

Innsbruck, 17.11.2014

TO

Customer and User



LEONHARD LANG
Medizintechnik

Leonhard Lang GmbH, Archenweg 56
6020 Innsbruck, Austria
www.LeonhardLang.at

Tel. +43-512-33 42 57, Fax 39 22 10
Medical@LeonhardLang.at

Urgent Medical Device Recall concerning Defibrillation Electrodes

Dear Customer and User of our Defibrillation Electrode for Children
50125 GS Corpatch clip Neonate (DF61) GS: 04325.2 „corPatch clip Neonaten“
50531 GS Corpatch easy Pediatric (DF68) GS: 05120.2 „corPatch easy Pediatric“
50126 GS Corpatch easy Neonate (DF60) GS: 04324.2 „corpatch easy neonate“

During an internal investigation triggered by market feedback, it was discovered that during the use of these defibrillation electrodes a possibility for arcing and a resulting malfunction exists. This could lead to a situation, in which a patient who is in a life threatening situation requiring a defibrillation can receive such therapy only with a delay or not at all. In such a situation the inability to defibrillate or a delay in doing so can as a consequence lead to the death or severe injury of the patient. The precise cause for this is still under investigation.

The internal investigation has revealed, that this potential malfunction can occur with these electrodes after a duration of storage of about 2 years or more.

We have therefore decided to recall all lots of these electrodes older than 18 months. All electrodes with a duration of storage of 18 months or less show a faultless performance and can be used as usual according to the instructions for use.

All electrodes with the following lot numbers are affected:

50125 GS Corpatch clip Neonate (DF61) GS: 04325.2 „corPatch clip Neonaten“
Lot: 21127-0773

50531 GS Corpatch easy Pediatric (DF68) GS: 05120.2 „corPatch easy Pediatric“
Lot: 30219-0778, 30325-0778, 30521-0776

50126 GS Corpatch easy Neonate (DF60) GS: 04324.2 „corpatch easy neonate“
Lot: 30215-0770, 21213-0770, 21109-0773



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Please immediately stop the use and the distribution of the above quoted lot numbers of these electrode models and quarantine them.

Please report to us all quantities of these products you have in stock or in the field using the attached form immediately. We will arrange for these products to be returned to us and will replace them shortly.

We want to point out that all expired defibrillation electrodes of these models may also show this malfunction. You therefore need to make sure, that no expired electrodes of these types are used.

Please also inform your customers and make sure that they also place all quantities of these products they have in stock or in the field in quarantine and report them using the attached form.

Kind regards **LEONHARD LANG GmbH**
MEDIZIN-TECHNIK
Archenweg 56
A-6020 Innsbruck
Tel: +43 512 33425-7 Fax: 392210

Bettina Sarlay (on behalf of the Quality Manager Bernhard Ladner)

Bettina Sarlay
Sales Manager

tel: +43 512 33425 - 39
fax: +43 512 39 22 10
email: bernhard.ladner@leonhardlang.at

Leonhard Lang GmbH
Medical Products

Archenweg 56
A-6020 Innsbruck, Austria
www.leonhardlang.at
UID-Nr: ATU37320902, FN77514t, Innsbruck
Firmenbuchgericht: Innsbruck