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 13,069 TREO Abdominal Stent-Graft Systems have been distributed worldwide between March 2023 and March 2024. During this reporting period, there have been approximately 3,642 devices implanted in the US.

Table 1: TREO Devices Shipped and Implanted

Device Component	US	ROW	Global Total	Total Implanted in US
Bifurcate (B2)	1,028	2,691	3,719	1,099
Cuff (C2)	142	331	473	168
Leg Extension (L2)	2,144	6,705	8,849	2,347
Straight Extension (S2)	29	-1	28	28
Total	**3,343**	**9,726**	**13,069**	**3,642**

ROW: Rest of World

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 ongoing with some early 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 is currently enrolling and involves de novo and Pivotal Study investigational sites. Study enrollment is 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). Four (4) subjects reported with fracture are active in follow-up. Of those four (4), two (2) subjects completed their 9-year visits, and the other two (2) subjects are pending their 8-year and 9-year visits. The Core Laboratory found no evidence of endoleak, aneurysm sac expansion, patency compromise, or migration in any of the four (4) subjects. Furthermore, no clinical sequelae were 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. Twenty-nine (29) secondary interventions have been reported in twenty-four (24) for the Pivotal Study, and one (1) secondary intervention has been reported in one (1) for the Continued Access Study. The reasons for intervention include the following: any endoleak in ten (10), migration in one (1), occlusion/thrombus in four (4), and fifteen (15) others (including bowel resection due to mesenteric ischemia, artery harvest, fistula repair).

Table 2: Pivotal Study (Data Cut March 31st, 2022)											
	Day 30	**Month 6**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Total**
Aneurysm Related Mortality	0/150 (0.0%)	0/149 (0.0%)	0/144 (0.0%)	0/131 (0.0%)	0/119 (0.0%)	0/111 (0.0%)	0/94 (0.0%)	0/19 (0.0%)	0/14 (0%)	**NA**	**0**
All-cause Mortality	1/150 (0.7%)	2/149 (1.3%)	7/144 (4.9%)	6/131 (4.6%)	2/119 (1.7%)	5/111 (4.5%)	2/94 (2.1%)	1/19 (5.3%)	0/14 (0%)	**0/14**	**26**
Aneurysm Rupture	0/150 (0.0%)	0/149 (0.0%)	0/144 (0.0%)	0/131 (0.0%)	0/119 (0.0%)	0/111 (0.0%)	0/94 (0.0%)	0/19 (0.0%)	0/14 (0.0%)	**NA**	**0**
Major Adverse Events[1] (number of incidents)	4	3	12	11	8	10	2	1	0	**0**	**51**
Rate of Major Adverse Event[1] (total number of subjects with at least 1 MAE)	4/150 (2.7%)	2/149 (1.3%)	9/144 (6.2%)	8/131 (6.1%)	7/119 (5.9%)	8/111 (7.2%)	2/94 (2.1%)	1/19 (5.2%)	0/14 (0.0%)	**0/14**	**36**
Prosthesis Migration >10 mm [3]	0/148 (0.0%)	0/133 (0.0%)	0/131 (0.0%)	0/114 (0.0%)	0/97 (0.0%)	0/76 (0.0%)	0/62 (0.0%)	0/7 (0.0%)	0/1 (0.0%)	**NA**	**0**
Type Ia endoleak [3]	1/147 (0.7%)	1/134 (0.7%)	0/133 (0.0%)	1/113 (0.8%)	1/101 (0.9%)	0/79 (0.0%)	0/64 (0.0%)	0/7 (0.0%)	0/1 (0.0%)	**NA**	**4**
Type Ib endoleak [3]	0/147 (0.0%)	1/134 (0.7%)	0/133 (0.0%)	0/113 (0.0%)	0/101 (0.0%)	0/79 (0.0%)	0/64 (0.0%)	0/7 (0.0%)	0/1 (0.0%)	**NA**	**1**
Type IIIa endoleak [3]	0/147 (0.0%)	0/134 (0.0%)	0/133 (0.0%)	0/113 (0.0%)	0/101 (0.0%)	0/79 (0.0%)	0/64 (0.0%)	0/7 (0.0%)	0/1 (0.0%)	**NA**	**0**
Type IIIb endoleak [3]	0/147 (0.0%)	0/134 (0.0%)	0/133 (0.0%)	0/113 (0.0%)	0/101 (0.0%)	0/79 (0.0%)	0/64 (0.0%)	0/7 (0.0%)	0/1 (0.0%)	**NA**	**0**
Aneurysm enlargement >5 mm [3]	NA	0/103	1/122	0/114	9/99	4/78	6/65	2/21	0/2	**NA**	**22**
Occlusions/ stenoses [3]	0/150 (0.0%)	0/137 (0.0%)	0/137 (0.0%)	0/116 (0.0%)	0/102 (0.0%)	0/83 (0.0%)	0/66 (0.0%)	0/9 (0.0%)	0/1 (0.0%)	**NA**	**0**
Loss of device integrity [2,3]	0/148 (0.0%)	1/133 (0.8%)	3/131 (2.3%)	3/114 (2.6%)	2/97 (2.1%)	3/76 (3.9%)	2/62 (3.2%)	0/7 (0.0%)	0/1 (0.0%)	**NA**	**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%)	0/94 (0.0%)	0/19 (0.0%)	0/14 (0.0%)	**NA**	**0**
Secondary Interventions (Subjects with any intervention - site reported)	6/150 (4.0%)	4/149 (2.7%)	4/143 (2.8%)	2/130 (1.5%)	3/119 (2.5%)	3/106 (2.8%)	1/87 (1.1%)	1/18 (5.6%)	0/8 (0.0%)	**NA**	**24**

