



<Customer address>

Field Safety Notice

Name of the affected product: 3M™ Durapore™ Advanced Surgical Tape

FSCA-identifier: FSN 2019-11 FSCA Durapore advanced

Type of action: Disposal of affected products

Date: November 27th, 2019

Attention: 3M Health Care Business Customers

Dear Customer,

3M is notifying all users of the **3M™ Durapore™ Advanced Surgical Tape** of a field action.

Details on affected devices:

All lots of the following reference numbers of Durapore™ Advanced Surgical Tape are affected by this corrective action:

1590-0, 1590-1, 1590-2, 1590-3, 1591-0, 1591-1, 1591-2, 1591-3, 1590S-1, 1590S-2

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

While the product meets all safety and efficacy criteria, long term exposure of 3M™ Durapore™ Advanced Surgical Tape to continuous high moisture clinical applications has not fully met all of 3M's performance expectations. This usage may cause tape bond failure, so that the tape does not perform as intended. Furthermore, the tape fibers may fray which could be accidentally ingested or aspirated. As a result, we request that the user immediately cease use of the product and quarantine it for destruction/disposal. 3M has decided to stop sales.

Action to be taken by the user:

All users of the **3M™ Durapore™ Advanced Surgical Tape** are being asked to take the following actions:

- Ensure all your internal and external customers are informed about this corrective action.
- **Discontinue use and dispose of** any Durapore™ Advanced Surgical Tapes.
- Complete and return 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: mcobbers@mmm.com

Acknowledgement Form – FSN 2019-11 FSCA Durapore advanced

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

Please examine your inventory to determine if you have any stock of 3M™ Durapore™ Advanced Surgical Tape. Note, this corrective action only applies to 3M™ Durapore™ Advanced Surgical Tape (“purple tape”) and does NOT apply to 3M™ Durapore™ Surgical Tape or any other 3M medical or surgical tapes (see image below).

Acknowledge that you have read and understood this letter and will complete the actions requested.

We have examined our inventory and identified and disposed of the following number of rolls of 3M™ Durapore™ Advanced Surgical Tape:

Catalog Number (REF #)	Number of Rolls in Inventory/ To be Disposed
1590-0	
1590-1	
1590-2	
1590-3	
1591-0	
1591-1	
1591-2	
1591-3	
1590S-1	
1590S-2	



We have examined our inventory and **do not** have 3M™ Durapore™ Advanced Surgical Tape on stock.

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

Person completing this form:

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