

To:

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From:

Leonhard Lang GmbH
Archenweg 56
A-6020 Innsbruck

Innsbruck, October 27, 2016

IMPORTANT SAFETY NOTICE

Reference: FSN-16-0081

Product trade name: Defibrillation electrode SCHILLER DF87C and
Defibrillation electrode SCHILLER DF56C

REF: 0-21-0040

Article No. Leonhard Lang: 50812

REF: 2.155065

Artikel No. Leonhard Lang: 50594

Target group: User of Defibrillator DEFIGARD TOUCH 7

Dear Ladies and Gentlemen,

This letter is to inform you about the important safety notice of the article listed below:

- **REF: 0-21-0040 Defibrillation electrode SCHILLER DF87C and**
- **REF: 2.155065 Defibrillation electrode SCHILLER DF56C**

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

1. Description of the defect

Summary: During an investigation triggered by customer feedback, it was discovered that the use of the above mentioned defibrillation electrodes with the defibrillator **DEFIGARD TOUCH 7** may lead to a cable break. This cable break depends on the operating conditions and is caused by the repeated opening and closing of the device bag. Investigations have shown that this defect may occur after more than 400 opening and closing cycles at the earliest under certain aggravated mechanical conditions.

Conditions for the occurrence of the issue: Use of REF: 0-21-0040 defibrillation electrode SCHILLER DF87C or REF: 2.155065 defibrillation electrode SCHILLER DF56C with the defibrillator DEFIGARD TOUCH 7 exceeding 400 opening and closing cycles of the device bag.

Potential risk: There is a risk that the required treatment (ECG analysis or delivery of electric shocks) only can be realized after replacement of the electrode. This may cause a situation in which a patient, who is in a life-threatening condition and requires a defibrillation shock, cannot be treated in good time.

Safety information: With this letter, Leonhard Lang informs you of the fact that this important safety notice will also be forwarded to the competent authorities. Please note that under existing legislation you are obliged to execute this safety notice.

2. Actions and timeframe of the recall

a) Information:

Please make sure that within your organization all users of the product listed above and any other persons requiring this information receive this important safety notice.

b) Required actions:

- Disconnect the connector of current electrodes from the DEFIGARD Touch7.
- Keep a second pouch of defibrillation electrodes available in the DEFIGARD Touch7 bag
- Don't preconnect this new electrodes

c) FSN Report 1:

Please let us know how that you have understood the content of this safety notice, forwarded the notice and performed the necessary actions.

Please use the form "FSN Report 1" and return it to us not later than **November 09, 2016**.

Please send the confirmation with the subject:

FSN-16-0081: „*your company name*“

To your local distributor

3. Further procedure

Up to the disposal of spare electrodes the defibrillator DEFIGARD TOUCH 7 can be used without restriction using not preconnected electrodes. All other electrodes for Schiller defibrillators are not affected from this safety notice.

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 our staff by Leonhard Lang GmbH. or SCHILLER Médical SAS with any questions you may have.

List of annexes:

- FSN Report 1
- Identification of Products

Yours sincerely,

Mit freundlichen Grüßen

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