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 13,366 TREO Abdominal Stent-Graft Systems have been distributed worldwide between March 2022 and March 2023. During this reporting period, there have been approximately 3,101 devices implanted in the US.

Table 1: TREO Devices Shipped and Implanted

Device Component	US	ROW	Global Total	Total Implanted in US
Bifurcate (B2)	905	2,894	3,799	919
Cuff (C2)	388	461	849	159
Leg Extension (L2)	1,825	6,844	8,669	2,016
Straight Extension (S2)	32	17	49	7
Total	**3,150**	**10,216**	**13,366**	**3,101**

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 31st, 2023, all Pivotal and Continued Access subjects have completed their 5-year follow-up visits. During this prior reporting period, three (3) subjects had their study completion visit (5-year visit). The Core Laboratory found no evidence of endoleak, stent fracture, barb break, migration, kinking, component separation, aneurysm sac expansion, or graft patency compromise in any of these three (3) subjects. In addition, no adverse events or secondary interventions (endovascular and surgical) were reported.

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 7-year visits, and the other two (2) subjects completed their 8-year visits. The Core Laboratory found no evidence of endoleak, patency compromise, or migration in any of these 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

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 31st 2023, 330 subjects have been enrolled in the TREO PAS. Follow-up is on-going and partial 2-year follow-up is available. No aneurysm-related mortality or aortic rupture have been reported at any timepoint. Additionally, there were no conversions to open surgery.

Sixteen (16) secondary interventions in sixteen (16) subjects were reported through follow-up. A brief summary of the reasons for these interventions is provided below:

- *Endoleaks:* Six (6) interventions were to correct site reported endoleaks, which were not identified by the Core Laboratory (Three (3) Type I, one (1) Type IIIa, and two (2) 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). The site reported the Type I endoleaks and the Type III endoleak as unrelated to a device deficiency and were resolved with reinterventions.
- *Occlusion/Thrombosis:* Six (6) interventions were to correct reported occlusion/stenosis. Three (3) 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, 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 the 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. One-year Core Laboratory imaging follow-up is pending.
- *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. One-year Core Laboratory imaging follow-up is pending.
- *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. One-year Core Laboratory imaging is pending.

Regarding stent fractures, no stent fractures were reported at 30-days by the Core Laboratory. Two (2) subjects were reported with one stent fracture at 1-year by the Core Laboratory. One (1) 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. This subject is pending 2-year follow-up. 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. This subject is also pending 2-year follow-up. No stent-fractures were reported for 2 years. There have been no other reports of stent or strut fracture, or barb separation related to reinterventions.

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. One-year follow-up imaging is pending for both Type III cases. At 1-year, there was one (1) persistent Type Ia with no migration or reintervention reported. Two-year follow-

up is pending for this subject. No Type Ia, Type Ib, Type III, or Type IV were reported by the Core Laboratory at 2-year follow-up.

Table 4: PAS study data

	Day 30	Year 1	Year 2	Total
Aneurysm Related Mortality [a]	0/330 (0%)	0/257 (0%)	0/62 (0%)	**0**
All-cause Mortality [a]	8/330 (2.4%)	4/257 (1.6%)	0/62 (0%)	**12**
Aneurysm Rupture [a]	0/278 (0%)	0/94 (0%)	0/6 (0%)	**0**
Secondary Interventions [a]	9/308 (2.9%)	7/101 (6.9%)	0/6 (0%)	**16**
Conversions to open surgical repair [a]	0/330 (0%)	0/257 (0%)	0/62 (0%)	**0**
Type Ia endoleak [b]	2/268 (0.7%)	0/80 (0%)	0/5 (0%)	**2**
Type Ib endoleak [b]	2/268 (0.7%)	0/80 (0%)	0/5 (0%)	**2**
Type III endoleak [b,c]	2/268 (0.7%)	0/80 (0%)	0/5 (0%)	**2**
Aneurysm enlargement >5 [b]	N/A	4/83 (4.8%)	0/5 (0%)	**4**
Prosthesis Migration >10 mm [b]	0/275 (0%)	0/87 (0%)	0/4 (0%)	**0**
Occlusions/stenoses [b]	5/271 (1.8%)	1/84 (1.2%)	0/5 (0%)	**6**
Loss of device integrity [b]	1/237 (0.4%)	2/78 (2.6%)	0/4 (0%)	**3**
Rate of Major Adverse Events [a,d]	7/328 (3.1%)	2/154 (1.3%)	0/21 (0%)	**9**

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).

