I. Overview:

This annual clinical update provides a review of the ongoing experience with the TREO Abdominal Stent-Graft System used in the treatment of abdominal aortic aneurysms. The TREO Abdominal Stent-Graft System received CE Mark in 2015 and has subsequently been commercially available in the EU, Asia Pacific and Latin America; it has been commercially available in the United States since May 2020.

PMA Approval Order	https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190015A.pdf
Instructions for Use (IFU)	https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190015C.pdf
Summary of Safety and Effectiveness (SSED)	https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190015B.pdf
Post Approval Study (PAS) Webpage	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=668342&c_id=6086

II. Worldwide Device Distribution:

Approximately 18,472 TREO Abdominal Stent-Graft Systems have been distributed worldwide between March 2024 and March 2025. During this reporting period, there have been approximately 3,587devices implanted in the US.

Table 1: TREO devices shipped and implanted

Device Component	US	ROW	Total	Total Implanted in US
Bifurcate (B2)	1,573	3,470	5,043	1,058
Cuff (C2)	477	549	1,026	208
Leg Extension (L2)	3,493	8,859	12,352	2,303
Straight Extension (S2)	49	2	51	18
Total	**5,592**	**12,880**	**18,472**	**3,587**

III. Clinical Evaluations:

The data presented in this report show a continued favorable performance of the TREO device in the long-term follow-up of the Pivotal and Continued Access studies.

Enrollment in the Post-Approval Study (PAS) is closed with some follow-up data available.

US Pivotal Study (including Continued Access Study):

The Treovance Phase II study was initiated in 2013 to evaluate the safety and effectiveness of the Treovance Stent-Graft in subjects with infrarenal aortic aneurysm. Selection criteria reflected patient anatomy consistent with the indications for use. The primary study endpoints include successful aneurysm treatment 12 months post-implant and composite major adverse event rate at 30 days. Key secondary endpoints include major adverse events, all-cause mortality, aneurysm rupture, secondary interventions, conversion to open surgery losses of device integrity, device occlusions, stenosis or kink, aneurysm enlargement (>5 mm), stent graft migration (>10 mm), all types of Endoleaks and other device-related events. A total of 150 subjects were enrolled in the Pivotal Study from November 2013 to February 2016 and 8 subjects were enrolled in the Continued Access study from May 2016 to June 2017. Results of the primary analysis are available in the IFU and SSED and published in the Journal of Vascular Surgery. A summary of the most recent subject follow-up is provided below.

Post Approval Study (PAS):

A multi-center, non-randomized, single arm clinical study was initiated to collect real world safety and effectiveness outcomes of the TREO Abdominal Stent-Graft System in an all-comers population eligible for endovascular treatment of AAA in routine clinical practice, with emphasis on subjects that experience a device stent-strut or barb fracture. The study enrollment is complete and involves de novo and Pivotal Study investigational sites. Study enrollment was open to any subjects deemed appropriate for treatment by the treating physician. The primary study endpoints include Stent-strut fracture/barb separation as confirmed by the Imaging Core Laboratory and Secondary intervention for adverse events related to/caused as a result of Stent-strut fracture/barb separation as confirmed by the Clinical Events Committee (CEC). Key secondary endpoints include technical success, major adverse events, all-cause mortality, aneurysm-related mortality, aneurysm rupture, secondary interventions, conversion to open surgery, losses of device integrity, device occlusions, stenosis or kink, aneurysm enlargement (>5 mm), stent graft migration (>10 mm), all types of Endoleaks and other device-related events. Follow-up is ongoing.

Pivotal Study (including Continued Access Study) Results:

As of March 31, 2024, all Pivotal and Continued Access subjects have completed their 5-year follow-up visits.

Subjects that were reported with a fracture were asked to consent for an additional 5-years of follow-up (for a total of 10-years of follow-up). Two (2) subjects reported with a fracture remain active in follow-up. One (1) is pending the 10-year visit, and the other subject completed through 8-year follow-up and is pending data entry for end of study.

The Core Laboratory found no evidence of endoleak, aneurysm sac expansion, patency compromise, or migration in any of the 2 subjects that remain active. Furthermore, no clinical sequel was reported.

