Z-MEDICA

It's QuikClot Or It's Not

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March-2022

URGENT – FIELD SAFETY NOTICE

Type of Action	Advisory Notice
Z-Medica Reference	HHE 2022-0001
Commercial Name	QuikClot® Interventional Hemostatic Bandage™ CE – English, n/slit with 3M™ Tegaderm™ – Sterile Gauze Pad 1.5 IN x 1.5 IN (3.8CM x 3.8CM) QuikClot® Interventional Hemostatic Bandage™ CE – English Language, pre-slit with 3M™ Tegaderm™ – Sterile Gauze Pad 1.5 IN x 1.5 IN (3.8CM x 3.8CM)

Product Code	Lot Number					
183	12414	12461	12494	12557	12701	12763
	44F21K0012	44F21L0020	44F22A0004			
188	12413	12493	12553	12746	44F21K0011	44F21L0022
	44F22A0021					

Dear Customer,

Details of affected devices

Z-Medica LLC, a subsidiary of Teleflex Incorporated, has initiated a voluntary Field Safety Corrective Action (FSCA) for QuikClot® Interventional Hemostatic Bandage™ CE – English, n/slit with 3M™ Tegaderm™ – Sterile Gauze Pad 1.5 IN x 1.5 IN (3.8CM x 3.8CM) and QuikClot® Interventional Hemostatic Bandage™ CE – English Language, pre-slit with 3M™ Tegaderm™ – Sterile Gauze Pad 1.5 IN x 1.5 IN (3.8CM x 3.8CM).

Description of the problem & immediate actions required

Z-Medica, a subsidiary of Teleflex Incorporated, is voluntarily issuing an advisory notice for the affected products referenced above. One of the components within the packaging, the 3M™ Tegaderm™ Transparent Film Dressing Frame Style (1626W), did not include the CE mark, translations of the product name, an EU packaging recycling symbol, or the EC Representative information on the labelling. Refer to the adjacent image of the non-CE Marked 3M™ Tegaderm™ Transparent Film Dressing Frame Style (1626W). The 3M™ Tegaderm™ Transparent Film Dressing Frame Style, is received by Z-Medica, a subsidiary of Teleflex Incorporated, in its original primary sterile packaging and is included and sold with the affected products referenced above.

The QuikClot® Interventional Hemostatic Bandage™ products referenced above including the 3M™ Tegaderm™ Transparent Film Dressing Frame Style are suitable for continued use. There is no difference in form, fit, function or intended use of the 3M™ Tegaderm™ Transparent Film Dressing Frame Style included with the affected products and those that are labelled with the appropriate CE and other markings. Users are advised to continue to adhere to the pictorial instructions for use on 3M™ Tegaderm™ Transparent Film Dressing Frame Style (1626W) as well as the Z-Medica instructions for use accompanying the affected products.

The EC Representative for 3M™ Tegaderm™ Transparent Film Dressing Frame Style (1626W) continues to be 3M Deutschland GmbH Health Care Business, located at Carl-Schurz-Str.1, 41453 Neuss, Germany.

Our records indicate you have received products that are in scope of this Field Safety Corrective Action.

Please complete the acknowledgement form (Appendix 1) and return it to Z-Medica LLC, a subsidiary of Teleflex Incorporated, at the email address indicated therein.

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	**1**
Distributors	**2**

Action list number 1 – Medical facilities
Our records indicate your facility has received products that are in scope of this Field Safety Corrective Action. Please complete the acknowledgement form (Appendix 1) and return it to Z-Medica, a subsidiary of Teleflex Incorporated, at the email address indicated therein. Additionally, please provide this Field Safety Notice to all those who need to be aware of it within your organisation including clinicians, supply chain/distribution centres, and all other interested parties. Affected products may continue to be used as outlined on page one of this Field Safety Notice.

Action list number 2 – Distributors
If you are a distributor, provide this Field Safety Notice to all of your customers who have received products that are in scope of this Field Safety Corrective Action. Should you have stock remaining, place this notice with each shipment/sale of the product to ensure it is delivered to the end user so they are made aware of the instructions outlined on page one of this Field Safety Notice. If you have further distributed product outside of your country, please notify Z-Medica, a subsidiary of Teleflex Incorporated, by return email to the e-mail address below. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Z-Medica, a subsidiary of Teleflex Incorporated.

Z-Medica
Z-Medica, a subsidiary of Teleflex Incorporated, informs all customers, employees of Z-Medica/Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice
This Field Safety Notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider end users, clinicians, supply chain/distribution centres, etc., in the circulation of this Field Safety Notice. Maintain awareness of this Field Safety Notice until all required actions have been completed in your organisation.

Contact reference person
Should you require any further information or support concerning this issue, please contact:

Customer Service:
Contact: Nicole Morawiec **Telephone:** +41 (0) 31 818 40 90
Email: info.ch@teleflex.com

Z-Medica, a subsidiary of Teleflex Incorporated, is committed to providing high quality, safe and effective products. We sincerely apologise for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Z-Medica LLC,

Lizabeth Kurjiaka

Lizabeth Kurjiaka, Director of Strategic Initiatives and Quality Manger

Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY Z-MEDICA – IMMEDIATE ATTENTION REQUIRED

Ref. HHE 2022-0001

RETURN COMPLETED FORM IMMEDIATELY TO:

E-Mail: info.ch@teleflex.com

☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory **DOES** include products affected by this Field Action.

Complete this Acknowledgement form and return immediately by using the contact information above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**Phone/FAX**
FORM COMPLETED BY	**Number of Products at the Site**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	