

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:

Defibrillation electrode Mindray MR62

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
MR62	170614-0970
	170810-0973
	170911-0974
	180420-0974
	180615-0975
	180829-0971
	181113-0974
	190226-4016
	190227-4017

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.

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 Mindray Beneheart D1, D2, D3, D5 or D6:

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 your inconvenience. 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.

Please do not hesitate to contact our staff by Leonhard Lang GmbH with any questions you may have.

Yours sincerely,

Bernhard Ladner
Head of Quality Management

E-Mail: cap190115mr@leonhardlang.at

(Please send us your requests / information in German or in English.)

Annex:

- Recall response form CAP-19-0115

RECALL RESPONSE FORM

Reference: CAP-19-0115

Trade name of the product: Defibrillation electrode Mindray MR62

Type of measure: Replacement and destruction of the affected electrodes

Please indicate in columns 3 and 4 the quantity of electrodes (pouches) you have in stock or in use. If you have sold or passed on affected electrodes, please sum up the quantities of electrodes of all your customers (see column 6) and enter it in column 5.

You will receive replacement electrodes for these.

Please sign the form and send it to the organization that sent it to you.

Thank you very much for your efforts!

Leonhard Lang GmbH

1	2	3	4	5	6
REF	LOT	In stock	In use	Sum of electrodes reported by your customers	Total
MR62	170614-0970				
	170810-0973				
	170911-0974				
	180420-0974				
	180615-0975				
	180829-0971				
	181113-0974				
	190226-4016				
	190227-4017				
				Total	

- a. We have read and understood the Safety Instructions from Leonhard Lang GmbH of May 15, 2019. We confirm that we have informed all users and other persons affected in our organization about this Safety Information.
- b. We confirm that once we have received the replacement electrodes, we will **replace and destroy** the affected electrodes.
- c. If you have sold or passed on the affected electrodes:

We confirm that we have forwarded this Safety Information in writing and without delay to all organizations / persons to whom we have sold or passed on the affected electrodes.

Note:

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Filled out by:

Organization:			
Address:			
Zip code / City:		Country:	
Last name, title:		First name:	
Phone:		Fax:	
E-mail:			

Date / signature:

Company stamp:
