Technomed
medical accessories

Taking you further. Step by step.

Maastricht-Airport, The Netherlands, 4th of August 2022

FIELD SAFETY NOTICE

DISPOSABLE SUBDERMAL NEEDLE ELECTRODE, Pt/Ir

MRI Safety Information

(NCR 22-063)

Dear customer,

The purpose of this communication is to inform you that Technomed is issuing a Field Safety Notice for Disposable Subdermal Needle Electrode, Pt/Ir (commercial numbers TE/S46-638 and TE/S46-638/01, LOT numbers are specified in the table below).

<table>
<tr><td>Field Safety Notice Overview:</td><td>In September 2021, Technomed has performed a labelling update for Disposable Subdermal Needle Electrode, Pt/Ir (commercial numbers TE/S46-638 and TE/S46-638/01). MRI Safety Information was added to the Instructions for use as we were informed of skin burns occurring after the product stayed applied on the patient while the patient was in an MRI scanner.

There are still products in the market that are accompanied with a version of the Instructions for use that does not have the MRI Safety Information included. The affected product codes and LOT numbers, being accompanied with an old version of the Instructions for use, are listed in the table below.</td></tr>
<tr><td>Details on affected Devices, to assist in identification of the product involved:</td><td>
<table>
<tr><th>Commercial number</th><th>UDI on box</th><th>LOT number</th></tr>
<tr><td>TE/S46-638/01 (Disposable Subdermal Needle Electrode, Pt/Ir)</td><td>08718375866924</td><td>046241</td></tr>
<tr><td rowspan="8">TE/S46-638 (Disposable Subdermal Needle Electrode, Pt/Ir)</td><td rowspan="8">08718375861530</td><td>042236</td></tr>
<tr><td>042903</td></tr>
<tr><td>044220</td></tr>
<tr><td>045077</td></tr>
<tr><td>045443</td></tr>
<tr><td>045831</td></tr>
<tr><td>046574</td></tr>
<tr><td>047126</td></tr>
</table>
</td></tr>
</table>

			047843 048428 049285	
Why you are being contacted:	You are receiving this letter because our records indicate that you have received products from the above mentioned range.			
Description of the problem:	In September 2021, Technomed has performed a labelling update for Disposable Subdermal Needle Electrode, Pt/Ir (commercial numbers TE/S46-638 and TE/S46-638/01). The following MRI Safety Information was added to the Instructions for use: ***MRI Safety Information:*** *The medical device has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. Performing an MR exam on a person who has this medical device inserted or positioned on them may result in injury or device malfunction.* Products from the LOT numbers as described above do not have this section included yet in their Instructions for Use, while it has come to our attention that in some occurrences these products have been used in MRI environment, which may result in skin burns of varying degrees. To prevent further improper use of the products as listed above, we are sending this Field Safety Notice. For your convenience, the updated Instructions for Use are sent with this Field Safety Notification.			
Description of Hazard:	A few cases were observed in which the product stayed applied on the patient while the patient was in an MRI scanner. A risk that has been reported to us: - Development of skin burns of varying degrees due to tissue heating.			
Actions requested from you:	We request these actions from you: - Read this Field Safety Notice. - Review the list of affected products. - Inform any customers who have received or will receive products from the affected LOT numbers about this issue, by forwarding a copy of this notice and the updated Instructions for Use to them. - Review, complete and sign the included acknowledgement form at the end of this letter and return it to us via regulatory@technomed.nl. Only you as the distributor, not your end user, has to complete the acknowledgment form.			

	- Maintain awareness of this notice until all affected product has been utilized.
Available assistance:	If you have any questions or concerns, please contact regulatory@technomed.nl, your local representative or call us on +31 43 608 48 48.
Additional information:	- Please be assured that the relevant regulatory agencies have been informed of this issue. - Please note that this security information is not a recall.

Maintaining a high level of safety and quality is our highest priority. We appreciate your help in completing this action and apologize for any inconvenience this issue may have caused.

Yours Sincerely,

Ronnie Stolec - Campo

Chief Executive Officer, Welcony Inc.

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

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

Acknowledgment form

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

Name: _____

Position: _____

Company: _____

Telephone number: _____

E-mail address: _____

Date: _____

Signature: