

# INCOR®

Superior Pump



Implantable Left Ventricular Assist Device

# The Well-Proven Way of Treating Patients with Severe Heart Failure

The Implantable VAD System INCOR® by Berlin Heart

## INCOR® – Bridging and Permanent Therapy in Severe Heart Failure

The INCOR® LVAD is indicated for patients with acute advanced heart failure refractory to optimal medical treatment. The system allows patients to get back to their daily life, enables them to manage their everyday tasks and pursue their hobbies. The system has performed well worldwide in several hundred patients with proven benefits and safety.

## Bridging or Permanent Therapy: INCOR® – the Fully Developed System Even for Long Term Therapy Support

INCOR® is the only CE-certified 3rd generation axial flow pump with magnetically levitated impeller. It is able to provide a flow of 6 L/min against a pressure of 80 mmHg. This is achieved at an impeller speed of 7500 rpm and a low power consumption of 4 Watts.

The unique bearing system operates without any mechanical contact and ensures wear-free long term support of patients with severe terminal heart failure. Therefore INCOR® LVAD is the ideal device for both permanent and bridging therapy.

As a manufacturer specialized in precisely this form of therapy, we have incorporated unequalled clinical experience and scientific competence, so that today a fully developed product with proven therapeutic success and minimized complications is available for clinical use.

The entire production, research and development, distribution and service process is located in Berlin. Our customers appreciate the centralized Berlin Heart services constantly.

## State-of-the-Art Material Research: INCOR® is Made of Biocompatible Materials

The inner surface of INCOR® is made from titanium with Carmeda® (Heparin) coating. Medical grade silicon is used for the inflow and outflow cannula. All implanted components CFD-optimized for best flow and lowest blood trauma.



## Indications

INCOR® LVAD System is intended for use in acute or chronic left ventricular failure refractory to optimal medical and interventional therapy (NYHA class IV, INTERMACS Level 2-6).

INCOR® is an implantable left-ventricular assist device (LVAD), which in addition to BTT (bridge to transplantation) and BTR (bridge to recovery) therapy is also approved for use as permanent therapy or alternative to transplantation (ATT) in Europe with the CE mark.

INCOR® has been Successfully Used Amongst Others in Patients with:

- Dilatative cardiomyopathy
- Ischemic cardiomyopathy
- Myocarditis
- Congenital HD
- Peripartal cardiomyopathy
- Toxic cardiomyopathy
- Restrictive cardiomyopathy

Contraindication

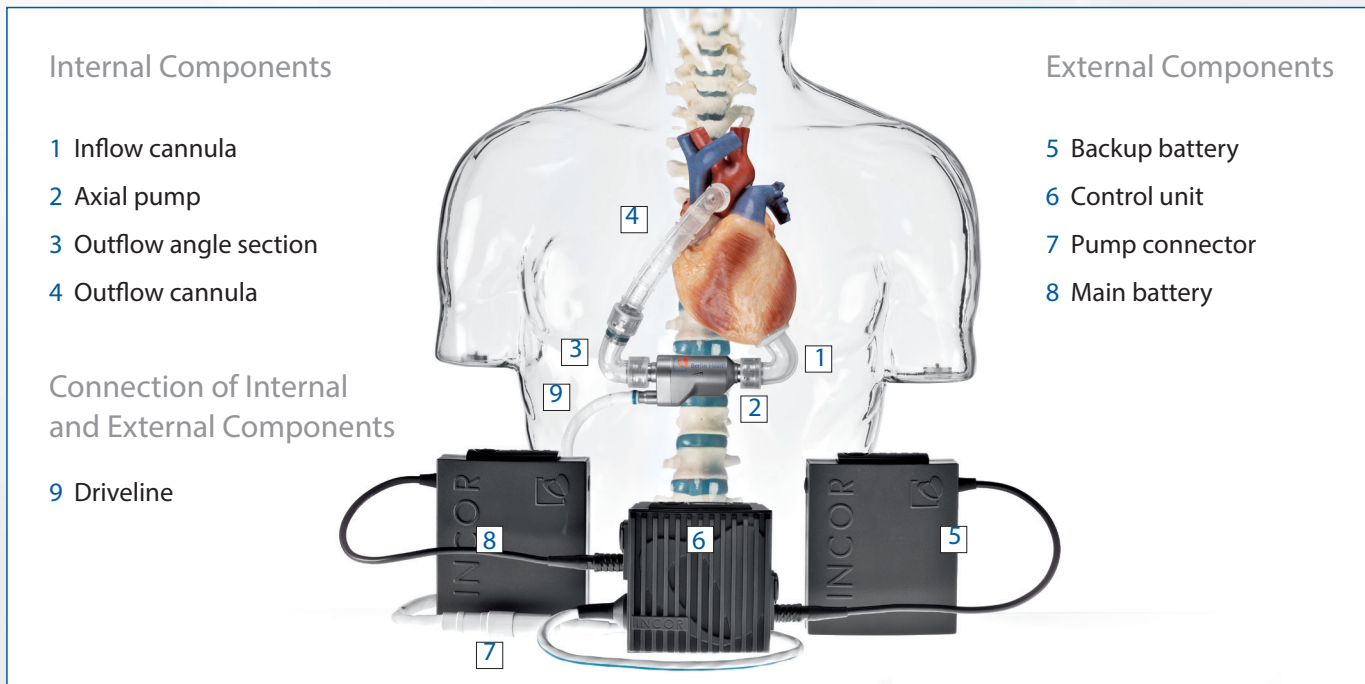
- Predominantly right-ventricular heart failure
- Biventricular heart failure
- Signs of infection which do not correspond to a sepsis-like syndrome
- Sepsis
- Progressive multi-organ failure

## Benefits at a Glance

- High operational safety for unlimited long term use due to magnetic bearing system with no wear and no heating
- Easy, quick and intuitive implantation due to unique pump/cannulae design and snap-in connectors
- Optimal LV washout, low risk of ventricular collapse, suction and very low risk of pump thrombosis due to intelligent software features
- Surgical pocket preparation is unnecessary. Implantation via median sternotomy and via left lateral thoracotomy possible
- Accurate and reliable information for an effective clinical patient follow-up:
  - Pressure difference
  - Blood flow/Blood pressure
  - Movement of the aortic valve
  - Suction due to hypovolemia or RV dysfunction
  - Arrhythmias
- The unique weaning plug allows a safe pump explantation, the inflow cannula can be left in place
- Reduced infection rate due to optimal velour length on the driveline



# The Available System Components at a Glance



INCOR® in situ (configuration for median access)  
with all permanently active components

The inflow cannula leads from the left ventricle to the pump which is connected to the outflow cannula via an angle section. The outflow cannula is anastomosed with the ascending aorta (median access) or the descending aorta (lateral access).

The outflow angle section may be omitted in lateral access. The percutaneous driveline connects the pump to the control unit. The power supply of the system is provided by two batteries (main and backup) which must always be connected to the control unit. The INCOR® system can optionally be driven by mains power using the mains power unit.

The control unit, main battery and backup battery are stored in a light-weight, ergonomic compact carrier bag, which offers both shoulder strap and belt carrying options. The transparent window on top of the INCOR® Smart Bag allows easy visual check of the control unit and alarm messages. Quick-access zippered top and Velcro® opening in the front facilitate battery exchange with minimal effort.

The system includes a charging unit for the batteries, a mains power supply unit and a laptop with the INCOR® monitor program.



# INCOR® – Driven by Innovation, Designed by Needs

## Superior Pump – The New Features

In our commitment to innovation and continuous product improvement we have launched new product features and an optimized anatomical design to further improve patient outcomes:

### Smart Software

#### PFC (Periodic Flow Change)

- Provides periodic pump flow reversal
- Promotes aortic valve opening
- Enhances effective washout of LV

#### PC (Pulsatility Control)

- Automatically adjusts pump speed
- Regulates sufficient LV filling

#### SP (Suction Protection)

- Rectifies acute suction events

All three Smart Software features complement each other to optimize patient treatment. As a result the desired situation in non-pulsatile LVAD systems was achieved:

Desired Situation	PC	SP	PFC
Pulsatile arterial blood flow	■		
Enhances effective washout of LV	■		■
Promotes aortic valve opening			■
No ventricular collapse and suction	■	■	
No aggregation of deposits in the pump			■

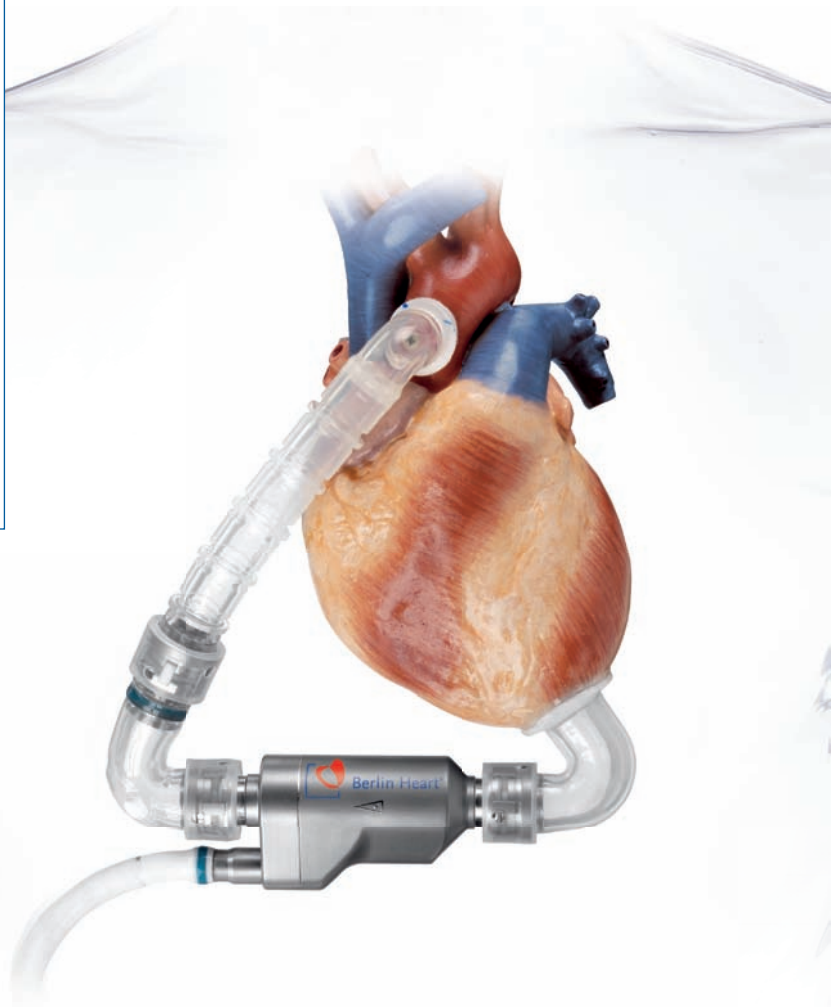
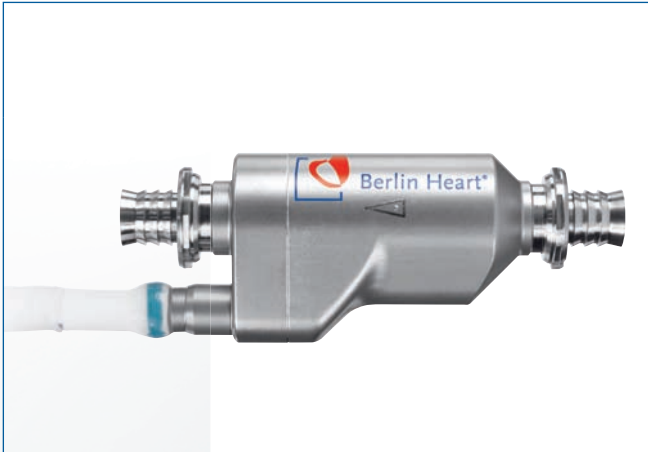
### Straight Cable Exit Enables Correct and Intuitive Positioning of the Pump in the Pericardium

- Optimized anatomical fit
- Less RV-compression

### Redesigned Driveline Reduces Infection Rate

The length of the Dacron®-velour adapts to anatomical conditions so that the silicone section is prevalently exposed at the percutaneous driveline exit site.

- Reduced infection rate
- Simplified handling



# Roadmap for the Surgical Procedure

The INCOR® is an implantable left ventricular assist device for human use which can be implanted via median or lateral access.

## General Surgical Principles to Follow for Median Access

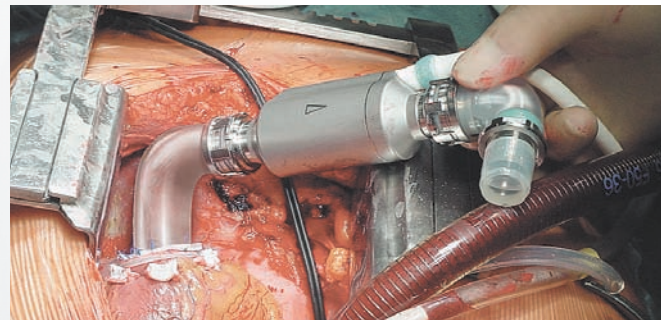
- Standard cardiovascular techniques are used
- Initiation of CPB with right atrial cannulation and aortic cannulation close to the aortic arch allowing proximal anastomosis of INCOR® outflow cannula
- INCOR® implantation can be done on beating heart
- Snap-in connectors allow easy and fast connection between the INCOR® pump and its cannulae



## Step by Step to Success: Surgical Steps in Particular

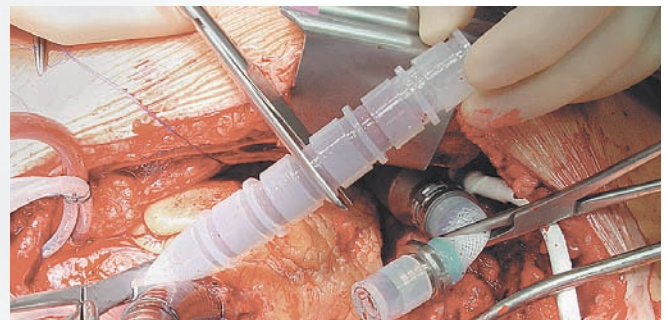
### Step 1

The LV apex hole is established by using the INCOR® coring knife. All trabeculae next to the inflow cannula must be excised to avoid thrombus formation and embolization. The suture ring holder should not be removed before all sutures are tied to maintain the round shape of the ring (preserved shape of the suture ring provides blood impermeability between suture ring and inflow cannula).



### Step 2

Connect inflow cannula with pump. Vent LV via outlet of pump (using the vent adapter supplied), thus de-airing the pump with antegrade flow.

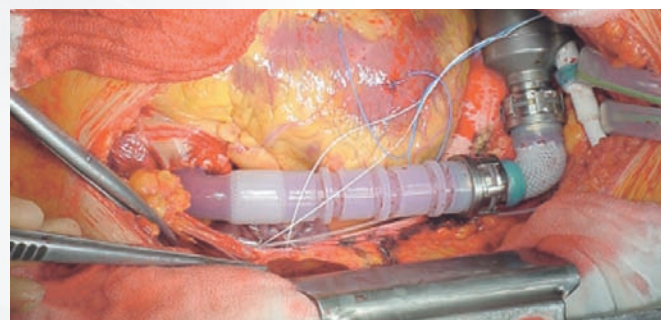


### Step 3

Aortic anastomosis with outflow cannula (end-to-side).

### Step 4

Trim outflow cannula to desired length, de-air with retrograde flow and connect to pump.



### Step 5

Tunnel driveline subcutaneously.

### Step 6

Start system, increase rpm as needed and wean from cardiopulmonary bypass.

# Patient Management

## Always Focus on the Patient's Specific Needs

### Keys to Success

- Patient selection and timing of LVAD implantation
- Patient-specific and individual management of anticoagulation and platelet function
- Switch from heparin to a vitamin K antagonist as soon as possible
- Aim for MAP 70 mmHg
- Remember: flow of axial pump depends on afterload and preload
- Low flow regime
- In-house logistics – dedicated VAD team
  - Assist device specialists
  - VAD outpatient clinic

### The Right Therapy: Anticoagulation and Antiplatelet

Start heparin 12 after implantation if no bleeding occurs. Start with 5–7 U/kg/hr and increase until PTT 60–80 sec. Give AT III to achieve activity > 70%.

Add ASA 100 mg/d on POD4 when drains are out. Consider additional dipyridamol (up to 1 g/d) according to platelet aggregation test.

Switch to vitamin K antagonist (INR 2.5–3.0). LMWH can be given prophylactically when INR out of range.

### Keep an Eye on Anticoagulation

Check aPTT, ACT, ATIII, Fibrinogen, platelet count, D-Dimer, INR and Anti Xa. Platelet aggregation test (keep platelet aggregation induced by arachidonic acid and ADP below 30% of normal). Thrombelastography (modify anticoagulation and platelet inhibition according to clot firmness, clot formation time and rate of fibrinolysis). Remember that all infections can activate coagulation.

### The Right Ventricular Function

During implantation, inotropes (epinephrine, dobutamine) and phosphodiesterase-inhibitors (milrinone) should be used for right heart support. Additionally, iNO/Ilomedin® ventilation for reducing pulmonary vascular resistance should be taken into consideration.

