

# EXCOR® Pediatric VAD par Excellence





*Ein Kinderspiel  
A Children's Game*

*Paul Klee, 1939*

*The paintings of Paul Klee are among the most excellent creations of their time, internationally known and respected. As children inspired Paul Klee for his artistic creations, pediatric patients and their needs inspire us every day to create excellent worldwide-recognized products and services to save their lives.*

# Excellence in Engineering Meets Excellence in Support

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## **PARTNERSHIP**

Open, trustful and fair contact with customers, patients and employees.

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## **BERLIN HEART**

As your partner, the Berlin Heart Clinical Specialists will support you during the entire VAD therapy: from patient selection and the VAD implantation to patient care, including the post-operative management and social care of your patient.

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## **RESPONSIBILITY & SUSTAINABILITY**

Thorough and prudent work for results offering durability and substance.



24/7

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## FUTURE ORIENTATION

Great commitment in technical and clinical research.

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## QUALITY

High quality from the product to the service.



# Three Solutions to Meet every

The Berlin Heart portfolio of ventricular assist devices offers you the ability to treat your patients with uni- or biventricular support as bridge to recovery (BTR), bridge to transplantation (BTT) or destination therapy (DT).



## INCOR®

**Durable and reliable implantable LVAD for long-term support as BTT or DT**

- Unique magnetic levitation enables INCOR® to be the only continuous flow (cf) VAD simulating physiological conditions with an induced pulsatility<sup>1</sup>
- Innovative design, magnetic levitation and physiological control features
- Ongoing patients with up to 8 years support demonstrate the reliability and safety



## EXCOR® Adult

**Scientifically-proven BVAD device for BTT or BTR therapy**

- EXCOR® Adult demonstrates excellent results in the BVAD population<sup>10</sup> with support times of more than 5 years
- Mobile driver permits mobilization, discharge and a nearly normal life
- Wide portfolio of pumps and cannulae to meet every patient's individual needs

# Patient's Needs



## EXCOR® Pediatric

### Only approved VAD system for young patients $\geq 2$ kg

- Only system approved for pediatric VAD therapy, for LVAD, BVAD and RVAD support<sup>2,6</sup>
- Clinically reliable for support times of a few days up to several years<sup>3,6</sup>
- Supports pediatric patients of all ages, from newborns to adolescents
- Outstanding clinical performance proven in over 1,700 patients worldwide



## EXCOR® Pediatric – The Gold Standard to Support Your Smallest Patients

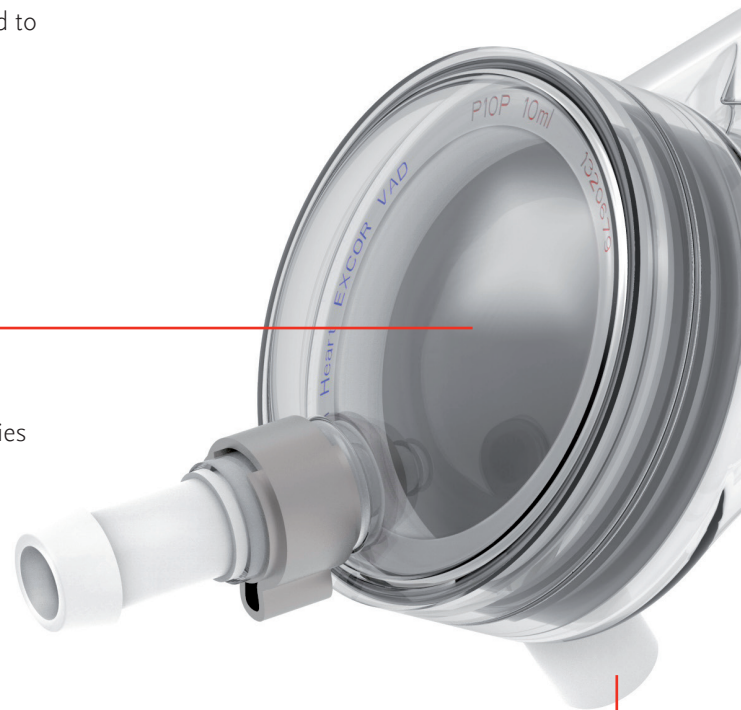
Its extensive worldwide experience shows the clinical superiority of the only approved VAD for pediatric patients – the EXCOR® Pediatric

