The new Valiant EVO device for TEVAR: What makes it better?

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* Valiant Evo is an investigational device
Disclosure

Speaker name:

...............................Fabio Verzini.............................................

I have the following potential conflicts of interest to report:

☒ Consulting for Cook, Gore, Medtronic,
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Low Profile Design
Delivery System & Stent-Graft enhancements

Minimized profile increases access to small and tortuous iliacs – *up to 4 Fr reduction in profile*

- Reduced taper tip length
- Internal flush port
- Increased working length

Valiant Captivia
- 25 Fr
- 24 Fr
- 22 Fr

Valiant Evo*
- 22 Fr
- 20 Fr
- 18 Fr

Multi-filament (same as Endurant) vs. Mono-filament Valiant graft material

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Broad size matrix

• Treat wide range of anatomies
  – Increased length (225 mm)
  – Smaller diameter (20mm)
  – Refined tapering (5 & 6 mm)

• Tailored pieces for specific use
  (increased tapering, cuff, sizing changes)

<table>
<thead>
<tr>
<th>Fr</th>
<th>SG Size (mm)</th>
<th>Covered Length (mm)*</th>
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<td>60</td>
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<td>18 Fr</td>
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Stent graft design overview

Closed Web
- Internal Stent 6 or 7 peak
- Support Stent 12 or 14 peak
- Multifilament Yarn
- Body stents 6 or 7 peak
- Stent Spacing 4/5/6 mm
- UHMWPE Suture (Body + Seal Stents)
- Distal Stent 6 or 7 peak

FreeFlo
- Bare Stent 6 or 7 peak
- Support Stent 6 or 7 peak
- Multifilament Yarn

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DELIVERY SYSTEM MODIFICATIONS VS. VALIANT CAPTIVIA

**Tapered Tip**
- Length reduced by ~1cm versus Valiant Captivia system (22Fr)
- Length proportionally sized to maintain taper

**Working Length and Hydrophilic coating Length**
- Working length increase: 10cm
  - Valiant Captivia WL = 83cm; Valiant Evo WL = 93cm
- Hydrophilic coating length increase: ~10cm
  - Valiant Captivia HCL ~ 70cm; Valiant Evo HCL ≥ 80cm
## Valiant EVO Global clinical trial

### Enrollment
- 37 sites worldwide in North America & EU
- Up to 100 subjects
- First patient in: April 2016

### Design
- Prospective, multi-center, pre-market, non-randomized, single-arm trial

### Endpoints
- **Safety**: Major Adverse Events (MAEs) within 30-days post-implantation
- **Effectiveness**: Technical success at index procedure and treatment success at 12-months
- Female, 83 y.o.
- Hypertension
- Hypercholesterolemia
- Type 2 diabetes mellitus
- Persistent atrial fibrillation under anticoagulant and antiarrythmic therapy
- COPD

Left vocal cord paralysis

Persistent coughing and dysphonia
Distal aortic arch penetrating aortic ulcer
Planning and sizing

Proximal landing zone

Distal landing zone
1 stage: L carotid-subclavian bypass, 2 stage: TEVAR w Rapid pacing
Valiant Evo 34-28-175
Prevertebral subclavian embolization

Amplatzer Vascular Plug II 10 mm
Post-procedural angiogram

30 days post-op CTA
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