Urgent Medical Device Correction Notification

concerning

EXCOR® Cannulae

Date: 2023-08-04

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 01-01-2019 to 03-07-2023, 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.

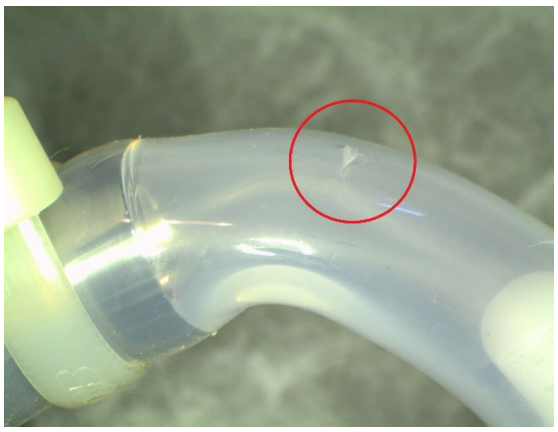
Description and Identification of the Incidence:

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.

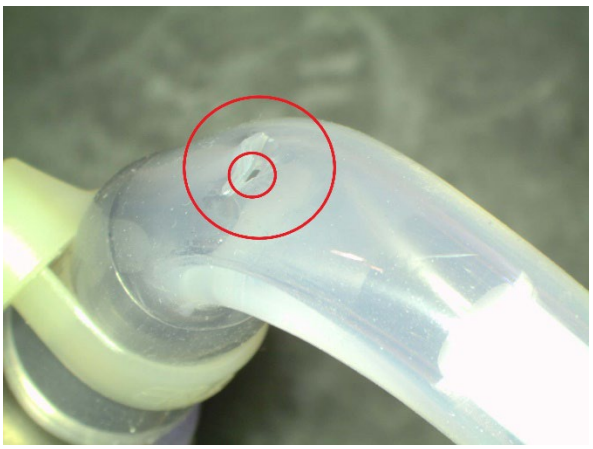
It is imperative that if a breach occurs, the cannula should be trimmed per the directions provided in the Instructions for Use (1000721x18 Revision 15, chapter 16 trouble shooting and correcting faults page 169 cannula rupture) by trained medical professionals.

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. 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 info@berlinheartinc.com 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 (888-826-9466) 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 888-826-9466.

All incidents of cannula breaches should be reported to Berlin Heart via the 24/7 hotline (888-826-9466)

Adverse reactions or quality problems experienced with this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form from www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 >

Contact person for this Urgent Medical Device Correction Notification:

Robert Kroslowitz

Berlin Heart Inc.
9391 Grogan's Mill Road, Suite A-6; The Woodlands, TX 77380, USA

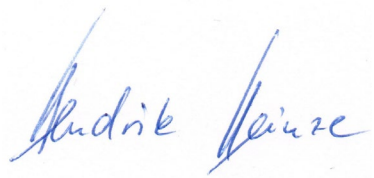
Tel.: 1-281-863-9700
Fax: 1-281-863-9701
E-Mail: info@berlinheartinc.com

Please kindly confirm receipt of this document by signing and returning the attached response form by E-mail to info@berlinheartinc.com.

Berlin Heart has notified and is working with FDA on this issue.

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 in the US with Berlin Heart via the 24/7 hotline (888-826-9466).

