1. Overview:

This annual clinical update provides a review of the ongoing experience with the RelayPro Thoracic Stent-Graft System used in the endovascular repair of thoracic aortic aneurysms/ penetrating atherosclerotic ulcers (PAU) covering the time period from August 5, 2021 to June 20, 2022 (referred to as RelayPro-A). The RelayPro received CE Mark in 2017 and has subsequently been commercially available in the EU, Asia Pacific and Latin America; it has been commercially available in the United States since August 2021 once approval to PMA P200045 was granted on August 5, 2021. In this update, up to 5 years of IDE clinical data, initial Post-Approval Study (PAS) data and 4 years of worldwide commercial experience is presented.

|  |  |
| --- | --- |
| PMA Approval Order | <https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200045A.pdf> |
| Instructions for Use (IFU) | <https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200045C.pdf> |
| Summary of Safety and Effectiveness (SSED) | <https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200045B.pdf> |
| Post Approval Study (PAS) Webpage | <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?tid=721614> |

1. Worldwide Device Distribution:

Approximately 5,500 RelayPro Thoracic Stent-Graft Systems, including the Bare Stent and Non-Bare Stent (NBS) configurations have been distributed worldwide between August 5, 2021 and June 20, 2022. During this period of time, there have been approximately 927 devices implanted in the US.

1. Clinical Evaluations:

The data presented in this report shows a continued favorable performance of the RelayPro device in long-term follow-up of the Pivotal and Continued Access cohorts.

*US Pivotal Study (including Continued Access Cohort):*

The RelayPro-A study was initiated in the US in 2016 to include 110 subjects at 45 Investigational sites. The study was designed to investigate the safety and effectiveness of the RelayPro Thoracic Stent-Grafts in subjects with fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers (PAUs) within the descending thoracic aorta with five-year follow-up. The Pivotal study expanded to include up to 15 investigational sites in Japan on April 20, 2018, and a Continued Access cohort with up to 50 patients was approved on July 19, 2019. The study remains open to follow-up with 115 subjects enrolled (110 in the Pivotal cohort and 5 in Continued Access). Subject follow-up is to continue through 5 years.

*Post Approval Study (PAS):*

The RelayPro PAS is part of the Terumo Aortic Global Endovascular Registry (TiGER-001). TiGER is a multi-arm, multi-center, open label, prospective observational registry designed to obtain safety and performance data on the use of US approved, CE marked and custom-made Terumo Aortic endovascular grafts. The study has three arms for specific device groups, Abdominal, Thoracic and Custom. To fulfill the PAS requirements for RelayPro, the study will enroll a minimum of 177 aneurysm subjects treated with the RelayPro Thoracic Stent-Graft System. Of these, a minimum of 88 patients will be enrolled in the U.S in the Thoracic arm. The primary endpoint is Aortic Related Mortality.

As of June 20th, 2022, a total of 435 subjects in Europe are enrolled in the overall TiGER registry. Twenty-two subjects were enrolled into the Thoracic arm with a RelayPro stent-graft (4 Bare Stent and 18 Non-Bare Stent) of which 13/22 (59%) subjects have a primary indication of Aneurysm/PAU.  A review of these enrolled subjects from European centers participating in TiGER was carried out to determine if they met the criteria for the approved RelayPro PAS protocol (P200045/S001).  Where eligibility was confirmed, these subjects were entered retrospectively into the RelayPro PAS. Eleven (11) subjects have been confirmed as eligible and included in RelayPro PAS. Six (6/11) subjects have retrospectively enrolled with the remaining five (5) enrolled prospectively. The other two (2) subjects were not eligible for inclusion in the PAS due to the site follow-up regime being different from the PAS requirements (Site 012, Netherlands).  Six (6) subjects have completed the early follow-up visit (Discharge/30 days), one (1) subject has completed 1 year follow-up and remains in active follow-up in the study, no subjects have expired or withdrawn, and none are lost to follow-up.

*Results:*

**Table 1** and **Table 2** summarize the current clinical data for the IDE cohort for the Pivotal and Continued Access Cohorts. **Table 3** contains the latest PAS data.

*US Pivotal Study (including Continued Access Cohort):*

Intervention Free Technical Success, based on site-reported data was achieved for all enrolled subjects (100%), with Type II endoleak being reported in 8 subjects and Type I endoleak being reported in 2 subjects at the end of the procedure.

