

23rd November 2017

URGENT - FIELD SAFETY NOTICE

Commercial Name		RUSCH Sensor (Series 400) Silicone Rectal Pharyngeal Temperature Sensor, Non-Sterile			
Teleflex Reference:		EIF-000225			
Type of Action		Recall			
Product code	Lot/Batch	Product code	Lot/Batch	Product code	Lot/Batch
179360-000120	Refer to Appendix 2	179361-000120	Refer to Appendix 3	1016	Refer to Appendix 4
179360-000140		179361-000140			
179360-000160		179361-000160			
179360-000180		179361-000180			

Dear Customer,

Details of affected devices

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

Description of the problem

The products referenced above are transurethral balloon catheters and rectal/pharyngeal catheters with integrated temperature sensors.

Teleflex is recalling the above referenced product codes following receipt of complaints of temperature measurement deviations. Inaccurate temperature readings may lead to misdiagnosis and result in the delivery of inappropriate patient therapies.

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: Shane Kenny
FAX:+353 (0) 1 4370773

Telephone: +353 (0)90 6460869
Email: Recalls.Intl@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 you or your patients. 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

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000225

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 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:	RUSCH Sensor (Series 400) Silicone Rectal/Pharyngeal Temperature Sensor, Non-Sterile	
PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)
<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 Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
179360-000120	17AE01	179360-000140	17AE01	179360-000140	17FE24	179360-000160	17DE15
	17AE02		17AE02		17FE25		17DE16
	17AE03		17AE03		17FE26		17DT03
	17AE04		17AE04		17GE27		17DT19
	17FE25		17BE05		17GE28		17EE18
	17BE05		17BE06		17GE29		17EE20
	17BE06		17BE07		17GE30		17EE21
	17ET03		17BE08		17HE31		17ET03
	17FE22		17BG17		17HE32		17ET24
	17IE35		17CE09		17HE33		17FE22
	17HE31		17CE10		17HE34		17FE23
	17BE07		17CE11		17IE35		17FE24
	17FE23		17CE12		17IE36		17FE25
	17GE28		17CE13		17IE37		17FE26
	17CE10		17CT11		17IE38		17GE27
	17CE11		17CT15		17AE01		17GE28
	17GE30		17CT25		17AE02		17GE29
	17CE12		17CT26		17AE03		17GE30
	17CE13		17DE14	17AE04	17HE31		
	17GE29		17DE15	17BE05	17HE32		
	17CT10		17DE16	17BE06	17HE33		
	17FE24		17DE17	17BE08	17HE34		
	17EE18		17DT03	17BG17	17IE36		
	17CT15		17DT19	17CE09	17IE38		
	17CT25		17EE18	17CE10	17BE05		
	17DE14		17EE19	17CE11	17BE06		
	17DE15		17EE20	17CE12	17BE07		
	17DT19		17EE21	17CE13	17CE13		
	17DE16		17ET03	17CT11	17CT26		
	17HE34		17ET24	17CT25	17EE19		
	17DE17		17FE22	17CT26	17EE21		
	17IE36		17FE23	17DE14	17FE24		
					17HE32		

EIF-000225 - Appendix 3 – Recall - Product Code 179361

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
179361-000120	17BE05	179361-000140	17EE20	179361-000140	17EE19	179361-000160	17EE20
	17BE06		17BE06		17AE02		17HE33
	17BE07		17BE07		17CE09		17BE08
	17CE09		17CE10		17CT25		17CE12
	17CE11		17DE14		17DE17		17HE34
	17CE13		17DE16		17CE13		17CT25
	17DE14		17FE22		17FE25		17IE36
	17DE17		17FE23		17BE07		17CE10
	17EE19		17FE24	17BG17	17DT03		
	17ET03		17FE25	17CE11	17HE31		
	17FE22		17GE27	17FE22	17IE36		
	17FE23		17GE28	17FE24	17FE25		
	17GE28		17GE29	17GE28	17GE29		
	17HE34		17GE30	17GE29	17HE33		
	17IE38		17IE35	17HE32	17AE03		
	17IE37		17CT10	17BE06	17EE19		
	17FE24		17HE31	17EE19	17FE24		
	17GE30		17BE05	17CE09			
	17HE33		17CE11	17BE05			
	17CT10		17EE18	17DE16			
	17CE12		17FE26	17EE21			
	17GE27		17HE33	17FE23			
	17HE32		17IE37	17FE26			
	17FE25		17BE08	17DT19			
	17IE36		17BG17	17DE15			

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
1016	11037706	1016	12481709	1016	12556886	1016	12679126	1016	12724114	1016	12794052
	11128137		12481710		12556887		12679127		12724115		12794053
	11132688		12481711		12556888		12679128		12724116		12794056
	11154651		12481712		12556891		12679129		12753906		12821074
	11216617		12524049		12556892		12679130		12753907		12821075
	11226193		12524050		12556893		12679453		12753909		12821076
	11251904		12524051		12556895		12679454		12753910		12821077
	11251905		12524052		12556896		12679455		12753911		12842665
	11259333		12524053		12556897		12679456		12778909		12842667
	11323440		12524054		12556898		12679457		12778910		12842668
	11341435		12524055		12621869		12679459		12778911		12842669
	11392179		12524056		12621871		12679460		12788168		12842670
	11444830		12524057		12621872		12723994		12788169		12842671
	11458837		12556869		12621873		12723995		12788170		12842672
	11477999		12556870		12621874		12723996		12788171		12875258
	11536557		12556871		12621875		12723997		12788172		12875259
	11560470		12556872		12655675		12723998		12788173		12875260
	11560471		12556874		12655676		12723999		12788175		12875261
	11566192		12556875		12655677		12724000		12794039		12875262
	11675429		12556876		12655678		12724107		12794041		12875263
	11697988		12556877		12655679		12724108		12794042		12875264
	11697989		12556879		12679121		12724109		12794046		12875265
	11705215		12556881		12679122		12724110		12794047		12875266
	11793618		12556883		12679123		12724111		12794048		12875267
	11917541		12556884		12679124		12724112		12794050		12875268
	11995193		12556885		12679125		12724113		12794051		12925375

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
1016	12925376	1016	12958088	1016	13060118	1016	13106578	1016	13233373
	12925377		12958089		13060119		13153376		13233374
	12925378		12981778		13060120		13153377		13233375
	12925379		12981779		13060121		13153378		13248822
	12925380		12981780		13060123		13153379		13307900
	12925381		12993443		13060124		13153381		13307901
	12925382		12993444		13060126		13169308		13313481
	12925383		12993445		13060128		13191145		13313482
	12925384		13001405		13060129		13191146		13313483
	12925385		13001406		13060130		13191147		13313484
	12925386		13001407		13060132		13191149		13313485
	12925387		13009813		13060133		13191160		13313486
	12925388		13009814		13060134		13191163		13327746
	12925389		13009815		13106565		13191164		13351105
	12925390		13009816		13106566		13191165		13360742
	12958076		13009817		13106567		13191166		
	12958077		13029778		13106568		13191167		
	12958078		13029779		13106569		13191203		
	12958079		13029781		13106570		13191206		
	12958080		13029782		13106571		13191208		
	12958081		13029784		13106572		13232817		
	12958083		13029991		13106573		13232818		
	12958084		13060113		13106574		13232819		
	12958085		13060114		13106575		13232821		
	12958086		13060116		13106576		13232826		
	12958087		13060117		13106577		13233372		