[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 51 instances of MAE's.

[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.

[3] Core Laboratory reported data.

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

Post Approval Study (PAS) Results:

As of March 13, 2024, 338 subjects have been enrolled in the TREO PAS. Follow-up is on-going and partial 3-year follow-up is available. No aneurysm-related deaths (CEC adjudicated), aortic ruptures, or conversions to open surgery have been reported at any timepoint.

Thirty (30) secondary interventions in twenty-seven (27) subjects were reported through follow-up. A brief summary of the reasons for these interventions is provided below:

- *Endoleaks:* Fourteen (14) interventions were to correct site reported endoleaks, which were not identified by the Core Laboratory (five (5) Type I, two (2) Type III, and seven (7) Type II). The imaging for 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). One (1) Type III was reported by the site as a device deficiency.
- *Occlusion/Thrombosis:* twelve (12) interventions were to correct reported occlusion/stenosis. Four (4) were related to site reported device deficiencies. Of these, one (1) was a right iliac artery occlusion within the implant, one (1) a right limb thrombosis, one (1) an acute occlusion, and one (1) a thrombosed left iliac limb. All were related to the adverse event 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 this as unrelated to a device deficiency and 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. One subject had a fracture present at the proximal aspect of stent (complete displacement). There were no clinical sequelae, with 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. The subject was withdrawn from the study due to opting for hospice care.

The second subject had a fracture present at the proximal aspect of the stent. Subject underwent uneventful reintervention for right iliac occlusion, which the CEC reported was not related to stent fracture. There was no evidence of endoleak (Type I or III), aneurysm sac expansion, or migration reported by the Core Laboratory through 2-year follow-up. However, at the 2-year follow-up, Core Laboratory identified a new fracture at the proximal aspect of the uncovered stent. The subject is pending 3-year follow-up. No stent-

fractures were reported for the 2-year or 3-year follow-up. There have been no other reports of stent or strut fracture, or barb separation related to reinterventions.

The third subject had a stent fracture located at the proximal aspect of the stent, similar to what has been previously reported in the TREO PAS / TREO IDE studies. The Core Laboratory did not observe any evidence of endoleak (Type I or III), migration, or patency compromise. The subject did have a reintervention (POD 732) due to an aneurysm enlargement caused by a Type II endoleak. The CEC adjudicated this event as not device related. The subject is pending 2-year follow-up.

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. None were associated with reinterventions. 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 was one (1) Type Ia endoleak was observed by the Core Laboratory. The subject resolved the Type Ia with a reintervention (relining). At 3-year, there were no Type I or Type III endoleaks observed by the Core Laboratory.

Table 4: PAS Data					
	Day 30	**Year 1**	**Year 2**	**Year 3**	**Total**
Aneurysm Related Mortality [a]	0/338 (0%)	0/324 (0%)	0/232 (0%)	0/55 (0%)	**0**
All-cause Mortality [a]	11/338 (3.3%)	12/324 (3.7%)	4/232 (1.7%)	0/55 (0%)	**27**
Aneurysm Rupture [a]	0/315 (0%)	0/245 (0%)	0/80 (0%)	0/4 (0%)	**0**
Secondary Interventions [a]	7/338 (2.1%)	17/324 (5.2%)	5/232 (2.2%)	1/55 (1.8%)	**30**
Conversions to open surgical repair[a]	0/338 (0%)	0/324 (0%)	0/232 (0%)	0/55 (0%)	**0**
Type Ia endoleak [b]	2/305 (0.7%)	0/222 (0%)	1/64 (1.6%)	0/2 (0%)	**3**
Type Ib endoleak [b]	2/305 (0.7%)	0/222 (0%)	0/64 (0%)	0/2 (0%)	**2**
Type III endoleak [b,c]	2/305 (0.7%)	0/222 (0%)	0/64 (0%)	0/2 (0%)	**2**
Aneurysm enlargement >5 [b]	NA	8/226 (3.5%)	4/72 (5.6%)	0/2 (0%)	**12**
Prosthesis Migration >10 mm [b]	0/305 (0%)	0/223 (0%)	0/69 (0%)	0/2 (0%)	**0**
Occlusions/stenoses [b]	7/308 (2.3%)	6/224 (2.7%)	1/64 (1.6%)	0/2 (0%)	**14**
Loss of device integrity [b,e]	0/259 (0.0%)	3/195 (1.5%)	1/65 (1.5%)	0/2 (0%)	**4**
Rate of Major Adverse Events [a,d]	7/338 (2.1%)	4/324 (1.2%)	3/232 (1.3%)	0/55 (0.0%)	**16**

