• Introducing the New RelayPro key features
• Clinical outcomes: REGENERATION study
• Summary

Disclosures

Consultant/Advisor/Research
• Terumo-Aortic
• Cardinal
• Medtronic
• Vascular
• Bayer
• MSD
• Ferrier
• GE
• Searle
• W.L. Gore
• B. Braun
• Jotec Cryolife

Proctor
• Terumo-Aortic
• Cook
• Medtronic
• W.L. Gore
• Cardinal
• Jotec Cryolife
• Lombard Micropore

Background

• RelayPro received CE Mark approval on April 2018
• RelayPro is waiting for US FDA approval

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Background

The RELAY evolution

And much more
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- Outer Diameter (OD): 19 Fr – 23 Fr
- 3 Fr to 4 Fr reduction in OD vs. RelayPlus
- Same stent design and materials as the proven RelayPlus
- Preservation of core technologies

RelayPro: stent-graft Fabric

- Same Material As RelayPlus
- Woven Polyester
- Optimized Weave Pattern
- Reduction In Profile

Optimized Weave Pattern Allows For A Reduction In Profile

RelayPro: stent material

- Electropolished Nitinol
- Optimal strength and fatigue properties (stiffness)
- Optimal mechanical properties for durability

RelayPro Stent-Graft Options

<table>
<thead>
<tr>
<th>Configurations</th>
<th>Bare Stent &amp; Non-Bare Stent (NBS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight</td>
<td>22 - 46mm</td>
</tr>
<tr>
<td>Tapered Options</td>
<td>4mm</td>
</tr>
<tr>
<td>Straight Lengths</td>
<td>100 - 250mm</td>
</tr>
<tr>
<td>Tapered Lengths</td>
<td>150 - 250mm</td>
</tr>
<tr>
<td>Neck Length</td>
<td>15 - 25mm</td>
</tr>
</tbody>
</table>

Custom Program Available In Europe

RelayPro: Modified S-bar length

- Improved conformability in S curved anatomies
- Provides column strength (STIFFNESS)
- Allows for the separation of the struts, increasing conformability and stability on deployment
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RelayPro: a combination of stiffness and flexibility

• Dual Sheath Technology (Flexibility)
• Proximal Clamping (Stiffness)
• Alignment Stent (Bare Stent Configuration)
• Non-Bare stent configuration
• Mechanical Advantage (Stiffness for easy tractability and stable deployment)

RelayPro: Solid Delivery System (stiffness)

Min Guidewire Length = 260 cm
Guidewire OD = .035"
Guidewire Type = Stiff (Lunderquist)

Working Length = 90 cm
Working Length is the length of the inner and outer sheath
Total Length = 171 cm

43 Day Follow-Up (n=31*)

Technical Success 31 (100%) 25 (80%) primary 6 (20%) assisted primary
Freedom from major graft failure 31 (100%)
related adverse events at discharge
Aneurysm-related mortality 0 (0%)
Endoleak Type I A 0 (0%)
Endoleak Type I B 1 (3%) (spontaneously limited)
Endoleak Type III, IV 0 (0%)
Stent-Migration 0 (0%)
Lumen Occlusion 0 (0%)

*Results are related to the flexibility and stiffness of the device, both well combined in its design


Sites:
• 4 sites in Italy
• 4 sites in Spain

Patients:
• 31 Patients underwent TEVAR with RelayPro between 2014-15

Pathologies: Thoracic Aortic Disease (TAD): Thoracic aortic aneurysms (TAAs), dissections, intramural hematomas, penetrating atherosclerotic ulcers (PAU), and aortic transections

Primary Endpoints: Freedom from aneurysm or dissection related mortality, and Stent-Graft performance at 30 days after implant

Follow-up: 30 days

REGENERATION – Physician assessment – per protocol

<table>
<thead>
<tr>
<th>Question</th>
<th>Results*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the Stent-Graft conformability-alignment appropriate?</td>
<td>Yes: 100% No: 0%</td>
</tr>
<tr>
<td>Was the introduction and advancement of delivery device appropriate?</td>
<td>Yes: 100% No: 0%</td>
</tr>
<tr>
<td>Was the deployment of the Stent-Graft appropriate?</td>
<td>Yes: 100% No: 0%</td>
</tr>
<tr>
<td>Was the handle manipulation appropriate?</td>
<td>Yes: 100% No: 0%</td>
</tr>
</tbody>
</table>

*Results are related to the flexibility and stiffness of the device, both well combined in its design
• RelayPro is Terumo-Aortic next generation Thoracic Stent-Graft System, which features a significant reduction in outer profile (ranges from 19 Fr to 22 Fr) without compromise for durability
• Some stiffness in design allows higher trackability, accuracy and precision on deployment
• Early clinical data demonstrated, accuracy on deployment and conformability for the best technical and clinical outcomes.

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