# PMEGs For Juxta-And Para-Renal Aneurysms Come Out Of The Shadows And Are Now Mainstream: When Should They NOT Be Done?

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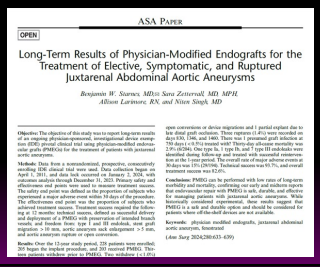
# Disclosures

- Terumo Aortic- Expert Consulting

# PMEG Long Term Results



ASA Paper

OPEN

Long-Term Results of Physician-Modified Endografts for the Treatment of Elective, Symptomatic, and Ruptured Juxtarenal Abdominal Aortic Aneurysms

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# Baseline Subject Demographics

- 228 Subjects Consented / 217 Completed Screening Process
  - 167 Male (77.0%)
    - 216 Non-Hispanic or Latino (99.5%)
    - 209 White or Caucasian (96.3%)
    - 2 Black or African American (0.9%)
    - 4 Asian (1.8%), 1 American Indian (0.5%), 1 Pacific Islander (0.5%)
  - Mean Age 75.6 years (range 59-93 years)

Ann Surg 2024;280:633-639

# Baseline Lesion Characteristics

| Baseline Lesion Characteristics | Mean mm (Range) |
|---|---|
| Maximum Aneurysm Diameter | **67.5** (49-124) |
| Proximal Neck Length | **5.4** (2-27) |
| Final Proximal Seal Zone Length | **41.6** (18.9-92.9) |

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# Procedural Details and Lengths of Stay

| Procedural Detail | Mean (Range) |
|---|---|
| Device Modification Time (minutes) | **48.7** (16-78) |
| Length of Anesthesia (minutes) | 198.2 (90-488) |
| Length of Procedure (minutes) | **137.7** (56-427) |
| Fluoroscopy Time (minutes) | **33.8** (8.9-164) |
| Volume of Contrast (cc's) | 93.0 (15-214) |
| Estimated Blood Loss (cc's) | 118.8 (20-1,000) |
| Length of ICU Stay (days) | **1.6** (0.5-15.9) |
| Total Length of Hospital Stay (days) | **3.7** (1.0-87.3) |

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## PMEG Long Term Results

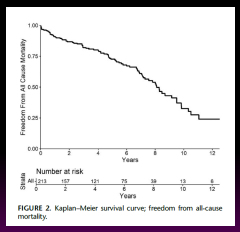


FIGURE 2. Kaplan–Meier survival curve; freedom from all-cause mortality.

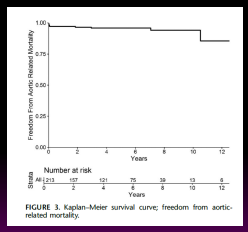


FIGURE 3. Kaplan–Meier survival curve; freedom from aortic-related mortality.

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## When to Consider PMEG

- Complex Aortic Anatomy:
  - Highly irregular or challenging aortic anatomy that cannot be treated with a standard endograft
- Limited Device Availability / Time Constraints:
  - When the required specialized endograft is not readily available.
- High Risk Patients:
  - Patients with significant health risks who cannot tolerate open surgery, PMEGs might be used even if the procedure is more complex.

## When ***NOT*** to use PMEG:

- Standard Device Suitability
  - Relatively straightforward aortic anatomy where a standard off-the-shelf endograft is sufficient
- Technical Complexity
  - Modifying a device can lead to potential issues with seal, deployment, and overall stability, increasing the risk of complications.
- Lack of Expertise
  - Physicians without extensive experience in modifying endografts should not attempt PMEGs due to the potential for complications.
- Regulatory Concerns
  - Modifying a commercially available device can fall under FDA regulations, requiring specific approvals or clinical trial participation.

## October 3, 2024

- First TREO-FIT Implant, Seattle
- First Fenestrated TREO in US, Seattle

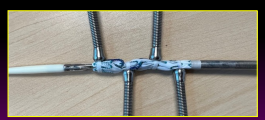
- FDA Protocol: How to Decide Who Gets What Device?

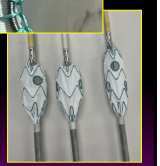
| | |
|---|---|
| – TREO-FIT | -Fenestrated TREO |
| – Symptomatic | - Asymptomatic |
| – Male > 6.5 cm | - Male < 6.5 cm |
| – Female > 6.0 cm | - Female < 6.0 cm |

*TREO FIT Template & Fenestrated TREO are available in United States via PS-IDE*

## TREO FIT

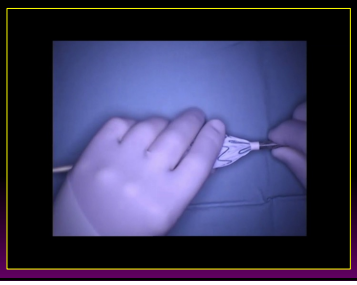
- Software generated 3-D Templates
- 4-0 Tevdek suture material
- Fenestration Rings
- Reloading Tools





*TREO FIT Template & Fenestrated TREO are available in United States via PS-IDE*

## Graft Modification: TREO



TREO Fit Consortium- VEITH 2023

TREO Fit Consortium-
Stent Summit 2024

When NOT to use PMEG:

- Standard Device Suitability
- Technical Complexity
- Lack of Expertise
- Regulatory Concerns

Thank you!