

# Product Catalog

**EXCOR®** Pediatric

The Ventricular Assist Device for Children





# About Berlin Heart

Berlin Heart Develops, Produces and Provides Innovative Devices for Mechanical Supporting of the Heart.

While only the EXCOR® Pediatric is approved for use in the US, our products INCOR®, EXCOR® Adult and EXCOR® Pediatric span the entire range of medical indications for patients of all ages – from newborn babies to adults. With reliable and globally successful products, Berlin Heart is one of the industry's market leaders.

Our claim is to develop innovative solutions with utmost precision and reliability. The short time to market and technological features of our products are unique and exemplary. Our future developments shall continue to meet the demands of our customers and the market.

With our solid position we will continue our course of worldwide expansion based on innovative products, while relying on strategic international partnerships.





# EXCOR® Pediatric

## The Ventricular Assist Device for Children LVAD / BVAD

EXCOR® Pediatric is a mechanical circulatory support system that provides short- to medium-term assistance to the failing left and 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 may benefit directly from restored hemodynamics, a result of the improved circulation provided by the device.

Treatment with the EXCOR® Pediatric may also improve the quality of life for patients with severe heart failure. Patients of every age accept the system and gain valuable time while waiting for an organ transplant or in some patients recovery of their own heart.

When using this system, many patients are able to participate in everyday activities and pursue their hobbies.

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 minimized 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.



## The Paracorporeal VAD System for your Youngest Patients

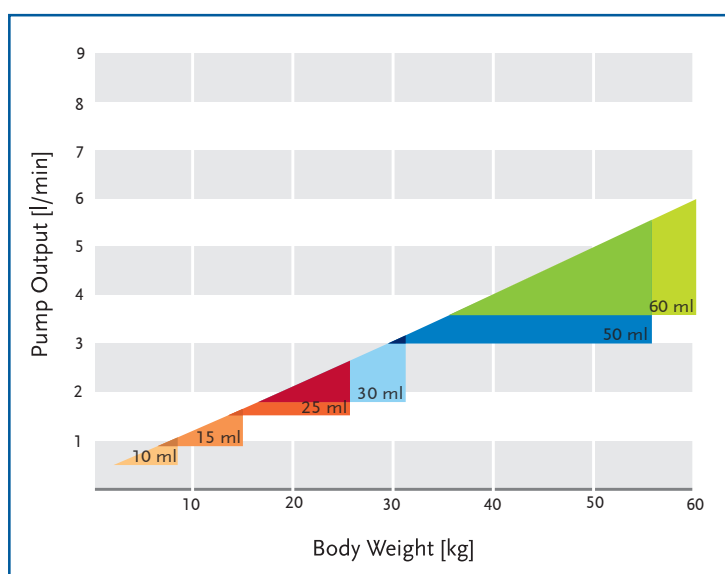


### Blood Pumps with PU Valves

Article no.	Pump volume [ml]	Connector diameter [Ø mm]
P10P-001	10	6
P15P-001	15	9
P25P-001x01	25	9
P30P-001x01	30	9
P50P-001	50	12
P60P-001	60	12

### Blood Pump Characteristics

Features	Description
Housing material	Polyurethane, transparent for permanent visual inspection
Coating	CARMEDA® BioActive Surface coating
Pump membrane	Three-layer redundant membrane
De-airing port	For air removal after pump connection
Pump valves	Tri-leaflet polyurethane (PU) valves
Weight	45 g to 140 g (10 ml / 60 ml pump)



Pump Size Selection for Young Patients



Driver rental

### Accessories

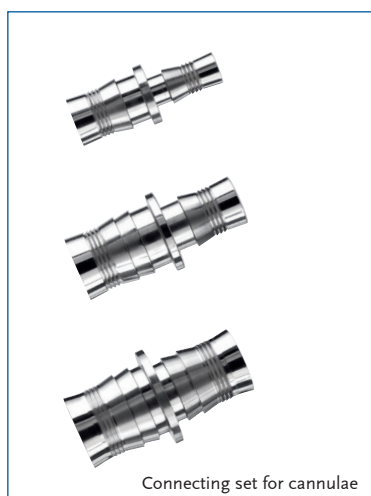
Article no.	Description
T00L-002	Accessory set PU valves
L20H-002x01	Driving tube, red
L20H-003x01	Driving tube, blue

### Connector Sets

Article no.	Description
A06-009	Connecting set, Ø 6 to Ø 9 mm
A09-012	Connecting set, Ø 9 to Ø 12 mm

### Cannula extension Sets

Article no.	Description
A06-006	Cannula extension set, Ø 6/6 mm
A09-009	Cannula extension set, Ø 9/9 mm
A12-012	Cannula extension set, Ø 12/12 mm



Connecting set for cannulae

# EXCOR<sup>®</sup> Pediatric System Overview



## Apex Cannulae

Ø 5 mm  
C14A-040m  
22 cm

Ø 6 mm  
C18A-020  
25 cm

Ø 9 mm  
C22A-004  
27 cm, 22 cm cut off\*

Ø 12/9 mm  
C22A-004  
27 cm

Ø 12 mm  
C27A-001  
26,5 cm

## Atrial Cannulae

C15V-040m  
20 cm

C19V-020 C19V-020m  
25 cm

C22V-004  
28 cm, 24 cm cut off\*

C23V-004m  
32 cm, 26 cm cut off\*

C25V-004  
28 cm, 24 cm cut off\*

C23V-004m  
32 cm

C22V-002 C22V-002m  
33 cm

C26V-002 C26V-002m  
33 cm

## Arterial Cannulae

C80G-040m  
20 cm

C80G-021 C80G-021m  
25 cm

C60G-004 C60G-004m  
28 cm, 24 cm cut off\* 32 cm, 26 cm cut off\*

C85G-004 C85G-004m  
28 cm, 24 cm cut off\* 32 cm, 26 cm cut off\*

C00P-004\*\*  
27 cm, 21 cm cut off\*

C60G-004 C60G-004m  
28 cm 32 cm

C85G-004 C85G-004m  
28 cm 32 cm

C00P-004\*\*  
27 cm

C60G-002 C60G-002m  
33 cm 37 cm

C85G-002 C85G-002m  
33 cm 37 cm

C00P-001\*\*  
26 cm

## Adapter

A06-006

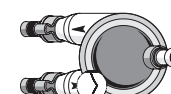
A06-009

A09-009

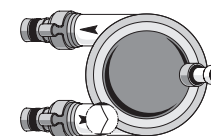
A09-012

A012-012

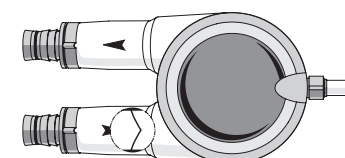
## Blood Pumps



P10P-001



P15P-001  
P25P-001x01  
P30P-001x01



P50P-001  
P60P-001

\* With/without stage

\*\* For use in Canada – Currently not approved in the US.

35 30 25 20 15 10 cm

35 30 25 20 15 10 cm

35 30 25 20 15 10 cm

## Cannulae

Article no.	Inner diameter [mm]	Cannula length [mm]	Head length [mm]	Head angle [°]	Remark
<b>Apex cannulae</b>					
C14A-040m	5/6	220	14	0	
C18A-020	6	250	18	0	
C22A-004	12/9	270/220*	28	0	
C27A-001	12	265	38	0	
<b>Atrial cannulae</b>					
C15V-040m	5/6	200	10	80	
C19V-020	6	250	19	80	
C19V-020m	6	250	14	80	
C22V-002	12	330	22	45	with flexibel metal reinforcement
C22V-002m	12	330	22	85	with flexibel metal reinforcement
C22V-004	12/9	280/240*	22	45	with flexibel metal reinforcement
C23V-004m	12/9	320/260*	23	85	with flexibel metal reinforcement
C25V-004	12/9	280/240*	25	45	with flexibel metal reinforcement
C26V-002	12	330	26	45	with flexibel metal reinforcement
C26V-002m	12	330	26	85	with flexibel metal reinforcement
<b>Arterial cannulae</b>					
C80G-040m	5/6	200	3.5	80	
C80G-021	6	250	5	80	
C80G-021m	6	250	3.5	80	
C60G-004	12/9	280/240*	0	60	with flexibel metal reinforcement
C60G-004m	12/9	320/260*	0	60	with flexibel metal reinforcement
C85G-004	12/9	280	0	85	with flexibel metal reinforcement
C85G-004m	12/9	320	0	85	with flexibel metal reinforcement
C60G-002	12	330	0	60	with flexibel metal reinforcement
C60G-002m	12	370	0	60	with flexibel metal reinforcement
C85G-002	12	330	0	85	with flexibel metal reinforcement
C85G-002m	12	370	0	85	with flexibel metal reinforcement
C00P-001**	12	260	0	-	graft adapter
C00P-004**	12/9	270/210*	0	-	graft adapter

