

24th August 2015

URGENT - FIELD SAFETY NOTICE

Type of Action:		Recall
Teleflex Reference:		005-2015
Flexi-Slip™ Endotracheal Tube Stylet		
Commercial Name	Product Code	Lot Numbers
FLEXI-SLIP ENDOTRACHEAL TUBE STYLET WITH SOFT DISTAL TIP	502501	Refer to Appendix 2
FLEXISLIP STYLET, STERILE PACK	503700-000060	
	503700-06	

Dear Customer,

Teleflex have initiated a voluntary Field Safety Corrective Action for the above listed products.

Description of the problem

Teleflex are recalling the products referenced above following receipt of reports of the plastic coating of the stylet splitting and/or breaking off of the stylet. This may result in a piece of plastic totally or partially occluding the patient's airway and impairing ventilation, or necessitating invasive removal procedures in order to prevent complications such as atelectasis or pneumonia. No patient injuries have been reported related to this issue.

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then 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 have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned in Section 6 who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.

2. As a Distributor you are 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.
3. 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.
4. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, 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 on this Field Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization 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: Herr Horst Erbe
Fax: +49 7151 / 406-566

Telephone: 07151 / 406 – 431
e-mail: horst.erbe@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 apologize 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,



Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION
Teleflex Ref. 005-2015

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

Fax: +49 7151 / 406-566

e-mail: horst.erbe@teleflex.com

Please check applicable box:

<input type="checkbox"/> 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.	<input type="checkbox"/> 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 has been stopped. All products are on hold and the quantity stated below will be returned.
	<div style="border: 1px solid red; padding: 5px; display: inline-block;">Return Authorisation No _____</div>

Please CLEARLY print the below return information:

Name of Affected Products:	FLEXI-SLIP ENDOTRACHEAL TUBE STYLET WITH SOFT DISTAL TIP FLEXISLIP STYLET, STERILE PACK		
Product Number (Size)	Lot Number	Quantity (Returning)	

Return Instructions:

- Please label product returns as "Field Action Returns".
- Include a copy of this form (including RAN Number) with product returns. Returns excluding ALL necessary documentation CANNOT be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	Email Address:
	Phone Number:
Form completed by:	
Print Name :	Institution Stamp:
Signature :	
Date:	

Appendix 2

Product Code	Lot	Product Code	Lot	Product Code	Lot	Product Code	Lot	Product Code	Lot
502501	12EE20	502501	13LG20	502501	15BG05	503700-000060	13GG07	503700-000060	14HE32
	12FE26		14AG25		15CG24		13GG33		14IE36
	12GE27		14BG27		15DE18		13HG05		14JE43
	12GE30		14CG09		15DG38		13IG21		14JG05
	12IE36		14CG19		15EG08		13IG23		14KG11
	12IE37		14DG24		15FG21		13JG06		14LG06
	12IE39		14FG03		15GG21		13KG04		15AG28
	12JE41		14FG21		12GE27		13LG06		15AG34
	12KE48		14GG01		12HE33		13LG20		15BG05
	12LG25		14GG03		12IE37		13LG27		15CG24
	12LG29		14HE32	12JE40	14AG04		15DE18		
	13AG21		14HE34	12KE48	14BG24		15DG38		
	13BG26		14IE36	12LE50	14CG09		15EG12		
	13BG36		14JE43	13AT24	14DG01		15FG21		
	13DG06		14JG05	13AT43	14DG24		15GG21		
	13DG24		14KG11	13CG05	14FE25		503700-06	12GE27	
	13GG06		14KG27	13DG09	14FG03			12HE33	
	13GG33		14LG06	13EG19	14FG06			12IE37	
	13KG04		15AG28	13FG19	14FG21			13AT43	
	13LG06		15AG34	13GG06	14GG01				