INCRAFT system: Update from the Pivotal INSPIRATION Study

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Disclosure

Speaker name: MICHEL MAKAROUN, M.D.

- **No Financial Compensation**

I have the following potential conflicts of interest to report:

- WL Gore: Scientific Advisory Board / Research Grants
- Medtronic: Study PI and Research Grants
- Cordis: Study PI and Research Grant
- Research grants from Cook, Trivascular, Lombard, Bolton, Endologix
The INCRAFT® Stent Graft System

- Modular Tri-Fab system
- Polyester graft fabric
- Electro-polished Nitinol stents
- Active suprarenal fixation barbs
Limbs are flexible with 2-3 cm *In-Situ length adjustment* that allows accurate distal landing.
Limited Number of Parts (23)

**Few Fits Most**

<table>
<thead>
<tr>
<th></th>
<th>4 Main Body diameters</th>
<th>5 Iliac Limb diameters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Graft Size</strong></td>
<td>22-26-30-<strong>34</strong></td>
<td>10-13-16-20-<strong>24</strong></td>
</tr>
<tr>
<td><strong>Vessel</strong></td>
<td>17-31</td>
<td>7-22</td>
</tr>
<tr>
<td><strong>OD Profile</strong></td>
<td><strong>14</strong> 16</td>
<td>12 13</td>
</tr>
</tbody>
</table>

[Image of medical devices]
Very low Profile (14 Fr OD) and Flexible Delivery System with an Integrated Sheath
GR / 79 year old woman

INSPIRATION STUDY:
44% of patients with iliac access < 7 mm bilaterally
No iliac ruptures or significant injuries reported
INSPIRATION Case From Japan with Iliac Tortuosity

Courtesy of Dr Takao Ohki, co-PI
Deployment System Allows for Slow, Deliberate, and Accurate Proximal Deployment
The INSPIRATION Pivotal Study

First Study to run in Japan and the US simultaneously satisfying the requirements of both Regulatory Agencies

Michel Makaroun Co-PI

Takao Ohki Co-PI
The INSPIRATION Pivotal Study

- Enrollment: July 2012 to Aug 2013
- 190 patients: 134 from US _ 56 from Japan
- 32 sites: 27 from US _ 5 from Japan
- All Imaging reviewed by a Core Lab (M2S)
- Clinical Events Committee (CEC): 3 Independent members adjudicated all untoward events
- Safety and Efficacy endpoint: “Performance goals”
- Comparison: Lifeline Registry Open Surgical Group
Selected Inclusion Criteria

- AAA ≥ 5 cm
- Neck length ≥ 10 mm
- Neck angulation ≤ 60 degrees
- Iliac access ≥ 5 mm

Primary Endpoints

- Safety Endpoint: MAE rate @ 30 days
- Effectiveness Endpoint: Composite of Technical and Clinical Success of AAA Rx @ 1 year
## The INSPIRATION Pivotal Study

<table>
<thead>
<tr>
<th>Selected Demographics Parameters</th>
<th>US</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (years) ± SD</td>
<td>74.5</td>
<td>72.1</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>86.6%</td>
<td>98.2%</td>
</tr>
<tr>
<td><strong>Co-Morbidities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>47.8%</td>
<td>23.2%</td>
</tr>
<tr>
<td>History of MI</td>
<td>20.1%</td>
<td>14.3%</td>
</tr>
<tr>
<td>Peripheral Arterial Disease</td>
<td>78.4%</td>
<td>76.8%</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>18.7%</td>
<td>5.4%</td>
</tr>
<tr>
<td>COPD</td>
<td>18.7%</td>
<td>5.4%</td>
</tr>
<tr>
<td>Renal Insufficiency (cr &gt; 1.5mg/dL)</td>
<td>6.7%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Current Smokers</td>
<td>19.4%</td>
<td>21.4%</td>
</tr>
</tbody>
</table>
## Procedure / Hospital Stay