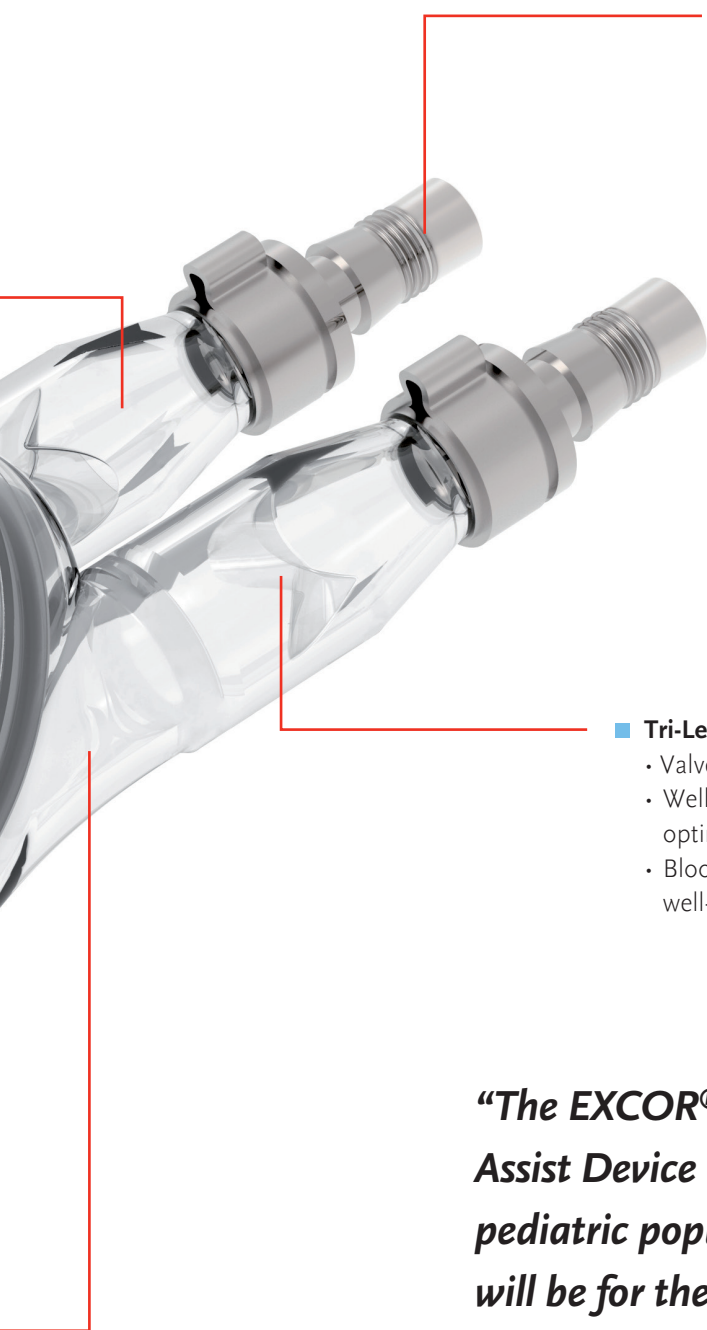
- **Carmeda® BioActive Coated Surfaces (Covalently Bound Heparin)**
  - Clinically proven thromboresistance, designed to minimize pump thrombosis rate

- **Triple-Layer Membrane**
  - Ensures safe, long-term operation
  - Draws blood into the blood chamber and pushes it back into the body's great arteries

- **De-Airing Port**
  - Enables easy and safe air removal during priming and after pump connection

- **Transparent Pump Chamber**
  - Allows permanent visual inspection of blood-contacting surfaces
  - Permits direct visual evaluation of pump performance, filling and emptying





■ **Titanium Connectors**

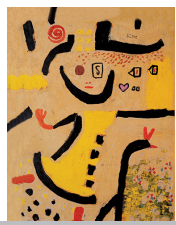
- Designed for easy and safe connection between blood pump and cannulae

■ **Tri-Leaflet Polyurethane Valves**

- Valves ensure blood flow in only one direction
- Well-proven tri-leaflet polyurethane valves permit optimal flow dynamics within the blood pump
- Blood pumps  $\geq 50$  ml are also available with well-proven Sorin Bicarbon™ bileaflet valves

***“The EXCOR® Pediatric is the only Ventricular Assist Device that is currently approved for the pediatric population, and is the only device that will be for the foreseeable future. This device has become an important option for our pediatric patients with severe cardiac failure, providing successful outcomes for even our smallest patients.”***

Mark Bleiweis, M.D., University of Florida, Shands Children’s Hospital (USA)



## EXCOR® Pediatric – The Optimal Treatment for Your Youngest Patients

### THE SYSTEM COMPONENTS DESIGNED ESPECIALLY FOR CHILDREN

Various pump and cannula sizes  
enable the support of every patient and  
the adaptation to their needs

The system is the only approved ventricular  
assist device that can support the most  
critical patient group: your pediatric patients.  
It allows:

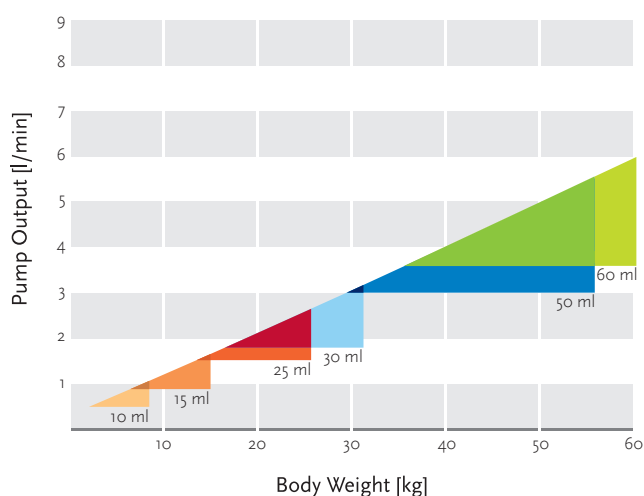
- Adjustable flows for both ventricles  
depending on the needs of your patient<sup>1,2,7</sup>
- Provides support from days up  
to several years<sup>3,6</sup>





## TAILORED BLOOD PUMPS – Six sizes to meet the circulatory requirements of children

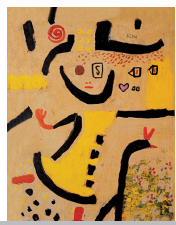
- Pump volumes as small as 10 ml permit support of even newborns and infants
- Combination of different blood pump sizes allows optimal BVAD support<sup>2,9</sup>
- Clinically proven and reliable for long-term VAD support<sup>3,6</sup>



### Pump size selection

- Various pump sizes to perfectly suit every patient's needs<sup>2,7</sup>
- Easy blood pump adaptation to the physical growth of the patient
- The large portfolio enables optimal selection of the pump size, which may reduce the occurrence of thromboembolic events, as a larger pump size in relation to the BSA has demonstrated to be a risk factor.<sup>8</sup>

The final decision of pump selection should be made by the implanting physician based on the individual patient's needs and the weight/pump output guidance represented in this graph. Note that the graph represents common clinical use and not the maximum technical performance of the blood pumps.



## The System Components Designed Especially for Children

### EXCOR® CANNULAE

Variety of cannulae diameters, lengths, angles and shapes for every patient's individual anatomic needs

#### Optimized design

- Permits intuitive and safe anastomosis

#### Biocompatible silicone material

- Ensures reliable performance and long-term durability

#### Polyester velour sheathing

- Promotes optimal ingrowth of the cannula and therefore decreases risk of infection



The bevelled titanium tip of the **apex** cannula prevents suction of the septum



The open structure of the **atrial** cannula head enables a continuous flow without suction



The **arterial** cannula enables easy and safe anastomosis, even to the smallest vessel



The **graft-adaptor** cannula can be used in connection with any graft material and allows easy and safe anastomosis



<http://t1p.de/x359>

**More information**  
about the combination  
options of the EXCOR®  
pumps and cannulae



Lara G. from Germany, successfully transplanted after almost 2.5 years of EXCOR® Pediatric support



## IKUS STATIONARY DRIVING UNIT

- Provides pulsatile pressures for 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
- 30 minutes of minimum battery operation for patient mobility

## EXCOR MOBILE DRIVING SYSTEM

- Provides a full day of mobility for adolescents with blood pumps  $\geq 60$  ml and enhances the patients' quality of life significantly
- High reliability through redundancy of core components
- Easy battery exchange with uninterrupted operation
- Battery operation of up to 10 hours for enhanced patient mobility





# EXCOR® Pediatric – Specifically Adopted Devices Lead to Scientifically-Proven Results in the Youngest Patient Cohort

## EXCELLENT OUTCOME CLINICALLY DEMONSTRATED

- The outstanding results of various studies worldwide on the EXCOR® Pediatric system, have shown and proven the advantages of the device
- Results present a high survival and an acceptable rate of adverse events compared to other therapy options

### Review of the IDE Trial Results

Fraser CD Jr et al., N Engl J Med. 2012; 367(6):532-41



Juniper S. from the USA, successfully transplanted after six months of EXCOR® Pediatric support

### Study Design

Prospective, multicenter, single-arm study

Patients (n=48) 16 years of age or younger were divided into two cohorts according to body-surface area:

- Cohort 1: n=24, BSA <0.7 m<sup>2</sup>
- Cohort 2: n=24, BSA ≥0.7 to <1.5 m<sup>2</sup>

The primary efficacy endpoint for the EXCOR® Pediatric VAD was time to death or weaning with an unacceptable neurological outcome.

For children in cohorts 1 and 2, the median duration of support with EXCOR® Pediatric VAD was 28 days and 43 days, respectively. The longest duration of support with EXCOR® Pediatric VAD in cohorts 1 and 2 was 174 days and 192 days, respectively.

Definition **death**: death while on support or within 30 days after weaning or before hospital discharge, whichever was longer

Definition **unacceptable neurologic outcome**: either coma or the presence of profound sensory, motor, language, or cognitive impairment as assessed with the Pediatric Stroke Outcome Measure (PSOM).

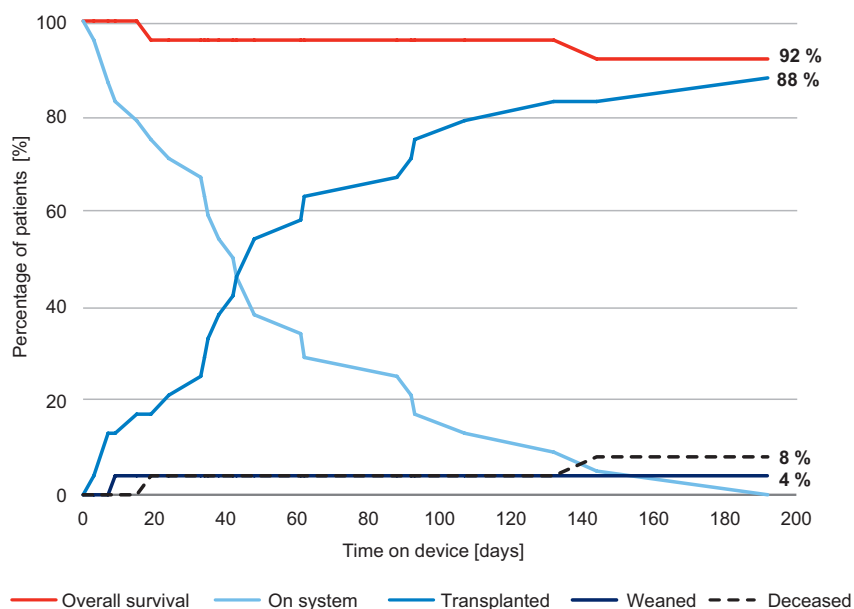
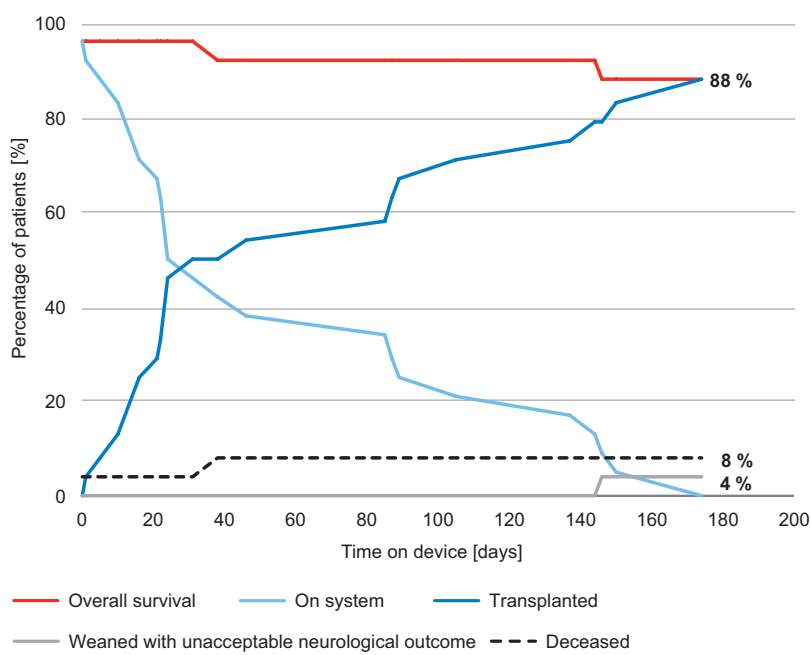
<http://t1p.de/i5pa>



**More information** about the excellent clinical results with EXCOR® Pediatric in experienced and new countries

**Overall for patients supported with EXCOR® Pediatric VAD, 88% in cohort 1 and 92% in cohort 2 were bridged to transplant or recovery with acceptable neurological outcome.**

### Competing outcome with overall survival of EXCOR® Pediatric VAD, cohort 1 and cohort 2





## Berlin Heart – Our Service for Your Benefit



Lenka W. from Poland, successfully weaned after 197 days of EXCOR® Pediatric support

We believe timing and interdisciplinary collaboration are two very important elements for a successful VAD program. Our Berlin Heart clinical specialists support you during the entire VAD therapy.

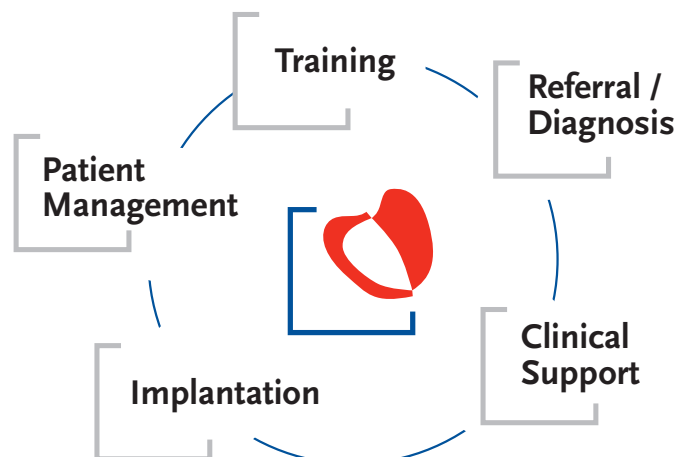
### LEARNING TO BE SUCCESSFUL – THE BERLIN HEART ACADEMY

The Berlin Heart Academy supports you in establishing a successful VAD team and VAD program. In order to train surgeons, cardiologists, nurses and perfusionists, we will either invite you for training at our Berlin Heart facilities or arrange an educational program at your site.

