



Field Safety Notice

Name of the affected product: Tegaderm™ - Transparent Film Dressing Frame Style,
Reference 1632P-10
FSCA-identifier: 2024-05 FSCA Tegaderm
Type of action: Disposal of affected products

Date: May 31st, 2024

Attention: 3M Healthcare Customers

Dear Customer,

3M is notifying all customers and users of the above-named product 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 the identification of a manufacturing issue. For the intended use the product is required to be provided in a sterile form. The affected products have been gamma-irradiated with a non-validated sterilization cycle and therefore sterility cannot be claimed.

The potential risk for patients for infection is deemed to be low, especially taking into account the bioburden of the affected products and the microbial colonization of the skin and wound surface.

Details on affected devices:
The following lots of Tegaderm™ - Transparent Film Dressing Frame Style are subject of this field safety corrective action.

Catalogue number	Lot number	Date of manufacture
1632P-10	104841330	September 23 rd , 2022
	106615553	January 24 th , 2024

Action to be taken by all customers:

1. Ensure all your internal and external customers are informed about this corrective action.
2. If you are a distributor, send this FSN to all affected customers.
3. Please inform us if you supplied the affected items to customers outside your home country.
4. Please identify the affected product listed above and immediately cease use and distribution of affected lots of Tegaderm™ - Transparent Film Dressing Frame Style 1632P-10.
5. Please discard all remaining affected product listed above per facility procedures.
6. Complete and return by e-mail to fsca-emea@solventum.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
Manager Regulatory and Vigilance
Mail: fsca-emea@solventum.com

Acknowledgement Form – FSN 2024-05 FSCA Tegaderm**Email completed form to: fsca-emea@solventum.com**

Please examine your inventory to determine if you have any of the Tegaderm™ - Transparent Film Dressing Frame Style, catalog number 1632P-10, listed. Note, this corrective action only applies to the affected catalogue number and lots listed. It does NOT apply to any other Tegaderm™ products.

- ☐ 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 Tegaderm™ - Transparent Film Dressing Frame Style:

Catalogue number	Lot number	Quantity of sets in inventory that have been disposed
1632P-10	104841330	
1632P-10	106615553	

- ☐ We have examined our inventory and do not have the affected Tegaderm™ - Transparent Film Dressing Frame Style in stock.

Email completed form to: fsca-emea@solventum.com

Person completing this form:

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