Data from the Pivotal and Continued Access studies are provided below. No subjects in either cohort have had an aortic rupture or aneurysm-related death. There has been a total of twenty-one (21) secondary interventions performed in 16 subjects through 5 years in the Pivotal Study, and one (1) secondary intervention has been reported in one (1) for the Continued Access Study. The reasons for intervention in the Pivotal Study include the following: any endoleak in ten (10), occlusion/thrombus in six (6), sac expansions in one (1), and four (4) others (including bowel resection due to mesenteric ischemia, and fistula repair).

Table 2a: Pivotal Study (Data Cut May 13th, 2024)[4]								
	Day 30	**Month 6**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Total [5]**
Aneurysm Related Mortality	0/150 (0.0%)	0/150 (0.0%)	0/148 (0.0%)	0/142 (0.0%)	0/128 (0.0%)	0/119 (0.0%)	0/105 (0.0%)	**0**
All-cause Mortality	0/150 (0%)	2/150 (1.3%)	2/148 (1.4%)	8/142 (5.6%)	4/128 (3.1%)	3/119 (2.5%)	6/105 (5.7%)	**25**
Aneurysm Rupture	0/150 (0.0%)	0/150 (0.0%)	0/148 (0.0%)	0/142 (0.0%)	0/128 (0.0%)	0/119 (0.0%)	0/105 (0.0%)	**0**
Major Adverse Events[1] (number of incidents)	1	5	6	13	8	6	10	**49**
Rate of Major Adverse Event[1] (total number of subjects with at least 1 MAE)	1/150 (0.7%)	4/150 (2.7%)	4/148 (2.7%)	9/142 (6.4%)	7/128 (5.7%)	6/119 (5.0%)	10/105 (9.5%)	**34**
Prosthesis Migration >10 mm [3]	NA	0/134 (0.0%)	0/128 (0.0%)	0/111 (0.0%)	0/97 (0.0%)	1/79 (1.3%)	0/68 (0.0%)	**1**
Type Ia endoleak [3]	1/147 (0.7%)	2/134 (1.5%)	1/133 (0.8%)	1/113 (0.9%)	1/100 (1.0%)	1/79 (1.3%)	1/67 (1.5%)	**4**
Type Ib endoleak [3]	0/147 (0%)	1/134 (0.7%)	0/133 (0%)	0/113 (0%)	0/100 (0%)	0/79 (0%)	0/67 (0%)	**1**
Type IIIa endoleak [3]	0/147 (0.0%)	0/134 (0.0%)	0/133 (0.0%)	0/113 (0.0%)	0/100 (0.0%)	0/79 (0.0%)	0/67 (0.0%)	**0**
Type IIIb endoleak [3]	0/147 (0.0%)	0/134 (0.0%)	0/133 (0.0%)	0/113 (0.0%)	0/100 (0.0%)	0/79 (0.0%)	0/67 (0.0%)	**0**
Aneurysm enlargement >5 mm [3]	NA	0/138 (0%)	0/136 (0%)	0/116 (0%)	5/101 (5.0%)	7/83 (8.4%)	6/70 (8.6%)	**11**
Occlusions/ stenoses [3]	0/147 (0%)	0/134 (0%)	0/134 (0%)	0/117 (0%)	0/102 (0%)	0/81 (0%)	0/67 (0%)	**0**
Loss of device integrity [2,3]	0/148 (0.0%)	1/133 (0.8%)	4/131 (3.1%)	7/111 (6.3%)	9/94 (9.6%)	12/75 (16.0%)	14/61 (23.0%)	**14**
Conversions	0/150 (0.0%)	0/149 (0.0%)	0/144 (0.0%)	0/131 (0.0%)	0/119 (0.0%)	0/111 (0.0%)	0/92 (0.0%)	**0**
Secondary Interventions (Subjects with any intervention - site reported)	7/150 (4.7%)	3/149 (2.0%)	1/144 (0.7%)	3/131 (2.3%)	2/119 (1.7%)	1/111 (0.9%)	1/92 (1.1%)	**16**

[1] Major Adverse Events (MAE's) are defined as all-cause mortality, myocardial infarction, stroke, renal failure, respiratory failure, paraplegia, bowel ischemia, and procedural blood loss of 1000 cc or greater. There have been a total of 49 instances of MAE's. Major adverse events incidence is the total through 5-year follow-up. As noted above, follow-up after 5 years will be updated accordingly.