Data from the RelayPro-A IDE Pivotal study subjects in **Table 1** shows that since the last reporting period (See SSED Data Snapshot/Lock Date of 7 Dec 2020) there have been 5 cases of all-cause mortality, 2 at 2-year and 3 at 3-year; 1 report of migration at 3-year; 3 new Type I endoleaks, 1 Type Ia and 1 Type Ib at 2-year, and 1 Type Ib at 3-year; 8 cases of new aneurysm enlargement, 4 at 2-year, 3 at 3-year and 1 at 4-year; and 2 secondary interventions, 1 at 2-year and 1 at 3-year. No lesion related mortality, rupture, fracture, surgical conversion or thromboembolic events have been reported.

In the Pivotal study, 2 subjects reported secondary interventions, 1 at the 2-year visit and 1 at the 3-year visit since the last reporting period (See SSED Data Snapshot/Lock Date of 7 Dec 2020). Reasons for the secondary interventions were reported as Type Ib Endoleak (subjects A88-008 and A88-005).

Data from the RelayPro-A IDE study Continued Access subjects in **Table 2** shows that there have been 3 cases of all-cause mortality, one considered lesion related. No other MAEs or failures in device integrity for this reporting period.

| **Table 1: IDE Study Data (Pivotal)** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Secondary Effectiveness Endpoints** | **30 Days**  **(Day 0-90)** | **6 Months**  **(Day 91-270)** | **1 Year**  **(Day 271-540)** | **2 Years**  **(Day 541-900)** | **3 Years**  **(Day 901-1260)** | **4 Years**  **(Day 1261-1620)** | **5 Years**  **(Day 1621-1980)** | **Total** |
| Eligible for Follow-up | 110 | 108 | 105 | 93 | 82 | 57 | 7 | 110 |
| Subjects with visit data | 109 | 96 | 93 | 81 | 59 | 8 | 1 | 109 |
| Subjects with Imaging data | 107 | 92 | 93 | 72 | 49 | 5 | 0 | 107 |
| **Events** |  |  |  |  |  |  |  |  |
| Intervention-Free Technical Success | 100.0% (110/110) | NA | NA | NA | NA | NA | NA | 110 |
| All-cause mortality | 1.8%  (2/110) | 2.0% (2/101) | 1.1%  (1/94) | 5.7%  (5/87) | 4.7%  (3/64) | 0.0%  (0/12) | 0.0%  (0/1) | 13 |
| Lesion-related mortality | 1.8%  (2/110) | 0.0% (0/101) | 0.0%  (0/94) | 0.0%  (0/87) | 0.0%  (0/64) | 0.0%  (0/12) | 0.0%  (0/1) | 2 |
| Rupture | 0.0%  (0/110) | 0.0%  (0/99) | 0.0% (0/104) | 0.0%  (0/83) | 0.0%  (0/62) | 0.0%  (0/12) | 0.0%  (0/1) | 0 |
| Migration\* | NA | 0.0%  (0/97) | 0.0%  (0/93) | 0.0%  (0/78) | 1.9%  (1/52) | 0.0%  (0/9) | 0.0%  (0/0) | 1 |
| All Endoleaks\* | 17.9% (19/106) | 16.7% (15/90) | 19.8% (17/86) | 28.2%  (20/71) | 25.0%  (11/44) | 11.1%  (1/9) | 0.0%  (0/0) | 34 |
| Type Ia | 0.9%  (1/106) | 0.0%  (0/90) | 1.2%  (1/86) | 2.8%  (2/71) | 2.3%  (1/44) | 11.1%  (1/9) | 0.0%  (0/0) | 5 |
| Type Ib | 1.9%  (2/106) | 2.2%  (2/90) | 1.2%  (1/86) | 2.8%  (2/71) | 4.5%  (2/44) | 0.0%  (0/9) | 0.0%  (0/0) | 4 |
| Type II | 15.1% (16/106) | 14.4% (13/90) | 17.4% (15/86) | 22.5%  (16/71) | 20.5%  (9/44) | 11.1%  (1/9) | 0.0%  (0/0) | 31 |