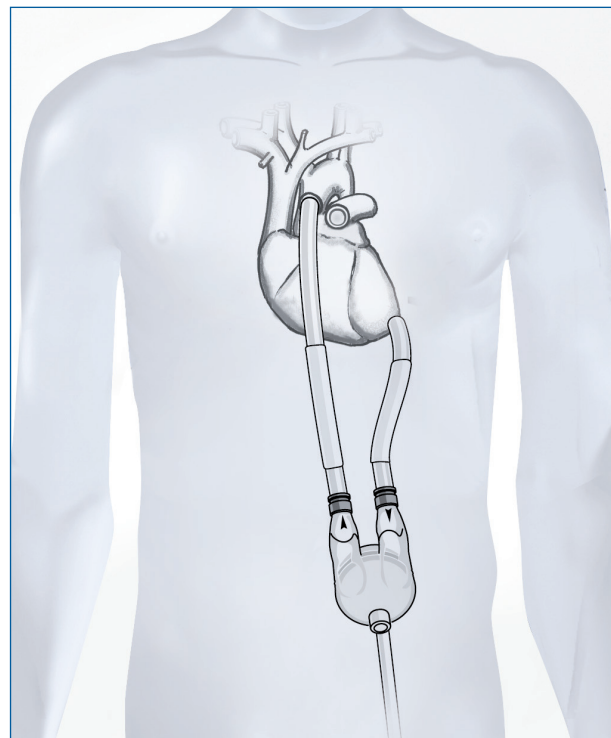
## Cannulae Characteristics

Features	Description
Shaft material	Flexible, long-term implantable, medical grade silicone
Velour	Polyester velour sheathing to promote tissue in-growth
Geometry	Variety of diameters, lengths, angles and shapes
Tunneling	Cannula tunneling tip(s) included in each cannula box

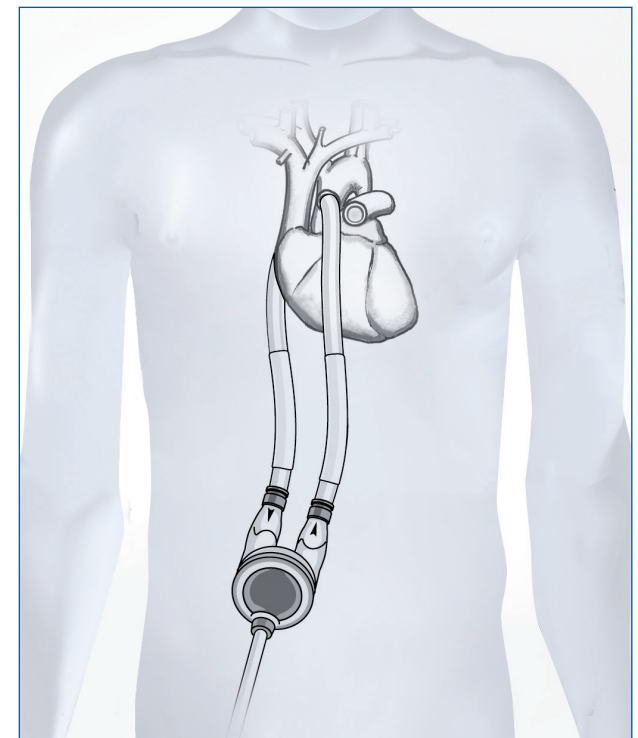
\* With/without stage. \*\* For use in Canada – Currently not approved in the US.

