

Addressee:

Sender:

Leonhard Lang GmbH
Archenweg 56

6020 Innsbruck
Austria

Innsbruck, December 18, 2019

URGENT FIELD SAFETY NOTICE

Reference: RKL-4453 / VGL-15814

Reference authority: BASG Bundesamt für Sicherheit im Gesundheitswesen,
Traisengasse 5, 1200 Wien, Austria

Trade name of the product: corPatch easy

Type of measure: Sorting and destruction of affected electrodes

Target group addressed: Dealers and users

Ladies and Gentlemen,

With this letter we would like to inform you about the recall of defibrillation electrodes concerning the article mentioned below:

Trade name of the product:	corPatch easy
REF:	04324.3
Lot number:	190711-3993

Please read this letter carefully and follow the steps in section 2 of this letter.

1. Description of Fault

Summary: In the course of an investigation triggered by a complaint, it was discovered that there is a possible contact problem between electrode and ring terminal in the mentioned lot number. The contact between electrode and defibrillator may be interrupted or partially interrupted.

Identification of the Affected Product

Electrodes with REF **04324.3** and LOT **190711-3993** are affected.

Example: affected electrodes (imprint case)



Electrodes with the same REF but different LOT number **are not affected**.

Potential risk: There is a potential risk that no signals or energy will be transmitted. This can result in failure to treat a patient in a life-threatening condition requiring a defibrillation shock on time.

Condition for occurrence of the error: Use of defibrillation electrodes with REF 04324.3 and the lot number 190711-3993 with a compatible defibrillator.

Safety information: With this letter, Leonhard Lang informs you of the fact that this field safety notice (short: FSN) will also be forwarded to the competent authorities. Please note that under existing legislation (Medical Device Regulation) you are obliged to comply with the requirements of this recall action.

2. Process for the Recall

a.) Please read this FSN carefully. If you have any questions or are unable to implement the required measures, please instantly contact the organization that provided you with this FSN.

b.) Please ensure in your organization that all users and other persons concerned are aware of this urgent FSN.

c.) If you should have affected electrodes **in storage**, ensure that they are not sold or passed on. Sort out the electrodes and **destroy** them immediately.

If you should have affected electrodes **in use**, ensure that you have at least one spare pair in reserve, if possible, until the electrodes have been replaced.

If you have **sold** the affected electrodes or **passed** them on **to third parties**, please forward this FSN to these customers immediately.

d.) Please fill out the Recall response form attached and return your response form to the organization that sent you this FSN by **March 31, 2020** at the latest.

Please note: If the feedback from your customers is not complete, you are obliged to take active measures to ensure that you receive the outstanding data.

3. Replacement Electrodes

After you have forwarded the Recall response form to the organization that sent you this safety information, you will receive replacement electrodes, with the same REF 04324.3, but with a different lot number. Replace them immediately and destroy the replaced electrodes.

If you have resold or passed on electrodes, you are asked to provide your customers with replacement electrodes.

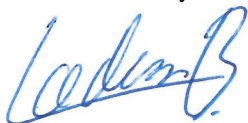
We apologize very much for the inconvenience caused. In order for patients and users to be able to use our products safely, however, it is absolutely essential that these measures are carried out immediately.

We assure you that safety and quality are our top priority, and that we take this incident as an opportunity to improve our procedures in order to prevent this kind of deviation in the future.
If you have any questions, please do not hesitate to contact us under:

rc4453dr@leonhardlang.at

Yours sincerely,

Bernhard Ladner
Head of Quality Management



Annex:

- Recall response form

RECALL RESPONSE FORM

Reference: RKL-4453 / VGL-15814

Trade name of the product: corPatch easy

Type of measure: Sorting and destruction of affected electrodes

Please indicate in columns 3 and 4 the number of electrodes (cases) you have in stock or in use. If you have sold or passed on affected electrodes, please sum up the quantities of electrodes of all your customers and enter it in column 5.

Enter the sum of columns 3, 4 and 5 in column 6. You will receive replacement electrodes for these.

Please sign the form and return it to the organization that provided you with the form.

Thank you very much for your efforts! Leonhard Lang GmbH

1	2	3	4	5	6
REF	LOT	In stock	In use	Sum of electrodes reported by your customers	Total
04324.3	190711-3993				

- We have read and understood the urgent field safety notice (short: FSN) from Leonhard Lang GmbH of December 20, 2019. We confirm that we have informed all users and other persons affected in our organization about this FSN.
- We confirm that we **will sort out** and **destroy** the electrodes with the lot number 190711-3993 at the latest upon receipt of the replacement electrodes.
- If you have sold or passed on the affected electrodes:

We confirm that we have forwarded this FSN in writing and without delay to all organizations / persons to whom we have sold or passed on the affected electrodes.

Note:

--

Filled out by:

Organization:			
Address:			
Zip code / City:		Country:	
Last name, title:		First name:	
Phone:		Fax:	
E-mail:			

Date / signature:

Company stamp:
