

P. J. Dahlhausen & Co. GmbH - Postfach 56 01 32 - 50986 Köln

P. J. Dahlhausen & Co. GmbH
Alles Gute fürs Krankenhaus

Emil-Hoffmann-Straße 53
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Fax: +49 (0) 2236 3913 - 109
info@dahlhausen.de
www.dahlhausen.de

Cologne, 5th July 2018

Important Safety Notice

Product: Trocar catheter, REF: 02.000.30.028, Lot 13.12.2017

Dear Sirs,

We herewith would like to inform you about an important safety information with regard to our trocar catheter, REF 02.000.30.028, Lot 13.12.2017.

You will find the supplied quantity of this affected Lot in the attached response form.

Description of the problem

The trocar catheters are designated for the draining of blood, secretion and air from the pleura gap. For the execution of the draining the catheters have lateral eyes.

In response to a feedback from the field it was discovered that trocar catheters of the mentioned LOT with missing lateral eyes had been applied by a user.

If trocar catheters with missing lateral eyes are applied, there is a risk of a tension pneumothorax as well as pleural effusions. Furthermore it is necessary to apply a new trocar catheter.

We kindly ask you to undertake the following action due to this safety notice:

1. Please control your existing stock of trocar catheters of this LOT at your facility. Stop the application and distribution of these products and separate them.

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2. Please fill in the attached response form and send it to the indicated Fax number or E-Mail address until 20th July 2018 latest:
 - a) If these catheters are still in your facility please tick off the corresponding field in our response form and advise us the quantity.
 - b) If you do not have any catheters in your facility and have applied them without any objection please tick off the corresponding field in our response form.
3. If these catheters are still in your facility we kindly ask you to return them at our expense. You will receive a replacement right upon receipt of the returned products.

Communication of the herewith described information

Please make sure within your organization that all users of this trocar catheter and any other persons requiring this information receive this important safety notice. In case of having submitted/sold this trocar catheter to a third party kindly forward a copy of this safety notice.

Please keep this information until this action is closed.

The Federal Institute for Drugs and Medical Devices and the responsible authority in your country have received a copy of this important safety information.

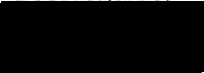
Should you have questions concerning this safety notice, please contact the below mentioned contact persons:

Petra Hardt
Manager QA/RA
Tel.: +49 2236 3913171
Fax: +49 2236-3913179
Email: petra.hardt@dahlhausen.de

Margit Stöckmann
Assistant QA/QA
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Fax: + 49 2236-3913179
Email: margit.stoeckmann@dahlhausen.de

We would like to apologize for any inconveniences caused by this issue and assure you that safety and quality are our first and foremost priorities. Thank you very much in advance for your support.

Best regards,


Petra Hardt
Manager QA/RA

Enclosure
Response form
Delivery note

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Commerzbank AG
IBAN: DE93 3708 0040 0980 8905 00
BIC: DRESDEFF370

Deutsche Bank AG
IBAN: DE07 3707 0060 0160 0196 00
BIC: DEUTDE33

Sparkasse KölnBonn
IBAN: DE94 3705 0198 0052 2029 59
BIC: COLSDE33

Geschäftsführer:
Ulrich Dahlhausen,
Gerhard Linnemann
Amtsgericht Köln: HRB 16846
ID-Nr.: DE 811177952

Customer No:

Response

Safety notice on Trocar Catheter - REF 02.000.30.028, 13.12.2017

Please return via **FAX (02236/3913-179)** or by **e-mail**
(m.stoeckmann@dahlhausen.de) **until 20th July 2018** latest

Trocarcatheter REF 02.000.30.028	Total quantity: pcs.
<input type="checkbox"/> The below indicated quantity of the corresponding Lot of the Trocar Catheter is still available and will be blocked for sales immediately. We assure that they will not be applied at any patient anymore: Quantity _____	
<input type="checkbox"/> The above indicated Trocar Catheters are not stocked anymore and have been used without any complaint.	
Contact	
	Email _____
Contact Person (in block letters)	Tel. _____
Place, Date _____	Signature/Stamp _____