

29th May 2015

URGENT - FIELD SAFETY NOTICE

Type of Action	Recall	
Teleflex Reference:	40005855	
Hudson RCI® SHERIDAN SHER-I-BRONCH® Endobronchial Tube		
Commercial Name	Material	Batch
Sher-I-SWIV/FO Double Swivel Connector	5-15401	Refer to Appendix 2
Sher-I-Bronch Left Sided	5-16028	
	5-16035	
	5-16037	
	5-16039	
	5-16041	
Sher-I-Bronch Right Sided	5-16128	
	5-16135	
	5-16137	
	5-16139	
	5-16141	
Sher-I-Bronch Accessory Pack	5-16142	

Dear Customer,

Details of affected devices

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

Description of the problem

Teleflex is recalling the products referenced above following receipt of customer complaints reporting that the double swivel connector may crack or separate on the endobronchial tube. Should this occur, the device may leak, causing a risk of respiratory distress or hypoxia that can, in some cases, lead to the need to re-intubate the patient.

1. 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.

2. Teleflex

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

3. 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

4. Contact reference person

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

Customer Service

Contact: Nicole Morawiec

FAX: +41 (0) 31 818 40 93

Telephone: +41 (0) 31 818 40 90

E-mail: nicole.morawiec@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,

[Redacted Signature]

[Redacted Name]

VP, Global RA/QA

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. 40005855

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93

E-mail: nicole.morawiec@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:	Hudson RCI® SHERIDAN SHER-I-BRONCH® Endobronchial Tube	
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:	Stamp
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

Product	Batch	Product	Batch	Product	Batch	Product	Batch
5-15401	01A1400436	5-16035	73H1400332	5-16037	73F1400189	5-16041	73J1400399
	01C1400086		73J1400259		73G1400053	5-16128	01A1400453
	01K1300254		73J1400260		73G1400176		01L1300155
	01L1300393		73J1400261		73H1400034		73B1500256
	01M1300212		73K1400130		73H1400161		73L1400096
	73A1500345		73K1400131		73H1400333	5-16135	01C1400406
	73B1500272		73K1400132		73H1400442		73A1500039
	73C1500255		73K1400225		73J1400538		73A1500040
	73D1400096		73K1400226		73J1400547		73B1500259
	73D1400496		73K1400227		73K1400341		73B1500293
	73E1400269		73L1400236		73K1400342		73C1500401
	73F1400153		73L1400382		73K1400343		73C1500426
	73F1400352		73L1400383		73K1400462		73D1400497
	73G1400052		73L1400384		73L1400098		73F1400095
	73G1400288		73L1400489		73L1400234		73J1400116
	73H1400331		73L1400583		73L1400235	73J1400133	
	73J1400401		73L1400608		73L1400584	73K1400464	
	73L1400106		01A1400121		73L1400609	73K1400465	
73M1400208	01A1400194	73M1400071		73K1400582			
5-16028	01A1400574	01A1400433		73M1400072	73L1400012		
	01L1300279	01A1400575		73M1400073	73L1400233		
	73A1500341	01B1400084		73M1400192	01B1400479		
	73C1500431	01B1400115		73M1400193	01K1300470		
	73D1400255	01B1400242		01A1400227	73A1500205		
	73F1400448	01C1400087		01A1400576	73A1500206		
	73J1400537	01C1400088		01B1400243	73B1500258		
	5-16035	01A1400226		01C1400285	01B1400478	73B1500354	
		01A1400432	01K1300143	01K1300469	73B1500355		
		01B1400083	01K1300144	01L1300082	5-16137	73C1500402	
01B1400356		01K1300346	01L1300083	73C1500427			
01B1400357		01K1300347	01L1300559	73D1400498			
01C1400260		01K1300579	01M1300214	73F1400096			
01J1300471		01L1300081	73A1500483	73H1400443			
01J1300472		01L1300280	73A1500484	73J1400117			
01K1300050		01L1300281	73A1500591	73K1400583			
01K1300073		01L1300384	73A1500592	73L1400094			
01K1300578		01L1300558	73C1400067	73A1500041			
01L1300382		01M1300074	73C1500112	73A1500203			
01L1300383		01M1300117	73C1500113	73G1400177			
01L1300557		01M1300213	73C1500258	73H1400444			
01M1300073		01M1300313	73C1500259	73L1400095			
01M1300312		73A1500342	73D1400340	01A1400452			
73A1500481		73A1500343	73E1400114	01L1300156			
73A1500482		73A1500344	73F1400353	73B1500257			
73B1500077	73A1500589	73G1400256	73G1400178				
73B1500078	73A1500590	73G1400377	73G1400510				
73B1500353	73B1500076	73J1400398	73H1400009				
73B1500529	73B1500532	73J1400408	73K1400553				
73B1500530	73C1500110	73K1400463	01A1400321				
73B1500531	73C1500111	73L1400097	01J1300535				
73C1500256	73C1500531	73L1400196	01M1300215				
73C1500257	73C1500532	73M1400194	73D1400579				
73C1500581	73C1500582	01A1400122	73E1400113				
73D1400097	73D1400256	01C1400261	5-16041				
73D1500099	73D1400627	01L1300385					
73E1400504	73D1500096	73A1500204					
73F1400449	73D1500097	73B1500533					
73G1400387	73D1500098	73C1500583					
73G1400597	73E1400270	73E1400115					
73H1400033	73E1400366	73G1400388					