Latest 5-Year Results With The INCRAFT Device (From Cordis/Cardinal Health) For Standard EVAR: Advantages And Limitations

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Disclosure
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Advisory Board /Consultant:
Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trimucular, Upstream Peripheral Technologies

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Advisory Board /Consultant:
Abbott, Bayer, Boston Scientific, Cook Medical, Cardionovum, CR Bard, Gardia Medical/Allium, Medtronic, Philips, Upstream Peripheral Technologies

The INNOVATION Study

OBJECTIVE
- To assess the technical success and safety of the Cordis INCRAFT® Stent Graft System in subjects with AAA

PRIMARY ENDPOINTS
- Successful deployment at desired location and absence of Endoleaks (I, II or IV) at conclusion of procedure
- Absence of device or procedural related major adverse events (MAE) 1 month post-procedure

MAJOR SECONDARY ENDPOINTS
- Absence of aneurysm enlargement ≥5 mm
- Absence of stent graft migration ≥10 mm
- NCS
- Absence of stent graft fracture
- Absence of MAE and Endoleaks (I, II or IV) at 1, 3, 6 and 12 months and annually out to 5 years post-procedure

FOLLOW-UP
- AF assessment
- CT scans at 3 and 12 months
- OPL questionnaire

INCRAFT® System Features

3-PIECE MODULAR SYSTEM:
- Low porosity polyester graft
- Segmented nitinol stents
- Supra-renal fixation

CUSTOMIZATION:
- Bilateral in-situ length adjustment up to 3 cm*
- Partial or total re-positioning
- Few units to fit broad anatomical coverage

ULTRA-LOW PROFILE:
- 13Fr Integrated Delivery System - 14Fr O.D.**
- Catheter-like shaft flexibility

* The overlap between the Aortic Bifurcate Prosthesis and the Iliac Limb Prosthesis can vary between 2 cm and 5 cm on the ipsilateral side, and between 2 cm and 4 cm on the contralateral side
** The O.D. of the prostheses diameter of 34 mm, the inner diameter of the integrated sheath introducer is 15F (outer diameter of 16F)

G. Torsello et al; JJ Cardiovascular Surg 2011; 52:661-7

VEITH 2013 presentations

Hostile anatomy distribution (based on CoreLab assessments)

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VEITH 2013 presentations
**INCRAFT® System Early outcomes**

<table>
<thead>
<tr>
<th>Event</th>
<th>30 days (N=18)</th>
<th>60 days (N=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful deployment: at desired location</td>
<td>98.3% (56/57)</td>
<td>-</td>
</tr>
<tr>
<td>Freedom from Endoleak: Type I</td>
<td>96.6% (54/56)</td>
<td>96.6% (54/56)</td>
</tr>
<tr>
<td>Freedom from Endoleak: Type II</td>
<td>100% (56/56)</td>
<td>100% (56/56)</td>
</tr>
<tr>
<td>Stent graft patency</td>
<td>100% (56/56)</td>
<td>100% (56/56)</td>
</tr>
<tr>
<td>Freedom from Migrations</td>
<td>N/A</td>
<td>100% (56/56)</td>
</tr>
<tr>
<td>Freedom from Fracture</td>
<td>N/A</td>
<td>100% (56/56)</td>
</tr>
<tr>
<td>Freedom from Sac Enlargement</td>
<td>N/A</td>
<td>100% (56/56)</td>
</tr>
<tr>
<td>Freedom from MAE</td>
<td>100% (56/56)</td>
<td>100% (56/56)</td>
</tr>
</tbody>
</table>

* Type I endoleak due to severe calcification in aortic neck, resolved after additional endovascular intervention on day 61.
† Type I endoleak present at 30 day follow-up and resolved after additional endovascular intervention on day 278.

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**Is there a trade-off with low profile stentgrafts?**

- Will lighter fabrics and stent material decrease EVAR durability?
- Will the rate of type III/IV endoleak increase in the future?
- Will the need for secondary procedures increase in the future?

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**INCRAFT® System Long-term outcomes**

<table>
<thead>
<tr>
<th>Event</th>
<th>4 Years (N=18)</th>
<th>5 Years (N=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Endoleak: Type I</td>
<td>100% (18/18)</td>
<td>100% (18/18)</td>
</tr>
<tr>
<td>Freedom from Endoleak: Type II</td>
<td>97.4% (17/18)</td>
<td>97.4% (17/18)</td>
</tr>
<tr>
<td>Freedom from Endoleak: Type III</td>
<td>100.0% (18/18)</td>
<td>100% (18/18)</td>
</tr>
<tr>
<td>Stent graft patency</td>
<td>37.6% (4/11)</td>
<td>37.6% (4/11)</td>
</tr>
<tr>
<td>Freedom from Migrations</td>
<td>100.0% (18/18)</td>
<td>100% (18/18)</td>
</tr>
<tr>
<td>Freedom from Fracture</td>
<td>97.5% (17/18)</td>
<td>97.5% (17/18)</td>
</tr>
<tr>
<td>Freedom from Sac Enlargement</td>
<td>89.3% (16/18)</td>
<td>89.3% (16/18)</td>
</tr>
<tr>
<td>Freedom from MAE</td>
<td>82.4% (15/18)</td>
<td>76.3% (14/18)</td>
</tr>
</tbody>
</table>

* Stent-graft fracture was defined as stent skeleton fracture and barb separation as identified by X-ray. Fracture occurred in one subject at 30 days and is ongoing at 5 years.
† Freedom from endoleak was defined as no endoleak present through 5 years.
‡ Both aneurysm enlargement and main body stent-graft migration were defined as being compared to the 30 day baseline CT assessment.
§ One subject did not have a 30 day CT and therefore could not be evaluated.

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**INCRAFT® System Endoleaks I – through 5 years**

**INCRAFT® System - Patency**

**INCRAFT® System Freedom from AAA enlargement**
INCRAFT® System
Conclusions

• The INCRAFT performs well on long-term while overcoming more difficult access morphologies
• The Endograft can be utilized in patients with demanding access vessel morphology, further extending its applicability
• The post-market INCRAFT® study (INSIGHT) is ongoing