3M Deutschland GmbH
Carl-Schurz-Straße 1
41453 Neuss

☎+49 (0)2131/140
🖷+49 (0)2131/142649
Internet: www.3M.de
E-Mail: innovation.de@3M.com
WEEE-Reg.-Nr. DE 36963167
VAT-ID: DE 120679179

<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Reston™ Self-Adhering Foam Pads, References 1560M, 1561H
FSCA-identifier: FSN 2019-03 FSCA Reston
Type of action: Communication of labeling error

Date: April 2nd, 2019

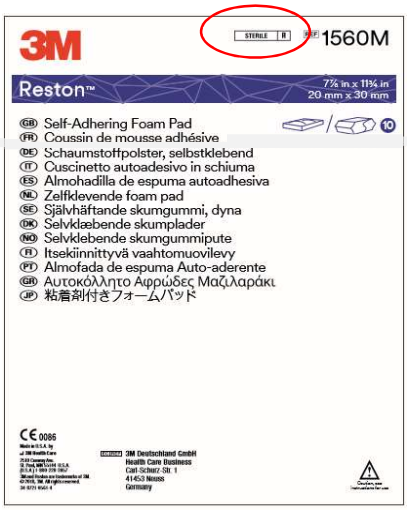
Attention: 3M Health Care Business Customers

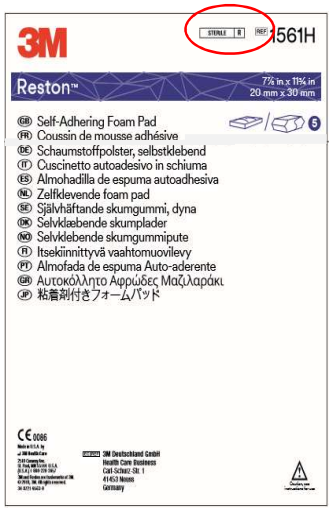
Dear Customer,

3M is notifying all users of the **3M™ Reston™ Self-Adhering Foam Pads, references 1560M and 1561H** about a labeling issue.

Details on affected devices:
All devices of references 1560M and 1561H distributed between May 5th, 2018 and March 18th, 2019 are affected by this corrective action.

Description of the problem and potential hazard and risk for the patient/user:
3M Healthcare has become aware of a labeling error impacting 3M™ Reston™ Self-Adhering Foam Pads. These products are supplied to the market as nonsterile devices. Multiple lots of Reston Foam Pads, Catalog numbers 1560M and 1561H were mistakenly marked as sterile in the following way:





In case the devices are not used in accordance with the intended use as given in the instruction for use, there could be the potential risk of a wound infection.
However, there have been no complaints received or adverse event reported associated with these labeling errors. The products remain safe for their intended use.

Action to be taken by the user:
All users of the **3M™ Reston™ Self-Adhering Foam Pads, references 1560M and 1561H,** are being asked to take the following actions:

- Ensure all users within your facility receive the information about this labelling error and are aware that the devices are **non-sterile**.
- The devices can be used safely according to the intended use communicated in the instruction for use.

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-Str. 1, 41453 Neuss, Germany
Mail: mcobbers@mmm.com
Tel.: +49-2131-144792