Berlin Heart®

EXCOR® Adult

The Ventricular Assist Device for Adults

LVAD I BVAD I RVAD

The Well-proven Way of Treating Patients with Severe Heart Failure

The EXCOR® Adult VAD System by Berlin Heart

EXCOR® Adult VAD System – Providing your Patients with Valuable Lifetime

EXCOR® Adult is a mechanical circulatory support system that provides short to long-term assistance of the failing left and/or right ventricle. EXCOR® has performed well in several thousand cases with proven benefits and safety. It is indicated for adults with severe heart failure. These patients profit directly from the hemodynamics as a result of the improved circulation provided by the device. The end-organ function is often improved significantly and even normalized in patients with profound cardiogenic shock.

With the Excor mobile driving system the patients are able to master their everyday tasks, pursue their hobbies and move freely, in- and outdoors. Treatment with the EXCOR® Adult restores the highest possible quality of life after severe impairment. Patients usually tolerate the system very well and gain valuable time while waiting for an organ transplant or at best for recovery of their own heart.

EXCOR® Adult – Proven Quality for Optimal Therapeutic Success

EXCOR® Adult is designed for reliable use over a period ranging from several months up to years. The selected materials, surfaces and geometries are optimized for minimal blood damage, 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 have been used so far in more than 150 specialized centers worldwide, with new centers requesting the device on a regular basis.

Extensive Product Range for your Individualized VAD Therapy

The EXCOR® system incorporates paracorporeal, pulsatile membrane pumps and implantable silicone cannulae. We offer the EXCOR® Pediatric system optimized for smaller volumes, especially for young patients or even infants. As LVAD, the implantable INCOR® axial pump system is available as an alternative for adults. The Berlin Heart EXCOR® system 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® Adult is intended for use in acute or chronic ventricular failure refractory to optimal medical and interventional therapy.

Patients in class IV according to NYHA heart failure with INTERMACS status 1–5 have been implanted with the device. EXCOR® Adult has been successfully used amongst others in patients with:

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

EXCOR® Adult can provide lifesaving treatment for severely sick patients with renal and/or hepatic failure and even after cardio-pulmonary resuscitation.

Switching from ECMO or other short term VADs to EXCOR® Adult is possible. Diagnostic and interventional catheterization is possible during support with EXCOR® Adult.

Support times can vary from hours to several months. Maximum use period: 500 days

Therapeutic options

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

Benefits at a Glance

Therapeutic Success in Severe Heart Failure Patients

- Restoration of the 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; fast and easy to implant
- High degree of mobility and patient satisfaction due to mobile driving system

The Available System Components

Blood pumps with polyurethane or tilting-disk valves: 50 ml, 60 ml, 80 ml

Blood Pumps – Make your Choice

- Transparent pump chambers for permanent visual inspection of the 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 after connecting the pump
- Tri-leaflet polyurethane valves or tilting-disk valves available
- Carmeda® BioActive heparin coating for effective protection against thromboembolic complications

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
- Can be explanted safely, since the silicone does not adhere severely to the pericardial tissues

Ikus – Stationary Driving Unit – Efficient Pneumatic Drive for Superior Circulatory Support

- Pneumatic pump supply system for pulsatile blood flow
- Flexible: for all pump sizes, driving pressures at rates from 30 to 150 bpm
- Triple redundancy of core components for maximum safety
- Up to 30 minutes battery operation for patient mobility within the hospital

Excor Mobile Driving System* – Maximum Flexibility for your Patients

- 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 currently not available in the USA.

Roadmap for Surgical Procedure

Step by Step to Success: Surgical Steps in Particular

1. Selection of Pump Size

Pump size is selected by body weight and/or body surface area to adequately meet the circulatory requirements of the patient. For BVAD, use a combination of a 80/60 or 60/50 cc pump. A larger pump volume 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) with 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 the cannulation of the LV apex.

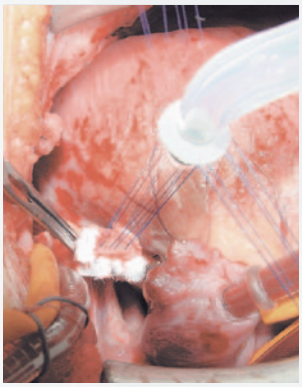
3. For the Left Sided Pump

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

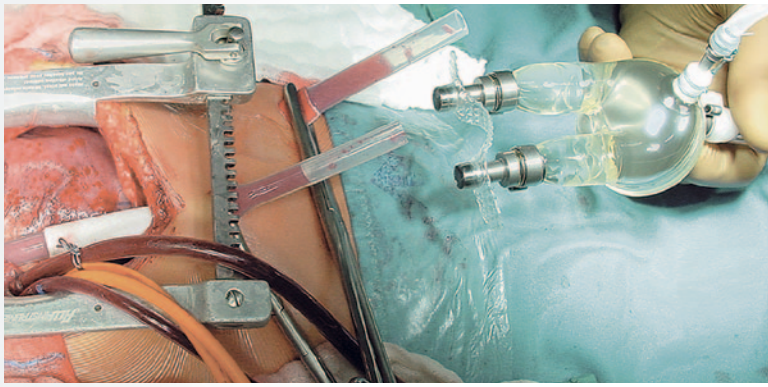
4. De-Airing

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 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

Patient Management

Always Focus on the Patient's Specific Needs

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 after removal of all chest tubes (100 mg/day initial dose).
Consider adding dypiridamole if appropriate after evaluating the platelet inhibition studies and thrombelastography if available (150 mg/day initial dose).

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, ACT, 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

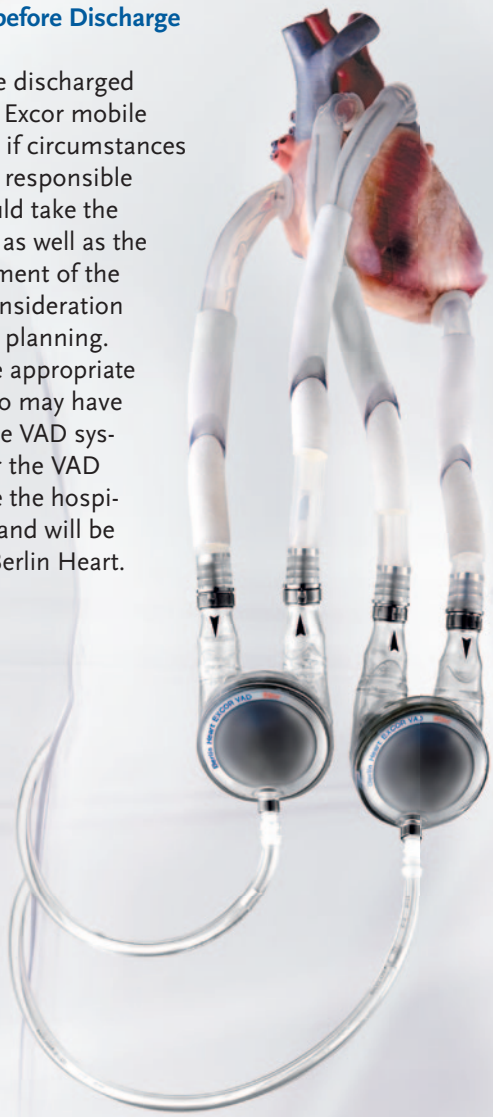
Heart failure agents, including ACE inhibitors and beta blockers administered according to ESC/ACC-guidelines may be useful and should be considered especially if recovery of the ventricular function is expected.

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. The responsible physician should take the medical status as well as the social environment of the patient into consideration with discharge planning. 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.



Berlin Heart – Our Services for your Benefit

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.

Emergency Hotline: +49 30 8187 2772

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 regulatory issues and provide you with the products and equipment you need – at any time, at any day of the year.

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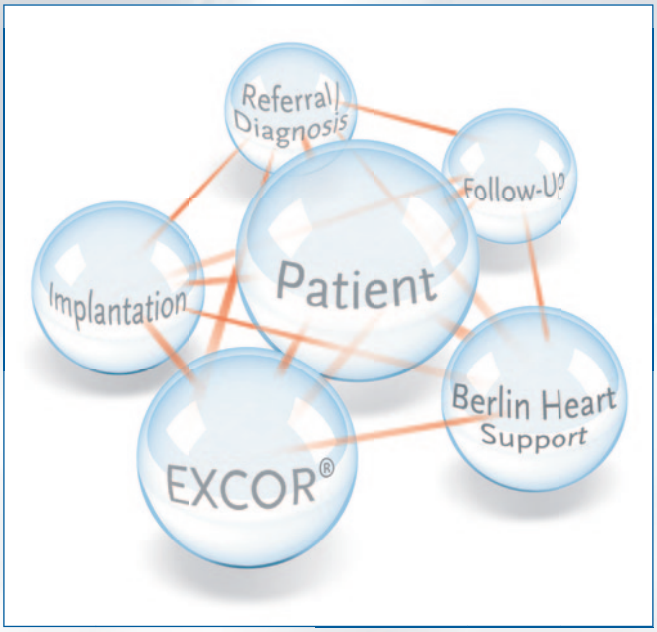

Successful VAD Treatment

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.

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References

1.
Schmid C. et al. The EXCOR device – revival of an old system with excellent results. Thorac Cardiovasc Surg. 2006 Sep; 54(6): 393-9.

2.
Drews T.N.H. et al. Outpatients on Mechanical Circulatory Support. Ann Thorac Surg 2003; 75: 780 –5

3.
Loforte A. et al. Levitronix CentriMag to Berlin Heart EXCOR: A "Bridge to Bridge" Solution in Refractory Cardiogenic Shock ASAIO Journal 2009; 55: 465-468

4.
Welp, H. et al. Effect of Pulsatile and Non-pulsatile Left Ventricular Assist Devices on the Renin-Angiotensin System in Patients with End-Stage Heart Failure. Thorac Cardiov Surg 2010; 58, Suppl. 2: S185–S188

Please read the instructions for use carefully for detailed information prior to use of the EXCOR® Adult. All information on procedures and patient management must be understood as recommendations made by the manufacturer based on a wide range of experience with the system. The described system benefits reflect common therapy results. Individual progress and outcomes may be significantly different from those described in this booklet. Patients undergoing VAD therapy are severely ill and the therapy follows a major and complex operation. There is a relevant risk of complications and even death of the patient during or after implantation of the VAD system. This risk should be calculated and balanced in comparison to the risk and prognosis without VAD therapy. Please also refer to the medical literature for further information.

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EXCOR® Adult is currently not available for use in the USA
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