LEONHARD LANG
Connect with Quality

Addressee:

<recipient address>

Sender:

Leonhard Lang GmbH
Archenweg 56

A-6020 Innsbruck

Innsbruck, May 15, 2019

IMPORTANT SAFETY INFORMATION

Reference: CAP-19-0115

Reference authority: BASG Bundesamt für Sicherheit im Gesundheitswesen, Traisengasse 5, 1200 Vienna, Austria

Trade name and article number of the products:

- Multifunction Electrodes, compatible with MEDUCORE Standard², for adults, REF: WM 45418
- Multifunction Electrodes, compatible with MEDUCORE Standard and MEDUCORE Easy, for adults, REF: WM 40116

Type of measure: Replacement and destruction of the affected electrodes

Target group addressed: Dealers and users

Dear ladies and gentlemen,

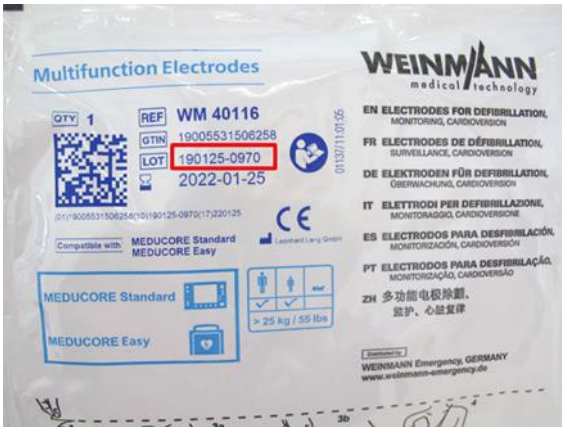
With this letter we would like to inform you about the recall of the lot numbers listed below:

REF	Lot numbers	
WM 40116	60519-0971	171113-0971
	60905-0976	171114-0972
	161212-0970	180314-0972
	170425-0978	180622-0979
	170703-0974	181024-0975
	171006-0979	190125-0970

REF	Lot numbers
WM 45418	180104-0971
	180118-0970
	180314-0973
	190225-4019

Identification of the Lot Numbers on the Product Packaging

The lot number is printed on each pouch and marked with LOT. Here highlighted in red as an example.



1. Description of Fault

Fault: Electrode material may be trapped between the eyelet of the cable and the rivet in the affected electrodes.

Potential risk: This means that there is a possibility that an ECG can neither be recorded nor can energy be delivered by the electrode pair. This may mean that timely treatment of a patient in a life-threatening condition who requires a defibrillation shock is not possible.

2. Process for the Recall

Please read this Safety Information carefully. If you have any questions or are unable to implement the required measures, please contact the organization that provided you with this Safety Information or the WEINMANN Emergency Customer Service (phone: +49 40 881896 120) .

Leonhard Lang GmbH hereby informs you that this Safety Information will also be forwarded to the responsible authorities. Please note that (according to applicable law) you are **obliged** to comply with this recall, particularly the destruction of the affected electrodes.

Measures

Please make sure that all users and other affected persons in your organization are aware of this Safety Information.

The further measures suitable for you depend on how you use the electrodes:

a.) **If you are a specialist dealer and have resold these electrodes, please carry out the following measures:**

If you should have affected electrodes in storage, ensure that they are not sold or passed on by destroying the electrodes.

Enter the number of affected electrodes you have in the corresponding line of column 3 of your response letter and note the LOT and REF number assignment when doing so.

If you have sold the affected electrodes or passed them on to third parties, please forward this Safety Information to these customers **immediately**. Your customers will then report back to you about how many electrodes have to be replaced. Please collect this feedback and enter the number of electrodes to be replaced in column 5 of your response letter and note the LOT and REF number assignment.

Please make sure that you receive feedback from your customers and return your response form to the organization that sent you this Safety Information by **July 26, 2019** at the latest.

Please note: If the feedback from your customers is not complete, you are obliged to take active measures to ensure that you receive the outstanding data.

After your feedback you will receive replacement electrodes for yourself and your customers. Please forward these replacement electrodes to your customers immediately.

Please retain all forms sent to you.

b.) **If you are the operator and user of the defibrillators MEDUCORE Standard, MEDUCORE Standard² or MEDUCORE Easy:**

Please leave the electrodes with the devices until you are provided with a replacement electrode.

If you are in possession of additional electrodes, ensure that a second additional replacement electrode is carried with each device or is enclosed with the device. Use this replacement electrode if you encounter a faulty electrode during use.

We would once again like to draw your attention to the urgency of this measure and to your obligation to cooperate. To ensure the functionality of your devices, it is **essential** that you **replace the electrodes as soon as possible**.

Enter the number of affected electrodes you have in the corresponding line of column 3 and column 4 of your response letter and note the LOT and REF number assignment.

Please fill out the enclosed form and forward it to the organization that sent you this Safety Information by **July 12, 2019** at the latest. You will receive the replacement electrodes from this organization after your response.

Important! As soon as you have received the replacement electrodes, replace the affected electrodes on all affected devices and in your warehouse immediately and **destroy** them.

We apologize very much for the inconvenience caused. In order for patients and users to be able to use our products safely, however, it is absolutely essential that these measures are carried out immediately. We assure you that safety and quality are our top priority.

If you have any questions, please contact the WEINMANN Emergency Customer Service (phone: +49 40 881896 120) as the manufacturer of the device used to operate our affected electrodes.

Yours sincerely,

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Annex:

- Recall response form CAP-19-0115