



رقم المحفوظات: ٣٧/٩٥
رقم الصادر: ٢٠١٢/٤/١٣٤٦٤
بيروت، في: ٢٤ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Vascular cannula and catheters, EXCOR arterial cannula with graft CGR-021
Trade Mark: Berlin Heart AG
Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خطأ في تصنيع الجهاز المذكور أعلاه مما يؤدي الى مضاعفات على المريض ، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع ✓
- مصلحة الهندسة الصحية
- المحفوظات



وثيقة معتمدة للأصدر
بيروت في ٢٧ آب ٢٠١٢
رئيس قسم امانة السر
عناية غصن

Urgent Safety Information DS-12-01

Recall

Regarding

EXCOR® arterial cannula with graft CGRG-021

Date: 26 July 2012

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

Addressee: All users and distributors of the EXCOR® arterial cannula with graft CGRG-021

Identification of the affected medical product:

Product	EXCOR® arterial cannula with graft CGRG-021
Product group	EXCOR® VAD System
Affected Lot-No.	all

Problem description:

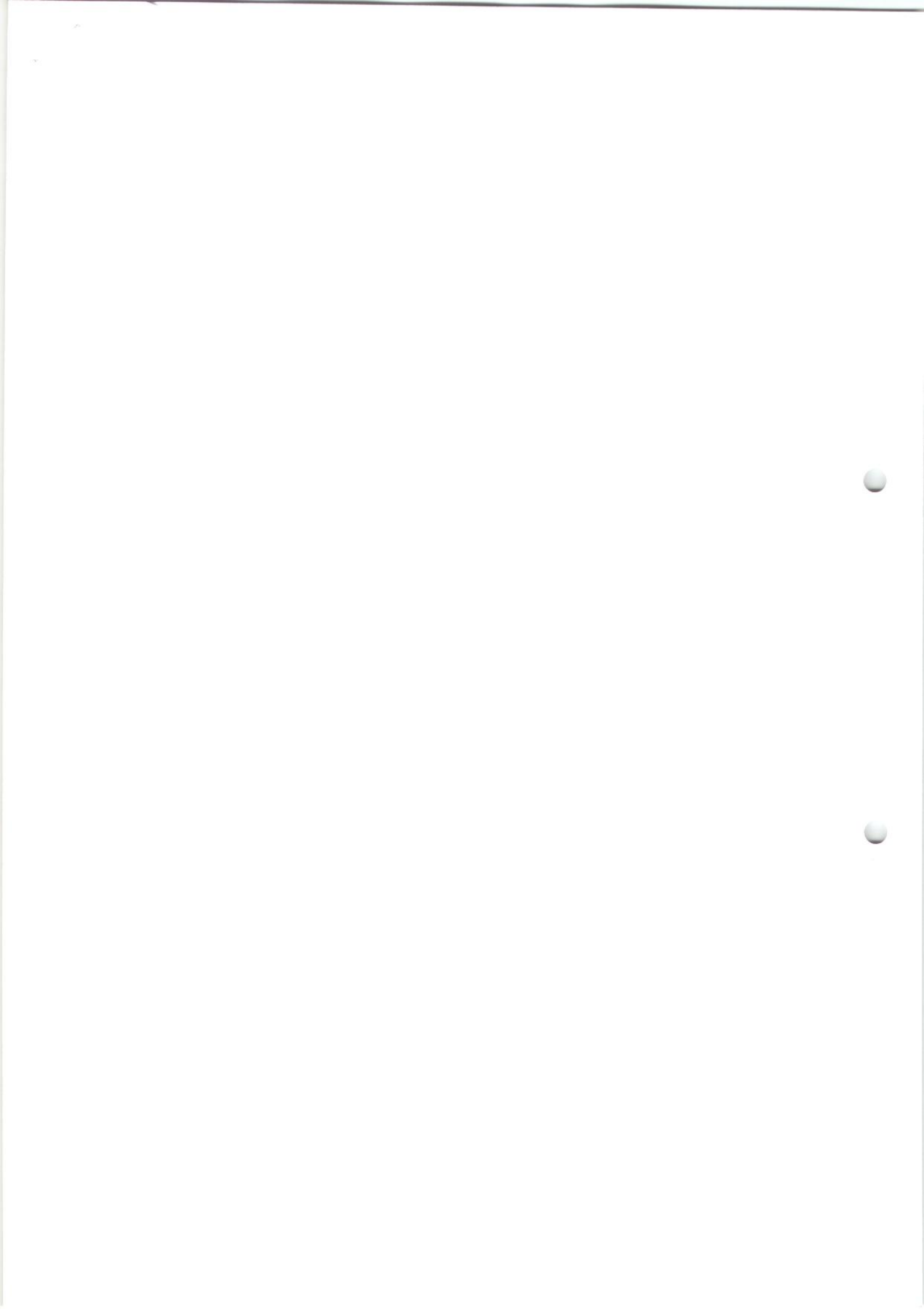
During the period from October 2011 to July 2012, the EXCOR® arterial cannula with graft CGRG-021 (6 mm graft arterial cannula) was subject to a limited market launch with product monitoring. While evaluating the clinical data, Berlin Heart received an increasing number of cases in which, according to customer feedback, seroma and bleeding in the region of the graft material occurred. An analysis of the cause is in process.

