

# Urgent Medical Device Correction Notification

concerning

## EXCOR® Cannulae

Date: 2023-08-08

**Sender:** Berlin Heart GmbH

**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® Cannulae                                  |
| REF            | All EXCOR® Cannulae No. (reference see Appendix) |
| Manufacturer   | Berlin Heart GmbH                                |
| Type of Action | Advisory Regarding the Use of the Device         |

### Attention: Healthcare Professionals, Implanting Physicians

Dear Valued Customer,

Berlin Heart is sharing information about the use of the EXCOR® Cannulae. The purpose of this letter is to advise you that Berlin Heart is conducting a voluntary correction concerning all EXCOR Cannulae (reference see Appendix) due to the potential of partial or complete breaches of an EXCOR Cannula.

Between the dates of 2019-01-01 to 2023-07-03, Berlin Heart has received 17 reports concerning EXCOR Cannula tears. Of the 17 reports received, 8 of these tears resulting in death of the patient. During this period a total of 3148 EXCOR cannulas were implanted worldwide.

A significant cannula breach may result in massive blood loss and/or an air embolism which could result in blood loss and/or death to the patient. We are aware that a small cannula tear can rapidly result in a significant breach.

Please note, that an exchange of your EXCOR components is not necessary unless the cannula is showing signs of breaching. There is no need to return unused inventory to Berlin Heart.

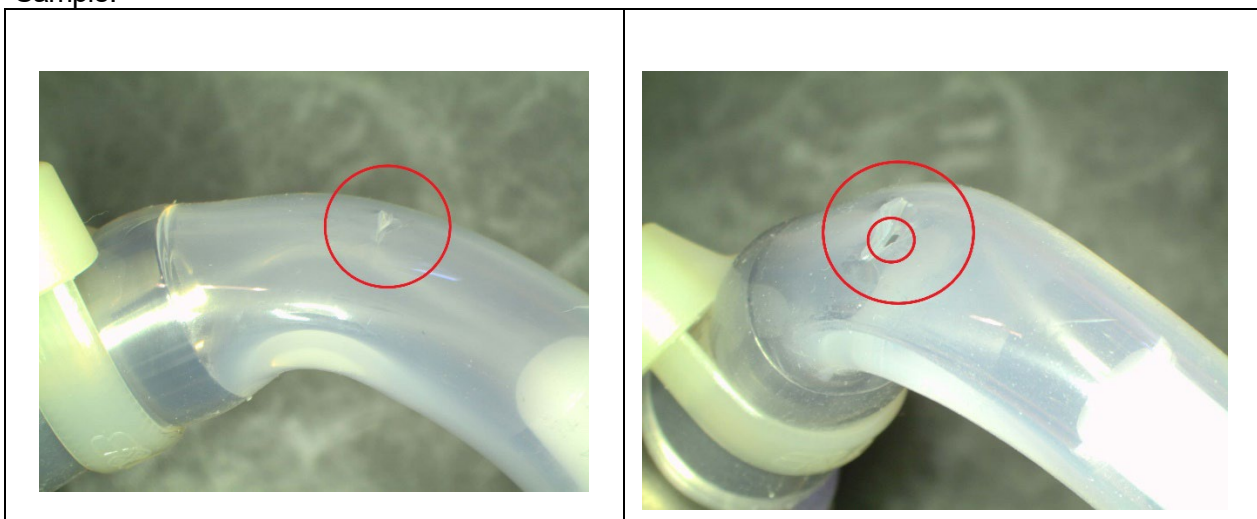
### Description and Identification of the Incidence:

Berlin Heart urges you to pay close attention to the integrity of the cannula and to situations in which incorrect use or improper handling of EXCOR cannulae may result in partial or complete breaches on the surface of the cannula.

It is imperative that if a breach occurs, the cannula should be trimmed per the directions provided in the Instructions for Use (EN: 1000477x06 Edition 6, chapter 16 "Identifying and Rectifying Errors Tab. 16-1 Possible error scenarios, Cannula damaged") by trained medical professionals.

