

Urgent Safety Information

Recall

Regarding: Forehead Reamer

26.04.2024

Sender:

Unintech GmbH
Monschauer Str. 12
40549 Düsseldorf Germany

Recipient:

Distributors

Identification of affected medical devices:

Affected products: Batch number 2301 of Forehead Reamer (Serial number: UNT-III-177588)

Description of the problem, including the identified cause:

An incident occurred during an operation with a forehead reamer from this specific batch. For safety reasons, we urge you to stop using all forehead reamers with batch number 2301 immediately. These forehead reamers should be returned to Unintech GmbH promptly. A replacement will be sent to you as soon as possible. The incurred transport costs will, of course, be borne by us.

Actions to be taken by the recipient:

1. **Stop usage:** Please immediately stop using the forehead reamers with batch number 2301.
2. **Return products:** Send these forehead reamers back to Unintech GmbH immediately.
3. **Replacement:** A replacement will be sent to you as soon as possible. The transport costs will be borne by us.
4. **Risk assessment:** We are currently investigating the cause of this incident and will keep you updated with further information.



Unitech GmbH – Monschauer Str. 12 – 40549 Düsseldorf

Distribution of the described information:

Please ensure that all users of the above-mentioned products and other relevant persons are informed of this urgent safety information. If you have forwarded the products to third parties, please forward a copy of this information or inform the contact information below.

Please keep this information at least until the action has been completed.

Contact information:

Unitech GmbH

Phone: +49 211 5066 1666

Fax: +49 211 5066 1665