Note: denominators may differ due to adequate imaging/data available to assess parameter.
[a] Clinical Events Committee (CEC) Adjudicated
[b] Core Laboratory Reported
[c] Core Laboratory identified two (2) Type III endoleaks. The sites reported one (1) as a Type IIIa, and the other was reported as a Type IIIb.
[d] Major Adverse Events is a composite of myocardial infarction according to SCAI definition, stroke according to the VARC-2 guidelines, new onset renal Failure requiring permanent dialysis, new onset respiratory failure requiring permanent home oxygen therapy through 30 days, permanent paralysis/paraplegia, bowel ischemia, and procedural blood loss (≥ 1000cc).
[e] Loss of device integrity includes stent strut facture and/or barb separation.

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

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

Within the period between March 2023 and March 2024, an on-going global recall was initiated for the TREO Abdominal Stent-Graft System. The recall was the result of the potential packaging of an incorrect size stent-graft within the labeled product box. All affected devices have been retrieved. The root cause for the packaging error was a gap in the inspection process at the time the complaint unit was assembled. The recall has been submitted for closure as all actions have been completed. No further actions are needed from physician users or patients. There was no impact to patient safety as a result of this field action.

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 an 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 March 2023 and March 2024.

Table 5: Complaints

Complaint Code	Failure Mode Description	# of complaints per failure mode	MDR Filed
Clinical Observations			
075	Type I Endoleak	14 8 (Ia) 2 (Ib) 1 (Ic) 3 (Undetermined)	Yes (13)
076	Type II Endoleak	12	Yes (11)
077	Type III Endoleak	8 0 (IIIa) 0 (IIIb) 1 (IIIc) 7 (Undetermined)	Yes (6)
078	Type IV Endoleak	2	Yes
059	Endoleak	34	Yes (30)
036	In-Stent Restenosis	3	Yes
043	Loss of hemostasis	1	Yes
051	Post-implant thrombus formation	20	Yes (19)
062	Perforation of vessel	2	Yes
088	Pyrogenic response	1	No
065	Other adverse event post-procedure resulting in death	3	Yes (2)
Delivery / Deployment Observations			
032	Device preparation difficulty	2	Yes (1)

Table 5: Complaints			
Complaint Code	**Failure Mode Description**	**# of complaints per failure mode**	**MDR Filed**
033	Unable / difficult to advance the device through entry vessel	2	Yes
034	Unable / difficult to advance device in the aorta	1	No
035	Unable to withdraw introducer sheath	11	Yes (10)
037	Inaccurate deployment of the stent graft / stent graft misplacement	7	Yes (6)
039	Unable / difficult releasing proximal stent	16	Yes
042	General delivery system malfunction	1	Yes
052	Check-valve leak	1	No
054	Difficult/ unable to remove inner DS components	4	Yes (3)
055	Improper loading of graft	1	No
057	Foreshortening of limbs	2	Yes (1)
058	Incorrect / inadequate pre-case planning	1	Yes
060	Unable / difficulty deploying stent-graft	10	Yes (8)
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	2	Yes (1)
066	Stent fracture	1	Yes
068	Inner control tube detached /broke separating tip and distal clasp from delivery system	3	Yes
069	Tip separated from the delivery system	10	Yes (9)
071	Stent-graft marker not positioned and/or sewn correctly	3	Yes (1)
072	Migration	2	Yes
085	Unable to advance device over the guidewire	1	Yes
092	Missing Stent Markers	1	No
093	Occlusion	4	Yes
Packaging / Manufacturing Observations			
046	Packaging damaged	3	No
050	Product damage	3	Yes
053	Manufacturing inconsistency observed - no effect	2	No
073	Particle found in sterile packaging	13	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)	1	No
Labeling Observations			
045	Mislabeling / illegible labeling	3	No
Other			
063	Shipping error / incorrect device provided to customer	1	No

For Clinical Observations, the highest adverse events rates were for Endoleak and Post-Implant Thrombus Formation. These are well known adverse events from AAA endograft treatments, and the adverse event rates themselves were well below known rates.

