



<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Red Dot™ Radiolucent Monitoring Electrode with Foam Tape, Catalog Number 2244

FSCA-identifier: 2021-09 FSCA Red Dot

Type of action: Disposal of affected products

Date: September 30th, 2021

Attention: 3M Health Care Business Customers

Dear Customer,

3M is notifying all users of the above-mentioned **3M™ Red Dot™ Radiolucent Monitoring Electrode** of a field safety corrective action.

Details on affected devices:

Only lot number 202302LK of 3M™ Red Dot™ Radiolucent Monitoring Electrode, reference number 2244, is affected by this field action.

Description of the problem and potential hazard and risk for the patient/user:

This corrective action has been initiated due to the potential of breakage of the ECG Electrode carbon stud from the eyelet, rendering the electrode unusable. Under this condition an ECG could not be started with the defective electrode and would require use of a replacement electrode. While 3M has received related complaints, no injuries or complications have been reported in association with this issue. 3M is executing a corrective action for this product lot in order to minimize customer inconvenience associated with the affected product.

Please note that only the lot number given above is subject to this Field Safety Corrective Action Notification.

Action to be taken by the user:

All users of the **3M™ Red Dot™ Radiolucent Monitoring Electrode** are being asked to take the following actions:

- Ensure all your internal and external customers are informed about this corrective action.
- Please identify the affected product listed above, remove from your inventory and do not use.
- Please discard all remaining affected product listed above per facility procedures.
- Complete and return by e-mail to meddev.de@mmm.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices you have disposed of.

Transmission of this Field Safety Notice:

Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

Contact reference person:

If you have questions, please contact your local 3M representative.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

xxx

3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss,
Germany

Acknowledgement Form – FSN 2021-09 FSCA Red Dot

Email completed form to: meddev.de@mmm.com

Please examine your inventory to determine if you have any stock of the affected product lots indicated below. Note, this notification only applies to the indicated lots of 3M™ Red Dot™ Radiolucent Monitoring Electrode.

We have examined our inventory, identified the following quantity of units on hand and have disposed of them per facility protocol.

Affected Lot	Quantity of electrodes
202302LK	

We have examined our inventory and do not have any above listed lot of 3M™ Red Dot™ Radiolucent Monitoring Electrode on stock.

I acknowledge that I have read and understood this letter and will complete the actions requested.

Email completed form to: meddev.de@mmm.com

Person completing this form:

Name		Company Name	
Signature		City, State, Country	
Date		Phone	
		E-mail	