

Richard Wolf GmbH • Postfach 11 64 - 65 • 75434 Knittlingen

Department.: Service
Person in charge: Thilo Musikant

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Your reference • Your letter dated • Our reference • Date
QM700013079 08.10.2019

Urgent Safety Information

Product concerned: IRRIGATION TUBE SET SPIKE
Product number: 8171223
Lot number: 4015874

Our reference no.: QM 700013079

Ladies and Gentlemen,

In the course of our continuous market monitoring activities we became aware of a potential problem in conjunction with IRRIGATION TUBE SET SPIKE 8171223.

According to our documentation you are using the product potentially affected. In the following, this letter will inform you about the procedure required to eliminate the problem.

Problem

The tube set is intended for 20 reprocessing / application cycles. Due to wrong programming, however, it is possible to use the tube set 255 times.

As this tube set is also used in pumps without a display, the user will not understand how many applications have already been carried out with this product.

On the basis of the programmed value and the applications already carried out, the integrated pump electronics check whether or not further applications can be carried out.

For this reason it cannot be excluded that tube sets with this programming error are used more often than specified.

To exclude any risk for the patient we decided to call back the tube sets affected.

Only irrigation tube sets spike 8171223 from LOT 4015874 are affected.

According to our documentation you have received products from the production lot affected. We therefore kindly ask you to check your inventory of new tube sets for LOT 4015874, and block them if you have products from that LOT in your inventory.

As described above, the product features an integrated electronic counting device. Without suitable pumps or reading devices, however, it is not possible to read out the programmed values. For this reason it is necessary to replace all type 8171223 tube sets.

This preemptive measure is taken to avoid the aforementioned situation.

Measures to be taken by the addressee

Please read this letter as well as the reference documents (see list of appendices) completely and keep

them until this measure is completed.

Please carry out the following steps:

1. Check your inventory for the aforementioned tube set spike 8171223 from lot 4015874 and note the number of sets on the answer sheet. Please discard the sets from LOT 4015874 and document the action.
2. Make sure within your organization that all users of the product mentioned above and other persons to be informed gain knowledge of this urgent safety information. If the product has been passed on to third parties, please pass on a copy of this information, and inform the contacts listed below.
3. Make sure that this information is observed in your organization until all necessary in-company measures are completed.
4. To verify receipt of this urgent safety information, we need the **included answer form** which we kindly ask you to return to **fax number ++49 7043 351360, or via e-mail to vigilance@richard-wolf.com by 28.10.2019**. Please fill in this form even if the product is no longer in your inventory. With the answer form you confirm receipt of this urgent safety information and avoid getting further reminder letters from Richard Wolf.
5. Inform Richard Wolf GmbH about any adverse events.

The affected tube set spike 8171223 from lot 4015874 may no longer be used.

Richard Wolf GmbH will provide you with the corresponding number of replacement products. Please make sure that the products affected in your facility are duly discarded.

The competent national authorities (amongst others the *Bundesinstitut für Arzneimittel und Medizinprodukte* in Bonn) have been informed about this **urgent safety information**.

Your contact person for

questions about the handling:

Mr. Thilo Musikant
Head of Customer Service & Service Center
Phone.: +49 7043 35 4189
Fax: +49 7043 35 1360
E-Mail: thilo.musikant@richard-wolf.com

safety-relevant inquiries is:

Mr. Oliver Ehrlich
Safety Officer for Medical Products
Tel.: +49 7043 35 1013
Fax: +49 7043 35 4300
E-Mail: oliver.ehrlich@richard-wolf.com

We apologize for the inconvenience caused by this measure and thank you on behalf of Richard Wolf for your support ensuring a timely implementation.

Kind regards,

Richard Wolf GmbH


i.V. Thilo Musikant
Head of Customer Service & Service Center


i.A. Oliver Ehrlich
Safety Officer for Medical Products

Enclosure:
Answer form

Answer form

Please return by fax to ++49 7043 351360 or via e-mail to vigilance@richard-wolf.com

This form refers to the Urgent Safety Information on IRRIGATION TUBE SPIKE 8171223 Lot number 4015874

Our reference number: QM 700013079

- We hereby confirm receipt of this urgent safety information.
- We also confirm that we will no longer use the affected product and will duly discard it.

Model/Type/Product	Lot	Units discarded
8171.223	4015874	_____
8171.223		_____
Remark:		

Company

Dept./Name

Address

Phone/e-mail

Place/Date

Signature/Stamp

We at Richard Wolf GmbH thank you for your understanding and your cooperation and apologize for the inconvenience caused by this measure!