

15 March 2019

URGENT - FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000353
Commercial Name	Gibeck HME Filter + Catheter Mount RUSCH Catheter Mount RUSCH Connectors Bulk for Breathing Circuits RUSCH Connectors for Breathing Circuits
Product Code/Lot Number	Refer to Appendix 4

Dear Customer,

Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action (FSCA) for the above listed product, refer to Appendix 4 for a list of product codes and lots impacted.

Description of the problem & immediate actions required

Teleflex Medical is initiating a Field Safety Corrective Action for the above-mentioned products because there is a possibility for the swivel and cobb connectors to detach during use. If detachment occurs prior to use, it should be readily identified by the user during set-up. If detachment occurs during use and presents as a leak in the breathing circuit, ventilator pressure alarms will alert, and intervention could be required to replace the connector with another catheter mount or else reconnect the breathing circuit directly to the Endotracheal tube until another new catheter mount is available. If there is a delay in replacing the catheter mount or a delay in reconnecting the breathing circuit, the leak may lead to desaturation until the catheter mount is replaced and normal ventilation is maintained.

Our records indicate that you have received product that is subject to this Field Safety Corrective Action. We are now notifying our customers to take the following actions.

Important note, depending on your device location please adhere to the following Action list only:

Device location	Action List Number
Home setting	1
Medical facilities (hospitals, medical staff, etc.)	2
Distributors	3

Action list number 1

Home setting

1. We request that you check your inventory for product within the scope of this FSCA, refer to Appendix 4 for the list of impacted codes & lots. Users should **cease use** of impacted product and quarantine immediately. For support, contact your customer service representative.
2. If product listed in Appendix 4 is already in use, Teleflex recommend replacing the catheter mount. Refer to Appendix 3 for a list of Teleflex substitute product codes.
3. If you do not have stock as listed in Appendix 4, 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 do have stock as listed in Appendix 4, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer Service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and 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.
6. **Should you require further information or support concerning sourcing alternative product, please contact your customer service representative.**

Action list number 2

Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately. Medical facilities have two options
 - a. You may then return all product in scope, refer to Appendix 4 for the list of impacted codes & lots, to Teleflex
 - b. Alternatively, you may inspect and return only product that is defective. Refer to Appendix 2 for detail on inspection instructions.
2. If product in scope is in situ, Teleflex recommend replacing the catheter mount. Refer to Appendix 3 for a list of Teleflex substitute product codes.
3. If you do not have stock in scope of this FSCA 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 do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer Service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and 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.

Action list number 3

Distributors

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. Refer to Appendix 3 for a list of Teleflex alternative product, please call Teleflex customer service should you require assistance regarding same.
3. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. Distributors have two options
 - a. You may then return all product in scope, refer to Appendix 4 for the list of impacted codes & lots, to Teleflex
 - b. Alternatively, you may inspect and return only product that is defective. Refer to Appendix 2 for detail on inspection instructions.
4. 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.
5. 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.
6. If you have further distributed product outside of your country, please notify Teleflex by return email to the email address below.
7. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, 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 of this Field Safety Corrective 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:

Kontakt: Customer Service

Telefon: 0711 / 20 90 80 00

Fax: 0711 / 49 05 06 08

E-Mail: recalls.de@teleflex.com

Produktmanagement:

Kontakt: Nadja Sommerfeld

Email: nadja.sommerfeld@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,



Appendix 1

Customer No.

**FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM
IMMEDIATE ATTENTION REQUIRED**

Ref. EIF-000353

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 (0) 1 4370773

Email: Recalls.Intl@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and have completed the required actions contained therein. We confirm our inventory DOES NOT include product impacted by this FSCA.	<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 FSCA. The use and further distribution of impacted product has stopped. All impacted product is on hold and the amount below will be returned. Return Authorisation No. _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

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	

INSPECTION INSTRUCTIONS

Applicable to Medical Facilities and Distributors only

Product in scope of this Field Safety Corrective Action (FSCA) contains identification numbers (ID's) embossed on the Cobb connector. While Teleflex could not refine the scope of this action via lot numbers, product may be segregated by the ID number into conforming and non-conforming. This is an optional inspection step for Medical Facilities and Distributors only. Should you wish to return all impacted codes and lots without performing this inspection you may do so.

Instructions:

1. If product is still in the packaging (i.e. not in situ) it may need to be manoeuvred within the package so that the ID number is clearly visible. See Figure 1 and Figure 2 below for the location of the ID number
2. Products should be visually inspected to identify the ID embossed on the product
3. If the ID number on the product is listed under table 1 below, the product is potentially non-conforming product and should be returned to Teleflex
4. If the ID number is not listed under table 1 below, those units are conforming, and you may retain that product for use/distribution

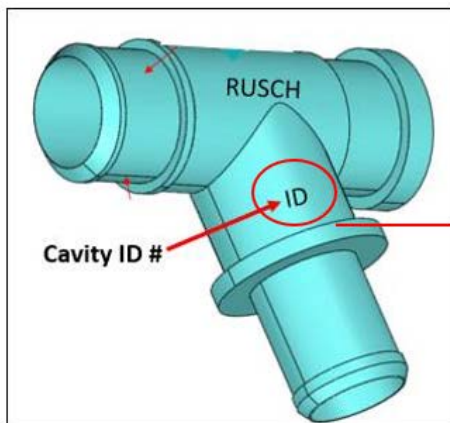


Figure 1 – Cobb Connector



Figure 2 – Identification number (ID)

ID Numbers Non-conforming Product	If the ID number embossed on the catheter mount is 39, 42, 45 or 48 – Return to Teleflex
39	
42	
45	
48	

Table 1

Substitute Teleflex Product Codes & Comments				
Product Code in scope of Field Action	Substitute 1	Substitute 2	Substitute 1 - Comment	Substitute 2 - Comment
191010-000100	191009-000100	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191010-000150	191009-000150	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191010-000200	191019-000200	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191010-T00150	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191011-000050	191009-000050	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191011-000100	191009-000100	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191011-000150	191009-000150	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191011-000200	191019-000200	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191011-000300	191020-000300 (only in 22F)	22531	straight connector	14-20cm with double Swivel but only with 22F to machine side
191013-000150	191009-000150	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191013-000200	191019-000200	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191013-000250	191020-000300	22531	straight connector in 30cm	14-20cm with double Swivel but only with 22F to machine side
191014-000100	191025-000100	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191014-000150	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191014-000200	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191014-T00150	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191015-000050	191021-000050	22531	straight connector	14-20cm with double Swivel but only with 22F to machine side
191015-000100	191025-000100	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191015-000150	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191015-000200	22531	-	14-20cm with double Swivel but only with 22F to machine side	-

Substitute Teleflex Product Codes & Comments				
Product Code in scope of Field Action	Substitute 1	Substitute 2	Substitute 1 - Comment	Substitute 2 - Comment
191015-T00150	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191033-000000	191009-000100	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191034-000000	191009-000100	22531	fixed elbow	14-20cm with double Swivel but only with 22F to machine side
191036-000000	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191037-000000	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191525-000000	1624	-	Elbow connector w/o Swivel	-
191526-000000	1624	-	Elbow connector w/o Swivel	-
191527-000000	1624	-	Elbow connector w/o Swivel	-
191569-000000	1624	-	Elbow connector w/o Swivel	-
191657-000150	19092	-	fixed elbow & Filter	-
191658-000100	19092	-	fixed elbow & Filter	-
191658-000150	19092	-	fixed elbow & Filter	-
191659-000150	19092	-	fixed elbow & Filter	-
191727-000150	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191727-000200	22531	-	14-20cm with double Swivel but only with 22F to machine side	-
191771-518150	19092	-	fixed elbow & Filter	-

