

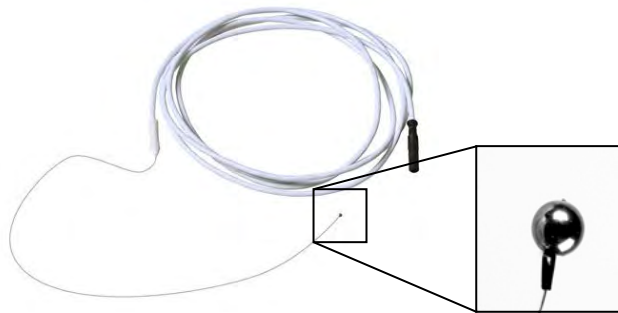
inomed Medizintechnik GmbH · Im Hausgruen 29 79312 Emmendingen GERMANY

To whom it may concern

**Tel.** +49 7641 94 14 - 0  
**Fax** +49 7641 94 14 - 94  
**Email** info@inomed.com  
**Date** 2017-02-15

## ***Urgent Field Safety Notice and voluntary Product Recall***

**Affected product:**        ***Ball Electrode, Article number 530455***



Dear customer,

During an internal review, it was discovered that the ball electrode (article number 530455) does not fulfill our quality standards.

There is the possibility that the ball detaches itself from the lead – see picture.  
It cannot be ruled out that this can happen during the application in the patient.

If unnoticed, the ball might permanently remain in the patient's body and would present a major health hazard.

We therefore strongly discourage further usage of the affected product due to preventative security measure.

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Managing Director:  
Dipl.-Ing. (FH) Rudi Mattmüller  
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HRB 260788  
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Tax no. 05019/24280  
WEEE-Reg. no. DE 55946849

National bank details:  
Sparkasse Freiburg-  
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Account 2000 34 27  
BLZ 680 501 01  
BIC-Nr. FRSP DE 66  
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0020003427

International bank details:  
Commerzbank Freiburg  
Account 150 80 3500  
BLZ 680 400 07  
BIC-Nr. COBADEFF  
IBAN: DE39 68040007  
0150803500

CIC CA CLIENTELE  
ENTREPRISE EUROPE  
Banque 30087 / Guichet 33085  
Account 00040 528 001 / Clé 81  
IBAN: FR 76 30087330  
850004052800 181  
BIC: CMCIFRPP

### Immediate Actions required by your facility

Our records indicate that you may have received one or more of the subject devices. Please complete therefore the following actions:

- 1) Do not use the article and immediately check your internal inventory.  
Quarantine all subject devices and return to inomed:

inomed Medizintechnik GmbH  
Im Hausgrün 29  
79312 Emmendingen  
Germany

Credit will be of course provided for the returned products and shipping costs.

- 2) Please fill out the following form, irrespective of existing stock or not, and send back within seven days of receipt of this information.
- 3) Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Please complete even if you longer have any of the subject devices in your physical inventory. We request that you respond to this notice within 7 calendar days from the date of receipt.
- 4) Circulate this Field Safety Notice internally to all interested/affected parties. If any of the subject devices have been distributed to other organizations, please forward a copy of this information.

We confirm an appropriate Regulatory Agency has been notified of this notice.

We appreciate your cooperation and we recognize the inconvenience this may cause to your facility. Thank you for your support regarding this important matter.

Should you have any queries concerning this matter please do not hesitate to contact your sales representative.

Yours Sincerely,

**inomed Medizintechnik GmbH**



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## Response form

### Urgent Field Safety Notice and voluntary Product Recall

**Affected product: Ball Electrode, article number 530455**

Our reference: CID17-007

Customer ID \_\_\_\_\_

Facility \_\_\_\_\_

Address \_\_\_\_\_

Contact person \_\_\_\_\_

Phone \_\_\_\_\_

E-mail \_\_\_\_\_

Please tick as appropriate:

- I have checked our internal inventory and confirm that we have not located the affected product in our inventory.
- I have checked our internal inventory and we have located the following devices:

Article number	Lot no.	Quantity quarantined, to be returned	Quantity distributed

- We have further distributed subject devices to:

Facility Name \_\_\_\_\_

Address \_\_\_\_\_

Contact person \_\_\_\_\_

Phone \_\_\_\_\_

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature