

The logo for LINIC, featuring the letters 'L', 'I', 'N', and 'C' in a white, sans-serif font. The letters are arranged in a slightly curved line. Behind the letters are three overlapping, brush-stroke-like shapes in dark blue, red, and yellow, suggesting a stylized flame or a dynamic motion.

LINIC

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

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# Disclosures

Speaker name:

**Theodosios Bisdas**

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

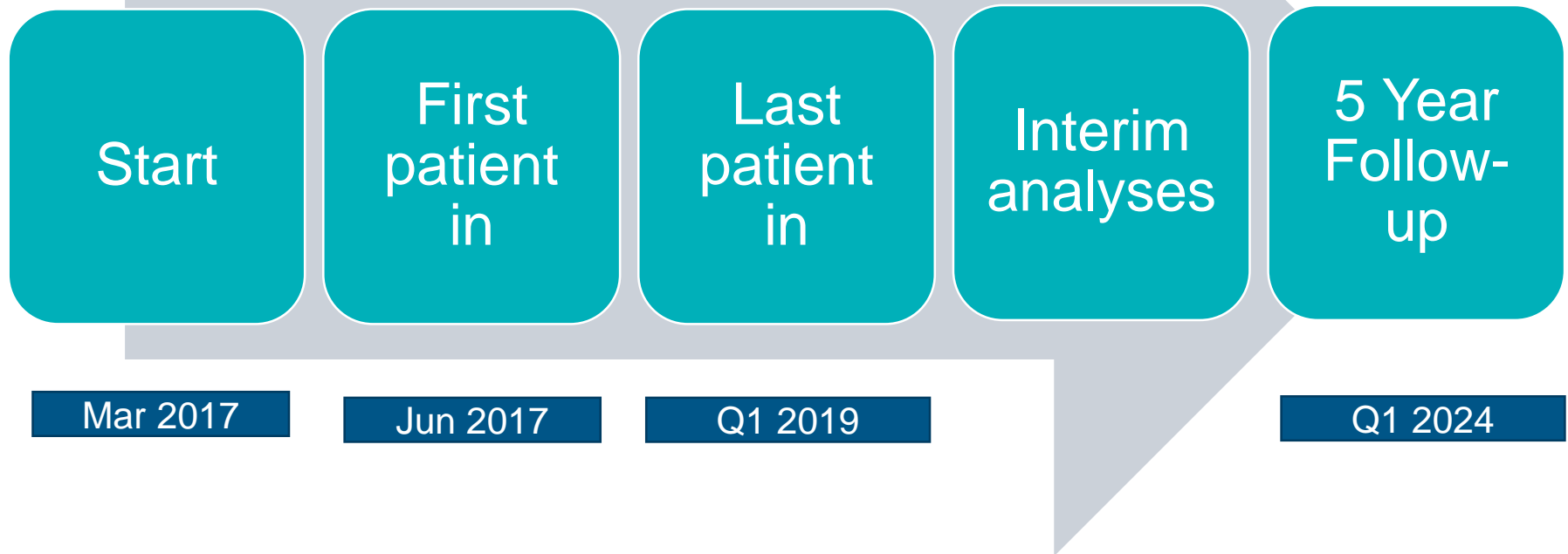
*This is a prospective, multicenter, post-market clinical follow-up, non-randomized registry of the TREO Stent-Graft.*

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

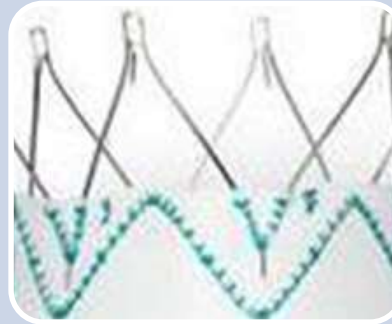
*Pre-procedure baseline data will be gathered as well as post-procedure assessments prior to hospital discharge and one to three months and 1, 2, 3, 4, and 5-year post-implantation.*

# THE TREO REGISTRY DESIGN

**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.



# ENDPOINTS



Traditional  
Clinical  
Endpoints

Device  
Specific  
Endpoints

Health  
Economic  
Endpoints

# TRADITIONAL CLINICAL ENDPOINTS



**Aneurysm Related Mortality**

**All Cause Mortality**

**Aneurysm Rupture**

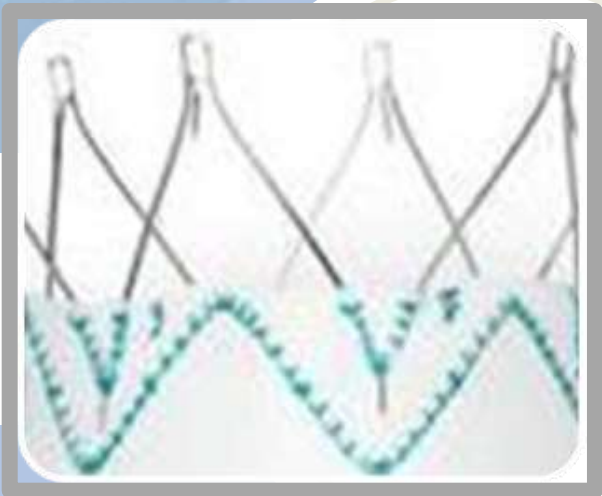
**Adverse Events**

**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**

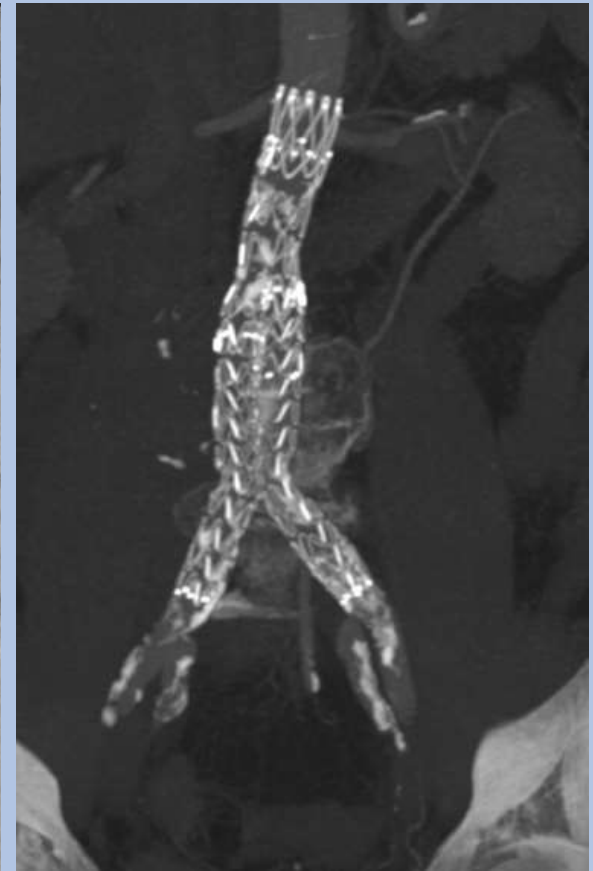
**Ancillary Device**



# 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
- Compensario 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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