



Study purpose	To prospectively collect global ‘real world’ performance data on the Endurant Stent Graft System for endovascular repair in anatomically challenging aneurysms and to critically assess whether the current guidelines for anatomic eligibility to endovascular treatment with this system are still applicable. To create a database that can be pooled/compared with the ENGAGE database.
Primary Endpoints	Treatment Success through given time-points <ul style="list-style-type: none"> ▪ Technical Success ▪ Clinical Success
Secondary Endpoints	<ol style="list-style-type: none"> 1. All-cause mortality through 30 days 2. Major Adverse Events through 30 days 3. Aneurysm related mortality through given time-points 4. Stent graft migration (> 10mm) through given time-points 5. Type I & III endoleaks through given time-points 6. Secondary procedure to restore stent graft function through given time-points 7. Secondary open surgical intervention through given time-points 8. Health Related Quality of Life Scores (EQ-5D) given time-points
Design	Multi-centre, post-market, non-interventional, non-randomized, single-arm prospective observational study.
Subjects	250 subjects
Inclusion Criteria	<ul style="list-style-type: none"> ▪ Age ≥ 18 years or minimum age as required by local regulations ▪ Indication for elective EVAR ▪ Challenging AAA anatomy defined by having one of the following measurements: <ul style="list-style-type: none"> - Proximal necks 5 - 10mm <i>i.c.w. ≤ 60° infrarenal AND ≤ 45° suprarenal angulation</i> - Proximal necks 10 - 15mm <i>i.c.w. 60° - 75° infrarenal AND ≤ 60° suprarenal angulation</i> OR <i>i.c.w. ≤ 75° infrarenal AND 45° - 60° suprarenal angulation</i> - Proximal necks ≥ 15mm <i>i.c.w. 75° - 90° infrarenal AND ≤ 75° suprarenal angulation</i> OR <i>i.c.w. ≤ 90° infrarenal AND 60° - 75° suprarenal angulation</i> • Intention to electively implant the Endurant or Endurant II Stent Graft System[®] ▪ Signed informed consent form
Exclusion Criteria	<ul style="list-style-type: none"> ▪ High probability of non-adherence to physician’s follow-up requirements ▪ Current participation in a concurrent trial which may confound study results ▪ Planned for following adjuvant procedures at the proximal aortic neck: chimney technique, branched device or endostaplers.
Sites	20 high-volume sites across 10 countries worldwide
Site Selection Criteria	<ul style="list-style-type: none"> ▪ Adequate patient volume (>50 AAA stent graft procedures annually) ▪ Endurant experience (≥25 successful Endurant stent graft procedures) ▪ Willingness to comply with all aspects of protocol ▪ Sufficient time to fill out CRFs
Study Duration	7-8 years (2012 to 2020) 2-3 years of Enrolment and 5 years of Follow-up
Anticipated FU Schedule	30-days, 1-year, 2-year, 3-year, 4-year and 5-year post-implant follow-up.
Sponsor	Department of Vascular Surgery, Catharina Hospital, (Eindhoven, The Netherlands)
Executive /Publication Committee	Members yet to be determined, but will be representatives of Investigators and Sponsor’s study management.
Trial Registration	ClinicalTrials.gov Identifier: NCT01810250