

To whom it may concern

Your contact: [REDACTED]
Department: Vigilance
Tel.: [REDACTED]
Fax: [REDACTED]
E-Mail: vigilance@inomed.com
Website: www.inomed.com

Date: 2023-09-14

Urgent Field Safety Notice and voluntary product recall

Dear customer,

Following reports of our customers, inomed Medizintechnik GmbH is conducting a voluntary corrective action, issuing a precautionary product recall for further investigation of a potentially affected production batch.

The following item(s) with serial number(s) potentially affected in your facility are:

Article no.: 217200

Description: C3 CryoProbe 2,1mm sharp

Serial Nr.:

20B157, 20B159, 20B160, 20B161, 20B163, 20B166, 20B203, 20B206, 20B207, 20B208,
20B209, 20B210, 20B211, 20C003, 20C004, 20C005, 20C006, 20C009, 20C010, 20H108,
20H109, 20H110, 20H111, 20H112, 20H113, 20H114, 20H115, 20H117, 21A247, 21A248,
21A250, 21A251, 21A252, 21A253

As of now, we cannot fully rule out a batch-related manufacturing issue, hence **we strongly advise you not to continue using these affected items.**

Regarding the previously affected products, it was observed that under significant mechanical bending stress, the stability of the probe tip could be compromised. This poses a risk of the probe tip breaking during such a handling.

Please identify and return any affected probes to us or your local representative if they are still at your facility. We will conduct a full service and if necessary, repair or replace returned products. Your local representative or our customer service department will get in touch with you regarding this matter after we have received the product. Please complete the form further below.

Best regards

inomed Medizinische Technik GmbH

**Urgent Field Safety Notice
Voluntary Recall for
C3 CryoProbe**

Please complete this form and return it to vigilance@inomed.com.

If you have any questions on completing or return of this form, please contact us as soon as possible.

Confirmation and disclosure form

I have read this Medical Device Field Safety Notice and understand its contents.
I will return all articles, which are affected of this Field Safety Notice:

Returned serial numbers: _____

Discarded serial numbers: _____

Name: _____

Position: _____

Healthcare facility / Distributer: _____

Email address: _____

Phone number: _____

Date: _____

Signature: _____