While root cause investigations are still ongoing, it is important to recognize possible hazardous scenarios (described in attached appendix) and what actions should be completed immediately.

Sample:



(a) Damaged cannula surface

(b) split open the crack by kinking

### What Actions Berlin Heart is Asking You to Take:

1. **EXCOR cannulae should be inspected every four hours by a healthcare provider.** (As defined in our Instructions for Use in Chapter 14).  
In particular, care must be taken to observe whether any sign of a cannula breach is present. Special attention should be given to the titanium connector – cannula junction as this location is the most common site of a breach. Signs of cannula breaches are as follows:
  - a. Cuts, tears, or any compromise to the integrity of cannula
  - b. Discoloration
2. Special care should be taken to ensure proper placement of cable ties at the titanium-connector/ cannula junction, that the velour wrap leaves at least 5 cm (2 inches) of cannula exposed at the titanium-connector/ cannula junction and that the cannula does not come into contact with sharp objects. Please refer to the Appendix for images of proper placement of cable ties and velour wraps.
3. **The correction does not require removal of the device from use. Please note, that an exchange of your EXCOR components is not necessary unless the cannula is showing signs of breaching.**
4. Please complete the included response form acknowledging receipt and understanding of recall communication. Please return the response form to [vigilance@berlinheart.de](mailto:vigilance@berlinheart.de) within 7 days of receipt.

### What to Do if the Issue Occurs:

In the event of a cannula breach,

- **Immediately stop the support by disconnecting the driving tube from driving unit,**
- **clamp the cannula and**
- **trim the cannula proximal to the breached or damaged area.**
- **reconnect the cannula to the blood pump.**

The 24/7 Berlin Heart Hotline (+49 (0)30 8187 2772) is available for further questions and reporting of known cannula breaches.

**Dissemination of the information described here:**

Please ensure that all users of the EXCOR® VAD system and pertinent medical professionals in your institution are informed of this **Urgent Medical Device Correction Notification**.

If you have provided the products to any third parties, please forward a copy of this **Urgent Medical Device Correction Notification** or provide us with a list of the third party and we will provide them with a copy of the **Urgent Medical Device Correction Notification**.

Please retain this information until notified to the contrary and store it with the Instructions for Use.

Pertinent regulatory bodies have received a copy of this letter.

If you have any further questions regarding this **Urgent Medical Device Correction Notification** and the EXCOR® system, please contact our hotline at +49 (0)30 8187 2772.

All incidents of cannula breaches should be reported to Berlin Heart via the 24/7 hotline (+49 (0)30 8187 2772)

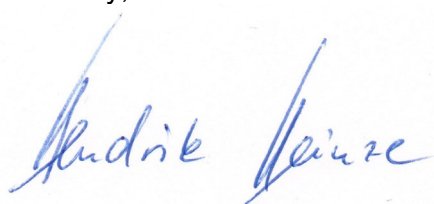
**Contact person for this Urgent Medical Device Correction Notification:**

Hendrik Heinze  
Director Quality and Regulatory Affairs  
Berlin Heart GmbH  
Wiesenweg 10  
12247 Berlin - Germany  
Tel.: +49 (0)30 8187 2772  
E-Mail: [vigilance@berlinheart.de](mailto:vigilance@berlinheart.de)

Please kindly confirm receipt of this document by signing and returning the attached response form by E-mail to [vigilance@berlinheart.de](mailto:vigilance@berlinheart.de).

Thank you for your attention to this matter. Berlin Heart is committed to providing high-quality products and partnering with you to ensure the safety of each patient.  
Please address any questions you may have via the 24/7 hotline (+49 (0)30 8187 2772).

