

Urgent FIELD SAFETY NOTICE

Device: **MedSphere Radio Frequency Systems – Electrode**

Reference: **R-2021-01, dated 2021-06-24**

Action: **Return**

Attention: Oncology, Interventional Radiology

Description of the problem

MedSphere International (Shanghai) Co. Ltd. has received two complaints reporting that wrong labelling of the unit pack labelling with wrong active product length.

The manufacturer received reporting from the distributor that the active length of the electrode (model 21-863271, active length: 15 cm) marked on the label was different from the actual length (20cm) of the device.

Further investigation confirmed the complaints and revealed that additional lots (other than the complaint lots) are impacted by this mis-labelling issue.

Details on affected devices

Effective immediately - Do not use or distribute the following product code/Lot. Refer to action required for further instructions.

Table 1: Affected products details

Product code	Lot Numbers	Expiry Date
21-843271	9429S0285	2022-07-18
21-863271	9399S0284	2022-06-19
21-883271	9401S0284	2022-06-19
21-843471	9419S0285	2022-07-08
21-863471	9430S0285	2022-07-24
21-843671	9402S0284	2022-06-19
21-883671	9415S0285	2022-07-08
10-181571	9215S0270	2021-08
L-121	9379S0284	2022-06-16
L-122	9380S0283	2022-05-14
L-221	9216S0270	2021-08
L-222	9217S0270	2021-08

Please utilize **Attachment 1** for assistant in identifying the product lot subject to this recall.

Potential hazard

Wrong labelling of the electrode dimension may lead to extending ablation area of the tissue or user inconvenience, including necessity to obtain additional product or ablate repeatedly, or potentially resulting in extending time of operation.

MedSphere has not received any reports of Injuries related to this issue, and this issue

would not have serious patient safety impact. We are implementing corrective actions to address the issue. We apologize for any inconvenience this may have caused.

Corrective actions of the Manufacturer

Root cause: Different lots were subjected to labelling process at the same period in one workshop which might lead to mis-labelling.

The corrective actions include:

- 1) Modify the labelling process SOP to prevent more than one batch of product be subjected to labelling process within the same labelling process area.
- 2) Line clearance SOP should be modified to ensure timely clearance of the previous product batch prior to labelling process of next batch.

Customer instructions

- 1) Stop using the product subject to recall.
- 2) Remove any affected (recalled) product from your inventory (whether in Shipping and Receiving or ANY other location). Segregate this product in a secure location for return.
- 3) This notice needs to be passed on to any organization where the potentially affected products have been transferred. Review this communication and ensure that all users have received notice of this issue.
- 4) Complete the related reply form (**Attachment 2**) and return this form as quickly as possible to the e-mail address indicated on the form.
- 5) Your local Terumo representative will contact you on behalf of Medsphere for further follow up.

The device manufacturer Medsphere International (Shanghai) Co. Ltd. has notified this *Field Safety Notice* to your national Competent Authority.

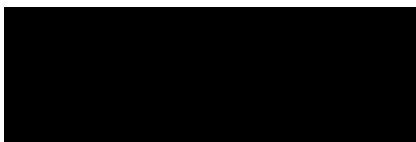
We encourage you to contact your local Terumo representative with any questions or concerns.

Organisation (to be completed by the sales or dealer)

Contact name (function)

Contact phone, mobile, email

For the manufacturer, Medsphere International (Shanghai) Co. Ltd.,



2021-06-24

Date

Attachment 1: Product Identification Tool

This tool will help customers identify the location of the product code, lot number and expiry date of MedSphere Radio Frequency Systems –Electrode, subject to this recall by using the packaging labels.

Sealed Device Package
(Representative Sample)

Individual Unit Box
(Representative Sample)

The diagram illustrates the layout of labels on two types of packaging: a Sealed Device Package and an Individual Unit Box. Both labels feature the MedSphere logo, product name 'MedSphere Electrodes', and CE marking. The labels include a barcode and fields for Reference (REF), Lot (LOT), and Expiry date. On the Sealed Device Package, the REF field is 'XX-XXXXXX', LOT is 'XXXX/SXXXX', and the expiry date is 'XXXX-XX-XX'. On the Individual Unit Box, the REF field is 'XX-XXXXXX', LOT is 'XXXX/SXXXX', and the expiry date is 'XXXX-XX-XX'. A callout box on the right side of the Individual Unit Box label points to the LOT and Expiry date fields, indicating their location for identification. The diagram also shows a technical drawing of the electrode with dimensions 'XXcm' and 'Xcm', and various safety symbols including 'STERILE R', '0°C', and '40°C'.

Sales Unit Box (Representative Sample)

The diagram shows the label layout for a Sales Unit Box. It features the MedSphere logo, product name 'MedSphere Electrodes', and CE marking. The label includes a barcode and fields for Reference (REF), Lot (LOT), and Expiry date. The REF field is 'XX-XXXXXX', LOT is 'XXXX/SXXXX', and the expiry date is 'XXXX-XX-XX'. A callout box on the right side of the label points to the LOT and Expiry date fields. The diagram also shows a technical drawing of the electrode with dimensions 'XXcm' and 'Xcm', and various safety symbols including 'STERILE R', '0°C', and '40°C'.

Attachment 2: Field Safety Notice - Customer Reply Form

Field Safety Notice - CUSTOMER REPLY FORM

Device: **MedSphere Radio Frequency Systems – Electrode**

Reference: **R-2021-01**

Action: **Return**

Please complete, sign and e-mail this form back:

To: **<to be completed by the sales or dealer>**

E-mail: **<to be completed by the sales or dealer>**

Hospital/Customer Name	
City	
Country	

Our records indicate that you have received devices from the involved device population.

By completion and return of this form, I am confirming receipt, reading and acting on this Field Safety Notice:

- We have no physical inventory of the involved devices
- We will return the devices and the following devices are ready to return:

Reference	Lot number	Number of units ready to return

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	