

Field Safety Notice
RECALL

regarding

REBELLION punch size 2 mm

06.Mai.2021

Sender:

Morpheus AG
Bahnhofstraße 20
78549 Spaichingen
Germany
Tel. +49 (0) 7461 70382-0
www.morpheus.com.ag
Dimitri Krutsch
Quality and Regulatory Affairs Manager

Dear Ladies and Gentlemen, Customers and Distributors,

Herewith we inform you about a field safety notice, which is addressed to the users and owners of our REBELLION punch size 2 mm. The competent authority in your country will be informed of this safety notice.

Identification of affected medical devices:

Article number	GTIN	LOT
REB-02-200	04260647240009	11944, 12061, 11890
REB-02-250	04260647240016	11945, 11887, 11945

Description of the problem including the identified cause:

During a procedure, the jaw component of a punch broke. The broken piece was found and no complications occurred during the operation. Initial internal tests have shown that there may be a material defect in the affected batches.

Risk Assessment:

Breakage of the sharp-edged jaw on critical anatomy (e.g., the dura) may lead to unanticipated complications and carry the potential for adverse events.

What actions should be taken by the addressee?

We request that you return to us the products listed above that have not been in use. Please complete the attached return form and return it to us by the end of week 21.

Passing on the information described here:

Please ensure in your organization that all users of the above products and other persons to be informed are made aware of this Field Safety Notice. If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below. Please keep this information at least until the measure has been completed.

Contact persons:

1. Dimitri Krutsch
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E-Mail: d.krutsch@morpheus.com.ag

2. Elvi Gediga
Tel +49 (0) 7461 703 820
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Return Sheet

We hereby confirm to Morpheus AG that we have returned the products listed below:

Article number	LOT	QTY
REB-02-200		
REB-02-250		

The letter was emailed as a PDF to the contact persons and the original was included in the delivery.

Date

Name

Signature