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*<Customer address>*

# Field Safety Notice

**Name of the affected product:** 3M™ Nexcare™ ColdHot Therapy pack classic, reference number N1570G
**FSCA-identifier:** 2022-04 FSCA ColdHot
**Type of action:** Disposal of affected products

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**Date:** April 13th, 2022

**Attention:** 3M Health Care Business Customers

Dear Customer,

3M is notifying all customers in impacted European countries of the above-mentioned 3M™ Nexcare™ ColdHot Therapy pack classic reference N1570G of a field safety corrective action.

**Description of the problem and potential hazard and risk for the patient/user:**
This corrective action has been initiated due to an unintended shipment of product of reference N1570G instead of N1570 into the European market. One lot of the product of reference N1570G was packed in shipper cartons which were incorrectly labelled as reference N1570. Reference N1570G is intended to be shipped to the Gulf region, whereas reference number N1570 is intended for the European market. Due to this error, N1570G was mistakenly distributed on to the European market.

The primary carton of product N1570G is providing information in English, French and Arabic only, whereas the instruction for use is giving all relevant information, including safety instructions, in all necessary European languages.

However, due to the missing languages on the primary carton, the user (in Austria, Belgium, Czech Republic, Denmark, The Netherlands and Sweden) might overlook the cautionary symbol to read the instruction before use.

Moreover, the EAN code printed on the product could cause problems in logistical handling upon customer receipt.

**Details on affected devices:**
The following lot of Nexcare™ ColdHot Therapy pack classic reference number **N1570G** is subject to this field safety corrective action: **50242N0341**

**Action to be taken by all customer:**
All customers of the **3M™ Nexcare™ Cold Hot Therapy pack** are being asked to take the following actions:

1. Ensure all your internal and external customers are informed about this corrective action.
2. Please inform us if you supplied the affected items to customers outside your home country.
3. Please identify the affected product listed above.
4. **Ireland/France only:** Please verify, if the usage of reference number N1570G instead of N1570 is feasible in your organization. If yes, please continue with action 6. If no, please continue with action 5.
5. Please discard all remaining affected product listed above per facility procedures.
6. 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.

Dr. Marie Isabel Cobbers
Safety Officer
3M Deutschland GmbH, Health Care Business
Carl-Schurz-Strasse 1, 41453 Neuss, Germany
Mail: meddev.de@mmm.com

**Acknowledgement Form – FSN 2022-04 FSCA ColdHot**

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

Please examine your inventory to determine if you have any stock of the affected product lot indicated below. Note, this notification only applies to the indicated lot of **3M™ Nexcare™ ColdHot Therapy pack.**

☐ **Ireland/France only**: We have examined our inventory, identified the affected products and we confirm that the devices can be continued to be used in our facility.

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

| Lot number | Number of products disposed |
|---|---|
| 50242N0341 | |

☐ We have examined our inventory and do not have any above listed lot of 3M™ Nexcare™ ColdHot Therapy pack on stock.

☐ I have communicated this information to all internal and external customers of my organisation.

☐ 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 /Hospital Name | |
| Signature | | City, Country | |
| Date | | Phone | |
| | | E-mail | |