Most Common Diagnosis Requiring Berlin Heart EXCOR® Pediatric Implant

- Cardiomyopathy

Benefits of Berlin Heart EXCOR® Pediatric as a Bridge to Transplantation

- Provides effective long-term management for patients with heart failure
- Improves the chances for patients to receive a transplant because they are supported by a ventricular assist device while waiting
- Enables the patient to participate in rehabilitation, increasing strength and conditioning
- Gives the patient time for improved nutritional status, which helps with recovery
- Allows patient to transition out of the Intensive Care Unit and into the Cardiology Patient Care Unit

Berlin Heart EXCOR® Overview

- Size of pumps (stroke volume: ml) 10, 25, 30, 50 and 60
- Only a portion of the device is implanted in the body
- Two tubes are inserted into the heart and tunneled out of the body to connect to the pump
- A pump and computerized driver are used to maintain blood flow

To learn more about Texas Children’s Heart Center or to schedule an appointment, contact us at:

Texas Children’s Heart Center
6621 Fannin St.
Houston, TX 77030
832-826-5600
texaschildrens.org/heart

Notes
Facts

• 46% of children with heart failure die or undergo a heart transplant within 5 years of diagnosis¹
• Heart donations are very limited for children
• The average wait time for a heart transplant is three months²
• Berlin Heart EXCOR® Pediatric VAD and ECMO are the only options to support heart failure symptoms in infants and small children

Berlin Heart EXCOR® Pediatric Prospective Trial (2007-2010)

• Texas Children’s Hospital was one of 17 study sites for the nation’s first prospective pediatric clinical trial of a ventricular assist device
• 48 patients from two groups were evaluated and implanted from 17 institutions; 24 patients had a smaller body size (Group 1) and 24 had a larger body size (Group 2)

Results

– Survival rate on Berlin Heart: 90% – Infection rate: 57%
– Stroke rate: 29% – Bleeding rate: 67%

• 13 patients were implanted at Texas Children’s Hospital during the study
• Berlin Heart EXCOR was approved by the FDA under the Humanitarian Device Exemption on December 16, 2011

Detailed Results³

<table>
<thead>
<tr>
<th>Events</th>
<th>Participants with events (% of 24)</th>
<th>Events</th>
<th>Participants with events (% of 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke*</td>
<td>8</td>
<td>7 (29%)</td>
<td>9</td>
</tr>
<tr>
<td>Infection</td>
<td>35</td>
<td>15 (62%)</td>
<td>24</td>
</tr>
<tr>
<td>Infection – Localized Non-Device</td>
<td>25</td>
<td>12 (50%)</td>
<td>18</td>
</tr>
<tr>
<td>Infection – Site or Pocket</td>
<td>4</td>
<td>4 (16%)</td>
<td>0</td>
</tr>
<tr>
<td>Infection – Sepsis</td>
<td>6</td>
<td>5 (20%)</td>
<td>6</td>
</tr>
<tr>
<td>Major Bleeding</td>
<td>35</td>
<td>10 (41%)</td>
<td>22</td>
</tr>
</tbody>
</table>

Outcomes in Patients with Neurological Dysfunction – Ischemic CVA, N=14x

<table>
<thead>
<tr>
<th>Normal</th>
<th>Mild Moderate</th>
<th>Severe Support Withdrawn</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Children (Group 1)</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Large Children (Group 2)</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

*Patients who had a stroke were evaluated at 45 Days post-explant