

27 Feb 2014

**URGENT
FIELD SAFETY NOTICE - EXTENSION**

COMMERCIAL NAME OF AFFECTED PRODUCTS:	MATERIAL NUMBER	LOT
Linton-Nachlas Tube	204700	Ref Appendix 2
Sengstaken Tube	204800	
Pediatric Sengstaken Tube	204801	
Sengstaken-Blakemore Tube	204802, 204803	
Subcutaneous ureter bypass set	335685	
Endoguide	680141, 680143, 680145, 680151, 680153, 680155	
TYPE OF ACTION:	Recall (Extension)	
TELEFLEX REFERENCE:	2013-08	

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 Medical has issued a voluntary recall for the above listed products as the packaging may be compromised, and therefore the sterility of the product cannot be guaranteed. If non-sterile products are used, there is a possible risk of infection.

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

FAX: +353 (0)1 4370773

Telephone: +353 (0)90 6460869

E-mail: orders.intl@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,

Padraig Hegarty

Padraig Hegarty

Senior Director of Quality International.

Customer No.

Appendix 1

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

<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 is stopped. All products are put on hold and the amount below will be returned. Return Authorisation No _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	Linton-Nachlas Tube / Sengstaken Tube / Pediatric Sengstaken Tube / Pediatric Sengstaken Tube / Sengstaken-Blakemore Tube / Subcutaneous ureter bypass set/ Endoguide (EXTENSION)	
PRODUCT NUMBER	LOT NUMBER	QUANTITY
<ul style="list-style-type: none"> 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
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

Appendix 2

204700-000210	204800-000160	204800-000160	204800-000160	204800-000180	204800-000180	204800-000180	204800-000180	204800-000210	204800-000210
10301	10211	11351	12451	10221	11121	12121	13091	10421	12021
10391	10241	11401	12481	10231	11141	12131	13101	10431	12031
10441	10251	11411	12511	10241	11191	12151	13121	10471	12051
10501	10261	11461	13021	10261	11211	12161	13131	10511	12061
11021	10271	11471	13041	10271	11221	12171	13141	11021	12071
11061	10291	11481	13051	10291	11231	12191	13151	11031	12081
11071	10301	11491	13061	10301	11241	12211	13161	11041	12091
11081	10311	11501	13101	10321	11251	12221	13171	11051	12111
11101	10381	12021	13111	10341	11261	12231	13181	11061	12121
12031	10391	12031	13121	10351	11271	12241	13191	11071	12131
12061	10401	12041	13131	10361	11291	12251	13201	11081	12191
12111	10421	12051	13141	10371	11301	12261	13211	11101	12211
12171	10441	12061	13151	10381	11321	12271	13261	11121	12221
12211	10451	12071	13161	10391	11351	12281	13381	11131	12231
12311	10461	12091	13171	10401	11461	12291	13401	11161	12241
12371	10471	12111	13181	10411	11471	12301	13411	11181	12251
12401	10501	12131	13201	10421	11481	12311	13421	11191	12261
12411	11021	12161	13211	10431	11491	12341	13431	11221	12281
12461	11071	12191	13401	10441	11501	12381	13441	11231	12291
13051	11111	12201	13421	10451	11511	12391	13471	11261	12321
13071	11121	12211	13431	10461	12021	12441	13491	11271	12371
13111	11141	12231	13461	10471	12031	12451	204800-000210	11281	12381
13181	11191	12241	13481	10481	12051	12461	10211	11291	12391
13261	11201	12251	100677513	10501	12061	12481	10271	11321	12461
13281	11211	12271	100686571	10511	12071	12501	10301	11461	12481
13311	11221	12281	100700730	11021	12081	13021	10381	11471	13021
13371	11231	12291	100709003	11031	12091	13031	10391	11491	13041
13411	11291	12301	204800-000180	11091	12101	13061	10401	11501	13051
13471	11321	12351	10211	11101	12111	13071	10411	11511	13081

Appendix 2

204800-000210	204801-000140	204802-000140	204802-000160	204802-000180	204802-000180	204803-000180	680141-000035	680141-000038	680143-000035
13121	11261	13461	13141	11081	13291	13321	11441	11471	9161
13151	11291	13471	13161	11141	13391	13381	11451	11491	9321
13161	11321	204802-000160	13171	11151	13411	13391	11501	12161	9391
13171	11351	10251	13181	11321	13421	13431	12031	12171	9451
13181	11381	10261	13201	11361	13441	13481	12501	12231	9511
13191	11401	10291	13381	11401	13461	335685-090120	13081	13171	10071
13211	11411	10391	13401	11421	204803-000180	9261	13161	13221	10211
13291	11421	10441	13441	11431	10201	11301	13221	13251	10311
13381	11431	10471	13481	11441	10251	680141-000028	13271	13261	10401
13391	11441	10481	204802-000180	11451	10301	11241	13281	13271	10441
13431	11451	10501	10201	12021	10381	12021	13371	13371	11051
13451	11471	11051	10221	12071	10401	680141-000035	13431	13411	11111
13461	11481	11091	10251	12131	10481	9041	680141-000038	13451	11171
13481	11491	11201	10261	12151	11041	9101	9301	680143-000028	11261
204801-000140	11511	11271	10271	12171	11061	9171	9421	9111	11291
10231	12031	11351	10291	12191	11201	9331	9431	9291	11401
10301	204802-000140	11401	10371	12241	11321	9411	9471	9491	11421
10351	10391	11411	10381	12271	12151	9481	9511	10271	11431
10381	10431	11431	10401	12471	12231	10051	10021	10441	11451
10391	10441	11441	10411	12491	12261	10081	10041	11031	11491
10401	10481	11491	10421	13021	12311	10121	10051	11141	12021
10421	11021	12021	10431	13061	12381	10231	10061	11321	12041
10471	11041	12061	10481	13081	12471	10401	10071	11471	12061
11081	11061	12121	10491	13131	13071	10501	10091	12101	12141
11121	11321	12211	10501	13151	13151	11041	10101	13171	12171
11151	13161	12241	11021	13161	13191	11121	10111	13431	12241
11161	13231	13061	11031	13171	13211	11201	10121	680143-000035	12461
11171	13311	13081	11051	13221	13241	11261	10161	9041	13021
11181	13451	13131	11071	13241	13261	11421	11451	9111	13141

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680143-000035	680145-000028	680145-000038	680151-000028	680151-000038	680153-000035	680153-000035	680153-000035	680155-000028	680155-000038
13211	13491	9301	13161	9311	9081	11321	13451	12211	9291
13351	680145-000035	10041	680151-000035	9421	9131	11351	13491	12401	9311
13371	9031	10091	9091	9441	9211	11401	680153-000038	13021	9451
13431	9131	10111	9291	10041	9261	11421	11151	13171	9471
680143-000038	9271	10191	9321	10071	9291	11451	11281	13281	10051
10401	9311	11261	9441	10091	9311	11471	11321	13381	10071
11451	9371	11421	10071	10111	9361	11501	11501	13401	10091
13041	9451	11451	10101	10141	9411	12021	12111	13431	10101
680145-000028	10051	11491	10151	10151	9451	12061	12451	680155-000035	10111
9041	10091	12031	10221	10211	9481	12091	12471	9151	10131
9171	10161	12121	10401	13191	10091	12161	13061	9321	10141
9411	10431	12251	10431	13211	10121	12181	13101	9471	11491
9431	11051	12401	10481	13271	10171	12201	13171	10021	13101
9481	11191	12411	11051	13281	10211	12311	13181	10111	13171
10101	11421	12431	11081	13411	10291	12351	13221	10161	13191
10211	11451	12481	11151	680153-000028	10301	12381	13251	10401	13351
10281	11491	12491	11241	9121	10371	12501	13431	10481	13471
10301	12101	12501	11321	10321	10391	13021	680155-000028	11131	
10481	12171	13081	11421	10341	10431	13041	10281	11231	
11181	12451	13221	11451	11101	10471	13081	10301	11281	
11241	12501	13251	12021	11211	10501	13091	10371	11421	
11261	13041	680151-000028	12141	11281	11051	13101	11051	11451	
11421	13061	11081	12251	11451	11131	13151	11101	12021	
11451	13171	11171	13021	11491	11141	13251	11261	12111	
12401	13241	11281	13111	13491	11151	13271	11281	13171	
12501	13301	11451	13171	680153-000035	11181	13301	11451	13281	
13171	13391	13021	13321	9031	11231	13351	12091	13391	
13181	13431	13041	13461	9041	11261	13391	12111	680155-000038	
13351	680145-000038	13111	680151-000038	9051	11271	13411	12121	9191	