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Your reference • Your correspondence dated • Our reference • Date
QM700016536 2021-08-09

Emergency safety notice

Affected product: COAG. ELECTRODE BIPO 24–26 Fr. 12/30°
Product number: 4623.0223
Lot number: 4500332889

Our reference no.: QM 700016536

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to a potential defect on the COAG. ELECTRODE BIPO 24 26 Fr. 12/30°. According to our records, you operate the potentially affected product. The procedure for rectifying the defect is set out in this letter.

The affected electrodes have the product label 4623.0223, lot: 4500332889. However, the package actually contains the following product type: 4622.2533, lot 4500332888.

Product number 4623.0223	Product number 4622.2533
<p>Coagulation electrode (pack = 3 pcs.)</p> 	<p>Cutting electrode (pack = 3 pcs.)</p> 

The problem

The labeling indicates that the package contains a coagulation electrode. It will not become apparent that it actually contains a cutting electrode rather than a coagulation electrode until the equipment is assembled. This may result in the procedure being delayed or not being carried out at all. We want to pre-empt this situation by implementing this measure.

Measures to be taken by the addressee

Read through both this letter and the attached reference documents (see list of attachments) and keep them on file until the measure has been implemented.

Please follow the steps below:

1. Check your stock of electrodes with the product label 4623.0223 from lot 4500332889. If you find a cutting electrode of the type 4622.2533 under product number 4623.0223, this product must be blocked for further use and then disposed of via a documented process.
2. Make sure, within your organization, that all users of the aforementioned product and other persons to be informed have received knowledge of this emergency safety notice. If you have passed on this product to third parties, please forward a copy of this notice and inform the contact persons stated below accordingly.
3. Make sure that this notice is retained within your facility until all the in-house measures required have been implemented.
4. Please confirm receipt of this emergency safety notice by returning the attached **Response form** by **e-mail to FSCA700016536@richard-wolf.com** on or before **2021-08-20**. We also ask that you complete this form even if you no longer have the product in stock. In doing so, you will be confirming receipt of this safety notice and you will not receive any further reminders from Richard Wolf.
5. Please inform Richard Wolf GmbH of any adverse events.

The affected electrodes from lot 4500332889 must no longer be used.

Two days after sending the emergency safety notice, Richard Wolf will automatically send you the replacement product free of charge in the relevant quantity.

The relevant national authorities have been informed of this **emergency safety notice**.

Your contact for

Questions concerning safety:

Mr. Marco Bruxmeier
Head of Quality Engineering Department

Tel.: +49 7043 35 4011
e-mail: FSCA700016536@richard-wolf.com

Questions concerning the procedure:

Mr. Thilo Musikant
Director Customer Service, Maintenance and Repair

Tel.: +49 7043 35 4189
e-mail: thilo.musikant@richard-wolf.com

Please accept our apologies for any inconvenience caused by this measure. On behalf of Richard Wolf GmbH, thank you in advance for your support in ensuring its timely implementation.

Yours faithfully,
Richard Wolf GmbH 

Attachments:
Response form

Response form



spirit of excellence

Return by e-mail to FSCA700016536@richard-wolf.com

**Emergency safety notice concerning
COAG. ELECTRODE BIPO 24–26 Fr. 12/30° 4623.0223 lot number 4500332889**

Our reference no.: QM 700016536

- We hereby confirm receipt of this emergency safety notice.
- Furthermore, we confirm that we have properly disposed of the affected products in the quantity listed below in order to prevent them from being used in clinical applications.
- Please use the table below to list the quantity of affected products recovered and disposed of at your facility. If you **no longer have any** products in your stocks, please check the box below.

No stock (please check the box)

Product type	Lot	Quantity disposed of	Quantity used
4623.0223	4500332889	_____	_____
Comment:			

Company
.....

Dept./Name
.....

Address
.....

Tel./e-mail
.....

Place/date
.....

Signature/
stamp

Richard Wolf GmbH would like to thank you for your understanding and cooperation. Please accept our apologies for any inconvenience caused!