

URGENT - FIELD SAFETY NOTICE

Type of Action:			Recall		
Teleflex Reference:			003-2014		
Commercial Name	Product Code	Lot Numbers	Commercial Name	Product Code	Lot Numbers
BRONCHIAL DOUBLE LUMEN TUBE SET (LEFT), STERILE	116100260	Refer to Appendix 2	BRONCHIAL DOUBLE LUMEN TUBE SET (RIGHT), STERILE	116200-000390	Refer to Appendix 2
	116100280			116200-000410	
	116100350			115900-000065	
	116100370		115900-000080		
	116100390		BRONCHIAL ONE LUMEN TUBE - LEFT	115901-000065	
	116100410		BRONCHIAL ONE LUMEN TUBE - RIGHT	115901-000080	
	116100-000260		CARLENS BRONCHIAL DOUBLE LUMEN TUBE SET (LEFT), STERILE	116101370	
	116100-000280			116101390	
	116100-000350			116101410	
	116100-000370			116101-000350	
	116100-000390			116101-000370	
	116100-000410			116101-000390	
	16100-000350			116101-000410	
	BRONCHIAL DOUBLE LUMEN TUBE SET (RIGHT), STERILE		116200260	Refer to Appendix 2	
116200280		116400-000850			
116200350		116400-000950			
116200370		TRACHEOPART SET (RIGHT), STERILE	116401-000750		
116200390			116401-000850		
116200410			116401-000950		
116201350		WHITE BRONCHIAL DOUBLE LUMEN TUBE SET (RIGHT), STERILE	116201-000350		
116201410			116201-000370		
116200-000260			116201-000390		
116200-000280			116201-000410		
116200-000350		(BRONCHIAL DOUBLE LUMEN TUBE SET (LEFT), EXTRA LENGTH, STERILE)	116164-000390		
116200-000370					

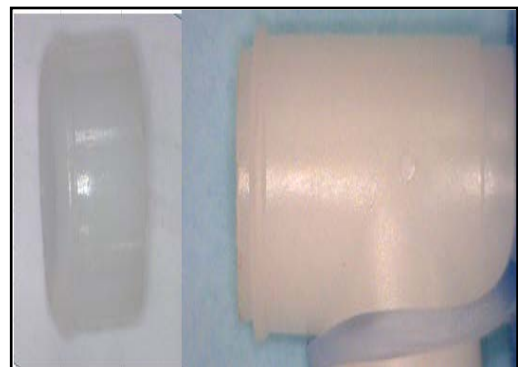
Dear Customer,

1. Details of affected devices

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

2. Description of the problem

Teleflex are recalling the products referenced above following receipt of customer complaints reporting that the Cobb connector detached from the main connector prior to use. This Cobb connector detachment should be readily identified by the user during set-up and prior to use of the device. If during use, Cobb connector separation occurs and presents as a leak in the breathing circuit and if it is unnoticed, then there is a remote probability that the patient may need to be re-intubated due to the risk of respiratory distress and hypoxia.



3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. Clinical recommendation regarding action that should be taken by users and/or healthcare professionals in relation to devices which are currently in use in patients: "The clinical end-user is advised to remove the Cobb connector which are currently in use in patients and replace with an alternative connector."
2. 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.
3. 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.
4. 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.
5. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
6. 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 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

6. Contact reference person

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



Customer Service

Contact: Livia Leone

Telephone: 0362 5890208

E-mail: livia.leone@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,

Karen Boylan

Karen Boylan
VP Global RA/QA

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION

Teleflex Ref. 003-2014

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

Telephone: 0362 5890208

E-mail: livia.leone@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; margin: 0 auto;"> Return Authorisation No _____ </div>	

Please CLEARLY print the below return information:

Name of Affected Products:	BRONCHIAL DOUBLE LUMEN TUBE SET (LEFT), STERILE BRONCHIAL DOUBLE LUMEN TUBE SET (RIGHT), STERILE BRONCHIAL ONE LUMEN TUBE – LEFT BRONCHIAL ONE LUMEN TUBE – RIGHT CARLENS BRONCHIAL DOUBLE LUMEN TUBE SET (LEFT), STERILE TRACHEOPART SET (LEFT), STERILE TRACHEOPART SET (RIGHT), STERILE WHITE BRONCHIAL DOUBLE LUMEN TUBE SET (RIGHT), STERILE		
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:
Form completed by:	Phone Number:
Print Name :	Institution Stamp:
Signature :	
Date:	