[2] All 'loss of device integrity' were associated with stent or barb fractures. None of the subjects with device integrity events had any related clinical sequelae. Numerator at each time point is cumulative.

[3] Core Laboratory reported data. Where applicable, the data is inclusive of both new and persistent (i.e., aneurysm enlargement > 5 mm, Type I and Type III endoleaks). The total column is reflective of the unique subjects unless specified otherwise.

[4]Table to be updated with remainder of data through 10-year follow-up after the last follow-up is complete for the remaining subjects with stent-fractures. Refer to the summary above the table for a brief narrative on follow-up status.

[5]Totals reflect follow-up through 5-years. As noted previously, follow-up after 5-years (i.e., 6-year, 7-year, and 8-year) will be updated accordingly.

*Please note, there was 1 incidence of procedural blood loss >1000 cc not captured in this table as it was observed during the procedure.

Table 2b: Pivotal Study Beyond the 5-year Follow-up (Data Cut March 31, 2022)[4]			
	Year 6	**Year 7**	**Year 8**
Aneurysm Related Mortality	0/19 (0.0%)	0/14 (0%)	**NA**
All-cause Mortality	1/19 (5.3%)	0/14 (0%)	**0/14**
Aneurysm Rupture	0/19 (0.0%)	0/14 (0.0%)	**NA**
Major Adverse Events[1] (number of incidents)	1	0	**0**
Rate of Major Adverse Event[1] (total number of subjects with at least 1 MAE)	1/19 (5.2%)	0/14 (0.0%)	**0/14**
Prosthesis Migration >10 mm [3]	0/7 (0.0%)	0/1 (0.0%)	**NA**
Type Ia endoleak [3]	0/7 (0.0%)	0/1 (0.0%)	**NA**
Type Ib endoleak [3]	0/7 (0.0%)	0/1 (0.0%)	**NA**
Type IIIa endoleak [3]	0/7 (0.0%)	0/1 (0.0%)	**NA**
Type IIIb endoleak [3]	0/7 (0.0%)	0/1 (0.0%)	**NA**
Aneurysm enlargement >5 mm [3]	2/21	0/2	**NA**
Occlusions/ stenoses [3]	0/9 (0.0%)	0/1 (0.0%)	**NA**
Loss of device integrity [2,3]	0/7 (0.0%)	0/1 (0.0%)	**NA**
Conversions	0/19 (0.0%)	0/14 (0.0%)	**NA**
Secondary Interventions (Subjects with any intervention - site reported)	1/18 (5.6%)	0/8 (0.0%)	**NA**

[1] Major Adverse Events (MAE's) are defined as all-cause mortality, myocardial infarction, stroke, renal failure, respiratory failure, paraplegia, bowel ischemia, and procedural blood loss of 1000 cc or greater. There have been a total of 49 instances of MAE's. Major adverse events incidence is the total through 5-year follow-up. As noted above, follow-up after 5 years will be updated accordingly.

[2] All 'loss of device integrity' were associated with stent or barb fractures. None of the subjects with device integrity events had any related clinical sequelae. Numerator at each time point is cumulative.

[3] Core Laboratory reported data. Where applicable, the data is inclusive of both new and persistent (i.e., aneurysm enlargement > 5 mm, Type I and Type III endoleaks). The total column is reflective of the unique subjects unless specified otherwise.

[4]Table to be updated with remainder of data through 10-year follow-up after the last follow-up is complete for the remaining subjects with stent-fractures.

*Please note, there was 1 incidence of procedural blood loss >1000 cc not captured in this table as it was observed during the procedural visit.

Table 3: Continued Access Study Data (Data Cut March 31st, 2022) [3]

	Day 30	Month 6	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Aneurysm Related Mortality	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	**0**
All-cause Mortality	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	1/8 (12.5%)	2/7 (28.6%)	1/5 (20%)	**4**
Aneurysm Rupture	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	**0**
Major Adverse Event[1] (number of incidents)	0	0	0	0	1	2	1	**4**
Rate of Major Adverse Event[1] (total number of subjects with at least 1 MAE)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1/8 (12.5%)	2/7 (28.6%)	1/5 (20%)	**4**
Prosthesis Migration >10 mm [2]	0/8 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	**0**
Type Ia endoleak [2]	0/8 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	**0**
Type Ib endoleak [2]	0/8 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	**0**
Type IIIa endoleak [2]	0/8 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	**0**
Type IIIb endoleak [2]	0/8 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	**0**
Aneurysm enlargement >5 mm [2]	N/A	0/6 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/6 (0.0%)	0/4 (0.0%)	0/2 (0.0%)	**0**
Occlusions/ stenoses [2]	0/8 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	**0**
Loss of device integrity [2] (subjects with any loss of device integrity)	0/8 (0.0%)	0/7 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	0/1 (0.0%)	**0**
Conversions	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/7 (0.0%)	0/5 (0.0%)	**0**
Secondary Interventions (subjects with any intervention - site reported)	0/8 (0.0%)	1/8 (12.5%)	0/8 (0.0%)	0/8 (0.0%)	0/8 (0.0%)	0/6 (0.0%)	0/3 (0.0%)	**1**

[1] Major Adverse Events (MAE's) are defined as all-cause mortality, myocardial infarction, stroke, renal failure, respiratory failure, paraplegia, bowel ischemia, and procedural blood loss of 1000 cc or greater.
[2] Core Laboratory Reported Data
[3] This table has not been updated since its previous review by the FDA. It will be revised as appropriate in the upcoming annual report submission later this year.

Post Approval Study (PAS) Results:

As of February 10, 2025, 338 subjects have been enrolled in the TREO PAS. Follow-up is on-going and partial 4-year follow-up is available. No aneurysm-related deaths (CEC adjudicated) or conversions to open surgery have been reported at any timepoint.

Forty-six (46) secondary interventions in thirty-eight (38) subjects were reported through follow-up. A brief summary of the reasons for these interventions is provided below:

- *Aortic Rupture:* One (1) intervention was to correct a site reported AAA rupture during the 2-year follow-up timepoint. It was due to a Type Ia endoleak with rupture of her abdominal aorta, both of which were identified when the subject presented at the emergency department with abdominal pain. The Clinical Events Committee adjudicated this event as related to the device and not related to the procedure.
- *Endoleaks:* Twenty-seven (27) interventions were to correct site reported endoleaks, (nine (9) Type I, two (2) Type III, and sixteen (16) Type II). The imaging for 14 of these cases did not meet the Core Laboratory's adequate imaging standards for the determination of the presence of an endoleak (images with contrast and non-contrast series were regarded as adequate for interpretation of endoleaks). Of these, two (2) Type I and one (1) Type III endoleak were reported by the site as a device deficiency. The CEC deemed the events as device related.
- *Occlusion/Thrombosis:* Fourteen (14) interventions were to correct reported occlusion/stenosis. Of these, four (4) were related to site reported device deficiencies: one (1) was a right iliac artery occlusion within the implant, one (1) a right limb thrombosis, one (1) an acute occlusion (of the main body and both limbs), and one (1) a thrombosed left iliac limb. All of these four events were adjudicated as related to the device and were resolved with reinterventions.
- *Limb Under-Expansion:* The subject underwent an uneventful balloon expansion of an under-expanded left common iliac stent. The site reported the event as related to procedure, and the CEC adjudicated the event as related to the device and procedure. The event was resolved with reintervention.
- *Spinal Cord Ischemia:* An unplanned adjunctive procedure was completed on post operative day 0, namely an additional balloon-expandable stent to address spinal cord ischemia. This resolved the adverse event. The CEC deemed this event as not device related. The subject was discontinued prior to the 1-year Core Laboratory imaging, due to the inability to follow-up.
- *Aortoenteric Fistula w/Infection:* The subject underwent an uneventful thoracoabdominal endovascular repair that successfully resolved the aortoenteric fistula with aortic infection. CEC reported this event as not related to the device or index procedure. The subject had a premature termination due to death prior to the 1-year Core Laboratory imaging.
- *Dissection:* The subject underwent an uneventful hemiarch replacement to successfully resolve a dissection. CEC determined this event was not related to the treated aortic pathology. The subject had a premature termination due to death prior to the 1-year Core Laboratory imaging.