### Other Drugs

All patients should receive optimal heart failure medical therapy according to ESC/ACC-guidelines.

### Extubation and Mobilization – the Sooner the Better

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



# 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 effort 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

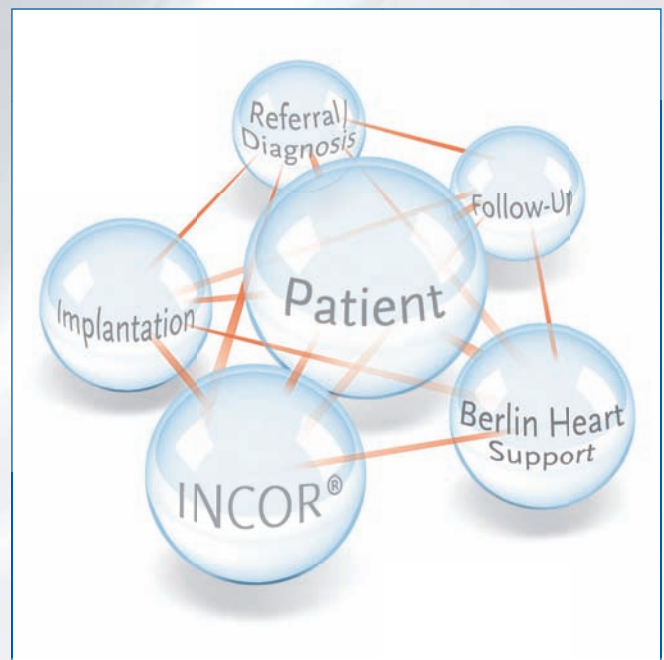
A team of doctors, perfusionists, ICU nurses and engineers with long standing experience within the field of mechanical circulatory support provides excellent support for all clinical and technical matters (patient selection, timing, implantation, follow up, data analysis and subsequent recommendations). 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 the local regulatory requirements, and provide you with the products and equipment you need – at any time, any day of the year.

Emergency Hotline: +49 30 8187 2772



### 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.

## References

1. Hetzer, R. et al. First experiences with a novel magnetically suspended axial flow left ventricular assist device. *Eur J Cardiothorac Surg* 2004. 25: 964-970.
2. Schmid, C. et al. First clinical experience with the Incor Left Ventricular Assist Device. *J Heart Lung Transplant* 2005. 24 (9): 1188-1194.
3. Garatti, A. et al. Clinical outcome and bridge to transplant rate of left ventricular assist device recipient patients: comparison between continuous-flow and pulsatile-flow devices. *Eur J Cardiothorac Surg* 2008. 34(2): 275-80
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 Cardiovasc Surg* 2010; 58, Suppl. 2: S185-S188
5. Schmid, C. et al. Influence of inflow cannula length in axial-flow pumps on neurologic adverse event rate: Results from a multi-center analysis. *J Heart Lung Transplant* 2008. 27; 3: 253-260.
6. Schmid, C. et al. Clinical situations demanding weaning from long-term ventricular assist devices. *Eur J Cardiothorac Surg* 2004. 26(4): 730-5.
7. Komoda, T. et al. Explantation of INCOR Left Ventricular Assist Device After Myocardial Recovery. *J Card Surg* 2008. 23(6): 642-647.
8. Genta, F. et al. Flow mediated dilation in patient with Berlin Heart Incor left ventricle assist device. *Monaldi Arch Chest Dis*. 2008. 70(1): 38-40.
9. Tschirkov, A. et al. New technique for implantation of the inflow cannula of Berlin Heart INCOR system. *Eur J Cardiothorac Surg* 2006. 30(4): 678-9.
10. Nakashima, K. et al. Off-pump replacement of the INCOR implantable axial-flow pump. *J Heart Lung Transplant* 2009. 28(2): 199-201.

Please read the instructions for use carefully for detailed information prior to the use of INCOR® LVAD. Additionally you may use our download section of the 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 experience with the system. The described system benefits reflect common therapy results. Individual progress and outcome may differ significantly. Patients undergoing VAD therapy are severely ill. The therapy adheres to 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 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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INCOR® is currently not  
available for use in the USA  
Version 5000033x04  
May 2013

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Photographs of surgical procedure:  
Courtesy of Prof. R. Hetzer,  
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