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Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number
116100260	13GT24	116100390	13KT23	115900-000065	13FT06	115901-000080	14JT21	116100-000280	14DT19	116100-000350	14ET23	116100-000370	14BT15
	13HT07		14AT12R		13GT24	13FT12	14DT20		14ET28		14BT16		
	13IT16		14BT09		13JT08	13FT17	14DT24		14FT04		14CT06		
	13KT23		14ET10		13KT12	13GT24	14ET04		14GT05		14CT11		
	14AT08		14ET11		13LT08	13HT07	14ET10		14GT10		14CT21		
	14DT19	13FT12R	14AT20		13HT12	14ET22	14HT09		14DT03				
	14ET10	13GT05	14DT19		13HT17	14ET23	14HT12		14DT10				
	14ET11	13HT07	14ET04		13IT05	14FT04	14HT17		14DT13				
	14FT04	13IT20	14GT10		13IT10	14FT05	14HT20		14DT24				
	14FT10	13JT25	14GT15		13IT20	14GT03	14IT05		14DT25				
	14GT03	13KT05	14IT11		13IT20R	14GT18	14IT17		14ET04				
	116100280	13GT24	116100410		13KT18	14JT09	13JT05R		14HT20		14JT04		14ET10
		13KT05			14JT24	13LT04	14IT14		14JT09		14ET22		
		13KT23			14DT19	14BT15	14JT12		14JT12		14ET23		
14AT12		14ET04		13JT11	14BT16	13FT06	14ET28						
14ET23		14ET10		13KT05	14CT16	13FT12	14FE23J						
116100350	13GT24	116101370	14ET11	115900-000080	13KT12	116100-000260	14DE14J	116100-000350	13FT17	116100-000370	13FT06	116100-000390	14FT04
	13HT07		14FT05		14AT04		14DT13		13FT18		14FT05		
	13IT16		14FT10		14BT04		14ET04		13GT23		14FT10		
	13JT08		13KT12		14BT15		14ET10		13GT24		14GT03		
	13KT05		13LT04		14DT19		14GT03		13HT07		14GT05		
	13KT18	116101390	13KT18		14ET04		13HT12		14GT10				
	13KT23	116101410	13FT12R		14ET22		14GT21		14GT15		14GT15		
	13LT14		13GT05		14GT15		14HT09		14GT18		14GT18		
	14CT06		13JT11		14GT18		14HT12		14HT12		14GT23R		
	14DT10		13JT15		14IT14		14HT20		13IT10		14HT09		
	14DT19	116200260	14CT11		14JT09		14IT05		13IT16		14HT12		
	14ET23	116200280	13JT05		14JT18		14IT08		13JT08		14HT17		
	13GT11		13KT18		13FT06		14JT12		13HT12		14HT23		
	13GT24		14CT11		13IT05		14JT24		13HT17		14HT24		
13HT07	14FT05		13JT08	13GT16	13IT05	14IT05							
13IT16	14FT10		13KT12	13GT23	13KT12	14IT08							
13JT25	116200350		13FT12R	14CT11	13HT17	13IT16	14IT11						
13KT23			13GT11	14DT03	13IT10	13IT20R	14IT17						
13LT04			13HT07	14DT24	13IT13	13JT05	14JT04						
13LT18			13KT23	14ET04	13IT16	13JT08	14JT12						
14CT11			14AT08	14FT04	13IT20	13JT15	14JT18						
14DT13	116200370		13KT23	14FT20	13IT20R	14AT16	14JT21						
14DT19			13LT14	14GT10	13JT08	13KT05	14JT24						
14DT24			14DT25	13GT16	13KT05	14BT15	13FT06						
14DT25			14ET23	13KT18	13KT18	14BT21	13FT12						
14ET10		116200390	13HT12	13LT08	14CT11	13LT04	13FT17						
14ET11	13JT08		14CT11	14AT08	13LT11	13FT18							
116100390	13FT12R		13KT18	14DT03	14AT12	13LT14	13GT05						
	13HT07		14ET10	14DT24	14BT16	13LT18	13GT16						
	13IT16	14ET05	14GT15	14CT06	14AT08	13GT24							
	13JT11	14ET22	14HT12	14CT11	14DT19	13GT29							
	13JT15	116201350	13FT12R	14HT20	14ET04	13HE35							
13JT25	116201410	13GT05	14JT04	14ET05	14AT20	13HT07							
13KT18		14ET04	14JT12	14DE14J	14AT16	13HT16							