Regarding stent fractures, at 30-days, the Core Laboratory did not observe any stent fractures. At 1-year, the Core Laboratory observed three (3) subjects with stent fractures, all at the proximal aspect of the stent. At 2-years, the Core Laboratory identified a second fracture at the proximal aspect of the uncovered stent for one (1) of these subjects. There were no clinical sequelae resulting from the stent fractures for any of the three subjects specified above, and none observed were related to reintervention for the study as reported

by the CEC. All of the subjects had no evidence of endoleak (Type I or III), aneurysm sac expansion, patency compromise, or migration reported by the Core Laboratory through 2-year follow-up. No new subjects with stent-strut fractures or barb separation have been observed at the 2-year, 3-year, or 4-year timepoints.

.

As referenced in **Table 4** below, regarding endoleaks, there were two (2) Type Ia, two (2) Type Ib, two (2) Type III, and one (1) unknown reported by the Core Laboratory at 30-days. One (1) Type III was localized and far away from any overlapping of the gates (at the level of the main body) and not associated with any loss of device integrity. The second Type III was due to the physician cannulating the same gate with two leg extensions. At 1-year, there were no Type I or Type III endoleaks observed by the Core Laboratory. At 2-year, there were two (2) Type Ia and one (1) Type III endoleak observed by the Core Laboratory. All were resolved with relining/cuffs. At 3-year and 4-year timepoints, there were no Type I or Type III endoleaks observed by the Core Laboratory.

Core Laboratory evaluations offer standardized, image-specific assessments, while site physicians rely on clinical judgment across multiple image sets and modalities. Full alignment between the two is often impractical, a pattern commonly seen across imaging studies. Since the last reporting period, PAS sites identified 3 more Type I Endoleaks, 1 more Type III Endoleaks, 2 more loss of patency observations which led to reintervention when compared to PAS Core Lab. These site-Core Lab discrepancies in endoleak and patency assessments reflect methodological and interpretive differences, consistent with findings in other imaging evaluation studies.

The rates of Type I and III endoleaks as well as the rates for patency-related observations were assessed between site- and Core Lab reporting and compared with rates in the literature and also reporting standards. The outcomes, events and contributing factors in the PAS continue to be evaluated.

Table 4: TREO PAS Data (Data cut February 10th, 2025)

	Day 30	Year 1	Year 2	Year 3	Year 4	Total
Aneurysm Related Mortality [a]	0/338 (0%)	0/323 (0%)	0/295 (0%)	0/179 (0%)	0/40 (0%)	**0**
All-cause Mortality [a]	11/338 (3.3%)	12/323 (3.7%)	12/295 (4.1%)	6/179 (3.4%)	0/40 (0%)	**41**
Aneurysm Rupture [a]	0/321 (0%)	0/266 (0%)	1/203 (0.5%)	0/70 (0%)	0/2 (0%)	**1**
Secondary Interventions [a,b]	7/338 (2.1%)	18/323 (5.6%)	14/295 (4.7%)	5/179 (2.8%)	2/40 (5.0%)	**38**
Conversions to open surgical repair[a]	0/338 (0%)	0/323 (0%)	0/295 (0%)	0/179 (0%)	0/40 (0%)	**0**
Type Ia endoleak [b,c]	2/310 (0.6%)	0/254 (0%)	2/168 (1.2%)	0/49 (0%)	0/2 (0%)	**4**
Type Ib endoleak [b,c]	2/310 (0.6%)	0/254 (0%)	0/168 (0%)	0/49 (0%)	0/2 (0%)	**2**
Type III endoleak [b,c]	2/310 (0.6%)	0/254 (0%)	1/168 (0.6%)	0/49 (0%)	0/2 (0%)	**3**
Aneurysm enlargement >5mm [b,c]	NA	10/260 (3.8%)	13/187 (7.0%)	4/52 (7.7%)	0/2 (0%)	**21**
Prosthesis Migration >10 mm [b]	0/309 (0%)	0/255 (0%)	1/185 (0.5%)	0/52 (0%)	0/1 (0%)	**1**
Occlusions/stenosis [b,c]	7/313 (2.2%)	8/224 (3.1%)	2/168 (1.2%)	1/50 (2.0%)	0/2 (0%)	**15**
Loss of device integrity [b,e]	0/259 (0.0%)	3/214 (1.4%)	2/169 (1.2%)	0/50 (0%)	0/1 (0%)	**3**
Rate of Major Adverse Events [a]	7/338 (2.1%)	5/323 (1.5%)	6/295 (2.0%)	3/179 (1.7%)	0/40 (0%)	**20**

Note:

[a] Denominators may differ due to adequate imaging/data available to assess parameter.

[b] This number reflects the incidence of secondary interventions. Subjects may have more than one secondary intervention in a timepoint. The total is the total incidence.

[c] Core Laboratory reported data. Where applicable, the data is inclusive of both new and persistent (e.g., aneurysm enlargement > 5 mm, Type I and Type III endoleaks, occlusions/stenosis). The total is reflective of the unique subjects.

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

For the period between March 2024 and March 2025, there are no on-going global recalls for the TREO Abdominal Stent-Graft System.

V. Worldwide Commercial Experience:

TREO is distributed globally and receives feedback/learnings from this worldwide commercial use in part by way of complaints. As each complaint is received, it is reviewed to determine if a trend is occurring, if there are common root causes, and/or if immediate corrective action needs to be implemented. This is documented in the complaint investigation form and is part of the feedback loop that potentially requires updates to the Design and/or Process FMEAs, as well as the Benefit-Risk Analysis (BRA).

Table 5 summarizes the associated complaints received between April 2024 and March 2025.

Table 5: Complaints

Complaint Code	Failure Mode Description	# of complaints per failure mode	MDR Filed
Clinical Observations			
075	Type I Endoleak	19 10 (Ia) 4 (Ib) 0 (Ic) 5 (Undetermined)	Yes (18)
076	Type II Endoleak	16	Yes (9)
077	Type III Endoleak	9 0 (IIIa) 2 (IIIb) 1 (IIIc) 6 (Undetermined)	Yes (8)
078	Type IV Endoleak	0	No
059	Endoleak	42	Yes (31)
036	In-Stent Restenosis	7	Yes (4)
043	Loss of hemostasis	3	Yes (2)
051	Post-implant thrombus formation	7	Yes (7)
062	Perforation of vessel	0	No
088	Pyrogenic response	0	No
065	Other adverse event post-procedure resulting in death	9	Yes (7)
Delivery / Deployment Observations			
032	Device preparation difficulty	1	No
033	Unable / difficult to advance the device through entry vessel	2	Yes (2)
034	Unable / difficult to advance device in the aorta	2	Yes (2)
035	Unable to withdraw introducer sheath	5	Yes (4)