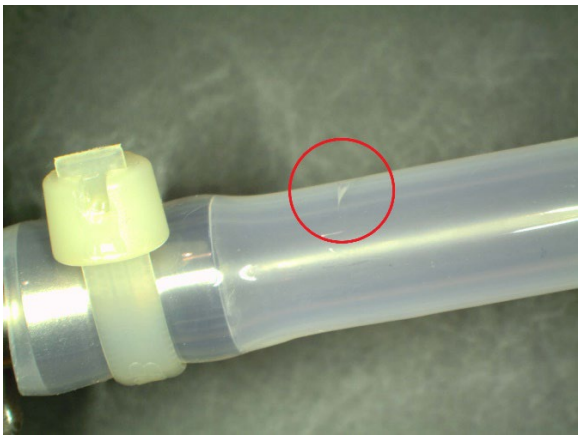
Sincerely,

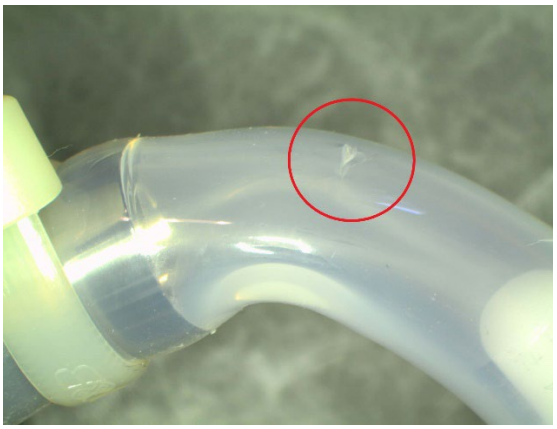


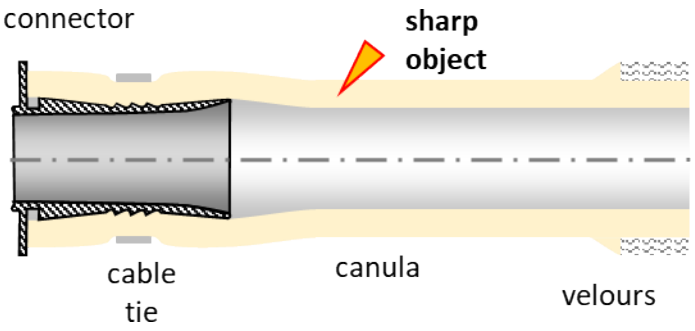
Hendrik Heinze
Director Quality and Regulatory Affairs
Berlin Heart GmbH

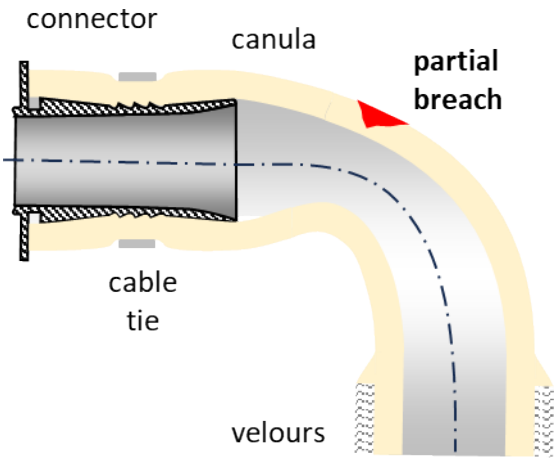
Begin Appendix

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



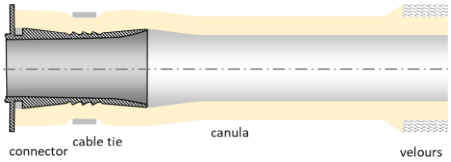
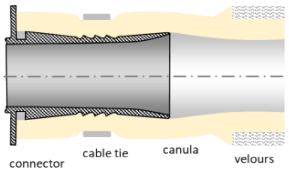
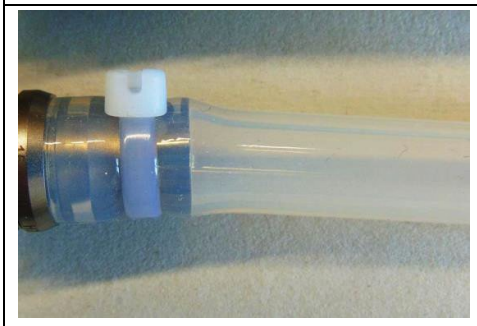
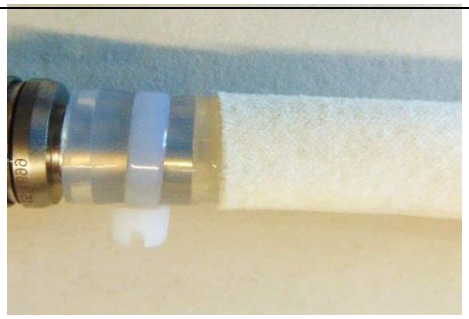
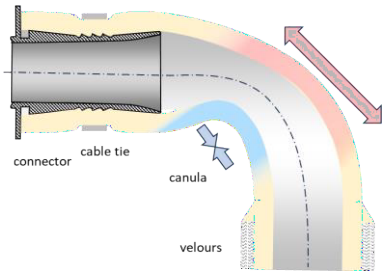
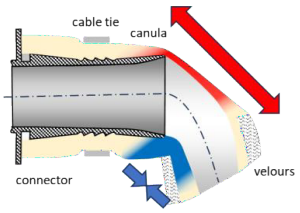
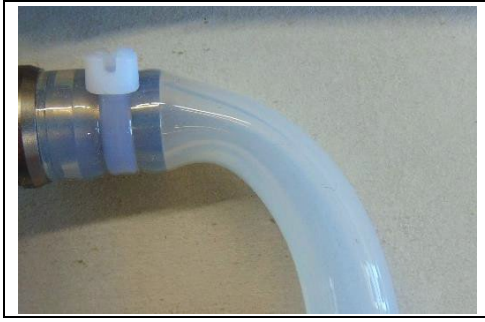
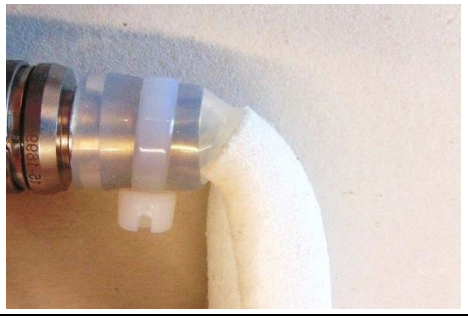




