

Urgent safety information

regarding

*REBELLION punch*

December 5, 2025

**Sender:**

Morpheus AG  
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 Germany  
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**Identification of the medical devices affected:**

Item number	LOT	QTY
REB-02-160	P24034	300
REB-02-160	P25003	40
REB-02-250	P24050	185
REB-02-250	16248	322
REB-03-160	P24035	500
REB-03-160	P25006	100
REB-04-160	P24036	300
REB-04-160	P25001	100
REB-04-200	P25004	50
REB-04-200	16226	162

**Description of the problem, including the identified cause:**

We have received reports of quality defects on the REBELLION punch. The lever in the punch broke off during two applications. After internal testing of comparable and similar products, no error or defect could be found. In addition, an independent laboratory was commissioned to carry out a material test. If the REBELLION punch is used to cut at the end of the lever, the parallel lever may break. As a result, the function of the punch can no longer be guaranteed during use. In our opinion, this is a case of defective material.

**Risk assessment:**

To date, we are only aware of two instances of the instrument breaking during use. No patient harm has been reported in this context. According to our internal risk assessment, in the worst case scenario, particles from the material may break off and fall into the surgical site. This can have the following consequences:

- Mechanical and local tissue damage (injury to vessels, nerves, or tissue).
- Foreign body reaction and inflammation.
- Embolic events.
- Chronic reactions and long-term effects.

**What measures should be taken by the addressee?**

We kindly ask you to return the above-listed products that have not yet been used to us. You will receive a credit note or a replacement delivery for the returned products. Please fill out the attached return form and send it back to us by January 2, 2026.

**Dissemination of the information described here:**

Please ensure that all users of the above-mentioned products and other persons who need to be informed within your organization are made aware of this urgent safety information. If you have passed on the products to third parties, please forward a copy of this information or inform the contact person listed below. Please keep this information until at least the measure has been completed.

**Contact person:**

[REDACTED]  
Tel +49 (0) [REDACTED]  
Fax +49 (0) [REDACTED]  
Email: [REDACTED]@morpheus.com.ag

## *Return form*

MORPHEUS AG hereby confirms that the products listed below have been returned by us.

Item number	LOT	QTY

The letter was sent as a PDF by email to the contact persons and the original was enclosed with the delivery.

\_\_\_\_\_

Date

\_\_\_\_\_

Name

\_\_\_\_\_

Signature