There is the risk that for patients who are provided with the EXCOR® arterial cannula with graft CGRG-021 could experience seroma and bleeding, and as a result may require re-operation with a cannula exchange in individual cases.

On the basis of this information the company Berlin Heart has decided to recall the EXCOR® arterial cannula with graft CGRG-021 from the market. All other arterial cannulae from the product range continue to be available without limitation and can be used for implantations.

Immediately required corrective measures:

1. Until further notice an implantation of the EXCOR® arterial cannula with graft CGRG-021 may not take place.
2. Patients who are provided with the current EXCOR® arterial cannula with graft CGRG-021 should be intensively monitored regarding seroma and bleeding. Should these symptoms be determined, please contact the Berlin Heart GmbH **Hotline** in order to determine coordinated corrective measures for the individual case, **+49 (0)30 8187-2772**



3. All EXCOR® arterial cannula with graft CGRG-021 that are not yet implanted will be withdrawn by Berlin Heart. We request return without delay.

Dissemination of the information described here:

Please ensure that in your organisation, all users of the products named above and others to be informed, obtain knowledge of this **Urgent Safety Information**. Insofar as you have given the products to third parties, please forward a copy of this information or inform the contact person given below.

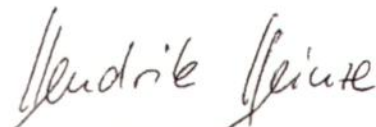
Please keep this information until the corrective measures have been concluded.

The national Competent Authority has received a copy of this Urgent Safety Information.

