LEONHARD LANG
Connect with Quality

Addressee:

Sender:

Leonhard Lang GmbH
Archenweg 56

6020 Innsbruck
Austria

Innsbruck, July 11, 2019

URGENT FIELD SAFETY NOTICE

Reference: RKL-4275 / VGL-15219

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

Trade name of the product: corPatch easy pre-connected

Type of measure: Sorting and destruction of affected electrodes

Target group addressed: Dealers and final customers

Ladies and Gentlemen,

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

Trade name of the product:	corPatch easy pre-connected
REF:	05120.1
Lot number:	190611-4017

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

1. Description of Fault

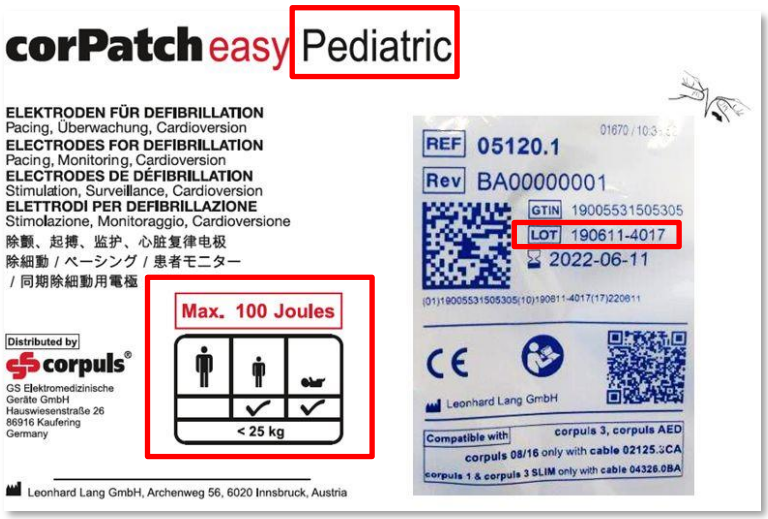
Summary: In the course of an investigation triggered by a complaint, it was discovered that two packaging pouches with different labels were used in one batch.

Beside the pouch with the correct imprint “corPatch easy pre-connected” a pouch with the imprint “corPatch easy Pediatric” was used. This means that some of the pouches labeled as pediatric electrodes contain electrodes for adults.

Identification of the Affected Product

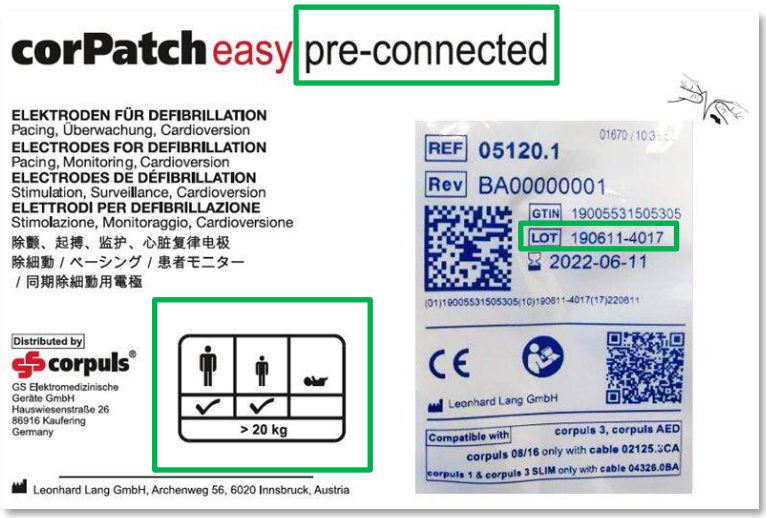
Electrodes with the lot number **190611-4017** <u>and</u> the label **“Pediatric”** are affected.

Example: affected electrodes (imprint pouch)



Electrodes of the same batch (lot number 190611-4017) and the label „pre-connected“ are **not affected**.

Example: not affected electrodes (imprint pouch)



Potential risk: There is a risk that electrodes for adults are applied on children with less than 25 kg. As a consequence the risk of side effects increases.

Condition for occurrence of the error: Use of wrongly labeled electrodes for adults of REF 05120.1 and the lot number 190611-4017 while necessarily defibrillating a child.

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.

(Note: Electrodes with the same REF but different lot number are not affected by this recall.)

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** or **in use**, ensure that they are not sold or passed on. Sort out electrodes with the lot number 190611-4017 labeled “Peditriac” and **destroy** them immediately.

(Note: Electrodes labeled “pre-connected” are not affected. They can be used as designated.)

Enter the number of destroyed electrodes in column 3 and 4 of the attached response form.

If you have sold the affected electrodes or passed them on to third parties, please forward this FSN to these customers immediately. Your customers will then report back to you about how many electrodes have to be replaced. Please collect this feedback and enter the number of electrodes to be replaced in column 5 of your response form.

Please make sure that you receive feedback from your customers and return your response form to the organization that sent you this FSN by **July 30, 2019** 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

As replacement you will get correctly labeled electrodes of REF 05120.1. If you have sold electrodes or passed them on to third parties, please forward the replacement electrodes to your customers.

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 our sales director Mrs. Bettina Sarlay (mailto: bettina.sarlay@leonhardlang.at).

Yours sincerely,

Bernhard Ladner
Head of Quality Management

Annex:

- Recall response form

LEONHARD LANG
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RECALL RESPONSE FORM

Reference: RKL-4275 / VGL-15219

Trade name of the product: corPatch easy pre-connected

Type of measure: Sorting and destruction of affected electrodes

Please indicate in columns 3 and 4 the number of electrodes (pouches) labeled “Pediatric” 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.

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**
05120.1	190611-4017				

a. We have read and understood the urgent field safety notice (short: FSN) from Leonhard Lang GmbH of July 11, 2019. We confirm that we have informed all users and other persons affected in our organization about this FSN.

b. We confirm that we **sorted out** and **destroyed** the electrodes labeled “Pediatric”.

c. 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: