

Safety Notice

Technical Bulletin No. 015



GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstraße 26
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Fax +49 8191 65722-22
info@corpuls.com
www.corpuls.com

No. 015	Target audience Affected users	Date 2015-02-18 ¹	Number of pages 8
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Affected products

04325.2 corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips
05120.2 corPatch easy Pediatric

Serial numbers / Lot identification

see the Recall Letter of the company Leonhard Lang (Innsbruck/Austria)

Dear sir or madam,

with this letter we would like to inform you about the extension of the recall (our Safety Notice Technical Bulletin No. 014). Affected are further production charges of the manufacturer Leonhard Lang GmbH pertaining to defibrillation electrodes of the following types:

- **04324.2 corPatch easy (Neonates) - defibrillation/pacing electrodes with cable (hard shell) [DF60]²**
Lots affected: **No further lots affected**
- **04325.2 corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips [DF 61]²**
Lots affected: **30822-0779, 31219-0776, 40507-0773**
- **05120.2 corPatch easy Pediatric [DF 68]²**
Lots affected: **30708-0777, 30822-0778, 31009-0773, 31121-0774, 40107-0771, 40213-0774, 40222-0773, 40320-0770, 40321-0770, 40324-0773, 40522-0779, 40704-0776, 40808-0773, 40923-0776, 41021-0778**

Internal investigations of the manufacturer **Leonhard Lang GmbH** have yielded results that make it necessary to reduce the shelf life of those electrodes to 18 months.

The electrodes are being used in connection with the defibrillators **corpuls 08/16, corpuls¹** and **corpuls³**.

According to the company Leonhard Lang GmbH, other defibrillation electrodes manufactured for the **corpuls[®]** defibrillators are not affected by this problem.

According to our records, your organization has purchased at least one of the affected electrodes.

Please do read the attached safety information of the manufacturer Leonhard Lang GmbH attentively and send back the filled-in confirmation form attached in Annex B (both pages) by 2015-03-20 at the latest.

The responsible supervisory authorities of the involved countries will be informed about this FSCA (Field Safety Corrective Action) directly by Leonhard Lang GmbH. Affected distributors and customers of GS Elektromedizinische Geräte G. Stemple GmbH will be informed by this letter.

¹ Date format: YYYY-MM-DD

² [DF XX]: Reference number of Leonhard Lang GmbH

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1. Error description

- See attached Safety Notice by Leonhard Lang GmbH.

2. Prerequisite for the Occurrence of the Error

- See attached Safety Notice by Leonhard Lang GmbH.

3. Potential Risk

- See attached Safety Notice by Leonhard Lang GmbH.

4. Safety information

- See attached Safety Notice by Leonhard Lang GmbH.

5. Troubleshooting for defective electrodes

- See attached Safety Notice by Leonhard Lang GmbH.

6. Immediate Measures

Please ensure within your organization that all users of the above mentioned products and all other persons who need to know are informed about the **Urgent Safety Notice of the Leonhard Lang GmbH.**

If you have supplied the products to third parties, please forward a copy of this safety information to them and also inform the below mentioned contact person.

Please keep this information at least until the corrective measures have been completed.

According to the manufacturer of the electrodes the following interim solution could be applied:

“If no pediatric defibrillation electrodes are available, standard adult electrodes may be used for defibrillation of patients <25kg.”

Attention:

Please make sure the correct energy level for pediatric defibrillation is selected, as the automatic reduction/limitation to 100 J is not coded in adult electrodes.

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7. Corrective Measures of the Manufacturer

Recall:

The electrodes

- 04325.2 **corPatch** clip (Neonates) - defibrillation/pacing electrodes for 3M clips [DF 61]²
Lots affected: **30822-0779, 31219-0776, 40507-0773**
- 05120.2 **corPatch** easy Pediatric [DF 68]²
Lots affected: **30708-0777, 30822-0778, 31009-0773, 31121-0774, 40107-0771, 40213-0774, 40222-0773, 40320-0770, 40321-0770, 40324-0773, 40522-0779, 40704-0776, 40808-0773, 40923-0776, 41021-0778**

must no longer be used.

For detailed information see the attached Safety Notice by Leonhard Lang GmbH.

As of 2015-02-24 the authorised sales and service partners of the company GS Elektromedizinische Geräte G. Stemple GmbH will be able to supply a sufficient quantity of electrodes to ensure the operation of your devices in the field.

Please notify your sales and service partners about the quantity you need.

In order to complete this FSCA successfully, it is necessary for you to return all the not-used electrodes to your sales and service partner as soon as you have received a sufficient quantity of replacement electrodes.

Alternatively, you may confirm in writing that you have disposed of those electrodes. Please use for this option the corresponding remark on the confirmation form Annex B (both pages).