<table>
<thead>
<tr>
<th>AAA Size (mm)</th>
<th>Mean ± SD</th>
<th>54.9 ± 6.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Anesthesia</td>
<td>%</td>
<td>Japan 33.9% US 60.4%</td>
</tr>
<tr>
<td>Totally Percutaneous</td>
<td>%</td>
<td>63%</td>
</tr>
<tr>
<td>Duration (min)</td>
<td>Mean ± SD</td>
<td>102.7 ± 42.9</td>
</tr>
<tr>
<td>Blood loss &gt; 500 ml</td>
<td>%</td>
<td>5.8%</td>
</tr>
<tr>
<td>Hospital Stay (days)</td>
<td>Mean ± SD</td>
<td>Japan 5.6 days US 1.5 days</td>
</tr>
</tbody>
</table>

### Successful Deployment

100% (190/190)

- Repositioning in 1 patient / Inadvertent coverage of 1 internal iliac in 1 patient
The INSPIRATION Pivotal Study

### 30 Day Results

- **Mortality**: 0.5% (1/190)
- **Major Adverse Event (MAE)**: 3.2% (6/190)
  - Myocardial Infarction: 0.5% (1/190)
  - Renal Failure: 0.0% (0/190)
  - Respiratory Failure: 0.0% (0/190)
  - Stroke: 0.5% (1/190)
  - Bowel Ischemia: 0.0% (0/190)
  - Procedural Blood Loss ≥ 1000cc: 2.1% (4/190)
- **No Limb occlusions in the first 30 days**
The INSPIRATION Pivotal Study

Imaging: Size Changes up to 1 Year

Size Changes ≥ 5mm considered significant

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<tr>
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<th>1 Month</th>
<th>6 months</th>
<th>1 year</th>
</tr>
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<tbody>
<tr>
<td>Mean AAA size:</td>
<td>56 mm</td>
<td>53 mm</td>
<td>51 mm</td>
</tr>
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</table>

INSPIRATION Study

- Mean AAA size:
The INSPIRATION Pivotal Study

FU to 360 days

- One year Survival 96.7%
- 7 deaths:  
  - Cardiac including MI: 3
  - Stroke: 1
  - Head Trauma: 1
  - Cancer: 2
- 4 Strokes and 6 MI’s
- 11 Re-Interventions: None for Endoleaks
The INSPIRATION Pivotal Study

Results up to 360 days

- No Migration
- No Ruptures
- No Aneurysm Related Mortality after 30 days
- Two fractures (1.2%)
- Two Conversions to Open Repair
- 7 Limb Thromboses (4%)
Results of the INCRAFT® Device up to One Year are very promising!

Two Minor Limitations!
1. Type IV Endoleaks in 16% (31/190)

Do not affect Long Term Outcomes but may require Procedural Troubleshooting (similar to other grafts)
1. Illustrative case: ES/ 72 Year Old Woman

- 1 month
  - 60 x 61 mm
  - No endoleaks

- 6 months
  - 45 x 52 mm

- 1 year
  - 33 x 45 mm
2. Possible Vulnerability of Limbs

- Flexible Limbs
- **Smaller Overlap Diameter (11 mm)**
- Tendency to Use in Disadvantaged Iliac arteries

Overlap Zones and Narrowed Areas Must be Ballooned
2. Possible Vulnerability of Limbs

- Flexible Limbs
- **Smaller Overlap Diameter (11 mm)**
- Tendency to Use in Disadvantaged Iliac arteries

Overlap Zones and Narrowed Areas Must be Ballooned
The INCRAFT® Device for EVAR

Summary and Conclusions

- The Incraft® is a very low profile device that allows In-Situ limb length adjustments and is safe in patients with small external iliac arteries.

- The INSPIRATION trial is the first regulatory device trial conducted simultaneously in the US and Japan.

- Results have met the target safety and effectiveness endpoints and are so far quite encouraging!
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