

21st September 2018

URGENT - FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference:	EIF-000291
Commercial Name	CrystalClear Plus RUSCH CARE CrystalClear (PVC) Tracheostomy Cannula (no Cuff) - Set RUSCH CrystalClear (PVC) Tracheostomy Cannula (Cuffed) RUSCH CrystalClear (PVC) Tracheostomy Cannula (no Cuff)
Product Code/Lot Number	Refer to Appendix 2

Dear Customer,

Details of affected devices

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

Description of the problem

Teleflex Medical is recalling the above-mentioned products because the inside diameter (ID) is outside the specified dimension tolerance and is not compliant to relevant ISO standards.

These tracheostomy tube ID inaccuracies for patients may lead to extra exertion with spontaneous respiration and may lead to inappropriate high lung pressures with lung ventilation.

The device anomaly is not easily recognised by the user, and therefore use may result in health consequences.

No complaints have been reported pertaining to this issue.

Our records indicate that you have received product that is subject to this recall. We are now notifying our customers to take the following actions:

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 below 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 have further distributed product outside of your country, please notify Teleflex by return email to the email address below.
5. 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: Peter-Han Messner
FAX: +41 (0) 31 818 40 93

Telephone: +41 (0) 31 818 40 90
Email: info.ch@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

VP, QA International

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED
Ref. EIF-000291

RETURN COMPLETED FORM BY IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93

Email: info.ch@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:		
PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- 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	

Commercial Name	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
Crystal Clear Plus	121300-000065	15KG05	121303-000085	15HG06	121303-000095	15JG36
		16HG13		15HG26		15LG13
		17CG27		15IG05		17FG16
		17HG35		15IG07		17GG16
		18AG14		15IG28	16AG03	
		17CG46		15JG21	858600-000065	16HG08
		16CG07		15JG29	18BG08	
	121300-000085	16JG15		15LG13	858600-000085	16GG25
		17DG15		16AG25	858603-000065	15IG15
		17IG26		17AG22		15LG31
		15IG22		17CG46		16CG25
		15IG25		17FG21		16KG07
		17EG31		17HG12		17IG23
		15JG11		17IG29		18AG38
	17GG06	17LG21		16AG03		
	121300-000095	15IG07		18AG28	858603-000085	16JG26
		15IG10		18CG06	17EG31	
	121303-000065	15IG15		15LG40	858603-000095	16EG34
		15JG30		16DG22		
		15LG33		16IG13		
		17FT33		16JG26		
		17IG11		17FG18		
		16AG19		17FG01		
		16GG33		17IG15		
		16IG22		17JG31		
		17FG06		17KG07		
		17KG07		17KG13		
		17LG15		17BG15		
		16KG25		17BG29		
		17JG33		17CG20		
		17JG29		17JG25		

Commercial Name	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
RUSCH CrystalClear (PVC) Tracheostomy Cannula (Cuffed)	121610-000065	17CG39C	121610-000065	14BG35	121610-000065	17IG36
		17HG26C		14CG07		17KG03
		17KG07C		14CG18		17LG04
		17KG13C		14CG30		17LG25
		17LG23C		14DG25		18AG38
		13JG15		14DG29		18CG04
		14CG10		14EG02		13JG04
		14CG12		14FG14		14CG24
		14JG28		14FG21		14DG15
		14JG13		15AG07		14IG08
		15AG32		15CG07		14JG06
		15BG23		15CG19		14KG21
		15DG27		15HG29		14LG05
		15EG28		15IG15		14LG26
		15FG03		15JG16		14LG11
		15GG21		15KG36		15CG05
		15IG07		16AG29		15DG39
		15JG30		16BG06		15DG43
		15KG13		16BG13		15EG09
		16AG16		16BG21		15FG06
		16AG19		16BG35		15IG06
		16CG23		16DG10		15LG31
		13IG07		16DG35		16DG02
		13JG24		16EG36		17KG33
		13JG47		16HG05		18BG33
		14AG01		16IG22		16EG28
		14AG22		16KG25		16EG26
		14AG29		17HG01		16FG30
		14BG05		17HG12		16GG08
		14BG08		17HG26		16GG27
		14BG16		17IG15		16GG29

