

Urgent Safety Information DS-14-01

EXCOR® Blood pumps

Safety Information

Date: 04/28/2014

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

Addressee: Users and distributors of the EXCOR® VAD system in the countries Germany, Greece and Switzerland.

Identification of the affected medical product:

Product	EXCOR® Blood pump
Product group	EXCOR® VAD System

Description of problem:

Berlin Heart has become aware of repeated cases in Germany, Greece and Switzerland in which a defect of one layer of the triple layer membrane of the product EXCOR® blood pump has occurred caused by external forces.

The EXCOR® blood pump is designed with a triple layer membrane separating the air chamber from the blood chamber for safety reasons to prevent damage to the patient by blood loss or air embolism should one of the membrane layers become compromised. The entire membrane consists of an air-side layer, a middle layer and a blood-side layer. In case of disruption in one layer of the triple layer membrane, there are two more layers that will maintain the integrity of the air and the blood chamber. The triple layer membrane of the EXCOR® blood pump is held in place by means of a stabilization ring.

This stabilization ring can be moved out of its appropriate position if the blood pump is exposed to excessive external forces such as pressing or squeezing on the pump housing and deforming its shape. Berlin Heart has become aware of repeated cases in Germany, Greece and Switzerland in which EXCOR blood pumps were exposed to external forces that may have contributed to dislodgement of the stabilization ring from the appropriate position. The dislodgement of the stabilization ring by external forces during operation in these cases resulted in a defect of one layer of the triple layer membrane of the blood pump.

In the product labeling (Instructions for Use) the user is expressly instructed to ensure that the blood pumps are not exposed to any external force such as pressure, tension or torsion (see important safety instructions on page 6 of the IFU Version 5.0 on EXCOR® VAD Ventricular Assist Device with Stationary Driving Unit IkuS Version 2.1).

These events occurred despite the warnings in the product labeling and professional training of the user by the Clinical Affairs department of Berlin Heart.

In these cases, the stabilization ring was temporarily pressed out of its frame by external forces during pump operation resulting in an asymmetrical load on the membrane which led to a defect only in one layer of the triple-layer membrane.

As designed, both of the other membrane layers remained intact and maintained the integrity of the air and blood chamber, so that there was neither permanent interruption of patient support nor irreversible damage to the patient. The defect in the single membrane layer resulted in reduced pumping function that was successfully remedied by a prompt exchange of the EXCOR® blood pump.

The frequent occurrence of membrane defects caused by external forces in the countries named, have led Berlin Heart to provide the end users in the affected countries with this urgent safety information about the danger of exposing the EXCOR® blood pumps to excessive external forces resulting in membrane defect.

Action to be taken immediately:

1. Retraining all users of EXCOR® VAD System of the intended handling of the product regarding the prevention of external force on the EXCOR® blood pumps.
2. Patients have to be especially trained that in the everyday handling of the device no excessive external forces, such as pressure, tension or torsion are applied to the EXCOR® blood pumps.
3. Furthermore patients have to be instructed that no forces, such as pressure, tension or torsion are applied to the EXCOR® blood pumps via the driveline.

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 a copy of this document for your records and future reference.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Germany, Swissmedic Schweizerisches Heilmittelinstitut and the National Organization for Medicines, Greece, have received a copy of this "Urgent Safety Information".

Should you have further questions on this urgent safety information and the EXCOR® VAD system, please contact the **Hotline** of 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

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



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