## EXCOR® Pediatric

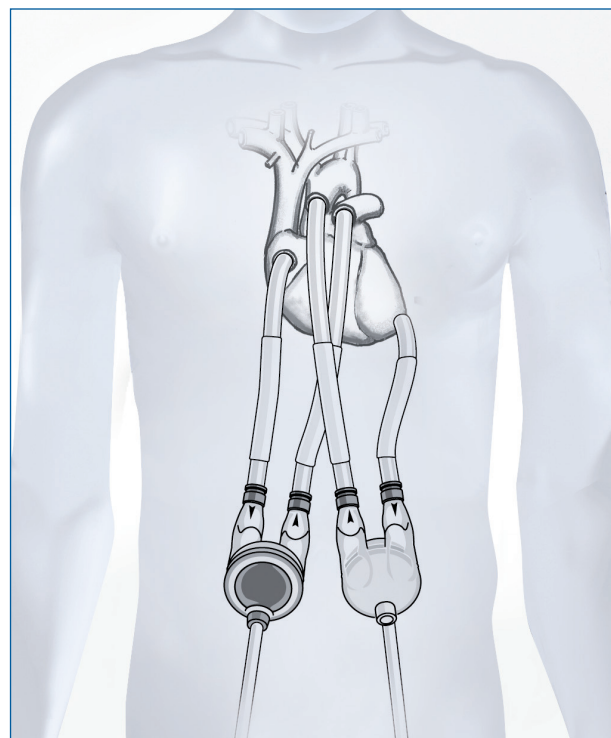
### Cannulation Options



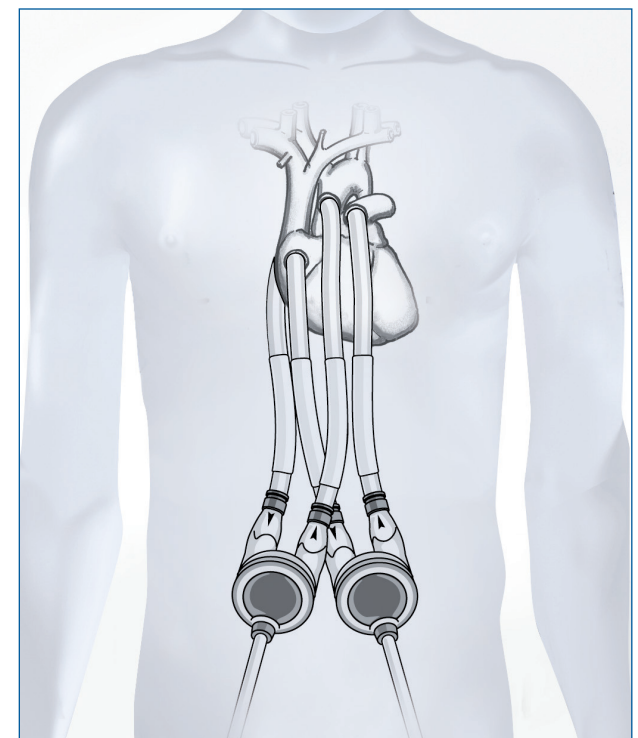
EXCOR® Pediatric LVAD apical



EXCOR® Pediatric LVAD atrial



EXCOR® Pediatric BVAD left apical



EXCOR® Pediatric BVAD left atrial

EXCOR® Pediatric

EXCOR® Drivers

Berlin Heart Services



# EXCOR® Driving Systems

## Ikus

### Stationary Driving Unit for EXCOR® Paracorporeal VAD System

The Ikus driving unit is designed for stationary use with the EXCOR® Adult and EXCOR® Pediatric blood pumps.