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Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number
116100-000390	13HT17	116100-000390	14IT14	116100-000410	14FT13	116101-000370	14GT10	116101-000390	14JT12	116200-000260	13LT04	116200-000350	13KT23
	13IT10		14IT17		14FT16		14GT11	13FT06	14DT03				
	13IT13		14JT04		14FT20		14GT15	13FT12	14ET04				
	13JT05		14JT09		14GT05		14GT21	13GT05	14ET10				
	13JT08		14JT12		14GT15		14HT17	13GT24	14ET22				
	13JT11		14JT21		14GT18		14IT05	13GT29	14FT04				
	13JT15		13FT06		14HT03		14IT11	13HT07	14GT11				
	13JT20		13FT12		14HT09		14JT09	13HT12	14GT18				
	13JT21		13FT18		14HT17		14JT14	13HT17	14GT21				
	13JT25		13GT05		14HT24		13FT06	13IT16	14HT09				
	13KT05	13GT11	14IT05	13FT12	13IT20R	14HT17							
	13KT12	13GT16	14IT08	13GT05	13JT08	13FT06							
	13KT18	13GT23	14IT17	13GT23	13JT11	13FT12							
	13KT23	13GT29	14JT09	13GT29	13JT15	13GE29J							
	13LT04	13HT07	14JT12	13HE35	13JT21	13HT12							
	13LT14	13HT12	14JT21	13HT17	13KT12	13HT17							
	14BT09	13HT17	116101-000350	13IT05	13KT15	13IT10							
	14BT14	13IT05	116101-000350	13IT16	13KT23	13JT11							
	14BT15	13IT10		13FT12	13IT20	13KT05							
	14BT16	13IT16		13FT18	13IT20R	13LT08							
	14BT21	13IT20		13GT05	13JT08	13LT14							
	14CT06	13IT20R		13GT29	13JT21	13LT18							
	14CT11	13JT08		13HT07	13KT12	14AT20							
	14CT20	13JT15		13HT12	13KT15	14BT21							
	14DT03	13KT05		13HT17	13KT18	14CT11							
	14DT06	13KT12		13IT16	13LT04	14CT16							
	14DT10	13KT18		13IT20R	13LT11	14CT20							
	14DT13	13KT23	13JT08	14BT14	14DT13								
	14DT15	13LT04	13JT21	14BT21	14DT19								
	14DT24	13LT08	13KT12	14CT11	14ET05								
	14EE21J	13LT18	13KT18	14CT21	14ET10								
	14ET04	14AT08	13LT04	14DT03	14ET28								
	14ET10	14AT16	116101-000370	14DT15	14FT13								
	14ET22	14AT20	14AT08	14DT19	14FT16								
	14ET28	14BT15	14BT14	14DT20	14GT15								
	14FT04	14CT06	14BT15	14DT25	14GT18								
	14FT05	14CT11	14CT11	14ET04	14GT21R								
	14FT10	14CT16	14CT16	14ET28	14HT03								
	14FT13	14CT20	14DT10	14FT04	14HT17								
	14GT03	14DT06	14DT15	14FT16	14HT23								
	14GT05	14DT10	14DT19	14GT10	14HT24								
	14GT15	14DT13	14DT24	14GT10	14JT09								
	14GT18	14DT24	14ET10	14GT11	14BT21								
	14HT03R	14EE21J	14ET11	14GT21	116164-000390								
	14HT09	14ET04	14ET22	14GT23R	116200-000390								
	14HT12	14ET05	14FT04	14HT17	13FT12								
	14HT17	14ET10	14FT05	14HT23	13GE29J								
	14IT05	14ET22	14FT10	14HT24	13GT29								
	14IT11	14FT10	14FT13	14IT08	13HT12								
				14JT09	13HT17								
					13IT10								
					13IT13								
					13JT08								
					13JT20								
					13JT21								
					13KT05								
					13KT12								
					13LT08								
					13LT14								
					14AT08								
				14AT12									
				14BT21									
				14CT06									

Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number	Product Code	Batch Number
116200-000370	14CT16	116200-000390	14FT04	116201-000350	13FT17	116201-000370	13KT23	116201-000390	14GT05	116400-000750	14GT03	116401-000750	13JT21R
	14DT03		14FT16		13GT05		13LT08		14GT18		14GT23		13KT23
	14DT13		14GT03		13GT24		13LT11		14GT21		14HT03		13KT23R
	14DT19		14GT15		13HT07		14AT08		14HT03		14HT23		14CT21
	14DT20		14GT21		13HT12		14CT06		14HT09		14IT05		14ET11
	14DT24		14HT03		13HT17		14CT11		14HT20		14IT17		14ET22
	14DT25		14HT17		13IT16		14CT20		14HT23		13FT18		14ET28
	14ET05		14HT23		13IT20		14DT19		14IT08		13GE31J		14FT16
	14ET23		14IT05		13JT20		14DT24		14IT14		13GT05		14GT15
	14ET28		14IT08		13JT21		14ET04		13IT20		13HT17		14GT23
	14FT04		14IT17		13JT25R		14ET10		13JT25R		13IT13		14IT17
	14FT13		14IT20		13KT05		14ET22		13KT05R		13JT15		14JT18
	14FT20		14JT12		13KT05R		14ET23		13KT12		13JT20		13IT05
	14GT03		14JT24		13KT12		14FT04		13KT15		13JT20R		13JT21R
	14GT18		13FT12		13KT23		14FT13		13KT18		13KT23R		13KT05
	14HT03		13GE30J		13LT08		14GT18		13LT11		13LT08		13LT08
	14HT09		13GT11		14CT06		14GT21		14AT08		14BT09		14CT16
	14HT12		13GT24		14CT11		14HT03		14CT11		14BT15		14DT19
	14HT17		13GT29		14CT20		14HT20		14CT16		14CT16		14ET10
	14IT08		13HT12		14DT03		14HT23		14CT21		14CT20		14ET22
14IT17	13HT17	14DT06	14IT05	14DT13	14DE15J	14FT16							
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14JT24	13IT13	14ET10	14JT14	14ET04	14FE24J	14GT18							
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	13FT18		13IT20R		14ET28		13FT06		14ET28		14GE28J		14HT09
	13GE28J		13JT05		14FT04		13GT11		14GT18		14GT18		13JT21R
	13GT16		13JT05R		14FT05		13HT07		14HT03		14GT21		14CT06
	13GT29		13JT20		14FT13		13HT12		14HT17		14HT09		14CT16
	13HT12		13KT05		14FT16		13IT10		14JT12		14IT05		14DT20
	13IT05		13KT12		14GT18		13IT16		13FT06		14IT14		14ET23
	13IT10		13LT04		14GT21		13IT20		13GE28J		14JT04		14FT04
	13IT13		13LT08		14HT03		13IT20R		13GE31J		14JT12		14GT05
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	13IT20R		14BT21		14HT24		13JT08R		13GT29		13GT29		14HT17
	13JT05R		14CT11		14IT08		13JT20		13IT05		13HT16		14IT08
	13JT08		14DT13		14JT14		13JT21		13IT16		13IT13		14DE14J
	13JT15		14DT15		14JT21		13KT12		13JT11		13LT08		14FE24J
	13JT20R		14DT19		13FT06		13KT18		13JT21R		14AE05J		14GE28J
	13KT05		14DT24		13GT11		14BT16		13JT25R		14DT10		
	13KT18		14ET04		13GT29		14CT06		13KT05R		14ET11		
	13LT08		14ET05		13HT12		14CT16		13LT11		14FT04		
	14BT15		14ET22		13HT17		14CT20		14BT09		14GT21		
	14BT16		14FT13		13IT10		14DT03		14BT15		14IT08		
14BT21	14GT15	13IT16	14DT13	14CT16	14IT14								
14CT11	14GT21	13IT20R	14DT24	14CT20	14JE43J								
14CT16	14HT03	13IT20R	14ET10	14DE16J	14JT18								
14DT13	14HT09	13JT08	14ET23	14DT19	14JT24								
14DT15	14HT17	13JT20	14ET28	14FE24J	13FT06								
14ET04	14HT20	13JT25	14FT13	14FT16	13GT24								
14ET10	14HT23	13KT05	14FT16	14GE29J	13JT21								
	14IT08	13KT12											