| Type III | 0.0%  (0/106) | 0.0%  (0/90) | 0.0%  (0/86) | 0.0%  (0/71) | 0.0%  (0/44) | 0.0%  (0/9) | 0.0%  (0/0) | 0 |
| Type IV | 0.0%  (0/106) | 0.0%  (0/90) | 0.0%  (0/86) | 0.0%  (0/71) | 0.0%  (0/44) | 0.0%  (0/9) | 0.0%  (0/0) | 0 |
| Aneurysm Enlargement\*‡ | NA | 0.0%  (0/96) | 1.1%  (1/93) | 10.3%  (8/78) | 13.5%  (7/52) | 33.3%  (3/9) | 0.0%  (0/0) | 14 |
| Loss of Patency | 0.0%  (0/109) | 0.0%  (0/96) | 0.0%  (0/93) | 0.0%  (0/81) | 0.0%  (0/59) | 0.0%  (0/10) | 0.0%  (0/1) | 0 |
| Decreased stent-graft lumen diameter | 0.0%  (0/106) | 0.0%  (0/90) | 0.0%  (0/87) | 0.0%  (0/74) | 2.1%  (1/48) | 0.0%  (0/6) | 0.0%  (0/0) | 1 |
| Fractures\* | 0.0%  (0/107) | 0.0%  (0/97) | 0.0%  (0/93) | 0.0%  (0/76) | 0.0%  (0/49) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Conversion to Open Repair | 0.0%  (0/110) | 0.0%  (0/99) | 0.0%  (0/94) | 0.0%  (0/83) | 0.0%  (0/62) | 0.0%  (0/12) | 0.0%  (0/1) | 0 |
| Secondary Intervention related to device or pathology | 1.8%  (2/110) a | 2.0%  (2/99) | 3.2%  (3/94) | 2.4%  (2/83) | 3.2%  (2/62) | 0.0%  (0/12) | 0.0%  (0/1) | 11 |
| Thromboembolic event attributed to stent-graft | 0.0%  (0/108) | 0.0%  (0/96) | 0.0%  (0/93) | 0.0%  (0/81) | 0.0%  (0/60) | 0.0%  (0/10) | 0.0%  (0/1) | 0 |
| Device-related Adverse Events (CEC-adjudicated) | 4.6%  (5/109) | 3.0%  (3/99) | 1.1%  (1/95) | 8.6%  (7/81) | 1.7%  (1/59) | 0.0%  (0/8) | 0.0%  (0/1) | 16 |
| Vascular access complications at the index procedure | 5.5% (6/110)\*\* | NA | NA | NA | NA | NA | NA | NA |
| All values expressed as % (n/N) for endpoints reported within the specified window.  \* This data represents Core Laboratory assessed endpoint, including any reports of fracture, migration, endoleak, or aneurysm enlargement within each interval, including observations previously identified at earlier intervals that are considered ongoing or persistent and observations identified that later resolved within the interval.  \*\*A06-002 - neck hematoma; A13-008 - right femoral artery dissection secondary to Perclose failure; A20-001 - right femoral artery laceration secondary to failed Perclose; A22-005 - right femoral and left common femoral artery injury; A24-001 - left CFA patch angioplasty (bovine pericardium); A30-002 - right iliac artery rupture & dissection of right superficial femoral artery  aA22-009 returned for follow-up since the last reporting period (See SSED Data Snapshot/Lock Date of 7 Dec 2020) | | | | | | | | |
| ‡ The aneurysm expansions noted were reviewed for potential contributing factors and were likely attributable to the following: Type II endoleaks (5 subjects), aneurysm degeneration (1 subject), Type I endoleak (3 subjects), and migration & Type Ib endoleak (1 subject). In four subjects, no discernable cause for the expansion was able to be identified. | | | | | | | | |

| **Table 2: IDE Study Data (Continued Access)** | | | | | | | |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Secondary Effectiveness Endpoints** | **30 Days (Day 0-90)** | **6 Months (Day 91-270)** | **1 Year (Day 271-540)** | **2 Years (Day 541-900)** | **3 Years (Day 901-1260)** | **4 Years (Day 1261-1620)** | **5 Years (Day 1621-1980)** | **Total** |
| Eligible for Follow-up | 5 | 5 | 4 | 2 | 1 | 0 | 0 | 5 |
| Subjects with visit data | 5 | 1 | 3 | 1 | 0 | 0 | 0 | 5 |
| Subjects with Imaging data | 5 | 4 | 2 | 0 | 0 | 0 | 0 | 5 |
| **Events** |  |  |  |  |  |  |  |  |
| Intervention-Free Technical Success | 100.0% (5/5) | NA | NA | NA | NA | NA | NA | 5 |
| All-cause mortality | 0.0%  (0/5) | 20.0% (1/5) | 50.0% (2/4) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 3 |
| Lesion-related mortality | 0.0%  (0/5) | 0.0%  (0/4) | 25.0% (1/4) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 1 |
| Rupture | 0.0%  (0/5) | 0.0%  (0/4) | 0.0%  (0/4) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Migration\* | NA | 0.0%  (0/4) | 0.0%  (0/2) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| All Endoleaks\* | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Type Ia | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Type Ib | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Type II | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Type III | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Type IV | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Aneurysm Enlargement\* | NA | 0.0%  (0/4) | 0.0%  (0/2) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Loss of Patency | 0.0%  (0/5) | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Decreased stent-graft lumen diameter | 0.0%  (0/4) | 0.0%  (0/4) | 0.0%  (0/2) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Fractures\* | 0.0%  (0/5) | 0.0%  (0/4) | 0.0%  (0/2) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Conversion to Open Repair | 0.0%  (0/5) | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Secondary Intervention related to device or pathology | 0.0%  (0/5) | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Thromboembolic event attributed to stent-graft | 0.0%  (0/5) | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Device-related Adverse Events (CEC-adjudicated) | 0.0%  (0/5) | 0.0%  (0/4) | 0.0%  (0/3) | 0.0%  (0/1) | 0.0%  (0/0) | 0.0%  (0/0) | 0.0%  (0/0) | 0 |
| Vascular access complications at the index procedure | 0.0%  (0/5) | NA | NA | NA | NA | NA | NA | 0 |
| All values expressed as % (n/N) for endpoints reported within the specified window.  \* This data represents Core Laboratory assessed endpoint, including any reports of fracture, migration, endoleak, or aneurysm enlargement within each interval, including observations previously identified at earlier intervals that are considered ongoing or persistent and observations identified during an identified that later resolved within the interval. | | | | | | | | | |

*Post Approval Study (PAS):*

Data from the TiGER RelayPro-PAS subjects in **Table 3** shows that there have been 2 MAEs reported in one patient (052-043) and no failures in device integrity in this reporting period.

No secondary interventions were performed due to the integrity of the RelayPro device. Six (6) additional procedures were reported in five (5) patients post implantation, none of which are deemed reinterventions as a result of RelayPro:

* One was an unplanned procedure (Subject 052-043 - Left axillary stenting and hematoma drainage)
* Three were planned second stage procedures for Thoracoabdominal aneurysm coverage with a fenestrated AAA device
* Two were extension procedures of the RelayPro;
  + One was reported by the site with the following reason: Extension for the relays. R&L common femoral punction, coeliac embolization (plug).106cc contrast, 10min.
  + The second was reported with the following reason: 2nd step: ensuring the distal sealing of thoracic edp (thoraco-abdominal aneurysm + T2EL on evita).

This is site reported data available at the time of report compilation, clarifications have been requested to obtain additional information on the procedures carried out.

No further information is available at this time.

There has been no clinically relevant change in trends compared to the data that supported the PMA approval.

| **Table 3: TiGER RelayPro PAS Data** | | | |
| --- | --- | --- | --- |
|  | **30-days** | **1 Year** | **Total** |
| Eligible for Follow-up | 11 | 7 | 11 |
| Subjects with visit data | 6 (54.5%,6/11) | 1 (14.2%,1/7) |  |
| Subjects with Imaging data | 6 (54.5%,6/11) | 1 (14.2%,1/7) |  |
| **Events** |  |  |  |
| Aneurysm-related Mortality | 0 | 0 | 0 |
| All-cause Mortality | 0 | 0 | 0 |
| Major Adverse Events | 2 (18.2%,2/11) | 0 | 1 |
| Aneurysm Rupture | 0 | 0 | 0 |
| Conversion to Open Surgery | 0 | 0 | 0 |
| All Endoleaks | | | |
| Type Ia | 0 | 0 | 0 |
| Type Ib | 0 | 0 | 0 |
| Type II | 0 | 0 | 0 |
| Type III | 0 | 0 | 0 |
| Type IV | 0 | 0 | 0 |
| Unknown | 1 (9.2%,1/11) | 0 | 1 |
| Aneurysm Sac Enlargement (> 5 mm) | 0 | 0 | 0 |
| Loss of Device Integrity | 0 | 0 | 0 |
| Migration > 10 mm | 0 | 0 | 0 |
| Loss of Patency | 0 | 0 | 0 |
| Any Secondary Intervention | 6 (54.5%,6/11) | 0 | 5 |

1. Worldwide Recalls, Safety Communications and Field Safety Notices:

There have been no US recalls, safety communications and/or Field Safety Notices for the RelayPro Thoracic Stent-Graft System in the period between August 5, 2021 and June 20, 2022. There was one field safety notification in September 2021 related to the incorrect identification of the tip to graft length on a subset of the RelayNBS Pro labels only OUS. The US product was unaffected.

