Address:

xxx

Sender:

Leonhard Lang GmbH
Archenweg 56
A-6020 Innsbruck

Innsbruck, 2019/04/11

IMPORTANT SAFETY NOTIFICATION

Reference: RKL-4141

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

Product trade name:

Product trade name	REF	LOT
Defibrillation Electrode SCHILLER	0-21-0003	180201-0773 180322-0777
Defibrillation Electrode SCHILLER	0-21-0020	180202-0976 180322-0979
Defibrillation Electrode SCHILLER	2.155061	180205-0774 180313-0779 180321-0775 180322-0776
Defibrillation Electrode SCHILLER	2.155065	180216-0973
Defibrillation Electrode SCHILLER	2.155063	180305-0797
Defibrillation Electrode SCHILLER	0-21-0037	180206-0775 180327-0773
Defibrillation Electrode SCHILLER	2.155067	180207-0776 180327-0774
Defibrillation Electrode SCHILLER	0-21-0040	180216-0972 180410-0971

Required action: Replacement and destruction of the affected electrodes

Target group: Distributors and wholesale customers

Important Note: This safety notification is intended for distributors and wholesale customers only. The end customers (consumers) will be informed and supplied with replacement electrodes separately. Therefore, forward this safety notification only to distributors and wholesale customers. In case of doubt, please forward this safety notification anyway.

Dear Ladies and Gentlemen,

This letter is to inform you of the recall of the electrodes and the concerned lot numbers listed above.

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

1. Description of the defect

Summary: In the course of an investigation triggered by two complaints regarding a malfunction during use, it was discovered that electrode material had been caught between a rivet and the ring terminal of the electrode cable leading to no or only intermittent electrical contact between the electrode and the defibrillator.

Condition for occurrence of the error: Use of the types of defibrillation electrodes listed above, matching with the lot numbers listed, with a compatible defibrillator.

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.

Safety information: With this letter, Leonhard Lang informs you of the fact that this safety notification 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.

Annotation: Electrodes on the market with the same REF, but different lot numbers than those listed in this letter, are not affected and can be used without restrictions.

2. Actions and procedure of the recall

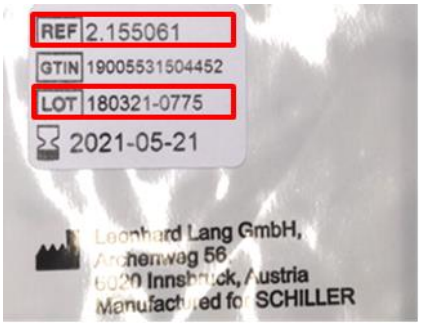
a.) Please read this safety notification carefully. If there are any questions or you are unable to implement the required actions, please urgently contact the organization, which has sent you this safety notification.

b.) Please ensure in your organization that all users and other persons concerned are aware of this important safety notification, and confirm the notice in form **Confirmation Safety Notification**. Please return the completed form without any delay to the organization, which has sent you this safety notification.

c.) Please determine the quantities of affected electrodes in your stock, sold and used by yourself. Enter the REF-numbers, LOT-numbers and quantities in form **Quantity Determination** in column 1 – 4.

If you have defibrillation devices in your organization yourself, please check if any affected electrodes are included. If so, please include the number in column 3 as well.

Note: The REF and LOT numbers can be found at the electrode package (see example below).



d.) Please quarantine the identified electrodes you have in stock.

e.) Please enter the required quantity of replacement electrodes in form **Quantity Determination** in column 5 and send the form to the organization, which has sent you this safety notification no later than **2019/05/31**.

f.) Once you have received replacement electrodes, all stored / quarantined affected electrodes must be destroyed. Please confirm the destruction of these electrodes with the form **Confirmation of Destruction** and send it to the organization, which has sent you this safety notification no later than **2019/06/30**.

g.) Please make sure that you have received the three signed forms from each of your customers (see annexes) and retain them.

We would like to point out that you are obliged to take measures actively in order to get the outstanding data.

3. Replacement electrodes

Replacement electrodes will be provided by the organization, which has sent you this safety notification. In case you have sold electrodes, you are asked to provide your customers (only distributors and wholesale customers) with replacement electrodes.

We apologize for any inconvenience caused by this issue. However, to allow patients and users to safely utilize our products, these measures have to be taken immediately. We assure you that safety and quality are our first and foremost priorities. Please do not hesitate to contact us under rc4141dr@leonhardlang.at with any questions you may have.

Yours sincerely,

Bernhard Ladner
Head of Quality Management
Tel: +43 512 33425 - 39

List of annexes:

Annex A: Confirmation Safety Notification
Annex B: Quantity Determination
Annex C: Confirmation of Destruction