Product Name	Product Code	Lot/Batch Number	Product Name	Product Code	Lot/Batch Number	
Gibeck HME Filter + Catheter Mount	191657-000150	201745	RUSCH Catheter Mount	191015-000100	18BT13	
		201749			18CT03	
		201802			18CT12	
		201811			18CT19	
		201816			18CT27	
		201818			18CT32	
		201821			18DT04	
		201828			18DT29	
		201831			18ET21	
		201832			18ET36	
		201836			18FT03	
		201841			18FT07	
		201842			18FT30	
		201852			18FT40	
		191658-000100			17KT09	18FT45
	17KT20				18GT07	
	17KT24				18GT15	
	17LT18				18GT21	
	17LT19				18GT30	
	18AT29				18HT14	
	18DT24				18HT21	
	18FT27				18HT26	
	18FT42				18HT34	
	18FT44				18IT05	
	18GT14				18IT24	
	18GT28				18JG07	
	18HT02				18JG28	
	18HT16				18JG29	
	18HT20				18JT05	
	18IT01				18JT11	
	18IT14				18KG06	
	18IT19				18KG20	
	18IT27				18KG31	
	18JT14				18KG32	
	18KT02				18KG42	
	18KT10				18KT06	
	18LT12				18LG10	
	18LT17				18LG20	
	19AT01				18LG32	
	19AT03	18LG35				
	191658-000150	17KT08			18LG36	
		17KT15			18LT21	
		17LT07			19AG06	
		17LT11			191015-000150	201826
		17LT21				17KT03
18DT24		17KT10				
18FT37		17KT17				
18GT24		17KT25				
18KT02		17LT05				
18KT24		17LT12				
18LT08	17LT22					
18LT26	17LT31					
191659-000150	18AT05					
191659-000150	17LT10	18AT10				
	18BT04	18AT11				
	18FT36	18AT18				
18IT07	18AT27					
191771-518150	201820	18BG09				
	201822	18BT02				
	201825	18BT07				
	201826	18BT13				
	201828	18BT20				
	201836	18CT03				
	201837	18CT12				
	201841	18CT19				
	201901	18CT27				
	201902	18CT32				
RUSCH Catheter Mount	191010-000100	201821	18CT13			
	191010-000150	201745	18DT13			
		201748	18DT14			

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Product Name	Product Code	Lot/Batch Number	Product Name	Product Code	Lot/Batch Number
RUSCH Catheter Mount	191010-000150	201802	RUSCH Catheter Mount	191015-000150	18DT17
		201805			18DT21
		201806			18DT29
		201808			18DT30
		201809			18ET04
		201811			18ET14
		201812			18ET21
		201816			18ET27
		201828			18ET36
		201831			18FT03
		201832			18FT19
		201837			18FT23
		201839			18FT25
		201842			18FT30
		201844			18FT40
		201846			18FT45
	191010-000200	201803			18FT49
	191010-T00150	201805			18GT15
		201810			18GT21
		201842			18GT30
	191011-000050	17KT10			18HT06
		17KT17			18HT14
		17KT25			18HT21
		17LT05			18HT26
		17LT12			18HT34
		17LT22			18IT05
		18AT18			18IT11
		18BT07			18IT17
		18BT20			18IT24
		18CT03			18JG28
		18DT13			18JT05
		18DT29			18JT11
		18ET37			18KG06
		18FT25			18KG12
		18GT07			18KG20
		18GT15			18KG31
		18GT21			18KG32
		18HT06			18KG42
		18HT14			18LG20
		18HT21			18LG32
		18IT05			18LG36
		18IT17			19AG06
		18LG32			19AG16
		19AG16			
	191011-000100	17KT10			17KT03
		17KT17			17KT10
		17KT25			17KT17
17LT05		17KT25			
17LT12		17LT05			
17LT22		17LT12			
17LT31		17LT38			
18AT11		18AT11			
18AT18		18AT18			
18AT18		18AT27			
18BG09		18BG09			
18BT07		18BT02			
18BT13		18BT07			
18CT12		18CT27			
18CT19		18DT13			
18CT32		18DT21			
18DT04		18DT29			
18DT13		18ET04			
18DT29		18ET14			
18ET21		18ET21			
18ET36		18ET27			
18FT19		18ET36			
18FT25		18FT03			
18FT45		18FT30			
18GT04	18FT40				
18GT07	18FT49				