The delivery of replacement electrodes will correspond to the amount indicated in the Annex.

The Federal Institute for Drugs and Medical Products („Das Bundesinstitut für Arzneimittel und Medizinprodukte“) has received a copy of this safety information.

Also, all affected national authorities will directly be informed by the manufacturer of the electrodes (Leonhard Lang GmbH).

8. Deadline

Briefing the users should be effected immediately by appropriate measures (e.g. via e-mail or by posting this letter at the bulletin board and depositing a copy with the user manual).

Please return the filled-in confirmation form (Annex B - both pages) to GS by 2015-03-20 at the latest.

The exchange will be carried out as soon as possible after the return of the filled-in confirmation form. By 2015-05-20 at the latest, the replacement of all electrodes from the lots affected by this recall will have taken place.

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9. Contact person at GS Elektromedizinische Geräte GmbH for technical questions:

Carsten Fuchs,
Vice President, Customer Support
Head of Customer Service

Tel.: +49 (0) 81 91 6 57 22 30
Fax: +49 (0) 81 91 6 57 22 22
E-Mail: md-vigilance@corpuls.com

We thank you for understanding and apologise for any inconvenience you may have in connection with this corrective action. Questions concerning this matter will be answered by your national sales and service partner (see also Annex C or www.corpuls.com).

Sincerely,

GS Elektromedizinische Geräte G. Stemple GmbH

Dipl.-Ing. Klaus Stemple
CEO/CTO

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Annex A

List of product numbers affected:

04325.2 corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips

Picture of product and package:

Position of the lot nu



Lots affected:

30822-0779, 31219-0776, 40507-0773

05120.2 corPatch easy Pediatric

Picture of product and package:

Position of the lot nu



Lots affected:

30708-0777, 30822-0778, 31009-0773, 31121-0774, 40107-0771, 40213-0774, 40222-0773, 40320-0770, 40321-0770, 40324-0773, 40522-0779, 40704-0776, 40808-0773, 40923-0776, 41021-0778

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GS Elektromed. Geräte
G. Stemple GmbH
Hauswiesenstr. 26
D-86916 Kaufering

Managing Board:
G. Stemple, K. Stemple, Dr. C. Klimmer, I. Klimmer
Registergericht: Augsburg HRB 3373
USt-Id.: DE 128 668 535

Bankverbindung:
IBAN DE20 7009 3200 0008 6801 24
BIC GENODEF1STH



Annex B (page 1)

Confirmation form

Please mark with a cross ALL fields that apply to your company:

- We have read and understood the safety information of Leonhard Lang GmbH of 2015-02-18.
- We have informed our users in an appropriate way about the contents of this safety information and the amendment to the user manual.
- The affected electrodes indicated in Annex B have been taken out of commission and have been replaced by other lots. The affected electrodes will be marked and retained.

Please indicate the amount pertaining to the affected lot number:

05120.2 corPatch easy Pediatric		
Lot numbers	Quantity	Remarks
30708-0777		
30822-0778		
31009-0773		
31121-0774		
40107-0771		
40213-0774		
40222-0773		
40320-0770		
40321-0770		
40324-0773		
40522-0779		
40704-0776		
40808-0773		
40923-0776		
41021-0778		

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Annex B (page 2)

04325.2 corPatch clip (Neonates) - defibrillation/pacing electrodes for 3M clips		
Lot numbers	Quantity	Remarks
30822-0779		
31219-0776		
40507-0773		

The affected electrodes indicated in Annex B have been taken out of commission and will be retained.

- We declare under our sole responsibility that the affected lots will not be used on patients and will be destroyed. (Only these amounts will be replaced free of charge).**

To be filled in by the customer (please print):

Organisation: _____

Address: _____

Location: _____

Country: _____

Name: _____

First name: _____

Mr/Ms/Title: _____

Fax: _____

Phone: _____

Company stamp: _____

E-Mail address: _____

Date/Signature: _____

Please return **both pages** of this confirmation form by 2015-03-20 at the latest to:

GS Elektromedizinische Geräte G. Stemple GmbH, Hauswiesenstrasse 26, D-86916 Kaufering
Fax: + 49 8191 65722 - 22

Or scanned as PDF attachment to:
md-vigilance@corpuls.com

← Also include page 6 ←

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Annex C

Authorised **corpuls**[®] sales and service partners

Germany

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Hauswiesenstraße 26
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phone: +49 8191 65722-0
fax: +49 8191 65722-22
e-mail: info@corpuls.com

Your local authorized **corpuls**[®] sales and service partner:

Please consult our homepage for international authorized sales and service addresses:

www.corpuls.com

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