First Report of a Confirmatory (Cohort B) Study of the Parachute Device in Ischemic Dilated Cardiomyopathy

Martyn R. Thomas, MD
St. Thomas’ Hospital
London, United Kingdom
Disclosure Statement of Financial Interest

I, Martyn Thomas, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.
Outcomes in Patients Hospitalized With Heart Failure

Among Medicare beneficiaries, 27% of HF patients are re-hospitalized within 30 days.

Median LOS: 6 days; N = 38,702

Aghababian RV. Rev Cardiovasc Med 2002; 3:S3
Jencks and Williams. NEJM 2009; 360:1418
Treatment Goal

Improve heart function by:

- Partition Scar
- LV Volumes Reduction
- LVED Pressure Reduction
- Restoring LV Conical Shape
- Not preventing Torsional Contraction
- Not causing arrhythmias

Procedural aspects similar to a standard PCI\(^1,2\) (Duration – 80 min / Fluoroscopy time – 20 min)

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Parachute Implant

- The Parachute™ device is comprised of a fluoropolymer (ePTFE) membrane stretched over a nitinol frame
- Nitinol frame to support torsional contraction and optimize LV outflow ejection
- Shape was designed to restore conical/longitudinal geometry
- The device is deployed into the apex of the left ventricle and partitions off non-contractile damaged myocardium to reduce LV volume and optimize performance of contractile, healthy myocardial

<table>
<thead>
<tr>
<th>Size Matrix</th>
<th>65</th>
<th>65s</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>75</td>
<td>75s</td>
</tr>
<tr>
<td></td>
<td>85</td>
<td>85s</td>
</tr>
<tr>
<td></td>
<td>95</td>
<td>95s</td>
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</tbody>
</table>

CE Mark approval for all sizes. In the U.S., the Parachute system is an investigational device limited by federal law to investigational use only and is not available for sale.
16/14F sheath
# PARACHUTE Clinical Program

<table>
<thead>
<tr>
<th>Year</th>
<th>Study</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>PARACHUTE Cohort A</td>
<td>CE MARK APPROVAL DATA (N=39)</td>
</tr>
<tr>
<td>2008</td>
<td>PARACHUTE US Feasibility</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>PARACHUTE Cohort B</td>
<td>EU CONFIRMATORY DATA (EST. N=70)</td>
</tr>
<tr>
<td></td>
<td><em>New guide catheters and 6 additional implant sizes</em></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>PARACHUTE III</td>
<td>EU POST MARKET DATA (EST. N=50)</td>
</tr>
<tr>
<td>Q4 2012</td>
<td>PARACHUTE IV</td>
<td>RANDOMIZED US PIVOTAL DATA (EST. N=478)</td>
</tr>
</tbody>
</table>
Parachute Technology Development

• 2005
  - Parachute design freeze for CE Mark approval trials.

• 2009
  - Feedback from early experience shows a need to improve the delivery system and offer more implant sizes for anatomy.

• 2011
  - EU Confirmatory trial started to utilize the new catheters and 6 additional implant sizes.
Trial Design: EU Cohort B

Design

- **DESIGN:** Non-randomized, multi-center, observational study
- **PATIENTS:** Up to 100 Treated
- **SITES:** 20
- **Key Inclusion**
  - NYHA II-IV
  - EF 15% - 40%
  - LV Wall Motion Abnormality
- **Key Exclusion**
  - Clinically significant untreated CAD
  - Revasc, CRT / ICD, or AMI within 60 days of enrollment
  - AR or MR > 2+
- **ANALYSIS PLAN:** Cohort B and PARACHUTE III will be combined to satisfy EU Post Market commitment

64 patients enrolled as of October 2012

Treatment Arm (N=57)

Control Arm (N=7)

Clinical follow-up at 6 months (N=32)

Clinical follow-up at 6 months (N=2)

Annually through 5 years
EU Post Market Interim Analysis

• 32 Treated Patients with 6M Follow-up
• Primary Endpoint
  - 6-month follow-up without the occurrence of Major Adverse Cardiac Events (MACE) related to the investigational device.
• Secondary Endpoints
  - Change in Left Ventricular Volume Indexes at 6 months
  - Change in 6 minute walk test at 6 and 12 months
  - Combined cardiovascular mortality and morbidity that includes all cause death, hospitalization for heart failure, myocardial infarction and stroke at 6 and 12 months
## Demographics

<table>
<thead>
<tr>
<th></th>
<th>N = 32</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>53.1 ± 10.3</td>
</tr>
<tr>
<td>Gender, male</td>
<td>87.5%</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>80.7 ± 13.3</td>
</tr>
<tr>
<td>Height, cm</td>
<td>173.6 ± 9.1</td>
</tr>
<tr>
<td>Smoking History</td>
<td>81.3%</td>
</tr>
<tr>
<td>History of Stroke</td>
<td>9.4%</td>
</tr>
<tr>
<td>History of Hypertension</td>
<td>75.0%</td>
</tr>
<tr>
<td>History of Diabetes</td>
<td>25.0%</td>
</tr>
<tr>
<td>History of Dyslipidemia</td>
<td>81.3%</td>
</tr>
<tr>
<td>Prior ICD Implantation</td>
<td>28.1%</td>
</tr>
<tr>
<td>Prior CRT Device</td>
<td>12.5%</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>84.4%</td>
</tr>
<tr>
<td>Prior CABG Surgery</td>
<td>12.5%</td>
</tr>
<tr>
<td>HF Hosp. 12M Before Enrolled</td>
<td>34.4%</td>
</tr>
</tbody>
</table>
Parachute Procedural Summary
32 Treated Patients

- **Vascular / Valve Procedure Complications**
  - **Major Complications** – 9.3%
    - 1 aortic valve complications
    - 2 access site major bleeds
  - **Minor Complications** – 6.3%

- **Stroke rate at 6 Months** – 0%
- **Death (device related) at 6 Months** – 0%

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Primary Endpoint: 6 Month MACE (device related)

N=32 Treated at Baseline
**Secondary Endpoint: LV Volume Reduction by Echo**

<table>
<thead>
<tr>
<th></th>
<th>EDV (ml)</th>
<th>ESV (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline (N=26), 6M (N=29)</strong></td>
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</tr>
<tr>
<td></td>
<td>217</td>
<td>185</td>
</tr>
<tr>
<td></td>
<td>156</td>
<td>127</td>
</tr>
</tbody>
</table>

- **Baseline**: 217 (EDV), 156 (ESV)
- **6M**: 185 (EDV), 127 (ESV)

*p < 0.05*
Secondary Endpoint: 6 Month Functional Outcomes

NYHA

Baseline 6M

Baseline (N=32), 6M (N=31)

6 Minute Walk (meters)

Baseline (N=32), 6M (N=29)

Baseline
6M

p<0.01

0%

0%

p=ns
6 Month Repeat HF Hosp. + Death

N=32 Treated at Baseline

Time (Days from Procedure)

12.5%
6 Month Mortality and Morbidity

N=32 Treated at Baseline, Morbidity = hosp. for HF, MI, and stroke
Conclusions

• Heart Failure patients have a very high hospitalization and mortality rate
• The Parachute procedure has shown to be a safe procedure
• Data trends continue to show improved outcomes for ischemic heart failure patients receiving the Parachute