

# The Treovance Endograft: Final results from the RATIONALE registry

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For the TREOVANCE investigators

# Disclosure

Speaker name:

.....Jörg Tessarek MD.....

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Study design of the RATIONALE registry

Global, observational, prospective, clinical investigation in AAA patients who underwent EVAR

Safety and effectiveness of Treovance up to one year

32 institutions in 17 countries

202 patients → recruitment Feb 2014

→ End of FU Apr 2017

## Device characteristics:

### 3 piece modular device with unique features



#### SUPRARENAL FIXATION

Suprarenal laser cut barbs allow for primary proximal fixation once deployed.

#### INFRARENAL FIXATION

Infrarenal laser cut barbs provides supplemental fixation. Forces increases proportionally with the infrarenal angulation.

Device characteristics:  
3 piece modular device with unique features



# Patient characteristics I

Male sex, n (%)	187 (92.6%)
Mean age (years) (SD)	73.0 ( $\pm$ 7.8)
Race, n (%)	
White	185 (91.6%)
Asian	16 (7.9%)
Other	1 (0.5%)
ASA class, n (%)	
I (normal healthy patient)	15 (7.4%)
II (mild systemic disease)	70 (34.7%)
III (severe systemic disease)	107 (53.0%)
IV (severe systemic disease/ constant threat to life)	10 (5.0%)

# Patient characteristics II

## Medical History, n (%)

Peripheral vascular disease	29 (14.4%)
Coronary artery disease	74 (36.6%)
Chronic obstructive pulmonary disease	34 (16.9%)
Diabetes mellitus	41 (20.3%)
Hypertension	159 (78.7%)
Hypercholesterolemia	97 (48.0%)
Hyperlipidemia	74 (36.6%)
Smoking	126 (62.4%)
Ex-smoker	87 (43.1%)
Current smoker	35 (17.3%)
Renal insufficiency	33 (16.3%)
Current antiplatelet/anticoagulant therapy	119 (58.9%)
Limb ischemia	8 (4.0%)
Vascular intervention	18 (8.9%)

# AAA characteristics: covered by IFU

	Mean (SD)
Lesion lengths (mm)	
Proximal neck (0-75°)	20.7 (±12.1)
Lowest renal to bifurcation	116 (±17.7)
Diameters (mm)	
Proximal neck	23.6 (±3.0)
Aneurysm sac size	58.6 (±10.8)
Angles (degrees)	
Suprarenal angle	14.8 (±14.6)
Infrarenal angle	27.7 (±20.2)
Device oversizing (%), mean (SD)	16.3 (±5.1)
Patients with infrarenal angle $\geq 60^\circ$ , n (%)	21 (10.4%)
Iliac artery involvement, n (%)	34 (16.8%)
Moderate/severe calcification, n (%)	36 (17.8%)
Moderate/severe tortuosity, n (%)	50 (24.8%)



# Periprocedural outcome

Technical success, n (%)	194 (96.0%)
defined as deployment without any EL or technical failure	
Conversion to open repair	0
Procedure attempted but aborted	0
Kinking or twisting	0
Tears or fractures	0

- Of 8 patients (4%) with Type I Endoleak at end of procedure:
  - 5 resolved spontaneously
  - 1 required an adjunctive procedure (aortic cuff)

# Rational 12 mo FU results

	≤ 30 days n (%)	One year n (%)
Type Ia	3 (1.6%)	1 (0.6%)
Type Ib	2 (1.1%)	0
Type II	28 (14.8%)	26 (15.3%)
Type III	0	0
Type IV	0	0
Unknown	0	1 (0.6%)
Stent-graft patency	199 (98.5%)	
Stent-graft migration	0	
Wire form fractures	0	
AAA Diameter	97.4% / 54.1%	

# Rationale 12 mo FU results in comparison

<b>Sac reduction (&gt;5 mm) at one year</b>	
TREO (Rationale)	54.1%
ENGAGE	41.3%
Ovation	32%
GREAT	36%
<b>Reintervention rates at one year</b>	
TREO (Rationale)	4%
ENGAGE	4.6%
GREAT	7%

# Overall outcome in terms of migration and component separation

Migration is an issue

- Up to 5% migration reported within one year in other AAA IDEs
- Healthcare provider information from FDA in September 2017: FDA Expressed Concern: Increase in Type III Endoleak reports after previous stable repair

RATIONALE Registry shows

0% migration and Type III EL

and 100% freedom from ARM (Aneurysm Related Mortality)

## In conclusion:

The Treovance allows safe and reliable treatment of a wide range of AAA morphologies

-96% 12 mo clinical success with 0% migration and ARM

The unique design adds further stability to prevent migration (EL I) and component separation (EL III)

The Rational results showed superiority to other study devices in terms of freedom from reintervention, EL III, migration and sac size reduction

Long term Fu for 5 yrs is part of the protocol



Thank you for your attention

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