

REBOTEC* Rehabilitationsmittel GmbH

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Quakenbrück, den 01.07.2025

Urgent safety information

Recall concerning - Forearm crutches Magic-Soft - black 10510

Dear Ladies and Gentlemen,

With this letter we would like to inform you about a recall of our product

Magic-Soft forearm crutches, black article 10510 and ask for your attention:

Identification of the affected medical device:

Item: 10510 Batch: 25/21-L00244 Quantity: 220 pairs

Date: 03.06.2025 Document: delivery note 2025 - 207124

Description of the problem, including the cause identified:

Upper part of the forearm crutch broken in the shaft area

Weakening of the cross-section in the fracture area due to air inclusion

Determined cause: The upper parts had not cooled down enough in the area of the shaft when they were demolded. When the pipe core was retracted, the still liquid mass was then pulled into the pipe holder. This creates a cavity in the part, which seriously weakens the cross-section of the part.

Since we cannot rule out that the forearm crutches from the delivery specified here are affected, we would like to recall all potentially affected items.

What measures are to be taken by the addressee?

Attached you will find a form which please use as soon as possible for a collection of all

should be returned to us.

Please ensure that all users of the above products

and other persons to be informed are aware of this "urgent

Safety Information".

Please keep this information at least until the action has been taken.

was completed.

The Federal Institute for Drugs and Medical Devices has a copy

of this "Urgent Security Information".

Contact person at **REBOTEC** Rehabilitationsmittel GmbH for exchange and pick-ups:

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Magic-Soft Art. 10510 - Recall

Customer/Stamp	_	
Customer-No.:		
customer-no		
Contact:	_	
Phone:	Fmail:	
box(es) Magic-Soft, black Art. 10	510	pair (please specify both)
Chargen-Nr.:	_	
Delivery note number:		
Delivery note number.		
Ready for collection from:		
, 		
Different pick-up address:		
Company:		
Street:		
Zip code: City:		

Please reply an: m.weinberger@rebotec.de

R€BOT€C Rehabilitationsmittel GmbH

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