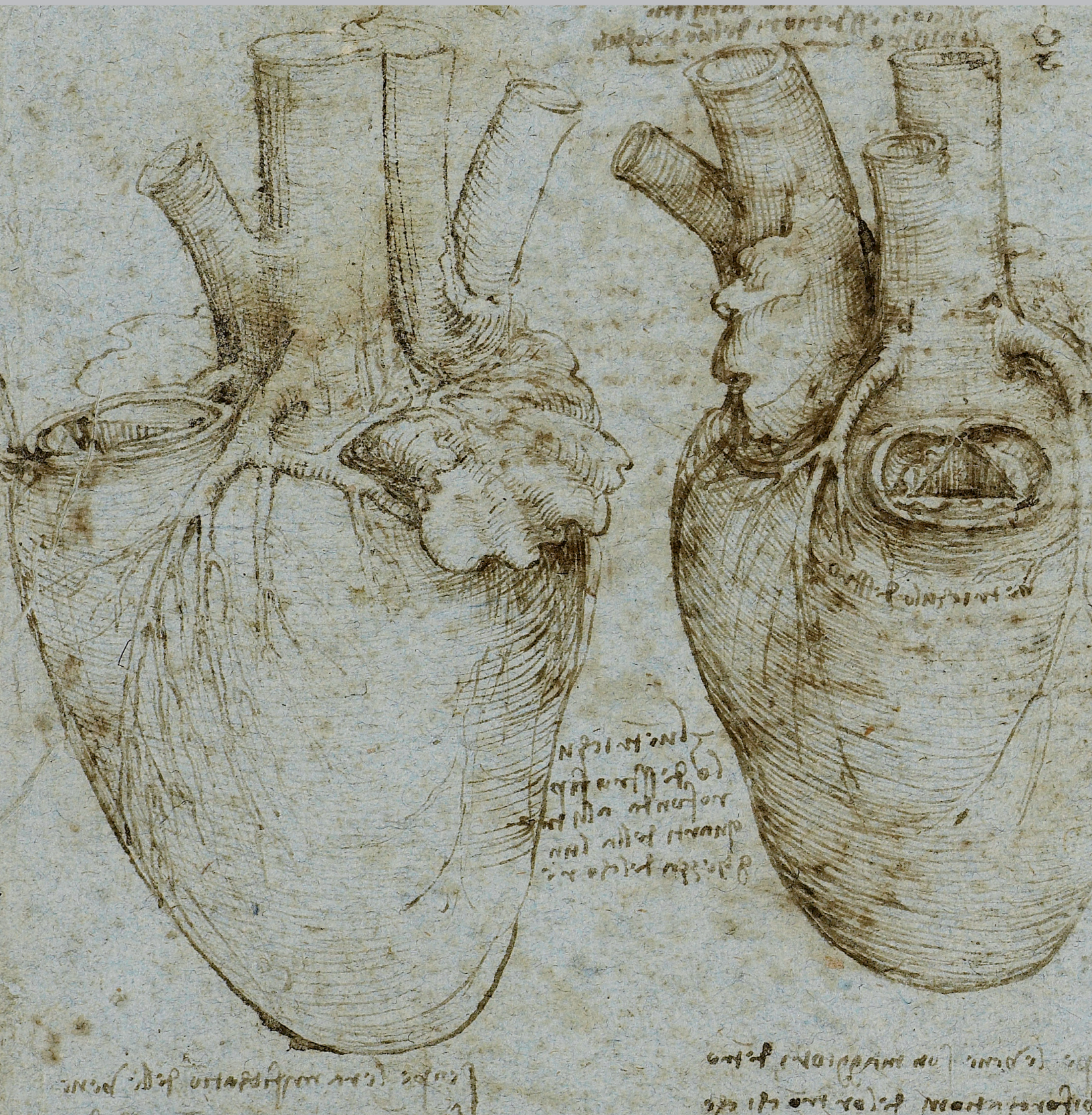
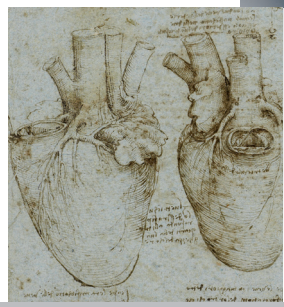


EXCOR® Adult VAD par Excellence





Studies of the coronary vessels and valves of the heart

Leonardo da Vinci, 1510

The drawings of Leonardo da Vinci are among the most excellent creations of their time, internationally known and respected. Da Vinci is referred to as one of the most diversely talented artists and symbolizes what drives our daily work: to find solutions for all patient groups and provide them with excellent and worldwide-recognized products and services.

Excellence in Engineering Meets Excellence in Support

PARTNERSHIP

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

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.

RESPONSIBILITY & SUSTAINABILITY

Thorough and prudent work for results offering durability and substance.



24/7

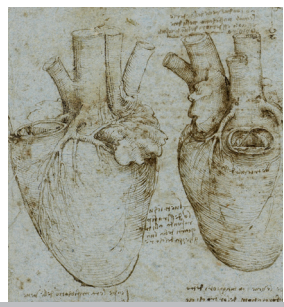


FUTURE ORIENTATION

Great commitment in technical and clinical research.

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 pulsatility¹
- Innovative design, magnetic levitation and physiological control features
- Ongoing patients with up to 8 years support demonstrate the reliability and safety



EXCOR® Pediatric

Only approved VAD system for young patients ≥ 2 kg

- Only system approved for pediatric VAD therapy, for LVAD, BVAD and RVAD support^{2,3}
- Supports pediatric patients of all ages, from newborns to adolescents, from a few days to several years
- Outstanding clinical performance proven in over 1,700 patients worldwide

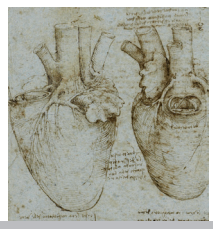
Patient's Needs



EXCOR® Adult

Scientifically-proven BVAD device for BTT or BTR therapy

- EXCOR® Adult demonstrates excellent results in the BVAD population⁴
- Support times of more than 5 years show the liability and safety of the system
- Mobile driver permits mobilization, discharge and a nearly normal life
- Wide portfolio of pumps, cannulae and driver settings to meet every patient's individual needs, especially in case of right ventricular failure



EXCOR® Adult – An Excellent and Established Device

■ 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

■ Carmeda® BioActive Coated Surfaces (Covalently Bound Heparin)

- Clinically proven thromboresistance, designed to minimize pump thrombosis rate



■ **Titanium Connectors**

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

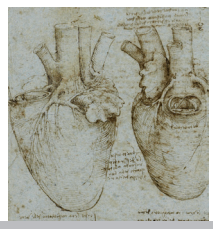


■ **Bileaflet Valves**

- Valves ensure that the blood flows only in one direction
- Well-proven Sorin Bicarbon™ bileaflet valves permit optimal flow dynamics within the blood pump
- Blood pumps also available with well-proven tri-leaflet polyurethane valves

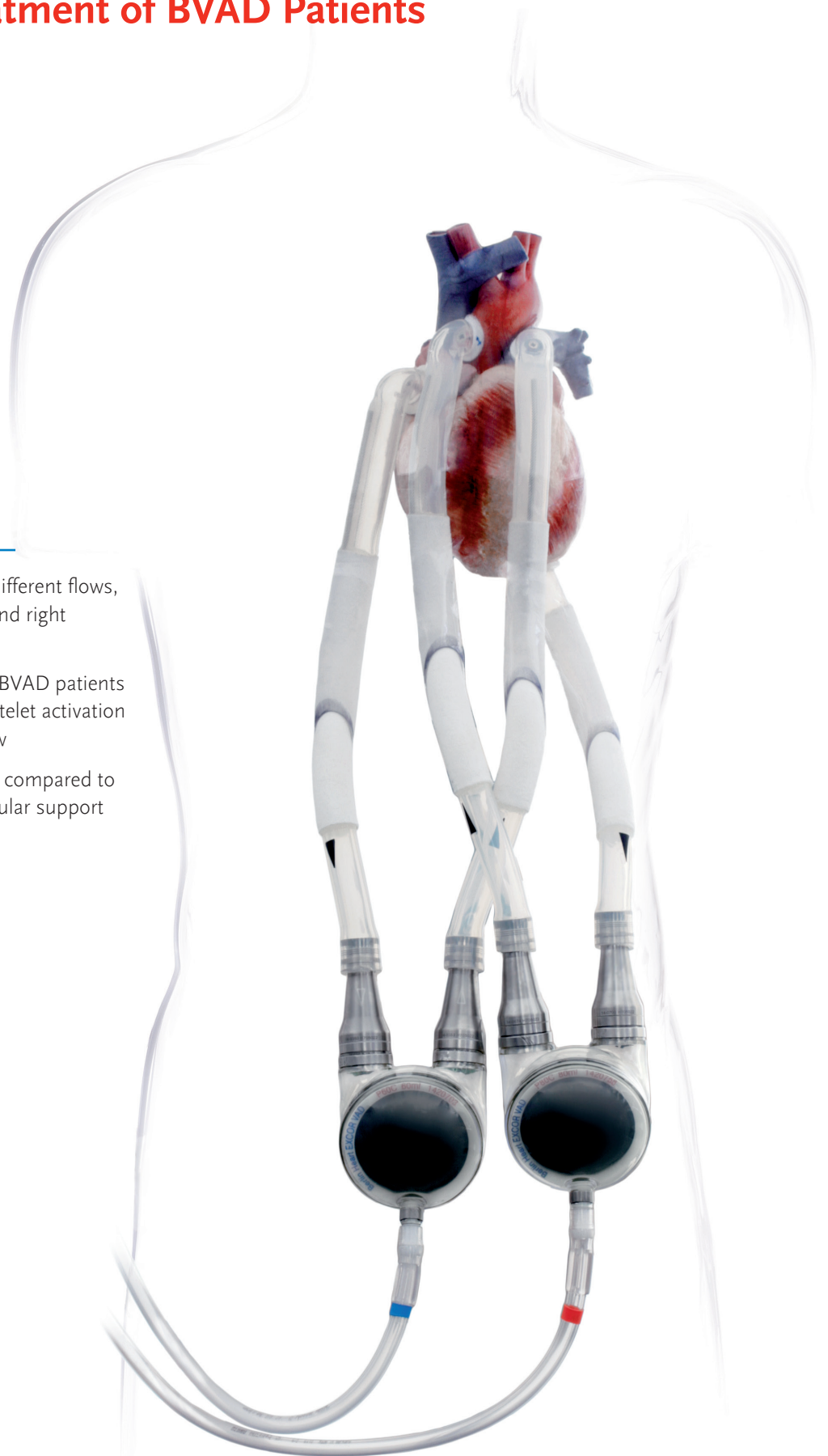
■ **Transparent Pump Chamber**

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



EXCOR® Adult – A System Specifically Adapted for the Optimal Treatment of BVAD Patients

- System optimized for different flows, adjustable for the left and right ventricle
- Long-term support for BVAD patients possible due to low platelet activation and pulsatile blood flow
- Improved quality of life compared to temporary right ventricular support and to long-term ECLS



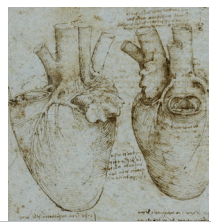
TAILORED BLOOD PUMPS –

Three sizes and two valve types to meet the circulatory requirements of each patient



“In INTERMACS 1 patients with biventricular heart failure and severe end-organ dysfunction, restoring a high cardiac output is imperative for patient recovery. The Berlin Heart EXCOR® Adult system is our treatment of choice as it allows immediate, high pulsatile cardiac output and swift patient mobilization.”

Prof. Dr. Arjang Ruhparwar, Director of Heart Transplantation and Mechanical Circulatory Support, Heidelberg University Hospital (Germany)



The System Components for the Best Clinical Performance

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



<http://t1p.de/my4a>

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



Olaf M. from Germany, successfully transplanted after more than 2.5 years of EXCOR® support

EXCOR MOBILE DRIVING SYSTEM

- Provides patients a full day of mobility and enhances the quality of life significantly
- High reliability through redundancy of core components
- Runs 60 ml and 80 ml EXCOR® Adult blood pumps
- Easy battery exchange with uninterrupted operation
- Battery operation of up to 10 hours for enhanced patient mobility



IKUS STATIONARY DRIVING UNIT


- Provides pulsatile pressures for pulsatile blood flow
- Triple redundancy of core components for maximum safety
- 30 minutes of minimum battery operation for patient mobility





Excellent Outcome Clinically Demonstrated

EXCOR® Adult is the only approved VAD with different sizes of blood pumps to enable biventricular support for all patients



Jenny K. from Sweden, successfully transplanted after almost six months of EXCOR® support

Biventricular assist devices (BVAD) are the most effective strategy for patients with severely decompensated heart failure with signs of significant right ventricular failure

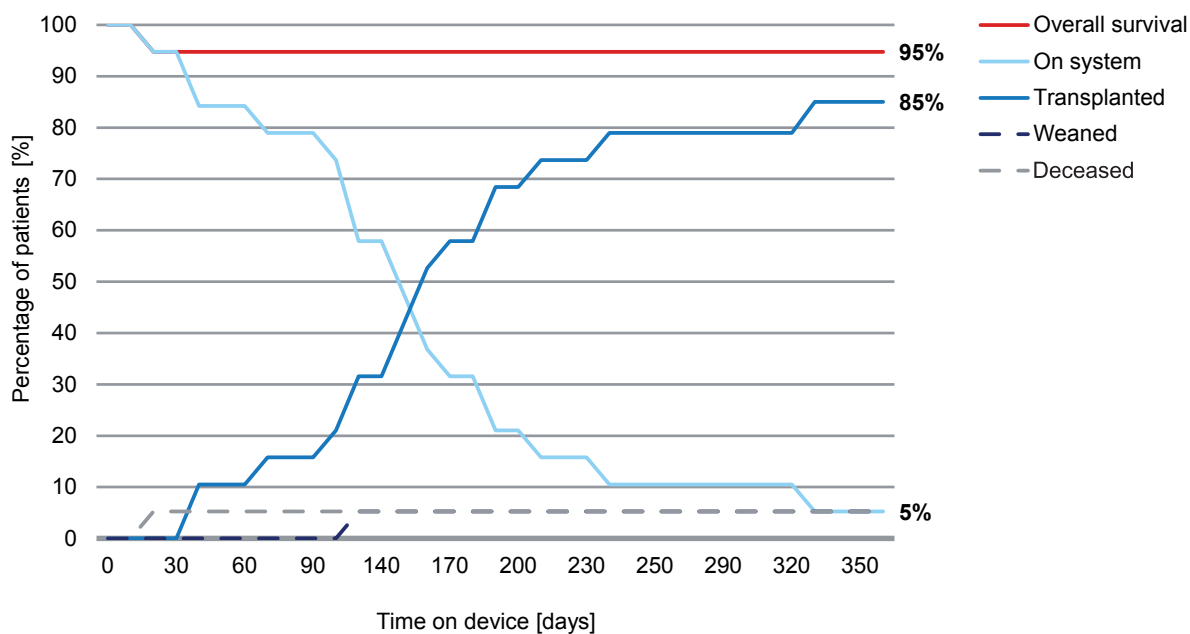
- In the case of severely decompensated heart failure patients with signs of significant right ventricular failure, an LVAD alone may not provide adequate circulatory support. In such cases, a BVAD is the most effective strategy.⁵
- Approximately 20% of patients develop RV failure after LVAD placement. For those patients with RV failure, unexpected RVAD insertion is necessary to establish adequate end-organ support.⁵
- Takeda et al. demonstrated that the overall hospital mortality was 50% for the unplanned RVAD group and 30% for the planned BVAD group. This finding supports a previous study showing that early planned BVAD implantation improved outcomes, compared to delayed conversion of LVAD to BVAD.⁶
- In a review of their EXCOR® Adult experience, Bartfy et al. concluded that “BVAD as a bridge-to-transplantation results in high survival rates comparable to those observed in patients with LV failure treated with LVAD”.⁴

REVIEW OF THE SWEDISH EXPERIENCE – ONE OF MANY EXCOR® ADULT SUCCESS STORIES⁴

During the observation period (February 2010 to February 2014) 19 patients were supported with EXCOR® Adult BVAD. The overall median support time was 150 days (19–380 days), with a total of 2,898 days of cardiac support.

Overall survival was 95%, thereof 90% of the patients were transplanted and 5% were weaned.

1-year survival was 95%, thereof 85% of the patients were transplanted, 5% were weaned and 5% were still on system.



Patient characteristics

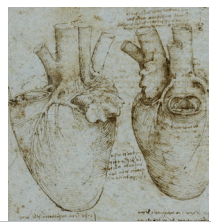
Variable	EXCOR® Adult BVAD patients (n=19)
Median age [years] (range)	35 (20–61)
Median BSA [m ²] (range)	2.0 (1.5–2.6)
Preoperative ECMO/IABP [%]	63
INTERMACS Level [%]	
1	21
2	53
≥3	5
n.s.	21

Outstanding survival of 95 % was demonstrated in patients with biventricular heart failure supported with EXCOR® Adult



<http://t1p.de/t1oj>

More information
about the excellent
clinical results with
EXCOR® Adult



Berlin Heart – Our Service for Your Benefit



Matthias K. from Germany, currently waiting for a heart transplantation while being supported with the EXCOR® system for more than 1.5 years

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.

