Teleflex Medical
IDA Business & Technology Park,
Dublin Road, Athlone
Westmeath, Ireland

July 2021

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000478
Commercial Name	PERCUQUICK ONE-STEP SET, PDT PERCUQUICK ONE-STEP DILATOR
Product Code/Lot Number	Refer to Appendix 2

Dear Customer,

Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action (FSCA) for Percuquick One Step Set, PDT and Percuquick One-Step Dilator; refer to Appendix 2 for a list of impacted product codes and lots.

Description of the problem & immediate actions required

Teleflex is initiating a Field Safety Corrective Action due to reports of cracked/deformed dilator tip on the product as seen in Figure 1. If the cracked/deformed dilator tip is used, then it may fail to achieve an adequate percutaneous dilative tracheostomy to enter the trachea, therefore resulting in a delay in treatment because another dilator is required.

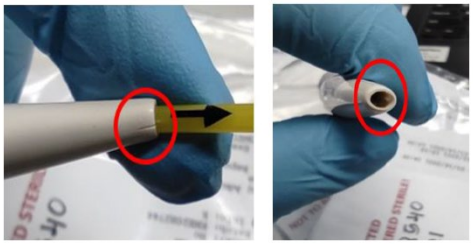

Figure 1.

Our records indicate you have received products that are subject to this Field Safety Notification.

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

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
3. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Action list number 2 – Distributors

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope, refer to Appendix 2 for the list of impacted codes & lots, to Teleflex.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
4. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This 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, risk managers, supply chain/distribution centres etc. in the circulation of this notice. Maintain awareness of this 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

FAX: +41 (0) 31 818 40 93 **Email**: info.ch@teleflex.com

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex 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 Teleflex,

Padraig Hegarty

Padraig Hegarty VP, Global QA (Manufacturing)

Teleflex

Appendix 1

Customer No
_____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000478

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93 **Email**: 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. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. **Return Authorisation No** _____

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number is clearly visible** on the returns package
- Please label returns as **"Field Safety Returns"**

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSITIUTION ADDRESS	**Phone/FAX**
FORM COMPLETED BY:	**Stamp**
PRINT NAME: _____ **SIGNATURE:** _____	
DATE	

Appendix 2: Scope of Product for EIF-000478

Product Code	Batch						
121560-000070	16FT27	16IT31	16KT17	17AT09	17CT35	17FT38	17JT26
	17LT06	17LT13	18FT41	19BT12	19DT43	19HT73	19JT25
	19KT59	19LT35	20BT08	20ET43	KME20H1891	KME20M0102	KME21A2133
121560-000080	16FT27	16GT28	16KT17	17AT15	17LT06	17LT13	18FT46
	18HT31	19BT12	19DT39	19ET67	19FT51	19IT07	20ET51
	20FT34	KME20L1796	KME20M2070	KME20M2618	KME21A1128	KME21A2134	KME21C0215
121560-000090	16FT27	16JT04	16KT17	16LT20	17CT35	17DT28	17FT05
	17GT17	17JT06	17LT13	18AT19	18GT26	19BT12	20CT06
	20ET43	20FT28	KME20H2746	KME20J0809	KME20M0100	KME20M2188	KME20M2619
	KME20M2999	KME21A0434	KME21C0217				
121565-000070	19ET49	KME21C1297					
121565-000080	16KT17	16LT20	17AT09	17BT22	17CT29	17JT06	17KT27
	18CT16	18GT06	19BT11	19CT77	19ET08	19ET67	19IT26
	19JT09	19JT50	20BT08	20FT28	KME20H0158	KME20L0674	KME20M2620
	KME21A1688	KME21B0025					
121565-000090	19BT11	20FT11					