Commercial Name	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
RUSCH CrystalClear (PVC) Tracheostomy Cannula (Cuffed)	121610-000065	16GG31	121610-000085	17BG37C	121610-000085	14BG16
		16GG40		17DG32C		14BG10
		16HG01		17CG46C		14DG06
		16HG25		17HG10C		14DG09
		16IG13		13LG15		14DG13
		16KG12		13LG17		14DG15
		17CG29		14CG30		14DG16
		17CG46		15DG16		14DG20
		17DG18		15FG14		14DG22
		17LG06		15FG23		14DG23
		18AG25		15FG21		14DG29
		17JG19		15GG29		14EG02
		17JG34		15HG02		14EG15
		17KG01		15GG31		14FG16
	14AG34C	15HG29	14GG08			
	14BG16C	15IG10	14GG30			
	14CG22C	15IG28	14HG04			
	15CG23C	15JG09	14HG06			
	15EG02C	15JG26	14HG08			
	15GG24C	15JG30	14HG20			
	15IG23C	16BG35	14HG21			
	15IG28C	13IG01	14LG19			
	15KG17C	13IG07	15AG08			
	16AG14C	13IG14	15AG31			
	16AG24C	13LG37	15CG08			
	16BG17C	14AG15	15GG24			
	16GG08C	14AG26	15LG23			
	16GG23C	14AG22	15LG36			
	16KG02C	14BG01	16AG02			
	17AG26C	14AG32	16AG16			
	17BG15C	14BG05	16AG23			

Commercial Name	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
RUSCH CrystalClear (PVC) Tracheostomy Cannula (Cuffed)	121610-000085	16BG33	121610-000085	17JG31	121610-000095	14LG19
		16BG03		17KG01		15AG04
		16CG25		17KG17		15AG29
		16DG31		17LG02		15EG01
		16DG34		17LG10		15FG23
		16EG07		17LG23		16BG39
		16EG01		18AG32		17AG07
		16FG12		18BG07		17DG05
		16GG08		18CG04		17GG36
		16GG23		18CG06		17HG10
		16HG19		18CG22		15JG14
		16HG27		15JG38		16BG01
		16JG02		15KG23		16EG36
		16JG17		15LG04		16FG07
		16KG02		16CG04		16GG08
		16KG07		16FG30		16HG10
		16KG27		18AG14		16IG34
		16KG21		18BG35		17JG31
		17CG46		16EG16		
		17DG29		16GG01		
		17EG03		16GG15		
		17FG03		16GG31		
		17FT23		16HG01		
		17FG34		16HG36		
		17GG30		17BG37		
		17HG03		17CG07		
		17HG35		17JG06		
		17HG20		17JG25		
		17HG24		16BG33		
		17IG36		14IG11		
		17IG31		14IG21		

Commercial Name	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	
RUSCH CrystalClear (PVC) Tracheostomy Cannula (no Cuff)	121710-000065	16JG19C	121710-000065	16FG30	121710-000085	15LG18	
		14ET16		17JG17		15LG42	
		15DG27		17JG29		16CG28	
		15JG14		17JG31		16FG12	
		14BG05		17KG05		16EG30	
		14AG24		18BG26		16HG07	
		14IG01		16DG33		16IG03	
		14IG21		16FG20	17IG08		
		14KG19		16GG06	15JG29		
		14KG38		16GG31	16AG29		
		16BG13		16HG03	16EG36		
		16DG20		16HG15	16FG10		
		16FG37		16IG08	16HG33		
		16GG27		17BG06	RUSCH CARE CrystalClear (PVC) Tracheostomy Cannula (no Cuff) - Set		
		16HG10		14KG19			
		16IG22	14JG18				
		16JG29	16CG01	858511-000095		16JG21	
		16LG14	13JG28				
		17AG19	14IG21				
		17DG32	14JG06				
		17GG34	15DG38				
		17IG39	18BG26				
		18AG25	14BG03				
		13JG19	14CG06				
		14HG01	14HG04				
		15CG18	14JG08				
		15EG07	15JG25				
		15KG26	15JG14				
		15LG31	15KG29				
		15LG33	15LG25				
		16BG35	15LG21				