

To:

Final Consumer

From:

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: Final Consumer

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 timeframe of the recall

You received this letter, because you were identified as having bought a potentially affected electrode, as accessory, or with a new device. Together with this letter, you received the replacement for this/these electrode(s).

- a) Please read this safety notification carefully. If there are any questions or you are unable to implement the required actions, please contact the organization, which has sent you this safety notification urgently.
- b) Please ensure in your organization that all users and other persons concerned are aware of this important safety notification. Replace all affected electrodes you have received, together with this letter.
- c) Please let us know, no later than **2019/06/30** how many of the affected electrodes you have destroyed.

Please use the web based form <https://www.leonhardlang.com/recall-4141-er> for the confirmation. Click the button and enter password: **er4141rc**

- c1) Even if the electrode, for which you received a replacement, has already been used, please also use the form on our Website for the confirmation.

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 rc4141er@leonhardlang.at with any questions you may have.

Yours sincerely,

██████████
████████████████████

PS: In case you can't fill out the form on our website, please fill out annex 1 and send it, no later than 2019/06/30 to rc4141er@leonhardlang.at or the following postal address:

Leonhard Lang GmbH
████████████████████
Archenweg 56
6020 Innsbruck, AUSTRIA

Annex 1: Confirmation of Destruction



Annex 1

CONFIRMATION of DESTRUCTION

Reference: RKL-4141

Dear Partner,

Please fill out the following declaration to help us to define which electrodes you have destroyed after receiving the replacement electrodes.

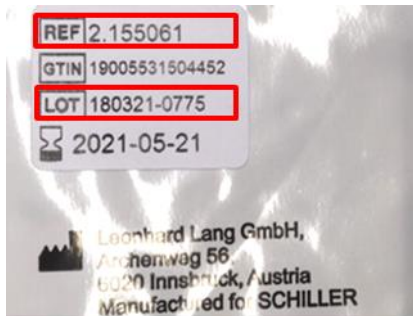
Thank you in advance for your cooperation.

The SCHILLER Medical and Leonhard Lang teams.

1. REF and LOT numbers

Please indicate the quantity of the destroyed electrodes in the table below.

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



REF number	LOT number	Quantity of electrodes destroyed
0-21-0003	180201-0773	
	180322-0777	
0-21-0020	180202-0976	
	180322-0979	
0-21-0037	180206-0775	
	180327-0773	
0-21-0040	180216-0972	
	180410-0971	



REF number	LOT number	Quantity of electrodes destroyed
2.155061	180205-0774	
	180313-0779	
	180321-0775	
	180322-0776	
2.155063	180305-0797	
2.155065	180216-0973	
2.155067	180207-0776	
	180327-0774	

2. Your contact data

Company name:

Contact person:

Address:

Email:

Date / Signature:

3. Mailing address

Please send this form to rc4141er@leonhardlang.at or the following postal address:

Leonhard Lang GmbH

Archenweg 56
6020 Innsbruck, AUSTRIA