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

12 Feb 2014

URGENT - FIELD SAFETY NOTICE

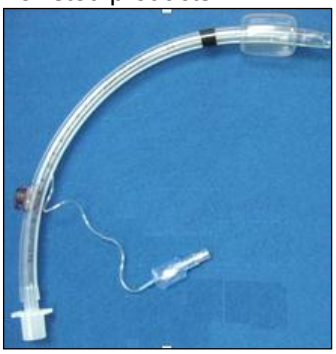
COMMERCIAL NAME OF AFFECTED PRODUCTS:	Teleflex ISIS™ Tracheal Tube with Subglottic Secretion Suction Port
TYPE OF ACTION:	Recall
TELEFLEX REFERENCE:	008/13
Product Code	**Lot Number**
112662-000060	**Refer to Appendix 2**
112662-000065	
112662-000070	
112662-000075	
112662-000080	
112662-000085	
112662-000090	

Dear Customer,

1. Details of affected devices

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

2. Description of the problem



Teleflex is recalling the products referenced above because we have received complaints that the tracheal tube can kink during patient use. If a tracheal tube kinks, it can cause decreased oxygen saturation and require re-intubation of the patient.

3. 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 affected product 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 he fax number or e-Mail-address mentioned there.
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.

4. Teleflex

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

5. Transmission of this Field Safety Notice

This notice should be passed on 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

6. Contact reference person

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

Customer Service:
Contact: Shane Kenny **Telephone:** +353 (0)90 6460869
FAX: +353 (0)1 4370773 **E-mail**: orders.intl@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations.

For and on behalf of Teleflex,

[redacted]

_____

[redacted]
International VP Quality Assurance & Regulatory Affairs

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Appendix 1

Customer No. _____

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX

IMMEDIATE ATTENTION REQUIRED

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 (0)1 4370773 **E-mail**: orders.intl@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.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Teleflex ISIS™ Tracheal Tube with Subglottic Secretion Suction Port (112662)	
PRODUCT NUMBER	**LOT NUMBER**	**QUANTITY**

- 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 Action Returns"**

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

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	**Phone / Fax**
FORM COMPLETED BY:	**TITLE/ROLE**
DATE:	

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Appendix 2

List of Product Codes with lot numbers listed underneath.

112662-000060	112662-000070	112662-000075	112662-000075	112662-000080	112662-000085
10EE22	10GE27	10JE44	13KG01	13DG33	13AG20
10FE24	10JE40	10KE46	13KG33	13EG15	13BG21
10GE27	10JE44	10LE51	13LE50	13EG24	13CG17
10JE40	10KE46	10LE52	**112662-000080**	13EG28	13CG39
10JE44	10LE51	11AE04	10EE22	13EG36	13DG33
10KE46	11AE04	11DE17	10GE30	13FG18	13EG15
11AE04	11CE13	11EE21	10GE31	13FG37	13EG24
11CE13	11DE17	11FE24	10HE32	13GG14	13FG37
11EE21	11EE21	11GE28	10JE40	13GG25	13GG25
11GE28	11FE24	11HE35	10KE46	13HG03	13HG03
11HE35	11GE28	11IE37	10LE51	13HG09	13IG08
12BE08	11HE35	11JE40	10LE52	13HG14	13IG20
12KE48	11JE40	11KE48	11AE04	13IG02	13JG21
13CG39	11KE48	11LE51	11BE08	13IG08	13KG01
13DG22	11LE51	12AE03	11CE13	13IG20	**112662-000090**
13HG03	12AE03	12BE08	11DE17	13IG36	10EE22
13IG08	12BE08	12CE12	11EE21	13JG21	10LE51
13JG31	12CE12	12DE17	11FE24	13KG01	10LE52
13KG01	12DE17	12EE21	11GE28	13KG33	11BE08
112662-000065	12KE45	12FE24	11IE37	13LE50	11EE21
10EE22	12KE48	12FE25	11JE40	**112662-000085**	11FE24
10FE24	13BG33	12KE48	11JE42	10EE22	11IE37
10GE27	13CG17	13AG20	11KE48	10FE24	11KE48
10JE40	13CG19	13BG21	11LE51	10GE30	12FE24
10JE44	13CG28	13CG17	12AE03	10JE40	12FE25
11AE04	13CG39	13CG28	12BE08	10JE44	12KE45
11EE21	13DG33	13CG39	12CE12	10KE46	12KE48
11GE28	13EE20	13DG33	12DE17	10LE51	13AG20
12BE08	13EG15	13EG15	12EE21	11AE04	13BG21
12KE48	13FG18	13EG24	12FE24	11CE13	13CG28
13CG39	13GG31	13FG18	12HE32	11EE21	13DG22
13DG33	13GG43	13FG37	12IE37	11IE37	13DG33
13EG15	13HG03	13GG14	12JE42	11JE40	13EG15
13EG24	13HG09	13GG31	12KE45	11KE48	13FG28
13FG30	13HG14	13GG43	12KE48	11LE51	13GG33
13FG37	13IG02	13HG03	13AG20	12AE03	13HG14
13GG43	**112662-000075**	13HG09	13BG21	12BE08	13IG02
13HG14	10EE22	13IG02	13CG17	12CE12	13IG20
112662-000070	10FE24	13IG20	13CG28	12DE17	13JG21
10EE22	10GE30	13IG36	13CG39	12EE21	13KG33
10FE24	10JE40	13JG31	13CT44	12KE48	