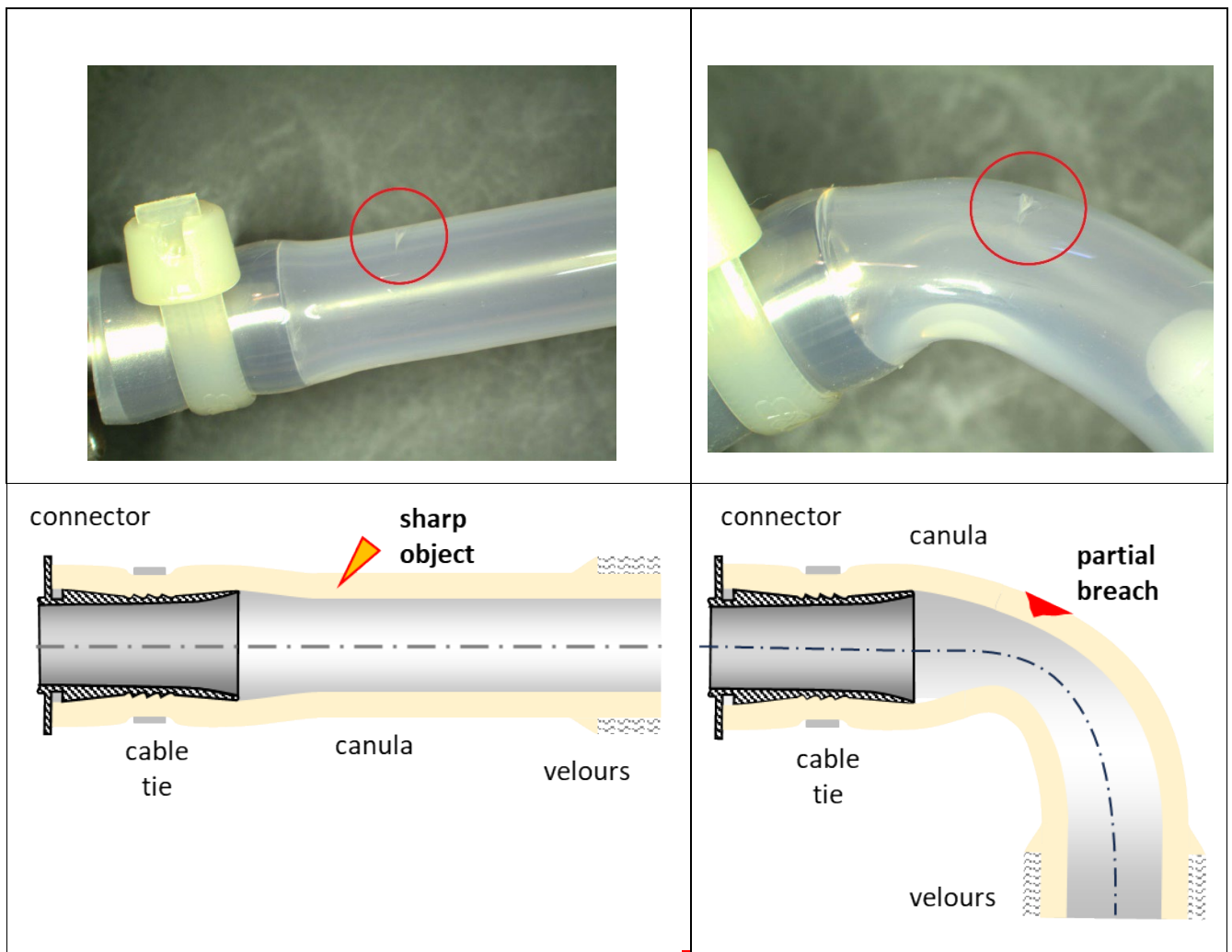
Sincerely,



Hendrik Heinze  
Director Quality and Regulatory Affairs  
Berlin Heart GmbH

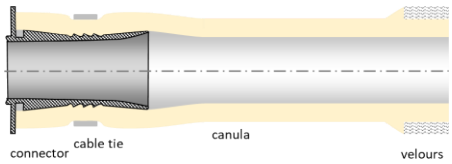
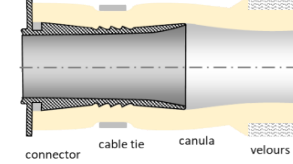


