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Department: Technical Service
Person in charge: Marek Rast

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• Your reference AD019347 • Your message dated • Our reference QM700008645 • Date July 18, 2017

Urgent safety information

Product concerned: ARTHROline punch W 4.6 mm H 1.6 mm
Product number: 89140.0105
Lot: 4500197481
Our reference no.: QM 700008645

Dear Sir or Madam,

within the scope of our continuous market monitoring activities we have become aware of a production-related defect in 12 punches of lot number 4500197481 of the aforementioned model.

Problem:

The punches model 89140.0105 of lot 4500197481 may have a burr in one section of the joint. When the punch is open, there is an increased potential of injury. This problem has occurred in punches of lot number 4500197481. **To guarantee maximum safety for users and patients, the product must no longer be used.**

Measures by the addressee

Please read this letter as well as the pertaining reference documents (see list of appendices), completely and keep this letter until the measure is completed.

Please carry out the following steps:

1. Check your stock for the aforementioned punch 89140.0105 from lot no. 4500197481 (the lot number can be identified on the moveable grip) and return the product to Richard Wolf GmbH with reference to this letter.
2. Please make sure that all users of the aforementioned product within your organization and other persons to be informed obtain knowledge of this urgent safety information. If you have passed on the product to third parties, please send a copy of this information to such third parties and inform the contact persons listed below.

3. Make sure that this message is observed in your facility until all required internal measures are completed.
4. To verify that you have received this urgent safety information, we require the enclosed answer form. Please send this form back to us by **August 02, 2017**: via e-mail to **marek.rast@richard-wolf.com** or via **Fax to 0049-7043-354467**. Please fill in this form even if you do not have the product in your stock anymore. The answer form confirms receipt of this safety information and avoids any further reminder letters from us.
5. Inform Richard Wolf GmbH about any undesirable events regarding the aforementioned product.

The punch concerned (89140.0105) from lot number 4500197481 must not be used anymore.

This urgent safety information is sent out to all customers concerned.

When this letter is answered, the addressee will receive a free replacement. It is also necessary to send back to us the punch concerned.

The competent national authorities (such as the Bundesinstitut für Arzneimittel und Medizinprodukte / Federal Institute for Drugs and Medical Products in Bonn) have been informed about this urgent safety information.

Your contacts for

Safety-related questions:

Oliver Ehrlich
Safety Officer
Tel.: 0049 7043 35 1013
Fax: 0049 7043 93 0048
E-mail: oliver.ehrlich@richard-wolf.com

Questions concerning handling:

Marek Rast
Head of Technical Service Dpt.
Tel.: 0049 7043 35 1046
Fax: 0049 7043 35 4467
E-mail: marek.rast@richard-wolf.com

We would like to apologize for the inconvenience caused by this measure and thank you on behalf of Richard Wolf for your support in promptly implementing this measure.

Kind regards,
Richard Wolf GmbH


per pro. Oliver Ehrlich
Safety Officer


per pro. Marek Rast
Director Technical Service

Enclosed: Answer form