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:

For the period between March 2022 and March 2023, there is an on-going global recall 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. Devices have been retrieved and a root cause investigation is underway. 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 2022 and March 2023.

Table 5: Complaints

Complaint Code	Failure Mode Description	# of complaints / failure mode
Clinical Observations		
075	Type I Endoleak	**17** **16 (Ia)** **1 (Ib)**
076	Type II Endoleak	**11**
077	Type III Endoleak	**2** **0 (IIIa)** **0 (IIIb)** **2 (Undetermined)**
078	Type IV Endoleak	**3**
036	In-Stent Restenosis	**5**
043	Loss of hemostasis	**2**
051	Post-implant thrombus formation	**12**
062	Perforation of vessel	**1**
064	Stroke	**1**
081	Thromboembolism / thrombosis	**4**
086	Aortic rupture	**2**
088	Pyrogenic response	**2**
065	Other adverse event post-procedure resulting in death	**3**
Delivery / Deployment Observations		
032	Device preparation difficulty	3
033	Unable / difficult to advance the device through entry vessel	3
034	Unable / difficult to advance device in the aorta	1
035	Unable to withdraw introducer sheath	8

Table 5: Complaints		
Complaint Code	**Failure Mode Description**	**# of complaints / failure mode**
037	Inaccurate deployment of the stent graft / stent graft misplacement	6
039	Unable / difficult releasing proximal stent	9
042	General delivery system malfunction	1
048	Unable to reset the tip in position	1
054	Difficult/ unable to remove inner DS components	7
057	Foreshortening of limbs	1
058	Incorrect / inadequate pre-case planning	1
060	Unable / difficulty deploying stent-graft	10
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	3
066	Stent fracture	3
068	Inner control tube detached /broke separating tip and distal clasp from delivery system	2
069	Tip separated from the delivery system	7
071	Stent-graft marker not positioned and/or sewn correctly	1
072	Migration	3
080	Difficulty / unable to advance balloon or device through leave behind sheath	2
084	Inner control broke, resulting in separation of tip and distal clasp from delivery system	1
085	Unable to advance device over the guidewire	2
Packaging / Manufacturing Observations		
046	Packaging damaged	6
050	Product damage	1
053	Manufacturing inconsistency observed - no effect	2
073	Particle found in sterile packaging	4
Labeling Observations		
45	Mislabeling / illegible labeling	2
Other		
063	Shipping error / incorrect device provided to customer	1

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.

• Difficult/ unable to remove inner DS components (054) - In these complaints, the delivery system tip was getting stuck in the leave behind sheath. This was a benign event in all cases, in which the delivery system and left behind sheath had to be pulled out at the same time, rather than separately. Nevertheless, CAPA 1276 was initiated for this issue, and has identified a tolerance stack-up issue that will be corrected in the implementation phase of the CAPA.

• 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 planning 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 investigation phase.

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 four (4) 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	*Marone, Enrico Maria, Giulia Marazzi, Chiara Brioschi, and Luigi Federico Rinaldi. "Five-Year Outcomes of Endovascular Aortic Repair With the TREO Abdominal Endograft." *Journal of Endovascular Therapy: An Official Journal of the International Society of Endovascular Specialists*, April 28, 2023, 15266028231170160. https://doi.org/10.1177/15266028231170161.	*Newer generation abdominal endografts, including Treo (Terumo Aortic, Sunrise, Florida), have shown optimal safety and effectiveness in treating abdominal aortic aneurysms (AAAs), even with hostile anatomy over the short- and mid-term. The durability of such results, however, is still a controversial issue, due to the paucity of long-term data. Our aim is to show the long-term outcomes of endovascular aortic repair of both standard and hostile AAAs with the Treo endograft on a cohort of patients treated between 2016 and 2017. We analyzed the postoperative follow-up of 37 consecutive patients who have undergone endovascular aortic repair (EVAR) with the Treo Endograft between 2016 and 2017, whose baseline clinical conditions, operative data, and short-term outcomes had been published in 2018. All patients were followed up by computed tomography angiography (CTA) at 6 and 12 months and 5 years postoperatively. Primary endpoints were aortic-related mortality, type I–III endoleak (EL), and reintervention rate. Secondary endpoints were the rates of type II ELs and aneurysm sac regression. Of 37 patients, 27 had at least one criterion of anatomic hostility and 11 were performed outside the device-specific instructions for use (IFU). In the perioperative period, we observed 100% technical success, with no perioperative mortality. Over a mean follow-up of 5.5 years (66 months), 3 patients (8.1%) were lost to follow-up and 3 (8.1%) died of non-aortic causes (overall survival: 91.9%). One type IA EL of an AAA with a hostile neck (but within the IFU) and a type III EL of an AAA with standard anatomy were observed and treated by endovascular relining (overall reintervention rate: 5.5%). Four type II ELs were associated*