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Product Name	Product Code	Lot/Batch Number	Product Name	Product Code	Lot/Batch Number	
RUSCH Catheter Mount	191011-000150	18KG06	RUSCH Catheter Mount	191034-000000	201744	
		18KG12			201750	
		18KG31			201751	
		18KG32			201803	
		18LG10			201805	
		18LG32			201808	
		18LG36			201819	
		19AG06			201820	
		191011-000200			17KT03	201822
		17KT17			201825	
17LT05	201826					
17LT12	201828					
18AT11	201829					
18AT18	201832					
18AT27	201839					
18BT07	201840					
18CT12	201842					
18CT19	201844					
18DT04	201846					
18DT13	191036-000000	201744				
18DT29		201745				
18ET37		201750				
18FT03		201751				
18FT07		201752				
18FT19		201801				
18GT07		201806				
18GT15		201807				
18GT21		201808				
18JG29		201809				
18JT05	201810					
18KG06	201812					
18KG12	201817					
18KG31	201818					
18LG10	201819					
191011-000300	17KT25	201820				
17LT22	201821					
18AT05	201822					
18AT27	201823					
18BG09	201826					
18DT14	201827					
18DT17	201828					
18FT07	201829					
18HT14	201830					
18IT17	201831					
18IT24	201832					
18JG28	201834					
18JT11	201836					
18KG06	201840					
18KG31	201848					
191013-000150	18HT26	201850				
18JG28	191037-000000	17KT03				
191013-000200		17KT10				
18AT27		17KT25				
18BT13		17LT05				
18ET04		17LT22				
18FT03		17LT31				
18GT04		18BT02				
18GT07		18BT07				
18GT30		18BT13				
18JG28		18CT12				
18JT11	18CT32					
18KG31	18ET21					
191013-000250	18BG09	18ET36				
18CT27	18FT03					
18FT03	18FT19					
18GT04	18FT25					
18HT06	18FT30					
18KG31	18FT45					
191014-000100	201746	18GT04				
201747	201747	18GT21				

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Product Name	Product Code	Lot/Batch Number	Product Name	Product Code	Lot/Batch Number
RUSCH Catheter Mount	191014-000100	201748	RUSCH Catheter Mount	191037-000000	18HT26
		201750			18IT11
		201806			18IT24
		201807			18JG07
		201808			18JG28
		201810			18JG29
		201816			18JT11
		201820			18KG12
		201822			18KG20
		201825			18KG42
		201828			18LG10
		201834			18LG20
		201836			18LG32
		201839			18LG35
	201841	18LG36			
	201843	19AG16			
	201844	191727-000150		201744	
	201846			201745	
	201848			201747	
	191014-000150			201747	201748
				201748	201749
				201749	201801
				201752	201802
				201801	201803
				201802	201805
				201803	201810
				201804	201811
				201805	201814
				201806	201815
				201810	201816
				201811	201818
201814			201820		
201815			201821		
201816		201822			
201817		201825			
201818		201826			
201819		201827			
201820		201828			
201821		201829			
201822	201830				
201825	201831				
201826	201832				
201827	201834				
201829	201835				
201830	201836				
201831	201838				
201834	201839				
201835	201841				
201836	201842				
201837	201844				
201841	201846				
201842	201848				
201843	201851				
201845	201852				
201846	191727-000200	201745			
201847		201747			
201848		201802			
191014-000200		201745	201805		
		201746	201810		
	201747	201811			
	201802	201815			
	201805	201820			
	201806	201821			
	201810	201823			
	201811	201826			
	201815	201828			
	201816	201841			
201817	RUSCH Connectors Bulk for Breathing Circuits	191569-000000	201743		
201822	RUSCH Connectors for Breathing Circuits	191525-000000	201752		

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Product Name	Product Code	Lot/Batch Number	Product Name	Product Code	Lot/Batch Number	
RUSCH Catheter Mount	191014-000200	201823	RUSCH Connectors for Breathing Circuits	191525-000000	201815	
		201825			201816	
		201828			201818	
		201847			201819	
		201848			201820	
		201849			201821	
		201850			201823	
		201852			201826	
	201902	201827				
	191014-T00150	201745			201828	201828
		201746			201833	201833
		201747			201840	201840
		201748			201844	201844
		201749			191526-000000	17KT17
		201801				17LT05
		201811				17LT12
		201815				17LT22
		201825				17LT38
		201826				18AT05
		201827				18AT11
		201828				18BT02
		201829				18CT12
		201830				18DT29
		201831		18ET04		
		201834		18ET21		
		201836		18ET27		
	201837	18FT30				
	201840	18FT49				
	201847	18GT15				
	201851	18GT21				
	201852	18GT30				
	191015-000050	18HT06		18HT14		
		18HT34		18JG29		
		18IT11		18JT11		
	191015-000100	17KT10		18KG12		
		17KT17		18KG20		
		17KT25		18KG31		
		17LT12		18KG32		
		17LT22		18LG10		
		17LT31		18LG20		
		18AT12		19AG16		
		18AT18		191527-000000	201745	
		18AT27			201746	
18BG09		201747				
18BT02		201751				
18BT07		201752				