A post-approval registry of the TREO stent-graft for patients with infrarenal abdominal aortic aneurysms

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Disclosures

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I have the following potential conflicts of interest to report:

- Consulting: Medtronic, Bolton Medical, COOK, Penumbra, BBraun, Bard, Boston Scientific
- Other: VASCUPEDIA (Co-founder)
The challenge of registries for CE-marked devices

- Increasing requirements for clinical data, including post-market clinical follow-up (PMCF) from CE-marked devices
- Assumptions about registries are not reflected in the new regulations (new EU MDR 2017/745)
- Registries are being encouraged by regulatory bodies (e.g. European Medicines Agency) to allow for clinical trials to be ‘embedded’
The advantages of a registry

• Medical device performance in a real-world setting
• Large number of patients
• Diverse clinical settings
• Registries permit follow-up that can span decades

TREO REGISTRY DESIGN

This is a prospective, multicenter, post-market clinical follow-up, non-randomized registry of the TREO Stent-Graft.

Subjects diagnosed with infrarenal aortic aneurysms and treated with the TREO Stent-Graft device can be included into the registry.

Pre-procedure baseline data will be gathered as well as post-procedure assessments prior to hospital discharge and one to three months and 1, 2, 3, 4, and 5-year post-implantation.
TREO Registry is to study the use and effectiveness of the TREO Stent Graft System in the real world. In order to accomplish this goal this registry will be designed as an Open Ended and All Comers study.

- **Start:** Mar 2017
- **First patient in:** Jun 2017
- **Last patient in:** Q1 2019
- **Interim analyses:**
- **5 Year Follow-up:** Q1 2024
ENDPOINTS

Traditional Clinical Endpoints
Device Specific Endpoints
Health Economic Endpoints
TRADITIONAL CLINICAL ENDPOINTS

- Aneurysm Related Mortality
- All Cause Mortality
- Aneurysm Rupture
- Adverse Events
- Conversion to Open
- Endoleak (Type II)
DEVICE-SPECIFIC ENDPOINTS

- Technical Success
- Endoleak (I, III)
- Patency
- Device Integrity
- Migration
- Sac Change
HEALTH-ECONOMIC ENDPOINTS

- Procedure Time
- Fluoro Time
- Contrast
- Blood Loss
- Number of Pieces
- Access Modality
- Hospital Stay
- ICU Time
- Ancillary Device
Cases in St. Franziskus Hospital
Muenster, Germany
Case #1 – Severely calcified access vessels
Cases in St. Franziskus Hospital
Muenster, Germany
Case #2 – Short proximal neck
TREO Registry update

- First patient in Jun 2017
- 35 patients enrolled to date
- 16 sites recruiting
- 18 pending initiation
- 5-year follow-up
- First results to be presented in 2019
TREO registry innovations & challenges

- Quality by design
- Endpoints adhering to EVAR reporting standards
- Core-lab adjudication
- Careful assessment of safety endpoints
- First EVAR registry initiated under the new MDR
- Ethical committees expectations of pharmaceutical clinical trials being applied to an observational study with CE-marked device
TREO Registry collaborating sites

- Imeldaziekenhuis, Bonheiden, BE
- AZ Sint Blasius, Dendermonde, BE
- Civico, Ospedale Regionale, Lugano, CH
- St. Franziskus Hospital, Muenster, DE
- St. Bonifatius Hospital, Lingen, DE
- Klinikum Peine gGmbH, Peine, DE
- University Hospital Tübingen, Tübingen, DE
- Klinikum Chemnitz, Chemnitz, DE
- Klinikum Augsburg, Augsburg, DE
- University Heart Center Freiburg, DE
- Policlinico S. Maria Alle Scotte, Siena, IT
- Policlinico Tor Vergata, Roma, IT
- Compensorio Sanitario Bolzano, IT
- Ospedale San Gerardo, Monza, IT
- Azienda Ospedaliera di Catania, IT
- Ospedale San Giovanni, Roma, IT
- CdC Villa dei Fiori, Acerra, IT
- Policlinico Consorziale di Bari, IT
- Rijnstate Hospital, Arnhem, NL
- UMC Groningen, NL
- UMCU, Utrecht, NL
- Haukeland University Hospital, Bergen, NO
- Hospital de Santa Marta, Lisboa, PT
- Hospital Clínic, Barcelona, ES
- Complejo Hospitalario Universitario de Ourense, ES
- Hospital Universitario Lucus Augusti, Lugo, ES
- Manchester Royal Infirmary, Manchester, UK
- John Radcliffe, Oxford, UK
- Royal Hospital Liverpool, UK
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