



LEONHARD LANG

Medizintechnik

Leonhard Lang GrnbH, Archenweg 56
6020 Innsbruck, Austria

www.LeonhardLang.at

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

Urgent Field Safety Notice

Recall

concerning

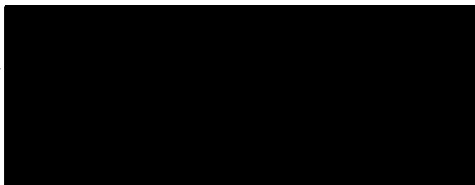
**DF53C GS corPatch easy pre-connected with 1.3m cable
GS product number 05120.1**

2014-05-01

Sender:

Leonhard Lang GmbH.
Archenweg 56
A-6020 Innsbruck

Adressee:



Identification of the medical products affected:

**DF53C GS corPatch easy pre-connected with 1.3m cable
GS product number 05120.1**

Lot No.:

30917-0770, 31014-0774, 31121-0773, 40121-0776, 40205-0776 and 40220-0771

The lot numbers are well visibly printed on each bag

Description of the problem and the cause:

During a use of this electrode the two leads of the pre-attached cable were pulled apart beyond the original split. Upon execution of the defibrillation, arcing was observed.

An investigation performed by us and the supplier of the cable shows, that a possibility of damaging the insulation of the cable of a particular make exists. When manually pulling apart the two leads of the cable, the conductive metal core of the leads can be exposed.

When executing defibrillation with an exposed metal core of the leads, arcing can occur and a potential risk of injury for both patient and user exists. We have therefore decided to recall all affected lot numbers of this product from the market.

Which action is to be taken by the addressee?

The leads of the cable of the electrodes of the lot numbers stated above must not be manually pulled apart. Should this be necessary for the therapy of a particular patient, the separated leads must be inspected for damages. Electrodes with damaged leads must not be used.

In addition, we urgently recommend that an additional number of replacement electrodes are carried by all users.

Please replace the electrodes of the lots listed above as soon as possible with electrodes of other lots. By Monday, May 5th 2014, replacement electrodes will be available at Corpuls regional distributors in quantities at least big enough to cover your ongoing use. These allow for a greater spacing apart of the electrodes and the leads of their cables thus do not need to be manually pulled further apart even when used on adipose patients.

GS Elektromedizinische Geräte and their distributors are organizing the retrieval and exchange of the electrodes of the affected lots. Please replace all electrodes of the affected lots you might have in your stock or with your users and report the quantities to your Corpuls distributor by May 16, 2014.

**DF53C GS corPatch easy pre-connected with 1.3m cable
GS product number 05120.1**

Lot No.: 40319-0776, 40414-0778 and 40415-0770

The lot numbers are well visibly printed on each bag

The wires of the electrodes of these lots are already split to a distance of 30 cm rendering unnecessary a manual pulling apart of the leads. However, when manually pulling apart the two leads of the cable, the conductive metal core of the leads can be exposed as well.

Which action is to be taken by the addressee?

The leads of the cable of the electrodes of the lot numbers stated above also must not be manually pulled apart. If this instruction is complied with there are no other restrictions in the use of these electrodes.

At this time there are not yet enough replacement electrodes at our disposal to replace the entire quantity of electrodes in the market immediately. For this reason, the electrodes with lot numbers 40319-0776, 40414-0778, and 40415-0770 will only be retrieved and replaced starting May 19, 2014.

All other types of electrodes of GS Elektromedizinische Geräte GmbH, which are manufactured by Leonhard Lang GmbH, are equipped with a different make of cable and are not affected by this problem. You can continue to use them in the manner familiar to you. The leads of their cable can be manually pulled further apart, if deemed necessary.

Passing on of this information

In your organization, make sure that all users of the products mentioned above (and any further person you deem necessary) are immediately made aware of this **urgent safety notice**.

In case you have passed on electrodes of the lots affected to third parties, please pass on a copy of this urgent field safety notice or inform a contact person named further below.

Please preserve this safety notice at least until the recall has been completed.

The competent authority in your country has received a copy of this „Urgent Field Safety Notice“.

Contact at GS Elektromedizinische Geräte:

GS Elektromedizinische Geräte
G. Stemple GmbH
Hauswiesenstrasse 26
DE-86916 Kaufering

Carsten Fuchs,
Vice President, Customer Support
Customer Service
Tel.: +49 (0)81 91 6 57 22 30
Fax: +49 (0)81 91 6 57 22 22
Email: md-vigilance@corpuls.com

Contact at the manufacturer:

Leonhard Lang GmbH.
Archenweg 56
A-6020 Innsbruck

Bernhard Ladner
Quality Manager
Tel: +43 512 33425 - 39
Fax: +43 512 39 22 10
Email: bernhard.ladner@leonhardlang.at

Best regards
Bernhard Ladner

Bernhard Ladner
Quality 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.: ATU17331901, FN775146 Innsbruck
Für den Verkauf in Österreich