1. Treovance/TREO design strengths
2. Treovance Clinical data: Rationale registry
3. Summary
PROXIMAL CLASPING
The clasp mechanism keeps control on the deployment allows cranial and caudal adjustment before the bare stent is released for precise placement.

INTRODUCER SHEATH
Low profile sheath with hydrophilic coating and flexible tip for easier navigation.

PRECISE DELIVERY SYSTEM
The mechanical deployment provides controlled and stable stent-graft deployment.

MAIN BODY D.S. LEG EXTENSION D.S.
30 to 36mm 20 to 28mm 9 to 15mm 17 to 24mm
19 F. (OD) 18 F. (OD) 13 F. (OD) 14 F. (OD)

LOW PROFILE DELIVERY SYSTEM

ADVANCED HEMOSTASIS VALVE
Double valve mechanisms, one passive and one active with 10 different positions, secures hemostasis.

TWO WAY FLUSH PORT

DETACH MECHANISM
DETACHABLE SHEATH
The sheath detaches from the Delivery System providing less access vessel manipulation and quicker access.

Safe and smooth removal of the Proximal Clasp
TREO’s proximal clasp is designed to smoothly remove and not snag on the bare stent.

Index
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RATIONALITY Registry
STUDY DEFINITION
• A Post-MarkIII Surveillance Clinical Registry of the Treovance Stent-Graft for Patients with Infrarenal AAA

STUDY DESIGN
• Prospective
• Multicenter and multinational
• EDC (Electronic Data Capturing) System

Baseline Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>185 (91.6%)</td>
</tr>
<tr>
<td>Asian</td>
<td>16 (7.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>ASA class</td>
<td></td>
</tr>
<tr>
<td>I (normal healthy patient)</td>
<td>15 (7.4%)</td>
</tr>
<tr>
<td>II (mild systemic disease)</td>
<td>70 (34.7%)</td>
</tr>
<tr>
<td>III (severe systemic disease)</td>
<td>107 (53.0%)</td>
</tr>
<tr>
<td>IV (severe systemic disease)</td>
<td>10 (5.0%)</td>
</tr>
</tbody>
</table>

The male sex was reported in 187 patients (92.6%). The mean age was 73.0 ± 7.8 years. The majority of the patients were white (91.6%). The majority of patients had severe systemic disease (53.0%).
**Technical success**, n (%): 194 (96.0%)

**Conversion to open repair**: 0

**Anesthesia type**, n (%):
- General: 94 (46.5%)
- Local: 44 (21.8%)
- Regional/epidural: 64 (31.7%)

**Mean procedure duration (min) (SD)**: 116.0 (±49.1)

**Percutaneous Approach**, n (%): 68 (34%)

**Mean estimated blood loss (mL) (SD)**: 177.2 (±219.8)

**Mean contrast used (mL) (SD)**: 107.3 (±57.4)

**Mean total fluoroscopy time (min) (SD)**: 22.7 (±12.2)

**Mean time to discharge (days) (SD)**: 3.9 (±3.5)

**Mean time in ICU (hours) (SD)**: 7.0 (±11.1)

* Defined as the successful introduction and deployment of the device in the absence of surgical conversion, mortality, type I/III endoleaks, or graft limb obstruction.

**RATIONALE. J Endovasc Ther 2018**

**Clinical success**, n (%): 194 (96.0%)

**Clinical failure**: 8 (4.0%)

**Graft infection or thrombosis**: 0

**Aneurysm rupture**: 0

**Surgical reintervention**: 1 (0.5%)

**Endovascular reintervention**: 7 (3.5%)

**Mean time to reintervention (months) (SD)**: 4.9 (±3.4)

**Deaths**:
- Operative deaths (≤30 days after procedure): 0
- Late deaths (>30 days after procedure): 13 (6.4%)
- All-cause mortality 1–6 months: 5 (2.5%)
- All-cause mortality >6 months: 8 (3.9%)

**Aneurysm-related death**: 0

**Mean time to death (months) (SD)**: 7.3 (±2.7)

* Defined as a successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I/III endoleak, graft infection or thrombosis, aneurysm expansion (diameter ≥5 mm or volume ≥5%), aneurysm rupture, or conversion to open repair.

**RATIONALE. J Endovasc Ther 2018**

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**Procedural data**

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>194 (96.0%)</td>
</tr>
<tr>
<td>Conversion to open repair</td>
<td>0</td>
</tr>
<tr>
<td>Anesthesia type</td>
<td></td>
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</tr>
<tr>
<td>Mean time in ICU (hours)</td>
<td>7.0 (±11.1)</td>
</tr>
</tbody>
</table>

**One-year Results**

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean time to final follow-up (days)</td>
<td>13.7 (±3.1)</td>
</tr>
<tr>
<td>Mean estimated blood loss (mL)</td>
<td>177.2 (±219.8)</td>
</tr>
<tr>
<td>Mean contrast used (mL)</td>
<td>107.3 (±57.4)</td>
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<tr>
<td>Mean total fluoroscopy time (min)</td>
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<td>Mean time in ICU (hours)</td>
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</tr>
</tbody>
</table>

**Other registries: reintervention rates**

<table>
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<th>Reintervention Rates at One Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bolton TREO (n=202) Rationale</td>
</tr>
<tr>
<td>Medtronic Endurant (n=500) ENGAGE</td>
</tr>
<tr>
<td>Gore Excluder (n=400) GREAT</td>
</tr>
</tbody>
</table>

**Change in diameter of lesion**, n (%):
- Reduction (≥5 mm): 106 (54.1%) (59.5%)
- Stable (decrease/increase <5 mm): 85 (43.4%)
- Increase (≥5 mm): 5 (2.6%)
**Other Registries: sac regression**

<table>
<thead>
<tr>
<th>Sac Reduction (≥5 mm) at one year</th>
<th>TRED (n=202) RATIONALE</th>
<th>54.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medtronic Endurant (n=500) ENGAGE</td>
<td>41.3%</td>
</tr>
<tr>
<td></td>
<td>Endologix Ovation (n=161) GREAT</td>
<td>32%</td>
</tr>
<tr>
<td></td>
<td>Gore Excluder (n=400) GREAT</td>
<td>36%</td>
</tr>
</tbody>
</table>

RATIONALE One Year Data Shows
97.5% Decrease or Stable Sac Size at Last Follow-Up

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**Summary**

- Treovance/TREO has unique design features
- Real life experience shows
  - 96% technical and clinical success
  - 96% freedom from reintervention
  - 0.5% type 1 endoleak and no Type III & IV
  - 97.5% decreased or stable aneurysm sac size
  - No open conversion, no fractures, no migration
  - No aneurysm related nor procedure-related or device-related mortality
  - Treovance/TREO represents a new generation device to improve trust in EVAR.

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**Index**

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3. Summary

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**Acknowledges to 32 centers/17 countries**

**Europe**
- DE - Bonifatius Hospital, Lingen
- DE - Theresienkrankenhaus St. Hedwig-Klinik, Hannover
- SE - Karolinska University Hospital, Stockholm
- SE - Linköping University Hospital
- SE - Karolinska University Hospital, Solna
- DE - Deutsches Herzzentrum Berlin
- IT - Casa Di Cura Villa Dei Fiori, Acerra
- IT - Azienda Ospedaliera San Camillo Forlanini, Roma
- GB - Manchester Royal Infirmary, Manchester
- GB - John Radcliffe Hospital, Oxford
- GB - Addenbrooke's Hospital, Cambridge
- ES - Hospital Germans Trias i Pujol, Badalona
- ES - Hospital Clinic Barcelona
- ES - Complexo Hospitalario Universitario de Ourense
- ES - Hospital Universitario Ramón y Cajal, Madrid
- ES - Hospital HM Modelo, A Coruña
- NL - ZiekenhuisGroep Twente, Almelo
- NL - University Medical Center Utrecht
- PL - Samodzielny Publiczny Szpital Kliniczny Nr 1, Lublin
- GR - Evangelismos General Hospital, Ipsilantou
- GR - Georgios Gennimatas General Hospital, Thessaloniki
- HU - Semmelweis Medical University, Budapest
- SE - Karolinska University Hospital, Solna
- SE - Linköping University Hospital
- IT - Azienda Ospedaliera Universitaria Senese, Siena

**South America**
- CL - Hospital Barros Luco Trudeau, Santiago
- CL - Fondo Hosp. Dir. Previsión de Carabineros, Santiago
- VE - Urológico San Román, Caracas

**Asia**
- HK - Queen Mary Hospital
- VN - Cho Ray Hospital
- TH - Lampang Hospital, Lampang

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**Update on the Treovance/TREO endograft from Bolton/Terumo-Aortic for EVAR: advantages and results from the RATIONALE registry**

V. Ramírez, MD, PhD
Prof and Chief of Vascular Surgery Division
Cardiovascular Institute, Hospital Clinic of Barcelona

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