

Your reference. • Your correspondence dated • Our reference • Date
QM 700015759 2021-04-07

Emergency safety notice

Affected product: HEAD DRILL Ø 8.5 MM
Product number: 89960.1085
Lot number: 01071955

Our reference no.: QM 700015759

Dear Sir / Madam,

As part of our continuous product monitoring procedure, our attention has been drawn to a potential defect on the HEAD DRILL Ø 8.5 MM, no. 89960.1085. The affected lot is 01071955.

According to our records, you operate the affected product. The procedure for rectifying the defect is set out in this letter.

The problem

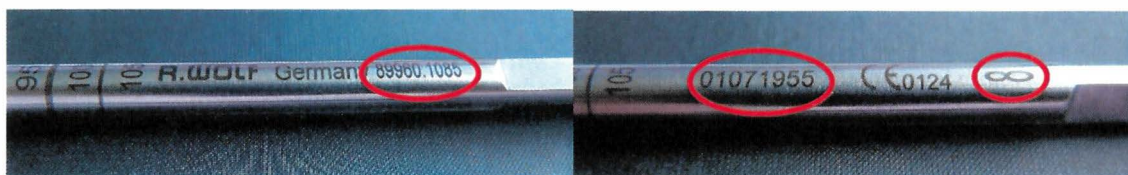
Due to a manufacturing error, the sheath of the HEAD DRILL Ø 8.5 MM has been labeled with 8 MM instead of 8.5 MM. It is possible that the hole made using this product will be 0.5 mm too large for the intended application. We want to pre-empt this situation by implementing this measure.

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 HEAD DRILL Ø 8.5 MM, no. 89960.1085 from affected lot 01071955 and look at the label on the drill.



Product number

Lot

Dimension

If you find a head drill of type 89960.1085 from lot 01071955 with dimension 8 MM in your stock, this drill is affected by this issue.

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 person 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. Notify Richard Wolf GmbH if the affected product has been passed on to other facilities. If so:
 - a) Please provide us with the relevant contact details so that Richard Wolf GmbH can inform the recipients accordingly.
 - b) Please note that you, as a dealer, are responsible for notifying the customers concerned.
5. Please confirm receipt of this emergency safety notice by returning the attached **Response form** by fax to **+49 7043 351360** or by e-mail to **FSCA700015759@richard-wolf.com** on or before **24.04.2021**. 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 GmbH.
6. Notify Richard Wolf GmbH about any adverse events occurring during use of the affected products.
7. Observe all national regulations for reporting adverse events to the competent national or local supervisory authorities in your country.

The affected HEAD DRILL Ø 8.5 MM, no. 89960.1085 of the affected lot 01071955 must no longer be used.

The emergency safety notice is being sent to all affected customers.

Once the response has been sent, the addressee will receive a replacement product free of charge. The affected products do not need to be returned to us; the addressee must confirm in writing via the response form that the affected products have been destroyed.

The competent national authorities (including the Federal Institute for Drugs and Medical Devices in Bonn) have been informed about this **emergency safety notice**.

Your contact for

Questions concerning the procedure:

Mr. Thilo Musikant
Head of Service Department
Tel.: +49 7043 35 4189
Fax: +49 7043 35 1360
e-mail: thilo.musikant@richard-wolf.com

Questions concerning safety:

Mr. Oliver Ehrlich
Safety Officer for Medical Devices
Tel.: +49 7043 35 1013
Fax: +49 7043 35 4300
e-mail: vigilance@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. We would like to assure you that Richard Wolf GmbH makes every effort to guarantee that only those products meeting our stringent quality criteria are available on the market.

Yours faithfully,
Richard Wolf GmbH


i.V. Thilo Musikant
Head of Service Department and Service Center


i.A. Oliver Ehrlich
Safety Officer for Medical Devices

Attachment:
Response form