Technomed
medical accessories

Taking you further. Step by step.

Maastricht-Airport, The Netherlands, 20th of December 2021

URGENT MEDICAL DEVICE RECALL

DISPOSABLE SUBDERMAL NEEDLE ELECTRODE, CORKSCREW

(NCR 21-081 / CAPA 21-009)

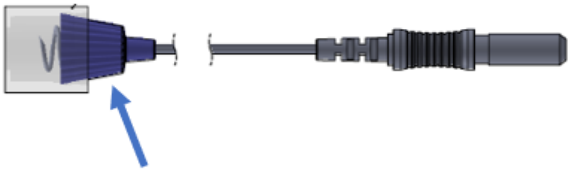
AMBU A/S
Baltorpbakken 13
2750 Ballerup
Denmark

Dear customer,

This is to inform you we identified an issue with some batches of Technomed Disposable Subdermal Corkscrew Electrodes (commercial number TE/S50715-001-C, unique device identifier [UDI] 08718375867549, and commercial number TE/S50725-001-C, unique device identifier [UDI] 08718375867563) of which we recently delivered several boxes to you.

Description of the hazard

Technomed is issuing a Medical Device Recall notice following the observation of a high risk that the needle electrode could detach from the hub and, in the worst case, lead wire in certain LOT numbers (see below). This may complicate the placement and removal of the needle from the patient, as a good attachment of the hub is needed to be able to screw the electrode in and out of the patient's skin. In case the hub and lead wire are not well-attached to the product, it may be difficult to remove the electrode from the patient. A worst case situation will potentially result in the need to remove the needle from the patient with a surgical forceps or via an incision, i.e. additional surgical intervention. Herewith, we would like to inform you about this quality issue.



Actions required

We request these actions from you:

- Inform any customers who have received products from the affected LOT numbers about this issue, by forwarding a copy of this notice to them.
- We ask you to sign the included acknowledgement form. Only you as the distributor, not your end user, has to complete the acknowledgment form.
- Technomed will schedule a call with you, in which we will discuss the replacement of affected products. This includes:
    1. Notifying us of the amount of products you can return to us, and the LOT numbers to which they belong (see acknowledgement form below);
    2. Returning the affected products as soon as possible (see our address below);
    3. Receiving a replacement for the affected products from us.

    After the call, you will need to sign the below acknowledgement form and return it to us via quality@technomed.nl, so we can contact you to arrange replacement of the product. All hereto related shipping costs will be at our charge.

What happens next?

All products will be replaced free of charge. We will send you a Sales Return Order (SRO) number as soon as we receive confirmation of the amount of products to be returned. Please use the provided SRO number for your return.

Maintaining a high level of safety and quality is our highest priority. Please be assured that the relevant regulatory agencies have been informed of this issue. We appreciate your help in completing this action and apologize for any inconvenience this issue may have caused.

Any questions?

If you have any questions or concerns, please contact quality@technomed.nl, your local representative or call us on +31 43 608 48 48.

Yours Sincerely,

Lothar Krinke, Ph.D.

Chief Executive Officer, Welcony Inc.

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Please complete this form and return it to quality@technomed.nl.

If you have any issues in completing or returning this form, please contact us as soon as possible to discuss.

Once you have returned this form, we will arrange for replacement items to be sent to your facility or technical personnel.

Acknowledgment form

I have read this Medical Device Recall Notice, understand its content, and will follow the instructions as described.

Name: _____

Position: _____

Company: _____

Telephone number: _____

E-mail address: _____

Date: _____

Signature:

Affected batches to be returned to Technomed Europe

Commercial number	LOT number	Number of boxes delivered	Number of boxes available to be returned	Number of boxes to be returned by your customers
TE/S50725-001-C	049166	1		
TE/S50715-001-C	049167	1		

Space for any additional remarks / comments:

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