EXCOR® Pediatric

The Ventricular Assist Device for Children
LVAD I BVAD I RVAD
EXCOR® Pediatric VAD System – Providing Even your Smallest Patients with Valuable Lifetime

EXCOR® Pediatric is a mechanical circulatory support system that provides short to medium-term assistance to the failing left and/or right ventricle. EXCOR® has performed well in several thousand cases with proven benefits and safety. The system is specifically designed for infants and children with life-threatening heart failure refractory to optimal medical therapy. Your young patients benefit directly from restored hemodynamics, a result of the improved circulation provided by the device. Additionally, end-organ function is often improved significantly and even normalized in patients with profound cardiogenic shock.

Treatment with the EXCOR® Pediatric restores the highest possible quality of life for patients with severe heart failure. Patients of every age tolerate the system very well and gain valuable time while waiting for an organ transplant or at best for recovery of their own heart.

For adolescents with larger pump versions (≥ 60 ml) the battery powered Excor mobile driving system is available. With the Excor mobile driving system you will provide your patients maximum flexibility as the system allows free maneuverability for extended periods of time. When using this system, patients are able to participate in everyday activities, pursue their hobbies, move freely in- and outdoors, and if allowed, be discharged from the hospital.

EXCOR® Pediatric – Proven Quality for Optimal Therapeutic Success in the Youngest Patients

EXCOR® Pediatric is designed for reliable use over a period ranging from days to several months and even years. The selected materials, surfaces and geometries are optimized so that complications are avoided even with long-term treatment. As a manufacturer specializing in mechanical circulatory support systems, we have incorporated unequalled clinical experience and scientific competence into our products, so that today a fully developed system with proven therapeutic success and minimized complications is available for clinical use. EXCOR® VAD systems are currently used in more than 150 specialized centers worldwide, with new centers requesting the device on a regular basis.

Extensive Product Range for Individualized VAD Therapy

The EXCOR® system incorporates paracorporeal, pulsatile membrane pumps and implantable silicone cannulae. The Berlin Heart EXCOR® satisfies all anatomical, clinical and practical requirements of VAD therapy with an extensive portfolio of differently sized blood pumps with different valve configurations, a wide selection of atrial, apex and arterial cannulae, as well as stationary and mobile driving units. You will find the appropriate system for each of your individual patient’s needs.
**Indications**

EXCOR Pediatric is intended for use in infants and children with acute or chronic ventricular failure refractory to optimal medical and interventional therapy.

Worldwide, patients in class IV NYHA heart failure, with INTERMACS status 1–5 have been implanted with the device. EXCOR Pediatric has been successfully used in patients with:

- Cardiomyopathy
- Acute myocarditis
- Post-cardiotomy failure
- Endstage congenital heart disease
- Post-transplant graft-failure

EXCOR Pediatric can provide life-saving treatment for severely sick patients with end-organ dysfunction secondary to severe heart failure.

Switching from ECMO or other short term VADs to EXCOR Pediatric is possible. Diagnostic or interventional procedures are possible during support with EXCOR Pediatric.

**Patient age and size:** from newborn (> 2 kg) to adolescent.

**Support times:** from hours to several months, with some patients being supported more than a year.

**Therapeutic options**

- Bridge to transplantation (BTT)
- Bridge to recovery (BTR)

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**Benefits at a Glance**

**Therapeutic Success in Severe Heart Failure Patients**

- Restoration of circulatory requirements and improvement in end-organ function and quality of life
- Documented excellent long-term results

**Proven VAD Therapy Concept**

- Wide range of perfectly matched system components
- Specifically designed to meet the circulatory requirements of infants and children
Blood Pumps – Tailored to Meet the Circulatory Requirements of Children

- Pump volumes down to 10 ml, suited for newborns and infants
- Transparent pump chambers for permanent visual inspection of blood-contacting surfaces
- Direct visual evaluation of pump performance, filling and emptying
- Possible deposits immediately detectable
- Three-layer membrane for safe long-term operation
- Blood chamber with de-airing port for easy and safe air removal during priming and after connecting the pump
- Tri-leaflet polyurethane valves
- Carmeda® BioActive heparin coating for effective protection against thromboembolic complications
- Pump change in the ICU possible

The Available System Components – Designed Especially for Children
Apex, atrial and arterial cannulae

Our Wide Spectrum of Cannulae

- Intuitive and safe anastomosis due to optimized design
- Bio-compatible silicone material for reliable performance
- Polyester velour sheathing promotes good ingrowth of the cannula and prevents ascending infection
- Cannulae in a variety of diameters, lengths, angles and shapes for individual anatomic needs
Ikus – Stationary Driving Unit – Efficient Pneumatic Support for Superior Circulatory Support

- Pneumatic pump supply system provides pulsatile blood flow
- Specially designed to supply high driving pressures for small volume pumps at high pump rates
- Triple redundancy of core components for maximum safety
- Up to 30 minutes battery operation for patient mobility

Excor Mobile Driving System* – Maximum Flexibility for your Patients (Adolescents with Blood Pumps ≥ 60 ml)

- Minimum weight for maximum flexibility and patient comfort
- High reliability by redundancy of the pneumatic components
- Easy battery changing with uninterrupted operation
- 10 hours univentricular battery operation

* Mobile driving system is currently not available in the USA.
Roadmap for a Successful Surgical Procedure

Step by Step to Success: Procedural Recommendations

1. Selection of Pump Size

Pump size is selected based on body weight and/or body surface area to adequately meet the circulatory requirements of the patient. For BVAD, use a combination of 60/50, 30/25 or 10/10 ml blood pumps. A larger pump size or rate on the left side prevents pulmonary congestion. Use the largest cannula diameter possible to achieve lowest drive pressures and minimize the risk of hemolysis.

2. Cannula Implantation Technique

Implantation of the cannulae is performed via median sternotomy using cardiopulmonary bypass (CPB) and standard cannulation techniques. For BVAD support, bicaval cannulation is preferred. Hypothermia and cardioplegic arrest should be avoided. Placement of an LA vent may be helpful. Electrically induced fibrillation may be necessary for cannulation of the LV apex.

3. For the Left Sided Pump

Cannulation of the apex is preferred to achieve sufficient unloading of the left ventricle.

4. De-Airing

In order to sufficiently prime and de-air the pump, insert de-airing needle and trocar through de-airing port. Take care not to touch the membrane with the de-airing needle. Move the membrane away from the de-airing port with the membrane set supplied prior to inserting the de-airing needle and trocar. Connect the tube and syringe to the de-airing trocar to prime the pump and evacuate air after connection of the blood pump to the cannulae.

Anastomosis of apical cannula with LV apex using single pledgeted sutures
End-to-side anastomosis to aorta (or pulmonary artery) with single pledgeted or running sutures
Connection of cannulae with primed pump; remaining air can be evacuated via the de-airing tube
The Right Medication: Anticoagulation

We recommend starting unfractionated heparin 24 hours after implantation. If no bleeding is present, starting with 10 IU/kg/hour and then increasing the dose until a target PTT of 60–80 seconds is achieved. ATIII activity of > 70% is desirable. ATIII concentrate or FFP is routinely used to achieve the desired level.

ASA is recommended (start 1 mg/kg/day) after removal of all chest tubes. Consider adding dipyridamole (4 mg/kg/day) if appropriate after evaluating the platelet inhibition studies and thrombelastography if available.

Transitioning to a vitamin K antagonist with a target INR of 2.8 – 3.5 or to a low molecular weight heparin with a target Anti-Factor Xa level of 0.6 – 0.8 IU/ml as soon as possible has been beneficial.

Monitoring of Anticoagulation

aPTT, PTT, ATIII, Fibrinogen, platelet count, D-Dimer, INR and Anti Xa levels should be monitored daily. Platelet aggregation studies (keep platelet aggregation induced by arachidonic acid and ADP below 30% of normal), and thrombelastography (modify anticoagulation and platelet inhibition according to clot firmness, clot formation time and rate of fibrinolysis) if available, should be monitored as appropriate. Remember that all infections can activate the coagulation system and that an infected patient may require higher doses of anticoagulation and platelet inhibition agents.

Right Ventricular Function

In LVAD-patients, nitric oxide, Iloprost, adrenaline and Milrinone are routinely used to decrease RV afterload and increase myocardial contractility. If worsening function of the RV is observed during weaning from CPB after LVAD placement, implantation of an RVAD should be considered. Late conversion to BVAD support after LVAD placement correlates with decreased patient survival.

Other Drugs to Consider

Heart failure agents, including ACE inhibitors and beta blockers administered according to ESC/ACC-guidelines may be useful and should be considered especially if recovery of the ventricular function is expected.

Extubation and Mobilization – the Sooner the Better

Primary chest closure is possible. Early extubation and enteral feeding are recommended. Patients should be mobilized as soon as possible after implantation.

User Training before Discharge*

Patients can be discharged home with the Excor mobile driving system if circumstances allow this. When planning discharge, the responsible physician should take the medical status as well as the social environment of the patient into consideration. Training for the appropriate individuals who may have to work with the VAD system or care for the VAD patient outside the hospital is required and will be supported by Berlin Heart.

* Only for adolescents with blood pumps ≥ 60 ml. The mobile driving system is not currently available in the USA.
1. Learning what’s Necessary

The Berlin Heart Academy

INCOR® & EXCOR® Adult and Pediatric Training: Within the Berlin Heart academy we will support you in establishing a VAD-team and a successfully functioning VAD program. In an effort to educate and train cardiologists, nurses, perfusionists and surgeons, we will either invite you for training at the Berlin Heart facilities or hold the training on your site.

2. The Scientific Method

Our Clinical Science

The Berlin Heart Clinical Science team will support you in your efforts to publish scientific results related to your experience with Berlin Heart products:
- Design of clinical trials or post-market follow-up evaluations
- Statistical analysis
- Scientific assessments of our continuous product development

3. You Need Support?

Call us 24 Hours, 365 Days a Year for Clinical Assistance

A team of doctors, perfusionists, ICU nurses and engineers with long standing experience within the field of mechanical circulatory support provides excellent support for all clinical and technical matters (patient selection, timing, implantation, follow up, data analysis and subsequent recommendations). In person, on site or advising by phone – they are available throughout the year, 24 hrs a day.

Outside North America:

Emergency Hotline: +49 30 8187 2772

Inside North America:

Emergency Hotline: 866 249 0128

4. Customized Service around the World

Customer Service – any Day and any Time

Our customer service team has specialized experience with worldwide shipping and customs matters to ensure the best shipping methods and the quickest possible delivery times in order to meet your most urgent needs. This team is able to organize shipments in any part of the world, always in accordance with the local regulatory requirements, and provide you with the products and equipment you need – at any time, any day of the year.

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Successful VAD Treatment

Interdisciplinary collaboration is necessary for optimum clinical success: not only is patient selection and VAD implantation crucial, but integration across all functional patient care disciplines including social care should be achieved.
The Berlin Heart EXCOR® Pediatric Ventricular Assist Device (EXCOR® Pediatric) is approved for use by the FDA under a Humanitarian Device Exemption. Version MMF11.2 August 2012

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