1. Worldwide Commercial Experience:

RelayPro is distributed globally and receives feedback/learnings from this worldwide commercial use. The following table summarizes the associated complaints received between August 5, 2021 and June 20, 2022.

| **Table 4: Complaints** | | |
| --- | --- | --- |
| **Failure Mode Description** | **# of complaints per failure mode** | **MDR Filed** |
| **Clinical Observations** |  |  |
| Type I Endoleak | 3 | Yes |
| Type II Endoleak; Migration /Displacement | 3 | Yes |
| Type III Endoleak | 1 | Yes |
| Migration / Displacement; Difficult to release proximal stent / Unable to remove the device safely; Other adverse event post-procedure resulting in death | 2 | Yes |
| Perforation of vessel; Intraoperative patient death; Unable / difficult to advance the device through the entry vessel | 1 | Yes |
| Paraplegia | 1 | Yes |
| Infolding of the stent-graft | 1 | Yes |
| Post-implant thrombus formation; Other adverse event post-procedure resulting in death; | 1 | Yes |
| **Delivery / Deployment Observations** |  |  |
| Unable / difficult to advance the secondary sheath out of the primary sheath; Unable / difficult advancement with mechanical advantage; Component detachment / malfunction / product damage | 5 | Yes (4) |
| Unable / difficult to advance the device through entry vessel – device stuck in introducer sheath; Component detachment / malfunction / product damage | 5 | Yes (3) |
| Device Preparation Difficulty; Component detachment / malfunction / product damage | 2 | Yes |
| Difficult to release proximal stent | 2 | Yes |
| Unable / difficult deployment with mechanical advantage | 1 | No |
| Unable / difficult to advance device in the aorta; Unable / difficult to advance the secondary sheath to the treatment site; | 1 | Yes |
| Unable to reset the tip in position #4; Unable / difficult advancement with mechanical advantage; Component detachment | 1 | Yes |
| **Packaging / Manufacturing Observations** |  |  |
| Delivery System component detachment / malfunction / product damage / packaging damaged | 8 | Yes (1) |

The reported complaints did show an increase after US commercialization of RelayPro began in September 2021. This is not unexpected with the start of commercialization in a region and was accompanied by the corresponding increase in sales volume.

The most prevalent Clinical Observation is Endoleaks. Terumo Aortic thoroughly reviews and investigates all complaints using the data and information provided. It is standard practice to request pre-case planning worksheets and measurements, CT scans, operative reports, fluoroscopy and any imaging that can assist the team in evaluating the complaint, but based on the level of data provided, it can be challenging to confirm the endoleak reported and determine causation. Endoleaks of all types are among the expected adverse events associated with TEVAR. For the Delivery / Deployment Observations, there was an increase in issues related to device preparation and loss of hemostasis (flushing of the device prior to use). Several were the result of manufacturing-related causes. These were addressed with the production personnel to mitigate future occurrences. In addition, there have been reports of difficulty advancing the inner sheath from the outer sheath. These were attributed to various causes such as patient vessel tortuosity and issues with use of the mechanical advantage of the delivery system. There was an increase in 2021 for difficultly in releasing the proximal stent. It is worth noting that Terumo Aortic implemented a design optimization of the NBS clasping mechanism in July 2021 that was intended to reduce the release force and enhance the user experience when deploying the device. For the Packaging Observations, these were various reports of component/delivery system damage detected prior to device use with no reported serious consequence to the patient.

The complaints reported have increased compared to those reported within the RelayPro Aneurysm IDE study. However, the occurrence levels are still within the values estimated by Terumo Aortic and all complaints are assessed within the risk management system. Terumo Aortic continues its diligence in monitoring and investigating product complaints and take necessary actions, as needed and concludes that the benefits of using the RelayPro Thoracic Stent-Graft system continue to outweigh the associated risks.

1. Explant Analysis:

Through the course of the investigational phase and following commercialization, there have been no reported explants of the RelayPro used to treat thoracic aortic aneurysms.

