THE PARACHUTE DEVICE IN ISCHEMIC DILATED CARDIOMYOPATHY

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Rationale: LV Volume and Geometry Link to Outcomes

Konstam et al, JACC 2011

Kramer et al, J Am Coll Cardiol 2010
Mechanism of Action

- Excludes akinetic/dyskinetic apex
- Partitions the left ventricle
- Restores conical apical shape
- Provides synchronized contraction
- Reduces diastolic and systolic volumes
Parachute Pre-Clinical Data
Mechanism of Action

Mechanical Efficiency Improved by 22%

External Work
[External Work + Potential Energy]
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>Matrix</th>
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<tbody>
<tr>
<td>65</td>
<td>65s</td>
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<tr>
<td>75</td>
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<td>85</td>
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CE Mark approval for 75, 75s, 85, and 85s. 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.
Parachute Guide Catheters

- 3D MSCT Modeling (Ao Arch, LVOT, LV Apex)
- 14Fr and 16Fr Delivery systems (multiple shapes)
- Kink Resistant construct

Ventricle axis
Aortic arch axis
# Parachute: First-in-Human Trials

<table>
<thead>
<tr>
<th></th>
<th>EU FIH (Cohort A) Oct '05 – Jun '07</th>
<th>US FIH Mar '08 – Jun '09</th>
<th>EU (Cohort B) May ‘11 - …</th>
<th>TOTAL</th>
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<tbody>
<tr>
<td>Enrolled</td>
<td>19</td>
<td>20</td>
<td>44</td>
<td>83</td>
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<tr>
<td>Implanted per Protocol</td>
<td>16</td>
<td>18</td>
<td>44</td>
<td>78</td>
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<tr>
<td>Discharged with Device</td>
<td>14</td>
<td>17</td>
<td>44</td>
<td>75</td>
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<tr>
<td>6M FU</td>
<td>14</td>
<td>15</td>
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<tr>
<td>1Y FU</td>
<td>14</td>
<td>14</td>
<td>4</td>
<td>32</td>
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<tr>
<td>2Y FU</td>
<td>14</td>
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<td>27</td>
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<tr>
<td>3Y FU</td>
<td>13</td>
<td>12</td>
<td></td>
<td>25</td>
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</tbody>
</table>

**Patient Population**
- NYHA Class II-IV, EF ≥15% and ≤40%, Post LAD MI
- Dilated apical region with akinetic or dyskinetic wall motion abnormality
- Warfarin and ASA 1yr post implant

*Independent Clinical Event Adjudication*

*Independent Echocardiographic, EKG, and MSCT Core Labs*
Parachute Safety Summary

• Procedural – All aspects similar to a standard PCI\textsuperscript{1,2}
  – Procedure duration – 80 minutes / Flouroscopy time – 20 minutes
  – 2 Inadequate Attachments
    • Corrective actions (MSCT screening, ePTFE membrane improvements)

• Procedure Complications\textsuperscript{3}
  – Major Vascular Complications – 0%
  – Minor Vascular Complications – 14.7%

• 0% device related Death or Stroke by 1 Year

3-Year NYHA

Baseline: 2.6
6M: 1.7
12M: 1.6
24M: 1.9
36M: 1.8

p < 0.0001
3-Year Cardiac Death

6.5%
3-Year Repeat HF Hospitalization

![Graph showing the percentage of repeat hospitalizations over time. The graph indicates that the percentage increases from 29.7% to 33.0% by the end of the 3-year period.](image_url)
3-Year Repeat HF Hosp. + Death

Ischemic HF

PARACHUTE

PARACHUTE Outcomes in Perspective

1-Year Repeat HF Hosp. + Death

Aggregate data from CHAMPION, MIRACLE, COMPANION, MIRACLE ICD, RETHINQ, CRT-HF, FIX, CARE, and PARACHUTE. 12M estimates were made if only 6M data was published (6M x 1.5 = 12M)
LV Geometric Analysis

Sphericity Index (SPI)

SPI = Volume cavity (EDV or ESV) / Volume of a sphere
(derived from LV long axis Length)

SID = 0.49
LAx = 94mm
EDV = 214

Ospedale Ferrarotto
Università di Catania
LV Geometric Analysis

Sphericity Index (SPI)
SPI = Volume cavity (EDV or ESV) / Volume of a sphere (derived from LV long axis Length)

SID = 0.29
LAx = 109mm
EDV = 198ml
Parachute Optimal Implant
Clinical Case

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Clinical Features

- Male
- 73 yrs old
- Hypertension, dyslipidemia, diabetes, prior smoke
- Post-ischaemic dilated cardiomiopathy
- Euroscore I → logistic 12%, standard 8%
Medical History

• **1992** ➔ inferior STEMI medically treated

• **February 2012** ➔ anterior STEMI treated with rescue PCI on LAD (multiple critical stenosis RCA, Circumflex were left to be treated electively)

• **March 2012** ➔ PCI and implantation of 4 DES on RCA, 2 DES on Circumflex artery and 1 DES on left main for dissecation.

• **May 2012** ➔ ICD implantation
Ventriculography
Foot Placement
Device Placement – 1° step

Device Deployment
Device Placement – 2° step
Balloon Inflation
Final Result
24 hrs Post-Implant 3D Echo
24 hrs Post-Implant Echo
24 hrs Post-Implant Echo

$\Delta = 4 \% \text{ EF only 24 h. after}$
Conclusions

✓ The first series of ischemic HF patients treated with Percutaneous Ventricular Restoration (PVR) using the Parachute™ device had a relatively low incidence of clinical events up to 3 years suggesting a plateau of the progression of heart failure.

✓ MSCT analysis provided important insights on factors that may impact outcomes after PVR therapy in the future. In particular, the present pilot data highlights the importance of patient selection and optimal device implantation.

✓ Recent enhancements in delivery system, availability of multiple shapes and device sizes, and use of MSCT for screening and procedure planning may further improve overall outcomes, which requires confirmation in the large scale PARACUTE III (EU) and PARACHUTE IV Pivotal (USA) Trials already underway.