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LEONHARD LANG

Medizintechnik

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Recall concerning GS Defibrillation Electrodes

Dear Customer and User of our Defibrillation Electrode for Children

GS	04325.2 (DF61 / 50125)
GS	05120.2 (DF68 / 50531)

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 malfunction can occur with defibrillation electrodes that are older than 2 years.

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. The precise cause for this is still under investigation.

The internal investigation has revealed that this potential malfunction can occur with these electrodes after duration of storage of about 2 years or more. All affected lot numbers of these types with a storage time over 18 months have been recalled in the recall of November 2014. All lot numbers that are currently on the market and are labeled with an expiration date of more than 2 years are called proactively in this recall from the market.



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All electrodes with the following lot numbers are affected:

Customer name	Name of product	Lot number
GS	04325.2 (DF61 / 50125)	30822-0779
GS	04325.2 (DF61 / 50125)	31219-0776
GS	04325.2 (DF61 / 50125)	40507-0773
GS	05120.2 (DF68 / 50531)	30708-0777
GS	05120.2 (DF68 / 50531)	30822-0778
GS	05120.2 (DF68 / 50531)	31009-0773
GS	05120.2 (DF68 / 50531)	31121-0774
GS	05120.2 (DF68 / 50531)	40107-0771
GS	05120.2 (DF68 / 50531)	40213-0774
GS	05120.2 (DF68 / 50531)	40222-0773
GS	05120.2 (DF68 / 50531)	40320-0770
GS	05120.2 (DF68 / 50531)	40321-0770
GS	05120.2 (DF68 / 50531)	40324-0773
GS	05120.2 (DF68 / 50531)	40522-0779
GS	05120.2 (DF68 / 50531)	40704-0776
GS	05120.2 (DF68 / 50531)	40808-0773
GS	05120.2 (DF68 / 50531)	40923-0776
GS	05120.2 (DF68 / 50531)	41021-0778

Please quarantine these lot numbers.

Please report to us immediately all quantities of these products you have in stock or in the field using the attached form.

Request the necessary amount of electrodes according to your demand by your dealer. Upon receiving the replacement goods dispose immediately the affected electrodes by the recall.

Confirm the disposal on a written and signed company letterhead stating the lot number and the pieces.



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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

Bernhard Ladner
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