Table 5: Complaints			
Complaint Code	**Failure Mode Description**	**# of complaints per failure mode**	**MDR Filed**
037	Inaccurate deployment of the stent graft / stent graft misplacement	2	Yes (2)
039	Unable / difficult releasing proximal stent	10	Yes (9)
042	General delivery system malfunction	3	Yes (1)
052	Check-valve leak	0	No
054	Difficult/ unable to remove inner DS components	7	Yes (6)
055	Improper loading of graft	1	No
057	Foreshortening of limbs	1	No
058	Incorrect / inadequate pre-case planning	0	No
060	Unable / difficulty deploying stent-graft	6	Yes (5)
061	Product performance compromised by improper use due to lack of knowledge, training or not understanding the IFU and / or label, including used of expired product	1	Yes
066	Stent fracture	1	Yes
068	Inner control tube detached /broke separating tip and distal clasp from delivery system	0	No
069	Tip separated from the delivery system	3	Yes (3)
071	Stent-graft marker not positioned and/or sewn correctly	1	Yes
072	Migration	4	Yes (3)
085	Unable to advance device over the guidewire	0	No
092	Missing Stent Markers	0	No
093	Occlusion	10	Yes (7)
Packaging / Manufacturing Observations			
046	Packaging damaged	3	No
050	Product damage	2	No
053	Manufacturing inconsistency observed - no effect	0	No
073	Particle found in sterile packaging	10	No
083	Breach of product packaging pouch (hole, slit, etc.) not caused by impact to product	1	No
095	Missing Final Packaging Assembly Component (Label, IFU, Patient Packet Information, Drawing)	0	No
Labeling Observations			
045	Mislabeling / illegible labeling	0	No
Other			
063	Shipping error / incorrect device provided to customer	0	No

For Clinical Observations, the highest adverse events rates were for Endoleak. This is a well known adverse events from AAA endograft treatments, and the adverse event rates themselves were well below known rates.

Bolton Medical is investigating the complaints regarding delivery and deployment observations and will implement mitigations if identified.

VI. Explant Analysis:

Following commercialization, three (3) explants have been reported from cases outside of the United States. None of these analyses have shown any obvious damage associated with the device.

VII. Literature Review:

Since the last clinical summary update, there have been two (2) publications with information that evaluates the safety and performance of the TREO Abdominal Stent-Graft System when used as intended by the manufacturer.

Table 6: TREO Publications since last update

	Article Citation	Brief Summary
1	Kedwai BJ, Geiger JT, Najjar S, Lehane DJ, Balceniuk M, Newhall KA, Mix DS and Stoner MC (2024). "TREO Aortic Endograft Demonstrates Superior Aneurysmal Sac Regression Over Mid-Term Follow-Up." J Surg Res 302: 495-500	*Retrospective analysis of 90 patients treated with EVAR for AAA in a single center in the US (n=21 with a TREO device, and n=68 with a non-TREO device). The primary objective was sac regression in TREO versus non-TREO patients at 12 and 24 months; secondary outcomes included rates of mortality, endoleak and reintervention.* *Sac regression over mid-term follow up was greater with the TREO device versus non-TREO devices; however, larger studies are needed to corroborate this finding. Furthermore, this article did not highlight any issues or concerns regarding the safety of TREO/Treovance and the data does not impact the known safety and effectiveness profile of the device.*
2	*Zerwes S, Ciura A-M, Eckstein H-H, Heiser O, Kalder J, Keschenau P, Lescan M, Rylski B, Kondov S, Teßarek J, Bruijnen H-K and Hyhlik-Dürr A (2024). "Real world experience with the TREO device in standard EVAR: Mid-term results of 150 cases from a German Multicenter study." Vasa 53(6): 411–9	*Multicenter retrospective analysis of 150 unselected patients treated with a TREO device for EVAR of AAA (n=17 symptomatic and n=6 ruptured AAA) across six hospitals in Germany. Primary outcomes were technical success, mortality and endograft related complications according to IFU status. Secondary outcomes were aneurysm/procedure related reinterventions.* *In this study, patients treated within the IFU tended to have better outcomes than those treated outside the IFU (occurrence of complications and number of secondary interventions) however these findings did not reach statistical significance. This publication did not highlight any issues or concerns regarding the safety or effectiveness of the device.*

*Publication mentions off-label use.

VIII. Conclusion:

Based on available clinical study data and world-wide clinical experience to date, endovascular therapy with the TREO Abdominal Stent-Graft System continues to be a viable treatment option for infrarenal abdominal aortic and aorto-iliac aneurysms. Bolton Medical recommends routine imaging follow-up to ensure subjects are evaluated for conditions that may necessitate intervention (as per recommendations outlined under Section 13 '*Follow Up Procedure'* and ~~s~~section 14 *'Additional Surveillance and Treatment'* of the device Instructions For Use (IFU).

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 TREO Abdominal 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.