For Delivery and Deployment Observations, the highest number of complaints were received for the following:

- Unable to withdraw introducer sheath (Code 035) and Unable / difficulty deploying stent-graft (Code 060) – In these complaints, there was difficulty or the inability to fully retract the introducer sheath to deploy the stent-graft.
- Unable / difficult releasing proximal stent (Code 039) – In these complaints, the user experienced difficulty with the clasp release system, which releases the stent graft from the delivery system. CAPA 1275 was initiated for this issue and is in the implementation phase.
- Tip Separated from the Delivery System (Code 069) – In these complaints, the tip is becoming detached from the delivery system. CAPA 1279 has been initiated and is in the implementation phase.
- Particle found in sterile packaging (Code 073) – In these complaints, particles are found within the sterile pouch packaging. CAPA 1268 has been initiated and was in the implementation phase. However, the scope was revised to include all particles. Therefore, the planning phase is being revised as well.

VI. Explant Analysis:

Following commercialization and within this reporting period, 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. Bolton Medical recommends routine imaging follow-up to ensure subjects are evaluated for conditions that may necessitate intervention.

VII. Literature Review:

There have been five (5) publications with information on the TREO Abdominal Stent-Graft System since the last clinical summary update.

Table 6: TREO Publications since last update

	Article Citation	Brief Summary
1	Martinelli, O., S. Cuozzo, F. Miceli, R. Gattuso, V. D'Andrea, P. Sapienza and M. I. Bellini (2023). "Elective Endovascular Aneurysm Repair (EVAR) for the Treatment of Infrarenal Abdominal Aortic Aneurysms of 5.0–5.5 cm: Differences between Men and Women." Journal of Clinical Medicine 12(13).	*The retrospective review assesses outcome in males vs females treated in a single centre for AAA with EVAR in 94 patients, two of whom were treated with a TREO device. The results of this study was not stratified by device. This publication 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	*Mezzetto, L., M. D'Oria, S. Lepidi, D. Mastrorilli, C. Calvagna, S. Bassini, J. Taglialavoro, S. Bruno and G. F.	*This literature review analyses proximal neck dilatation following EVAR or FEVAR. Of the 15 publications included within the review, one publication included one patient implanted with an physician modified TREO device used for FEVAR. The results of this study was not stratified by device. This*

Table 6: TREO Publications since last update		
	Article Citation	**Brief Summary**
	Veraldi (2023). "A Scoping Review on the Incidence, Risk Factors, and Outcomes of Proximal Neck Dilatation after Standard and Complex Endovascular Repair for Abdominal Aortic Aneurysms." Journal of Clinical Medicine 12(6).	*publication 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.*
3	*Nana, P., K. Spanos, G. Kouvelos, E. Arnaoutoglou, A. Giannoukas and M. Matsagkas (2023). "Conical Aortic Neck as a Predictor of Outcome after Endovascular Aneurysm Exclusion: Midterm Results." Annals of Vascular Surgery 90: 77-84	*This retrospective analysis aimed to assess the effect of conical neck anatomy on outcomes after EVAR for AAA in 150 patients, including some patients treated with a Treovance device. The results of this study was not stratified by device. This publication 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.*
4	Papadoulas, S., C. Pitros, C. Papageorgopoulou and F. Mulita (2023). "Endotension as a Rare Complication to Endovascular Abdominal Aortic Aneurysm Repair." Innovations: Technology and Techniques in Cardiothoracic and Vascular Surgery 18(5): 498-502	*This case report describes a 69 year old male EVAR patient treated with a Treovance device six years prior, who presented with aneurysm enlargement with no evidence of endoleak, which was determined to be caused by endotension. The patient was converted to open repair, was discharged on POD 7 and had no complications upon the one month follow up visit. The authors note that no commercially available device has proven worse than others. This publication did not highlight any issues or concerns specifically regarding the safety of TREO/Treovance and the data does not impact the known safety and effectiveness profile of the device.*
5	Spath, P., E. Pasqui, D. Angiletta, A. Spinazzola, F. Chegai, G. Isernia, S. Lepidi, R. Silingardi, G. de Donato, M. Gargiulo, M. D'Oria, G. Faggioli, E. Gallitto, M. Migliari, R. Pini and G. Simonte (2023). "Penumbra Indigo Percutaneous Aspiration Thrombectomy System in the treatment of Aortic Endograft Iliac Limb Occlusion: Results from an Italian Multicentre Registry." European Journal of Vascular and Endovascular Surgery 66(1): 77-84.	*This retrospective multicentre study presents outcomes of the use of a percutaneous aspiration thrombectomy system in order to treat limb occlusion following EVAR in 17 patients, one of whom was initially treated with a TREO device. The results of this study was not stratified by device. This publication 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.*
*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.

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.