



April 8, 2019

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CARDINAL HEALTH
CUSTOMER ADVOCACY

Dear Valued 3M Customer:

**Subject: Field Safety Action - Notice of Product Labeling Error
3M™ Reston™ Self-Adhering Foam Pads**

3M Medical Solutions Division has become aware of a labeling error impacting 3M™ Reston™ Self-Adhering Foam Pads. This product is supplied to the market as a nonsterile device.

All lots of Reston Foam Pads, catalog numbers 1560M and 1561H, with labeled expiration dates from **2020-0505 to 2022-02-08** were mistakenly marked as sterile with the following symbol:



There have been no complaints received, or adverse events reported, with these labeling errors. **The product remains safe for its intended use.**

Action to be taken by user:

All users of the **3M™ Reston™ Self-Adhering Foam Pads, 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.

We apologize for any inconvenience this matter may have caused you. At 3M, we are dedicated to ensuring the highest quality standards and doing the right thing for our customers, every time.

For questions and additional information related to 3M™ Reston™ Self-Adhering Foam Pads please contact your local 3M sales representative, or the 3M Health Care Customer Helpline at 1-800-228-3957, Monday through Friday, 7:30 a.m. – 6:00 p.m. Central Time.

Sincerely,

Michael J. Besser
Division Quality Manager
3M Medical Solutions Division