

To:

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From:

Leonhard Lang GmbH
Archenweg 56
A-6020 Innsbruck

Innsbruck, September 1, 2016

IMPORTANT SAFETY NOTICE FOR FINAL CUSTOMERS

Reference: CAP-16-0078

Product trade name: Defibrillation Electrode SKINTACT DF29N

Required action: Destruction of affected products

Target group: Final Customers

Dear Ladies and Gentlemen,

This letter is to inform you of the recall of the article listed below:

- **50028 Defibrillation Electrode SKINTACT DF29N**

You will be informed by your supplier about affected lot numbers and quantities delivered to you. A description of how to identify the lot number on the product packaging is attached (see annex).

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 it can be aggravated to connect these defibrillation electrodes with the defibrillator Welch Allyn AED 10. As a consequence, it may happen that the user does not connect the electrodes with the defibrillator in an emergency situation.

Conditions for the occurrence of the issue: Use of defibrillation electrodes DF29N with the defibrillator Welch Allyn AED 10.

Potential risk: There is a risk that these electrodes will be connected with the defibrillator only with delay or not at all. 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 safety notices will also be forwarded to the competent authorities. Please note that under existing legislation you are obliged to comply with the requirements of this recall action.

2. Actions and timeframe of the recall

- a) Please make sure that within your organization all users of the products listed above and any other persons requiring this information receive this important safety notice.
- b) Make sure all defibrillation electrodes DF29N you have received and not yet used are secured and destroyed. Confirm the disposition of the products (consumed/destroyed) by completing the form "Confirmation of Destruction / Consumption" (see annex), sign it and send it to your supplier not later than **October 14, 2016**.

Please keep the signed "Confirmation of Destruction / Consumption" form at least until your supplier informs you of the termination of this recall.

3. Compensation for the recalled electrodes

There will not be replacement electrodes for Welch Allyn AED 10 defibrillators. Please contact your supplier for compensation.

For the use with all other Welch Allyn defibrillators, we are able to offer you replacement electrodes with a compatibility limited to AED 20, PIC 30, PIC 40 and PIC50. Please inform us about your quantity requirements.

For the termination of the recall it is necessary that you confirm in writing the destruction of all electrodes that were not consumed. Compensation and replacement products will be provided on the basis of the data provided by you in the completed "Confirmation of Destruction / Consumption" form.

For processing compensation, please get in touch with your supplier.

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 sales staff with any questions you may have.

Yours sincerely,

[Redacted signature block]

List of annexes:

- Identification of the Lot Number on Product Packaging
- Form "Confirmation of Destruction / Consumption"