

## Urgent safety information DS-18-01

concerning

### EXCOR® blood pumps

#### Safety information

Date: 28.05.2018

**Sender:** Berlin Heart GmbH, Wiesenweg 10, 12247 Berlin, Germany

**Addressee:** All users and distributors of the ventricular assist device EXCOR® Pediatric

#### Identification of the affected medical device:

Product group	EXCOR® Pediatric VAD system
Product	EXCOR® blood pump
REF	P10P-001, P15P-001, P25P-001x01, P30P-001x01, P50P-001, P60P-001

Dear customer and/or patient,

Berlin Heart has become aware of an increasing occurrence of issues with one or more of the membrane layers separating the air and blood chambers within the EXCOR Pediatric Ventricular Assist Device System blood pumps. The EXCOR blood pumps are designed with a triple layer membrane separating the air chamber from blood chamber for safety reasons. The entire membrane consists of an air-side layer, a middle layer and a blood-side layer (see figure 1). In case of disruption in one of the triple layers, there are two more layers that will maintain the integrity of the air and blood chambers.

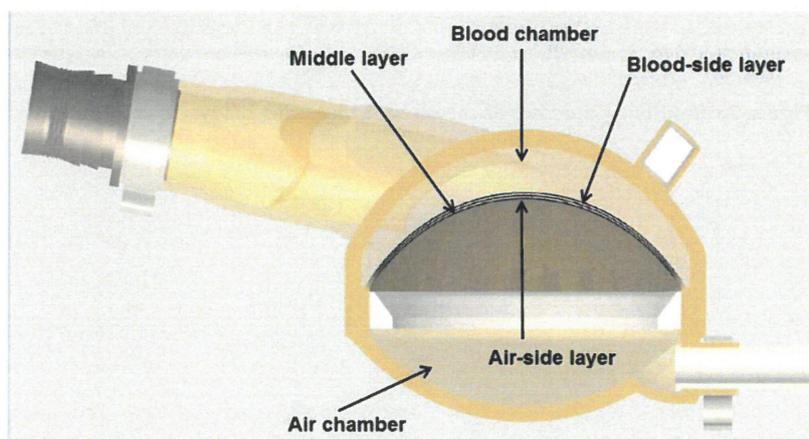


Figure 1: Schematic of the EXCOR Blood pump

### Background:

Over the past four months we have seen an increase in the disruption of one or more of the triple layer membranes of the EXCOR Pediatric pumps, however at least one membrane layer has always remained intact and there have been no reports of adverse events or injury to any patient supported with the device who has experienced one of these issues.

In certain circumstances, a disruption of one of the membrane layers may pose a risk of harm to patients supported with the EXCOR Pediatric Ventricular Assist Device if the issue is not immediately identified and the appropriate interventions are not promptly taken.

In the more frequent case where there is a disruption of the air side membrane layer, there is a chance that air could get trapped between the air side membrane layer and the middle membrane layer resulting in a pillow of air forming between the two membrane layers and diminished performance of the blood pump. Clinically in this situation it appears that the membranes are not moving or the pump is not filling or emptying completely (see figure 2). The patient may develop symptoms of circulatory insufficiency. It is imperative if this should occur that the blood pump be exchanged per the directions provided in the Instructions for Use by trained medical professionals.