1. Literature Review:

There has been one publication with information on the RelayPro Thoracic Stent-Graft System since PMA approval August 5, 2021. A second publication related to Compassionate Use of a modified RelayPro-based device is also presented for informational purposes.

| **Table 5: RelayPro Publications** | | |
| --- | --- | --- |
|  | **Article Citation** | **Brief Summary** |
| 1 | Szeto WY, Vallabhajosyula P, Matsuda H, Moainie SL, Sharafuddin MJ, Corvera J, et al. One-Year Results with a Low-Profile Endograft in Subjects with Thoracic Aortic Aneurysm and Ulcer Pathologies. The Journal of Thoracic and Cardiovascular Surgery [Internet]. 2022 Feb 1 [cited 2022 Feb 1]  Available from: https://www.sciencedirect.com/science/article/pii/S0022522322001015 | A study population of 110 patients had a median (interquartile range) age of 76 (70-81) years, 69 (62.7%) were male, and 43 (39.1%) were Asian. Patients were treated for 76 fusiform aneurysms (69%), 24 saccular aneurysms (22%), and 10 penetrating atherosclerotic ulcers (9%). Most patients (82.7%) were treated with a non-bare stent configuration. Technical success was 100%. The median (interquartile range) procedure time was 91 (64-131) minutes, and the deployment time was 16 (10-25) minutes. A total of 50 patients (73.5%) in the US cohort had percutaneous access, whereas centers in Japan used only surgical cutdown. The 30-day composite major adverse events rate was 6.4% (95% upper confidence interval, 11.6%; P = .0002): 2 strokes, 2 procedural blood losses greater than 1000 mL requiring transfusion, 2 paralysis events, and 1 renal failure. Primary effectiveness was 89.2% (lower 95% confidence interval, 81.8%; P = .0185). Nine subjects experienced 11 events (1 aneurysm expansion, 6 secondary interventions, and 4 type I endoleaks). There was no loss of stent-graft patency, no rupture, no fractures, and no migration. The low-profile RelayPro thoracic endograft met the study primary end points and demonstrated satisfactory 30-day safety and 1-year effectiveness for the treatment of patients with aneurysms of the descending thoracic aorta or penetrating atherosclerotic ulcers. Follow-up is ongoing to evaluate longer-term outcomes and durability. |
| 2 | Pappas G, Stoner M, Narins C, Westfall C, Candelaria A, Mix D. Modified Scalloped Endograft for Failed Endovascular Repair of an Aortic Arch Dissection. Journal of Vascular Surgery. 2021;74(4):e345-e346.  doi: 10.1016/j.jvs.2021.07.023 | This publication relates to a modified RelayPro-based device with a proximal scallop which was implanted under **Compassionate Use** approval.  The device was used for endovascular salvage after thoracic endovascular aneurysmal repair (TEVAR) to repair a Type Ia endoleak in a patient with continued rapid proximal arch aneurysmal degeneration after open type A dissection repair complicated by vocal cord paralysis and TEVAR failure. The patient was a 52-year-old woman with prior open sternotomy complicated by wound infection and vocal cord paralysis, deeming her at high risk of reoperative open sternotomy. Her native bovine arch and subsequent debranching with TEVAR necessitated an endovascular device configured to maintain cerebrovascular and upper extremity perfusion. The 6-month follow-up computed tomography scan showed resolution of the Type Ia endoleak. No impingement of the brachiocephalic artery origin was present, and no further proximal arch aneurysmal degeneration had occurred. At the last follow-up, the patient was doing well without evidence of device-related complications.  Further investigation is warranted to determine whether a proximal scalloped configuration of a thoracic endograft can provide a more effective seal in thoracic aortic pathology. |

1. **Conclusion:**

Based on available clinical study data and world-wide clinical experience to date, endovascular therapy with the RelayPro Thoracic Stent-Graft System continues to be a viable treatment option for fusiform aneurysms and saccular aneurysms/PAUs of the descending thoracic aorta.

**Adverse Event Reporting:**

As indicated in the Instructions for Use, adverse events or complaints should be reported by contacting 1-855-726-5866 (1-855-7BOLTON). Accurate and timely reporting of adverse events by the physician users to the device manufacturer and FDA (MedWatch Form 3500) is critical for monitoring device performance and detection of potential device-related safety issues.

**Patient Follow‑Up and Selection:**

Regular follow-up of all patients treated with the RelayPro Thoracic Stent-Graft System is required. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient following endovascular graft placement. Patients should be regularly monitored for endoleaks, lesion growth, or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is recommended.