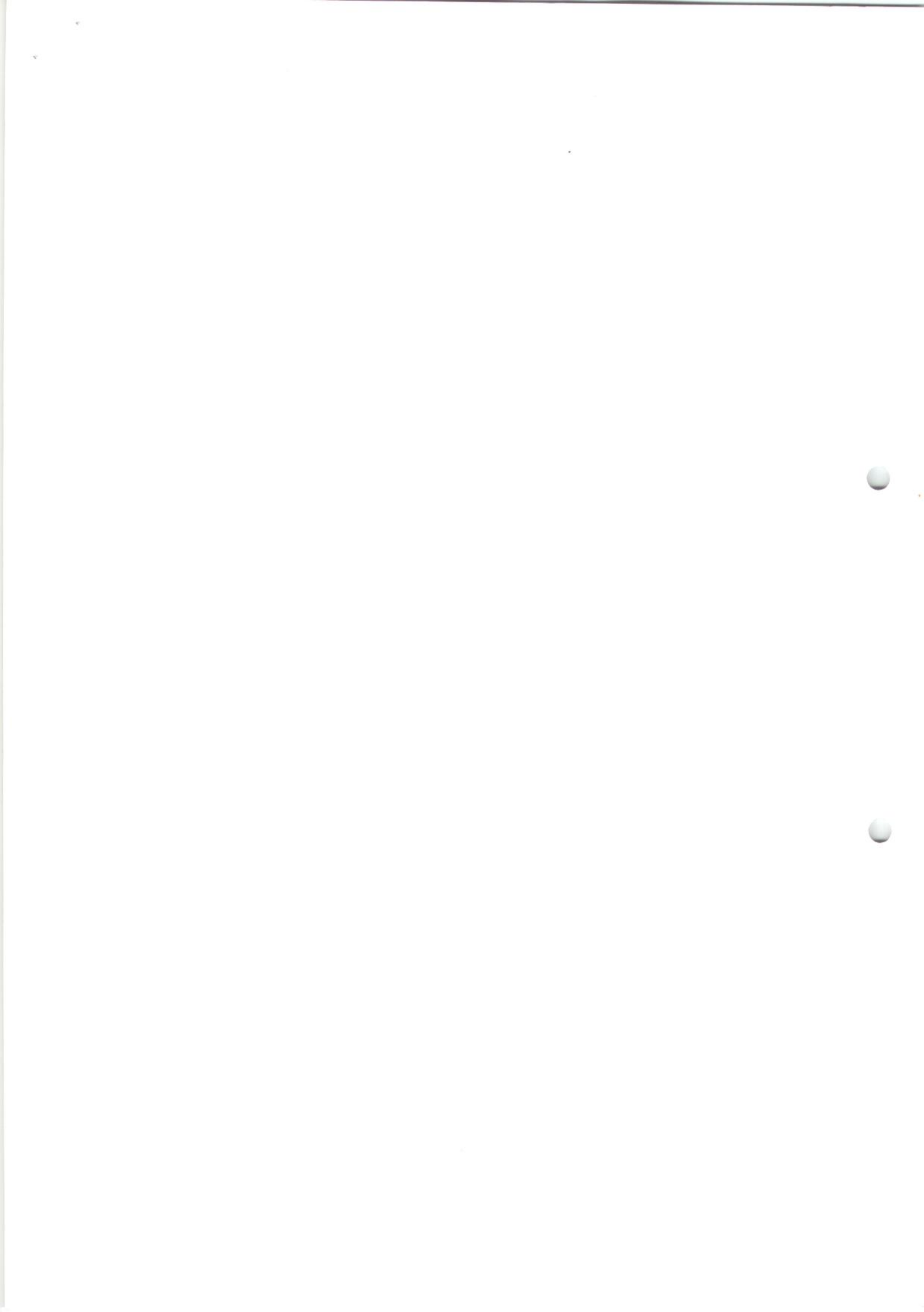
Contact person:

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

Please confirm that you have received this document on the form attached.



i.A. Hendrik Heinze
Management Representative,
Safety Officer of Berlin Heart GmbH



Confirmation Form

EXCOR® arterial cannula with graft CGRG-021

Please fill out this form completely and return promptly to:

<p style="text-align: center;">Berlin Heart GmbH Regulatory Affairs Fax: +49-(0)30 8187 22 2625 or vigilance@berlinheart.de</p>

Please mark all of the following fields before you return this form.

- I have understood that in connection with the use of EXCOR® arterial cannula with graft CGRG-021 bleeding and seroma can occur.
- I am aware of the risk information which is given in this communication from Berlin Heart.
- I confirm the receipt of the urgent safety information DS-12-01 for a medical product from Berlin Heart (Dated 26. July, 2012) concerning EXCOR® arterial cannula with graft CGRG-021. I further confirm that I have completely understood the content and have forwarded it to the responsible personnel.

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

Name (Printed):

Signature:

Name of the hospital/
medical facility:

Date:

Telephone number:

E-Mail