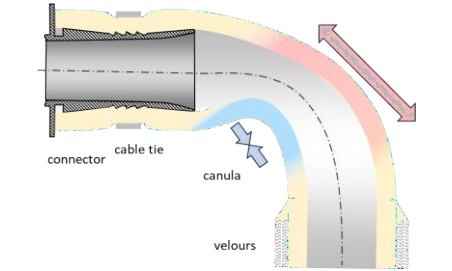
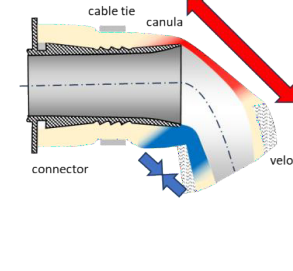


## Begin Appendix

### 1. Partial breach of canula surface by sharp objects

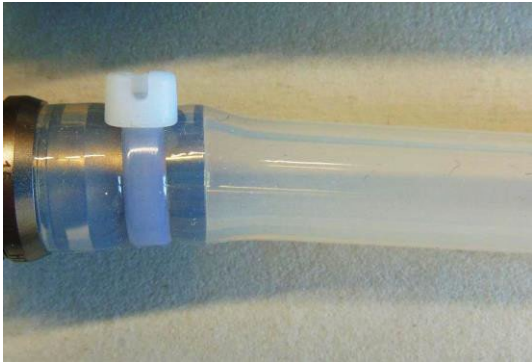
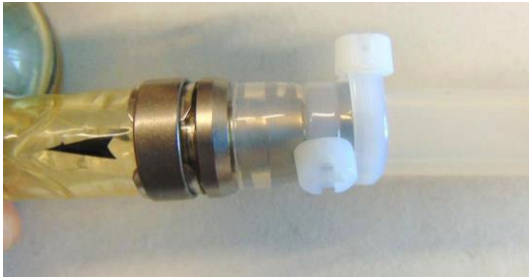



## 2. Distance between the connector and the velour of the cannula

If the distance between the connector and the velour of the cannula is too small, this may restrict the free movement of the cannula and cause damage to the material due to the force exerted during kinking.

| <b>Correct Length</b><br><b>(Minimum length of 5 cm)</b>  | <b>Incorrect Length</b><br><b>(Velour connected within less than 5 cm)</b>   |                          |
|---|--|--------------------------|
|  <p>connector cable tie canula velours</p>   |  <p>connector cable tie canula velours</p>   | <b>straight position</b> |
|   |   | <b>straight position</b> |
|  <p>connector cable tie canula velours</p> |  <p>connector cable tie canula velours</p> | <b>kinked position</b>   |
|    |    | <b>kinked position</b>   |

### 3. Position of cable ties

| Correct Position of Cable Tie  | Incorrect Position of Cable Tie   |
|--|---|
|  | <br> |



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 3, 7, 10, 14 and 16.

1. Do not use damaged or defective EXCOR components. Replace any damaged or defective EXCOR component immediately.
2. To avoid risk of damage to the EXCOR cannula, do not touch or manipulate the cannula with pointed or sharp-edged objects.
3. At least 5 cm (2 inches) of the cannula without the polyester velour covering must remain to avoid damage to the cannula stubs and to allow for visual inspection of the cannula/titanium-connector junctions.
4. Ensure that the cannula does not become kinked at titanium connector junction or anywhere along the cannula.
5. Visually inspect the cannula every four hours for any signs of kinking and/ or breaches (as defined in our Instructions for Use in Chapter 14).
6. When cleaning the exit sites, use chlorhexidine and avoid all use of acetone or petroleum products near the cannulas.
7. Advise treating clinicians, patients, and family members to avoid external forces being applied to the cannula. For example, any extreme bending or pulling of the cannula during play time or activities, avoid allowing patient to do “belly flops” or similar activities that could cause damage.