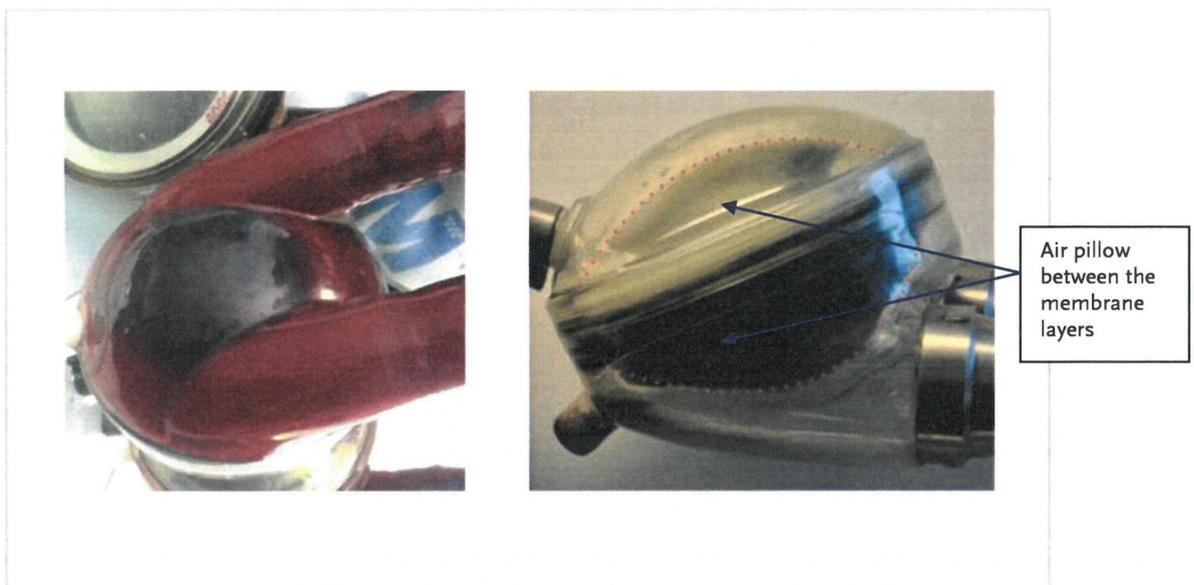


Figure 2: Identifying a defect of the air-side layer: Air pillow between the layers

A disruption of the blood side membrane layer is a less frequent occurrence. Most often in this case, blood collects and is visible in a ring around the middle of the blood pump where membranes separate the air and blood chamber (see figure 3).



**Figure 3: Identifying a defect of the blood-side layer: Blood in between the membrane layers in front of the stabilization ring.**

There are no other clinical findings that have been reported and although this has never been seen, there is also a chance that blood could get trapped between the blood side membrane layer and the middle membrane layer resulting in a pillow of blood forming between the two membrane layers and diminished performance of the blood pump. Clinically in this situation it appears that the membranes are not moving or the pump is not filling or emptying and the patient may develop symptoms of circulatory insufficiency. It is imperative if this should occur that the blood pump be exchanged per the directions provided in the Instructions for Use by trained medical professionals.

As always, we would like to remind you to always follow the information and instructions provided in our Instructions for Use that have been provided to you by Berlin Heart. Information related to the specific issues discussed above is included in Chapter 14 starting on page 77 and Chapter 16 starting on page 91:

## 14 Regular Inspections

### 14.1 Visual inspection

**WARNING**

Do not kink the driving tubes and cannulae. Use a mirror to inspect the underside of the blood pump(s). Otherwise, the cannulae may be damaged. They may then need to be replaced (requiring the blood pump to be stopped again!), or blood may be lost.

Check the filling and emptying of the blood pump and optimize, if necessary. Otherwise, support may be inadequate.  
Frequency of inspections: see Tab. 14-1, page 77.

Visually inspect the blood pump, cannulae (including cannula extension set / connecting set) and driving tubes for deposits, blood clots and damage.

Otherwise, deposits or damages may not be discerned in due time. There is a risk of thrombembolic complications or blood loss.  
Frequency of inspections: see Tab. 14-1, page 77.

If floating deposits are observed, replace the blood pump. Otherwise, the risk of thrombembolic complications will be increased.  
See chapter 16.5: Replacing the blood pump(s), page 97.

**ADVICE**

Clean the blood pump before inspection. Shine a flashlight into the blood chamber of the blood pump to inspect it, since deposits will thus be easier to identify.

**IMPORTANT:** If there are any unusual findings, See chapter 16: Detecting and Eliminating Errors, page 91.

**IMPORTANT:** Record the results of the visual inspections. See section 19.3: Blood pump log, page 118.

Components	Inspection for ...	Frequency (minimum)
Blood pump	Filling and emptying	3 times daily
Blood pump Cannulae, visible portion Connecting set Cannula extension set	Deposits, blood clots, damage	3 times daily
Cannulae in full, Driving tube	Deposits, damages	Once weekly

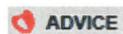
Tab. 14-1 Frequency of inspections

#### To be checked during inspection

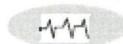
- Monitor the filling behavior of the blood pump over several pump cycles. The surface of the membrane must be smooth in the end-systolic and end-diastolic position.
- Membrane movement?
- Position and condition of driving tube and cannulae?

### 14.2 Inspection via the monitor program

Log the drive parameters and adjust them, if necessary. Target: complete filling and emptying of the blood pump in each cycle, with the lowest possible systolic and diastolic pressures.



Record the parameter values once a day.



Heed the instructions for use on the EXCOR driving system!

### 14.3 Modified hemodynamic requirements



If the hemodynamic requirements of the patient increase (e.g., due to an increase in weight or height), schedule replacement of the blood pump in good time. Otherwise, support may be inadequate.