- 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



#### Drives

##### Article no.

D03I-111	EXCOR® Stationary Driving Unit Ikus (115V/60Hz)
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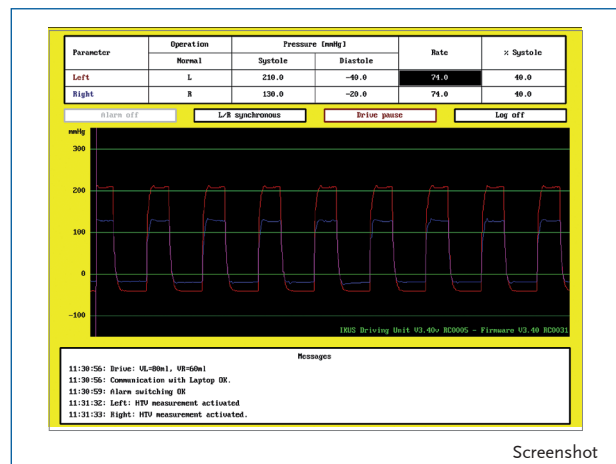
Features	Description
For use with pump sizes (univentricular/ biventricular)	10, 15, 25, 30, 50, 60 ml
Systolic pressure	60 to 350 mmHg
Diastolic pressure	-100 to 0 mmHg
Pump frequency	30 to 150 bpm
Relative systolic duration	20 to 70 %
Input voltage	AC 115 V
Power input	575 VA
Mains power fuse	5 A (115 V)
Protection class	IPX1
Battery operation	max. 30 minutes Alarm after 30 minutes (at max. 30 °C ambient temperature, otherwise less)
Battery charge duration	6 h
Maintenance interval	2000 operating hours or 6 months
Ambient temperature, operation	+10 to +30 °C with restrictions up to +35 °C
Ambient temperature, transportation and storage	-10 to +50 °C 6 h rest phase after transport before commissioning
Relative ambient air humidity	45 to 75 %

Please read the instructions for use carefully for detailed information prior to use of the Berlin Heart products.

# Ikus

## Safety and Flexibility for all patients

- Triple drive pneumatic redundancy safeguards against failure
- Flexible driving unit on castors, for the full pump range from 10 ml to 60 ml stroke volume
- For univentricular and biventricular support
- Synchronous, asynchronous or separate pulse operation mode for both ventricles
- Display allows perfect monitoring of actual drive parameters
- Acoustic and visual warning system
- Battery operation time of max. 30 minutes



# Berlin Heart Services

## Our Services for your Benefit

### 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

### Customized Service around the World Customer Service – any Day and any Time

Our customer service and logistics 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.

**Inside North America:**

**Emergency Hotline: 866 249 0128**

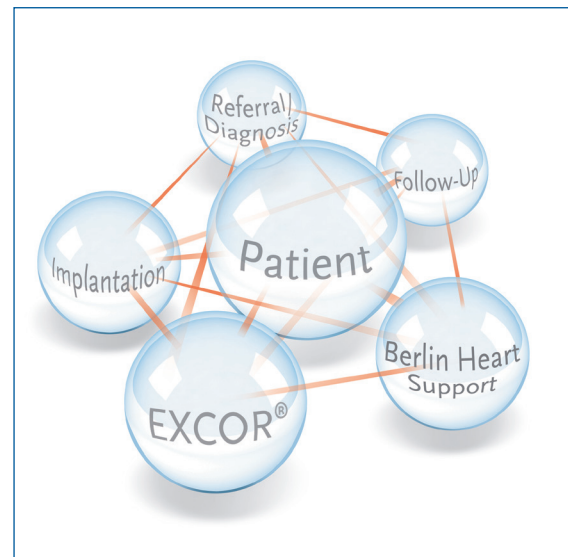
### You Need Support?

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

Our clinical affairs team with a long standing experience in 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.

**Inside North America:**

**Emergency Hotline: 866 249 0128**



### 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.

Please read the instructions for use carefully for detailed information prior to use of the Berlin Heart products.

If you have any additional questions, please don't hesitate to contact us.

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The EXCOR Pediatric Ventricular Assist Device (EXCOR® Pediatric) is approved for use in the US.

Federal law restricts this device to sale by or on the order of a physician.

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