A table with the cannula subject to this letter is included below:

| <b>Apex cannulas</b>                    |                |           |
|---|----------------|-----------|
| Apex cannula for small children         | 5mm            | C14A-040  |
| Apex cannula for small children         | 5/6mm          | C14A-040m |
| Apex cannula for small children         | 6mm            | C18A-020  |
| Apex pediatric cannula                  | 9/12mm staged  | C22A-004  |
| Apex cannula                            | 12mm           | C27A-001  |
| <b>Atrial cannulas</b>                  |                |           |
| Atrial cannula for small children       | 5mm            | C15V-040  |
| Atrial cannula for small children       | 5/6mm          | C15V-040m |
| Atrial cannula for small children       | 6mm            | C19V-020  |
| Atrial cannula for small children       | 6mm            | C19V-020m |
| Atrial cannula (with mandrel)           | 12mm           | C22V-002  |
| Atrial cannula                          | 12mm           | C22V-002m |
| Atrial pediatric cannula (with mandrel) | 9/12mm staged  | C22V-004  |
| Atrial pediatric cannula (with mandrel) | 9/12mm staged  | C23V-004m |
| Atrial pediatric cannula (with mandrel) | 9/12mm staged  | C25V-004  |
| Atrial cannula (with mandrel)           | 12mm           | C26V-002  |
| Atrial cannula                          | 12mm           | C26V-002m |
| <b>Arterial cannulas</b>                |                |           |
| Arterial cannula for small children     | 5mm            | C80G-040  |
| Arterial cannula for small children     | 5/6mm          | C80G-040m |
| Arterial cannula for small children     | 6mm            | C80G-021  |
| Arterial cannula for small children     | 6mm            | C80G-021m |
| Arterial pediatric cannula              | 9/12mm staged  | C60G-004  |
| Arterial pediatric cannula              | 9/12mm staged  | C60G-004m |
| Arterial pediatric cannula              | 9/12mm staged  | C85G-004  |
| Arterial pediatric cannula              | 9/12mm staged  | C85G-004m |
| Arterial cannula                        | 12mm           | C60G-002  |
| Arterial cannula                        | 12mm           | C60G-002m |
| Arterial cannula                        | 12mm           | C85G-002  |
| Arterial cannula                        | 12mm           | C85G-002m |
| <b>Connector sets</b>                   |                |           |
| Connecting set                          | ø 6 to ø 9 mm  | A06-009   |
| Connecting set                          | ø 9 to ø 12 mm | A09-012   |

## Acknowledgement Form

Urgent Medical Device Correction Notification  
concerning  
EXCOR® Cannulae.

Please complete all requested information and return to:

Berlin Heart GmbH  
Wiesenweg 10  
12247 Berlin - Germany  
Fax.: +49 (0)30 8187 2601  
E-Mail: [vigilance@berlinheart.de](mailto:vigilance@berlinheart.de)

**Please sign and return this form as soon as possible.**

- ✓ I understand that increased attention is necessary by the regular observation of the cannula. In particular, care must be taken to observe whether any defect on the surface of the cannula is visible. If there is a suspicion of a cannula defect, the 24/7 hotline **(+49 (0)30 8187 2772)** of Berlin Heart should be informed immediately.
- ✓ I understand the risk information that Berlin Heart has provided in this notice.
- ✓ I acknowledge receipt of this Urgent Medical Device Notification, number DS-23-01, concerning a medical device product from Berlin Heart (dated 2023-08-08), namely the EXCOR® Cannulas.
- ✓ I further confirm that I have completely understood the contents and have forwarded the information to the responsible personnel.

- 
- ☐ (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: \_\_\_\_\_