It is possible that the blood pump selected at the time of implantation cannot guarantee adequate support for the entire duration of therapy. Physical growth and/or an increase in weight on the part of the patient can mean that the patient is not adequately supported with the present pump. Therefore, replacement of the blood pump should be planned in good time. See chapter 17.3: Selection guide, page 111.

For information on replacing the blood pump, See chapter 16.5: Replacing the blood pump(s), page 97.

## 16 Detecting and Eliminating Errors


**WARNING**

If floating deposits are observed, replace the blood pump. Otherwise, the risk of thrombembolic complications will be increased. See chapter 16.5: Replacing the blood pump(s), page 97.

**IMPORTANT:** This chapter describes potential product-specific errors. When diagnosing errors, however, the clinical condition of the patient must always be taken into account.

Problem	Possible cause/solution?
Deposits beginning to form	Check the anticoagulation therapy and adjust if necessary.
Floating deposits	Replace the blood pump. See section 16.5, page 97.
Permanent end systolic position of the membrane (incomplete filling)	See section 16.1, page 92.
Permanent end systolic position of the membrane (incomplete emptying)	See section 16.2, page 93.
Condensation visible around the entire pump	Contact the Manufacturer.
Blood visible around the entire blood pump (between the membrane layers)	One layer of the membrane is defective. Replace the blood pump. See section 16.5, page 97.
Membrane visibly floating in the blood pump	One layer of the membrane is defective. Replace the blood pump. See section 16.5, page 97.

Tab. 16-1 Possible error scenarios

Problem	Possible cause/solution?
Driving tube damaged	<p>Replace the driving tube. See section 16.3, page 94.</p> <p><b>Possible immediate response:</b> seal the driving tube with airtight, adhesive tape.</p> <p><b>IMPORTANT:</b> This is not an alternative to replacing the driving tube! Replace the driving tube without delay!</p> <p>Monitor the patient closely until the new driving tube is available.</p>
Cannula damaged	<p>Clamp both cannulae of the respective blood pump. Pause the driving system.</p> <p>If possible, shorten the cannula in such a manner that the defect is eliminated. Use the cannula extension set, if needed. Connect the new blood pump (see section 16.5.2, page 98 or section 16.5.3, page 100).</p> <p>Take the appropriate medical action.</p>

Tab. 16-1 Possible error scenarios

## 16.1 Incomplete filling / end-diastolic membrane position

### Possible causes

- Cannula/driving tube kinked
- Hypovolemia due to bleeding
- Increased elimination (diuretics?)
- Tamponade



1. Ensure that there are no kinks in the cannula and driving tube.
2. Check the volume status and adjust if necessary.
3. If necessary, adjust the parameter values (diastolic driving pressure and/or relative systolic duration).
4. If necessary, support the patient with the manual pump/replacement driving system in order to eliminate a fault in the driving system as a possible cause.
5. Consider using echocardiography to check the cannula position.

**IMPORTANT:** Increasing the suction pressure will not achieve any significant improvement if the necessary volume supply is not available.

Under LVAD: use echocardiography to check the right cardiac function.

### Adjusting the parameter values

Only change the parameters if inspection and adjustment of the volume status have no effect, or:

- when mobilizing the patient: adjust the left and right systolic driving pressure. Once pressures have been increased, do not lower them again, even if the patient is lying down.
- if support appears to be inadequate: with good membrane movement, a decline in urine output, increase in lactate and shortness of breath are observed. In this case, increase the rate and adjust the other settings.



**Heed the instructions for use on the EXCOR driving system!**



**Contact the emergency hotline! +49 (0)30 81 87 27 72**

## 16.2 Incomplete emptying / end-systolic membrane position



**WARNING** If air or blood collects between any of the layers of the membrane, replace the blood pump. Otherwise, support may be inadequate.

### Possible causes

- Cannula/driving tube kinked
- High MAP
- Damage to a membrane: collection of air or blood



1. Ensure that there are no kinks in the cannula and driving tube.
2. Check the MAP and adjust if necessary.
3. If necessary, adjust the parameter values (systolic driving pressure and/or relative systolic duration).
4. Consider using echocardiography to check the cannula position.
5. If necessary, support the patient with the manual pump/replacement driving system in order to eliminate a fault in the driving system as a possible cause.

**IMPORTANT:** Increasing the suction pressure will not achieve any significant improvement if the necessary volume supply is not available.

Under LVAD: use echocardiography to check the right cardiac function.