Table 6: TREO Publications since last update		
	Article Citation	**Brief Summary**
		with aneurysm sac stability over time and are still under surveillance. Mean aneurysm shrinkage was 11.25±8.30 mm. The optimal results of the Treo Endograft in terms of complication and reintervention rates reported over the mid-term by the current literature (ITA-ENDOBOOT registry) are maintained on the long term, both in case of hostile and friendly aortic anatomy, with a satisfactory shrinkage rate of the aneurysm sac.
2	Pitros, Christos, Pietro Mansi, and Stavros Kakkos. "Endografts for the Treatment of Abdominal Aortic Aneurysms with a Hostile Neck Anatomy: A Systematic Review." *Frontiers in Surgery* 9 (August 15, 2022): 872705. https://doi.org/10.3389/fsurg.2022.872705.	*The purpose of the review is to define the improvement in the clinical management of the patient with hostile neck AAAs. Records were retrieved describing Alto, Ovation iX, Treovance, Aorfix, Anaconda, Conformable, and Endurant II/IIs endografts. Alto and Conformable report a 100% technical success rate, absence of AAA-related death, migration, ruptures, and limb occlusion during follow-up. Endurant II and Ovation iX report >99% technical success rate and are almost free from the AAA mortality rate, ruptures, migration, and limb occlusion, while Ovation iX has a high rate of sac dilation (15.5%) in a 5-year follow-up. Anaconda is slightly better than Aorfix and Treovance, which are related to the lowest technical success rates, 98.3%, 96.3%, and 96%, respectively. Aorfix has the highest AAA mortality rate, 4% in a 60-month follow-up. From a literature review including 640 EVARS, Aorfix seems to have a higher mortality rate than other available endografts, with the AAA-related mortality rate of up to 4%, while the secondary intervention rate was also high (17%) in 5-year follow-up. Limb occlusion incidents were comparable for Aorfix and Treovance in 12-month follow-up (~2%), while Anaconda had 7.9% limb occlusion incidents in a 60-month follow-up. The Excluder Conformable endograft had a high rate of type II endoleaks (43.6%) but was free from other endoleak types, ruptures, migration, or limb occlusion incidents. Treovance was free from ruptures, migration, and AAA-related mortality and had comparable endoleaks and limb occlusion rates with the other endografts in 12-month follow-up. Anaconda, Aorfix, and Treovance are well studied and have studies of quality reporting their clinical outcomes, unlike Excluder Conformable, which lacks big cohort studies and long-term follow-up.*
3	Nana P, Spanos K, Kouvelos G, et al. The impact of Iliac artery anatomy on distal landing zone after EVAR during the 12-month follow-up. Annals of Vascular Surgery. Epub ahead of print 30 June 2022. DOI: 10.1016/j.avsg.2022.06.011.	*The aim of this study was to assess iliac anatomy and its potential impact on distal landing zone adverse events after EVAR during the 12-month follow-up. A prospective data collection of patients treated with standard bifurcated EVAR devices for abdominal aortic aneurysm was undertaken between 2017 and 2019. In total, 268 iliac limbs (134 patients) were included. In all three levels, the mean iliac artery diameters increased at 12-month follow-up. At the origin of the CIA, the diameter increased from 18.7 ± 10.5 mm to 19.9 ± 9.4 mm (P = 0.04), at the middle portion of the CIA, the diameter changed significantly from 15.5 ± 5.1 mm to 17.4 ± 5.4 mm (P < 0.001) and at the distal CIA, from 14.6 ± 3.3 mm to 15.1 ± 3.9 mm (P = 0.03). The iliac angle remained stable (P = 0.14) while the CIA index decreased significantly from 1.17 ± 0.13 to 1.11 ± 0.09 (P < 0.001). The mean value of oversizing was 21.5 ± 14.5% and affected distal iliac diameter increase (P < 0.001). The composite outcome of distal landing zone adverse events was not associated to diameter changes at any level. In 57 cases, a distal iliac diameter ≥18 mm was recorded. The estimated oversizing was lower (16.3 ± 11.8%) compared to <18 mm arteries (22.5 ± 14.9%, P = 0.01). At 12-month follow-up, iliac diameters remained stable in the ≥18 mm group. Endoleak type Ib was more common in iliac arteries ≥18 mm [3 (5.3%) vs. 1 (0.5%) (P = 0.04)] at 12-months. : Prospective data of 268 iliac limbs (134 patients) treated with standard elective EVAR for infra-renal AAA, using currently available bifurcated endografts (Medtronic Endurant, Santa Ana, CA, USA; Cordis Incraft, Dublin, OH, USA; Treovance Bolton, Sunrise, FL, USA; Gore Excluder, W.L. Gore and associates, Flagstaff, AZ, USA; Endologix AFX 2, Irvine, CA, USA) was undertaken retrospectively in a single tertiary center. Post-EVAR iliac artery dilation does not seem to have an impact on distal landing zone adverse events during the 12-month follow-up. Aggressive oversizing may be related to iliac dilation. EVAR patients with iliac arteries ≥18 mm are at higher risk for EL Ib.*