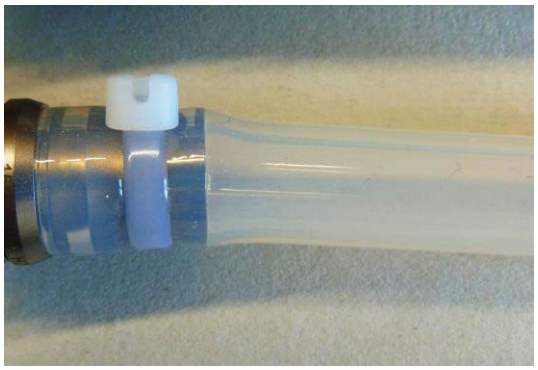
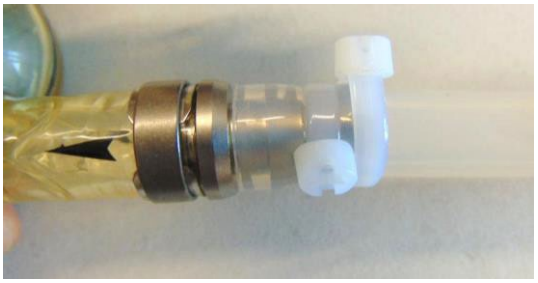


2. Distance between the connector and the velour of the cannula

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. See page 39 and page 40 of the Instruction for Use.

Correct Length (Minimum length of 5 cm)	Incorrect Length (Velour connected within less than 5 cm)	
		**straight**
		**straight**
		**kinked**
		**kinked**

3. Position of cable ties

Correct Position of Cable Tie	Incorrect Position of Cable Tie
	
	

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 6, 10, 12 and 16, starting on page 13.

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.
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:

Apex cannulas		
Apex cannula for small children	5/6 mm	C14A-040m
Apex cannula for small children	6mm	C18A-020
Apex pediatric cannula	9/12mm staged	C22A-004
Apex cannula	12mm	C27A-001
Atrial cannulas		
Atrial cannula for small children	5/6mm	C15V-040m
Atrial cannula for small children	6mm	C19V-020(m)
Atrial pediatric cannula (with mandrel)	9/12mm staged	C23V-004m
Atrial pediatric cannula (with mandrel)	9/12mm staged	C22V-004
Atrial pediatric cannula (with mandrel)	9/12mm staged	C25V-004
Atrial cannula (with mandrel)	12mm	C22V-002(m)
Atrial cannula (with mandrin)	12mm	C26V-002(m)
Arterial cannulas		
Arterial cannula for small children	5/6mm	C80G-040m
Arterial cannula for small children	6mm	C80G-021(m)
Arterial pediatric cannula	9/12mm staged	C60G-004(m)
Arterial pediatric cannula	9/12mm staged	C85G-004(m)
Arterial cannula	12mm	C60G-002(m)
Arterial cannula	12mm	C85G-002(m)
Connector sets		
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 Inc.
Regulatory Affairs
Fax: 1-281-863-9701 or
info@berlinheartinc.com

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 **(888-826-9466)** 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 25.07.2023), 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 _____