### Adjusting the parameter values

Only change the parameters if inspection and adjustment of the volume status have no effect, or:

- when mobilizing the patient: adjust the left and right systolic driving pressure. Once pressures have been increased, do not lower them again, even if the patient is lying down.
- if support appears to be inadequate: with good membrane movement, a decline in urine output, increase in lactate and shortness of breath are observed. In this case, increase the rate and adjust the other settings.

**If the action taken up to this point has no effect: consider the possibility that the membrane is damaged and air or blood may have collected**

One of the 3 membranes could be defective, and air or blood may have collected between the layers of the membrane.

**Air pockets:** if air infiltrates the space between the membrane layer facing the air chamber and the middle layer of the membrane, the accumulated air will create an air pocket. At worst, the visible membrane (facing the air chamber) may remain permanently in the end-diastolic position, whereas the other two membranes will be in the systolic position. The driving system will continue to generate suction and driving pressures; hence, the membrane will move slightly but the blood pump will not fill and empty completely.

**Blood pockets:** if blood becomes trapped between the membrane layer facing the blood chamber and the middle layer of the membrane, blood may become visible around the entire blood pump.

Another indication that blood has collected is a deviation between the nominal and real blood flow.



1. Replace the blood pump. See section 16.5: Replacing the blood pump(s), page 97.



**Heed the instructions for use on the EXCOR driving system!**



**Contact the emergency hotline! +49 (0)30 81 87 27 72**

### **Actions to be taken immediately:**

1. Increased attention to the regular control of EXCOR blood pumps. In particular, care must be taken to observe whether an air cushion results in a reduced pumping capacity or if blood is seen in the area around the stabilization ring.
2. If there is a suspicion of a membrane defect, the 24/7 Berlin Heart hotline (+49 (0) 30 8187-2772) must be informed immediately and in case of doubt, the EXCOR blood pump immediately exchanged by trained personnel in the clinic.

**Please note that an exchange of your EXCOR® components is not necessary.**

### **Dissemination of the information described here:**

Please ensure that all users of the EXCOR® VAD system and others to be informed in your institution are informed of this **urgent safety information**. If you have provided the products to any third parties, please forward a copy of this **urgent safety information** to them or inform the contact person given below.

Please retain this information at least until the action has been completed.

The Bundesinstitut für Arzneimittel und Medizinprodukte BfArM (coordinating authority in accordance with MEDDEV 2.12), as well as the affected regional authorities, have also received a copy of this "urgent safety information".

If you have any further questions regarding this urgent safety information and the EXCOR ® system, please contact the **hotline** at Berlin Heart GmbH: **+49 (0)30 8187-2772**.

### **Contact person for this urgent safety information:**

Hendrik Heinze  
Berlin Heart GmbH  
Tel. +49 (0)30 8187 2625  
Mobile: +49 (0)173 629 0831  
Fax: +49 (0)30 8187 22 2625  
E-Mail: [vigilance@berlinheart.de](mailto:vigilance@berlinheart.de)

Please kindly confirm receipt of this document using the enclosed acknowledgment form.



Hendrik Heinze  
Director Quality and Regulatory Affairs,  
Safety Officer for Berlin Heart GmbH

## Acknowledgement Form

EXCOR® Pediatric Blood pump

Please complete all requested information and return to:

<p>Berlin Heart GmbH Regulatory Affairs Fax: +49-(0)30 8187 22 2625 or vigilance@berlinheart.de</p>
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**Please sign and return this form until 07.06.2018.**

- ✓ I have understood that due to the increasing occurrence of the membrane defect scenario, increased attention is necessary by the regular control of the blood pump. In particular, care must be taken to observe whether an air cushion results in a reduced pumping capacity or if blood is seen in the area around the stabilization ring. If there is a suspicion of a membrane defect, the 24/7 hotline **(+49 (0) 30 8187-2772)** of Berlin Heart should be informed immediately and, in case of doubt, the blood pump immediately exchanged by trained personnel in the clinic.
- ✓ I understand the risk information that Berlin Heart has provided in this notice.
- ✓ I acknowledge receipt of this urgent safety information, number DS-18-01, concerning a medical device product from Berlin Heart (dated 28.05.2018), namely the EXCOR® blood pumps. I further confirm that I have completely understood the contents and have forwarded the information to the responsible personnel.

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(Optional) I need more information. Please call me at the number given below.

Name (block letters): \_\_\_\_\_

Signature: \_\_\_\_\_

Name of the hospital: \_\_\_\_\_

Date: \_\_\_\_\_

Telephone number: \_\_\_\_\_

E-Mail: \_\_\_\_\_

