

15th April 2015

URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:	Recall		
TELEFLEX REFERENCE:	FSN15C001/ NC 0114		
Commercial Name	Material	Batch	
PPH Basic Insertion Pack	AR13495-PPH	356258	417498
		358356	422837
		362208	425888
		367585	433763
		372326	441140
		376039	443266
		381731	446082
		390679	451137
		394338	356258
		402907	358356
		404539	362208

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 product referenced above following receipt of a Field Safety Notice from ArcRoyal. Terumo Europe (a supplier of Arc Royal) has received a number of reports on visual observation of white particle accumulation in the syringe barrel. This observation does not compromise the syringe performance. Terumo has issued a field safety notice indicating affected product is to be removed from the market. Arc Royal has placed the affected syringes into Custom Procedure Tray's (CPTs) which have been supplied to Teleflex. The observed white particles, determined as Oleamide by Terumo, are readily apparent to the end-user. There are no adverse health consequences or clinical risks associated with exposure to Oleamide.

3. 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 in Section 6 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/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:

Customer Service: Contact: Helene Sauvage

FAX: 01494 524650

Telephone: 01494 532761

E-mail: orders.uk@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

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED

RETURN COMPLETED FORM IMMEDIATELY TO:
FAX: 01494 524650 **E-mail: orders.uk@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:	PPH Basic Insertion Pack	
PRODUCT NUMBER	LOT NUMBER	QUANTITY
<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:	TITLE/ROLE
PRINT NAME: _____	
SIGNATURE: _____	
DATE	