First-in-Human Report:
Initial Experience with a Stentless and Retrievable Percutaneous Aortic Valve Prosthesis

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The Direct Flow Medical (DFM) Aortic Valve Prosthesis

- Consists of
  - a trileaflet valve made of bovine pericardium encased in
  - a slightly tapered, conformable polyester fabric cuff
  - Independently inflatable balloon rings constitute the upper (aortic) and lower (ventricular) margins of the cuff
- Transfemoral implantation

Investigational device currently in European clinical trial. Not available for sale in or outside the United States.
The DFM AV Prosthesis
European Clinical Trial

**Intention-to-treat population**
n = 31

- No iliac access (n=2)
- Functionally bicuspid valve (n=2)
- Excessive LVOT calcification (n=3)
- Annular Ø ↑↑, excessive calcification (n=1)
- Excessive valvular calcification (n=1)

**Device implanted**
n = 22 (71%)

- Surgical conversion (n=2)

**Permanent implant**
n = 20 (65%)

Sites:
- Hamburg, Germany (n=25)
- Siegburg, Germany (n=6)
The DFM AV Prosthesis European Clinical Trial

- Mean transvalvular pressure gradient in patients with a permanent implant

![Graph showing pressure gradient over time]

- Baseline (n=20)
- Post (n=20)
- 30 Days (n=13)
- 90 Days (n=11)

- Baseline: 52 mm Hg
- Post: 14 mm Hg
- 30 Days: 17 mm Hg
- 90 Days: 20 mm Hg

*Holm test

- $P<0.001$ (repeated-measures ANOVA)
The DFM AV Prosthesis
European Clinical Trial

- Aortic orifice area in patients with a permanent implant
The DFM AV Prosthesis
European Clinical Trial
• NYHA class in 14 patients with permanent implant

Baseline

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<th></th>
<th>I</th>
<th>II</th>
<th>III</th>
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<tr>
<td></td>
<td>7.1%</td>
<td>21.4%</td>
<td>71.4%</td>
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30 Days

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<td>64.3%</td>
<td>35.7%</td>
<td>0.0%</td>
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\[ P = 0.0002 \text{ vs. Baseline} \]
The DFM AV Prosthesis European Clinical Trial – Outcomes

- Aortic regurgitation by echo (Hamburg patients)

![Graph showing outcomes](chart.png)
The DFM AV Prosthesis
European Clinical Clinical Trial

• Major Adverse Events
  ▪ Death
    ➔ 30-day mortality 13% [95% CI, 4%–30%]
    • Myocardial infarction @ day 2
    • Pulmonary embolism 1h after failed attempt at implantation
    • Septal rupture during valvuloplasty
    • Decompensated congestive heart failure
  ▪ Major stroke (@ 12h) n = 1
  ▪ Surgical conversion n = 2
  Total n = 7 (23% [10%–41%])
  ▪ AV conduction block 3°
    (1 after surgical conversion)
The DFM AV Prosthesis

Conclusions

- The DFM aortic valve prosthesis gives the operator unprecedented freedom of handling the device during implantation.
- In the FIM experience with 31 patients, permanent implantation was achieved in 65% of patients with good hemodynamic results (mean gradient ≤20 mmHg, excellent sealing of native annulus).
- Despite the patients’ high surgical risk profile, implantation without hemodynamic compromise during the procedure appears safe.
- The amount and distribution of leaflet and LVOT calcification impacts procedural outcome.
- Patient selection is crucial!