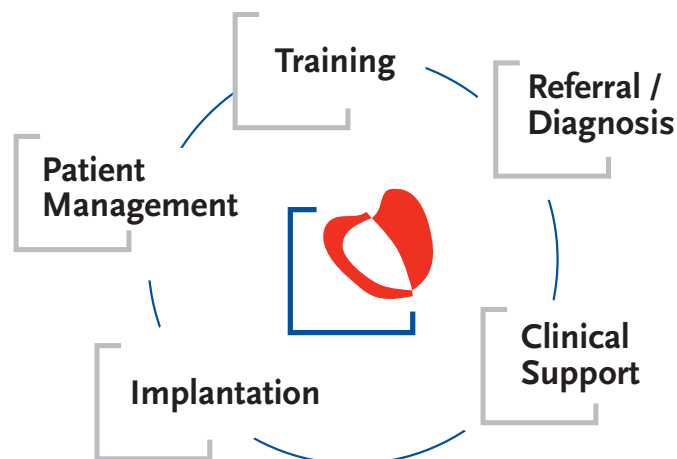
LEARNING TO BE SUCCESSFUL – THE BERLIN HEART ACADEMY

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

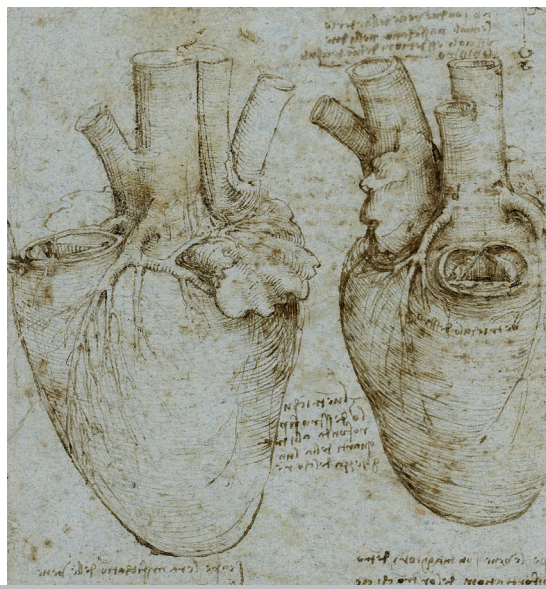
EXCOR®

2. Fraser et al., Prospective trial of a pediatric ventricular assist device, *N Engl J Med.* 2012; 367(6):532-41
3. Jaquiss et al., Berlin Heart Post Approval Outcomes in North America, Oral Communication ISHLT 2015
4. Bartfay et al., Gold standard in biventricular circulatory support – excellent results with an old school device, oral communication EUMS 2014
5. Takeda et al., Outcome of unplanned right ventricular assist device support for severe right heart failure after implantable left ventricular assist device insertion. *J Heart Lung Transplant.* 2014 Feb; 33(2):141-8
6. Fitzpatrick et al., Early planned institution of biventricular mechanical circulatory support results in improved outcomes compared with delayed conversion of a left ventricular assist device to a biventricular assist device. *J Thorac Cardiovasc Surg* 2009; 137:971-7



Title: Studies of the coronary vessels and valves of the heart (1510)
Artist: Leonardo da Vinci
Medium: Pen and ink on blue paper
Dimensions: 28.8 x 41.3 cms

Leonardo da Vinci (* April 15, 1452 in Vinci, Italy; † May 2, 1519 in Clos Lucé, France) was an Italian polymath. His areas of strength included painting, sculpting, architecture, science, music, mathematics, engineering, invention, anatomy, geology, astronomy, botany, writing, history, and cartography. Leonardo's genius, perhaps more than that of any other figure, epitomized the Renaissance's humanist ideal.



EXCOR® Adult

DESIGNED TO BE RESPONSIVE TO ALL PATIENTS

**EXCOR® Adult offers you the possibility to successfully
treat your patients with BVAD support**

- Outstanding clinical performance proven in over 2,200 patients worldwide
- Various combinations of pumps and cannulae to fit the individual needs of your patient
- 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). 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.

Version MMF21.1
September 2015
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