Table 6: TREO Publications since last update		
	Article Citation	**Brief Summary**
4	*De Guerre LEVM, O'Donnell TFX, Varkevisser RRB, et al. The Association between Device Instructions for Use Adherence and Outcomes after Elective Endovascular Aortic Abdominal Aneurysm Repair. Journal of Vascular Surgery. Epub ahead of print 9 March 2022. DOI: 10.1016/j.jvs.2022.02.037.	*This retrospective study was performed to determine the impact of neck characteristics outside of the IFU on perioperative and 1-year outcomes and mid-term survival after EVAR (i.e., Treovance, Zenith, Endologix, Excluder, Aorfix, Endurant, Talent, and Ovation stent-grafts). All patients undergoing elective infrarenal EVAR from December 2014 to May 2020 were identified in the Vascular Quality Initiative database. Of the 15,448 patients identified, 22.1% had neck characteristics outside of IFU, including 6.6% with a infrarenal angle, 6.8% with a neck length, 10.4% with a neck diameter, and 1.1% with a suprarenal angulation outside of IFU. Of these, 2.4% had more than one neck characteristic outside of IFU. Patients with neck characteristics outside of IFU were more often female (27.9% vs. 15.0%, P<.001) and were older (median age 75 vs. 73, P<.001). EVAR patients with neck characteristics outside of IFU had higher rates of type Ia endoleaks at completion (4.8% vs. 2.5%, P<.001), perioperative mortality (1.2% vs. 0.6%, P<.001), one-year sac expansion (7.1% vs. 5.3%, P=.017), and one-year reinterventions (4.4% vs. 3.2%, P=.03). In multivariable adjusted analyses, neck characteristics outside of IFU were independently associated with type Ia completion endoleaks (OR 1.6, [1.3–2.0], P<.001), perioperative mortality (OR 1.8; [1.2–2.7]; P=.005), one-year sac expansion (OR 1.4; [1.0–1.8]; P=.025) and one-year reinterventions (OR 1.4; [1.0–1.9]; P=.039). Unadjusted mid-term survival was lower for patients with neck characteristics outside of IFU than for patients without (5-year survival 84.0% vs. 86.7%, log-rank<.001). However, after adjustment, survival was similar for patients with neck characteristics outside of IFU to those within (HR: 1.1; [1.0-1.3]; P=.22). Of 15,448 EVARs in the VQI database, 22.1% had neck characteristics outside IFU. Patients with neck characteristics outside IFU were more often female (27.9% vs 15.0%; P < .001) and were older (median age, 75 years vs 73 years; P < .001). EVAR patients with neck characteristics outside IFU had higher rates of type Ia endoleaks at completion (4.8% vs 2.5%; P < .001), perioperative mortality (1.2% vs 0.6%; P < .001), 1-year sac expansion (7.1% vs 5.3%; P = .017), and 1-year reinterventions (4.4% vs 3.2%; P = .03). Contemporary devices have been designed to allow patients with more complex neck anatomy to be treated with EVAR with good results. The Aorfix endovascular endograft (Lombard Medical, Oxfordshire, United Kingdom) was designed for patients with highly angulated necks, and the Endurant stent-graft (Medtronic Vascular, Santa Rosa, CA), the Ovation stent graft (Trivascular Inc, Santa Rosa, CA), and the TREO stent-graft (Terumo Aortic Limited, Sunrise, FL) enable repair for patients with short necks although the long-term results in this subgroup of patients with hostile necks remains to be seen. Neck characteristics outside of the IFU are independently associated with completion type Ia endoleaks, perioperative mortality, 1-year sac expansion, and 1-year reinterventions among patients undergoing elective EVAR.*
*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.