

14 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:

Contact: Nicole Morawiec

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, Global QA (Manufacturing)

**FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM**

IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000353

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +41 (0) 31 818 40 93

Email: info.ch@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

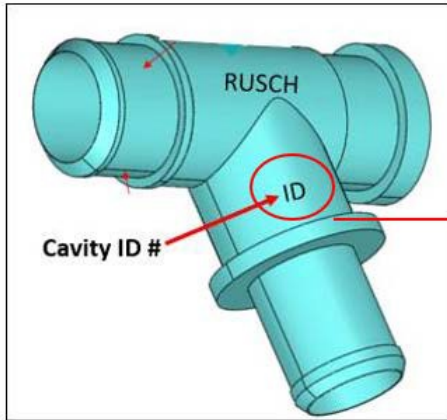


Figure 1 – Cobb Connector



Figure 2 – Identification number (ID)

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

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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	17LT10	18AT05				
	18BT04	18AT10				
	18FT36	18AT11				
	18IT07	18AT18				
191771-518150	201820	18AT27				
	201822	18BG09				
	201825	18BT02				
	201826	18BT07				
	201828	18BT13				
	201836	18BT20				
	201837	18CT03				
	201841	18CT12				
	201901	18CT19				
	201902	18CT27				
RUSCH Catheter Mount	191010-000100	201821	18CT32			
	191010-000150	201745	18DT13			
		201748	18DT14			

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
	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
17KT17			17KT10		
17KT25			17KT17		
17LT05	17KT25				
17LT12	17LT05				
17LT22	17LT12				
17LT31	17LT38				
18AT11	18AT11				
18AT18	18AT18				
18BG09	18AT27				
18BT07	18BG09				
18BT13	18BT02				
18CT12	18BT07				
18CT19	18CT27				
18CT32	18DT13				
18DT04	18DT21				
18DT13	18DT29				
18DT29	18ET04				
18ET21	18ET14				
18ET36	18ET21				
18FT19	18ET27				
18FT25	18ET36				
18FT45	18FT03				
18GT04	18FT30				
18GT07	18FT40				
	18FT49				

Product Name	Product Code	Lot/Batch Number	Product Name	Product Code	Lot/Batch Number	
RUSCH Catheter Mount	191011-000100	18GT15	RUSCH Catheter Mount	191015-000200	18GT04	
		18GT21			18HT26	
		18GT30			18HT34	
		18HT06			18IT11	
		18HT14			18IT17	
		18HT21			18JG29	
		18HT26			18KG06	
		18HT34			18KG12	
		18IT05			19AG16	
		18IT17			19AG28	
		18IT24				
		18JG28			191015-T00150	17KT10
		18JG29				17KT17
		18JT05				17LT12
		18JT11				18AT18
		18KG06				18BT07
		18KG12				18DT13
		18KG20				18FT25
		18KG42				18FT45
		18LG10				18HT21
		18LG35		18HT34		
		18LG36		18IT11		
		18LT21		18IT24		
		19AG06		18KG31		
		19AG16		18KG32		
				18LG10		
				18LG20		
				18LG35		
				19AG06		
				19AG16		
				19AT06		
				191033-000000	17KT03	
					17KT10	
					17KT25	
					17LT05	
					17LT22	
					17LT31	
					17LT38	
	18AT05					
	18BT02					
	18BT07					
	18BT13					
	18BT20					
	18CT03					
	18CT12					
	18CT19					
	18CT27					
	18CT32					
	18ET14					
	18ET36					
	18ET37					
	18FT19					
	18FT25					
	18FT30					
	18FT45					
	18FT40					
	18FT45					
	18GT04					
	18GT07					
	18GT15					
	18GT21					
	18GT28					
	18GT30					
	18HT06					
	18HT14					
	18HT21					
	18HT26					
	18HT34					
	18IT05					
	18IT17					
	18IT24					
	18JG28					
	18JG29					
	18JT05					
	18JT11					
	18LG20					
	18LG36					
	19AG06					

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			
		18DT29			
		18ET37			
		18FT03			
		18FT07			
		18FT19			
		18GT07			
		18GT15			
		18GT21			
	18JG29				
	18JT05				
	18KG06				
	18KG12				
	18KG31				
	18LG10				
	191011-000300	17KT25			
		17LT22			
		18AT05			
		18AT27			
		18BG09			
		18DT14			
		18DT17			
		18FT07			
		18HT14			
		18IT17			
		18IT24			
		18JG28			
		18JT11			
18KG06					
18KG31					
191013-000150		18HT26			
		18JG28			
191013-000200	18AT27				
	18BT13				
	18ET04				
	18FT03				
	18GT04				
	18GT07				
	18GT30				
	18JG28				
	18JT11				
	18KG31				
191013-000250	18BG09				
	18CT27				
	18FT03				
	18GT04				
	18HT06				
18KG31					
191014-000100	201746				
	201747				
			191036-000000	201744	
		201745			
		201750			
		201751			
		201752			
		201801			
		201806			
		201807			
		201808			
		201809			
		201810			
		201812			
		201817			
		201818			
		201819			
		201820			
		201821			
		201822			
		201823			
		201826			
		201827			
		201828			
		201829			
		201830			
		201831			
		201832			
		201834			
		201836			
		201840			
		201848			
		201850			
			191037-000000	17KT03	
		17KT10			
		17KT25			
		17LT05			
		17LT22			
		17LT31			
		18BT02			
		18BT07			
		18BT13			
		18CT12			
		18CT32			
		18ET21			
		18ET36			
		18FT03			
		18FT19			
		18FT25			
		18FT30			
		18FT45			
		18GT04			
		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					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					
	201817					
201822						
		RUSCH Connectors Bulk for Breathing Circuits	191569-000000	201841		
		RUSCH Connectors for Breathing Circuits	191525-000000	201743		
				201752		

EIF-000353 - Appendix 4

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			