### YOUR SCIENTIFIC PARTNER – THE BERLIN HEART CLINICAL SCIENCE DEPARTMENT

The Berlin Heart Clinical Science team supports you in publishing scientific results related to Berlin Heart products:

- Design of clinical trials or post-market clinical follow-up evaluations
- Statistical analysis
- Scientific assessments of our product developments



## SUPPORT ON-SITE – FROM IMPLANTATION TO PATIENT MANAGEMENT

If you need assistance during pre-operative care, implantation, post-operative care and patient management, our established clinical specialists will be glad to help.

## FROM EXPERT TO EXPERT – CALL US 24/7 FOR CLINICAL OR TECHNICAL QUESTIONS

A team of doctors, perfusionists, ICU nurses and engineers with long-standing experience within the field of mechanical circulatory support provides you with answers regarding all clinical and technical matters.

**Emergency Hotline: + 49 30 8187 2772**

## CUSTOMER SERVICE – ANY DAY AT ANY TIME

Our customer service team is able to deliver all the material you require at any time and worldwide.

**Emergency Hotline: + 49 30 8187 2772**

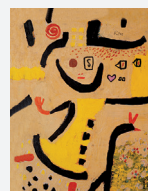
## References

### INCOR®

1. Arndt et al., Low Rate of Thromboembolism with the INCOR Ventricular Assist Device: Design Changes and Initial Clinical Results, oral communication ASAIO 2010

### EXCOR®

2. Fraser et al., Prospective trial of a pediatric ventricular assist device, *N Engl J Med.* 2012; 367(6):532-41
3. Hetzer et al., Single-center experience with treatment of cardiogenic shock in children by pediatric ventricular assist devices, *J Thorac Cardiovasc Surg* 2011; 141:616-23
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8. Miera et al., Pump size of Berlin Heart EXCOR pediatric device influences clinical outcome in children, *J Heart Lung Transplant.* 2014 Aug; 33(8):816-21
9. Kansy et al., First Multicenter Experience with EXCOR Pediatric in Poland – Successful introduction of pediatric VAD therapy, oral communication AEPC 2015
10. Bartfay et al., Gold standard in biventricular circulatory support – excellent results with an old school device, oral communication EUMS 2014



Title: Ein Kinderspiel (1939)  
A Children's Game  
Artist: Paul Klee  
Medium: Colored paste and watercolour on cardboard  
Dimensions: 43 x 32 cms

Paul Klee (\* December 18, 1879 in Münchenbuchsee, Switzerland; † June 29 1940 in Mural, Switzerland) was a famous painter whose highly individual style was influenced by movements in art that included expressionism, cubism, and surrealism. Klee was a natural draftsman who experimented with and eventually explored color theory in depth.



# EXCOR® Pediatric

## DESIGNED TO HELP YOU SAVE YOUR PATIENTS

**EXCOR® Pediatric is the only approved VAD worldwide that offers mechanical circulatory support to even the smallest patients**

- Outstanding clinical performance proven in over 1,700 patients worldwide
- Combinations of pumps and cannulae to fit the individual needs of your patients
- Excellent results for long-term support



<http://t1p.de/zl4y>

**EXCOR®  
animation video**

Please read the instructions for use carefully for detailed information prior to the use of EXCOR®. Additionally, you may use the Download section of our Berlin Heart homepage ([www.berlinheart.de](http://www.berlinheart.de)). All information on procedures and patient management is to be understood as recommendations made by the manufacturer on the basis of a wide range of experiences with the system. The described system benefits reflect common therapy results. Individual progress and outcomes may differ significantly. Patients undergoing VAD therapy are severely ill. The therapy involves a profound and complex intervention. 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 weighed 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 and INCOR®  
are currently not available for  
use in the USA.

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