www.arcroyal.ie
Virginia Road, Kells,
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Tel: +353 (0)46 928 0100
Fax: +353 (0)46 928 0110
Email: info@arcroyal.ie

Field Safety Notice

Date: 20March2015

Commercial Name: Terumo two part syringe

FSN Identifier: FSN15C001

Type of action: Removal of affected Product

Attention:
This letter is to inform you of a Field safety notice initiated by Terumo See appendix I

Description of the Problem
Terumo Europe has received a number of reports on visual observation of white particle accumulation in the syringe barrel by movement of the piston.
This observation does not compromise the syringe performance

Safety Action
Terumo has issued a Field safety notice which indicates that all affected product is to be removed from the market.
ArcRoyal has placed the affected syringes into CPT's which they have supplied to their customers. ArcRoyal is issuing this Field safety notice to all their customers to provide instructions on how to control the affected products to ensure that the affect product is not used by our customers on any patients.

Details on affected items

Reference	Description	Lot Number
10-007789	Terumo two part syringe 2ml	All Lots
10-007790	Terumo two part syringe 5ml	All Lots
10-007791	Terumo two part syringe 10ml	All Lots
10-007792	Terumo two part syringe 20ml	All Lots

Appendix II is a list of all Products which have been supplied to you from ArcRoyal that is affected by this Advisory

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Advice on Action to be taken by the user:
To minimize disruption and ensure continuous patient care, ArcRoyal is recommending the following:

1. Check your inventory to identify affected product
2. Place on Hold any product that are affected
3. Complete the attached verification form Appendix III **This should be done even if you have no affected product**
4. Return the completed Field Safety Corrective Action Response Form Appendix III to Arcroyal (iarmstrong@arcroyal.ie)
5. On receipt of the completed verification form Appendix III, ArcRoyal will forward you with Sterile Replacement Product
6. The sterile replacement is to be used instead of the affected Product
7. The affected product can be returned to ArcRoyal or destructed at the hospital
8. If the product destructed in the hospital appendix IV must be completed and return to ArcRoyal

Transmission of this Field safety notice:
Please immediately forward this information to all departments within your organisation in which the syringes may be stored. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected devices have been transferred. Please maintain awareness on this notice and resulting corrective action for an appropriate period to ensure effectiveness of the corrective action

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience that this may cause you. Should you have any questions or concerns about the matter, please don't hesitate to contact me.

Yours Sincerely,

Irene Armstrong
Compliance Engineer
ArcRoyal.

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Appendix I

TERUMO

Urgent FIELD SAFETY NOTICE

Device: **Terumo Two-Parts Syringe – Occasional Appearance of Lubricant Particles**
Reference: **FSN 1409 2015-03**
Action: **Return**

Attention: Chief of Hospital & Clinics, Medical staff

Description of the problem:

Terumo Europe has received a number of reports on visual observation of white particle accumulation in the syringe barrel by movement of the piston.

Two parts syringes contain an internal lubricant mixed in the polypropylene to reduce the gliding force of the piston. Occasionally, visible particles can be made apparent when the lubricant blooms to the surface of the syringe barrel and the plunger scrapes it off. This phenomenon, inherent to this device type as migration of lubricant to surface of barrel, is an intrinsic property of the material.

Despite raised customer concern, this observation does not compromise the syringe performance. However, Terumo Europe is recalling the affected device population listed in the table below as a precautionary measure.

None of the reported complaints involved any clinical consequences.

Details on affected devices:

Reference	Product Description	Lot Number
SS+T02S1	Terumo two parts syringe, 2 ml	All(*)
SS+T05ES1	Terumo two parts syringe, 5 ml	All(*)
SS+T10ES1	Terumo two parts syringe, 10 ml	All(*)
SS+T20ES1	Terumo two parts syringe, 20 ml	All(*)

(*) = all non-expired products.

Potential hazard:

If the circumstance would occur and a defective syringe with large number of particles is accidently used, unacceptable level of particulate matter can be harmful when introduced in the blood stream.

The lubricant is generally health harmless. Visible particles are likely to be detected before injection (during preparation). As none of the reported complaints involved any clinical consequences, it is currently concluded that the possibility of such hazard to cause injury is negligible.

TERUMO

Corrective action:

Terumo Europe is alerting its involved customers about the issue and is asking to return the remaining units from the affected population in their inventory.

Customer instructions:

1) Review this Field Safety Notice, and assure that all users are aware of this notice.
2) Indicate the number of unused syringes from the referred affected items on the related reply form and return this form as quickly as possible to the e-mail address or the fax number indicated on the form.
3) Your Terumo Europe representative will contact you to organize the pick-up and provide compensation/replacement.

We confirm that this *Field Safety Notice* has also been notified to your national Competent Authority.

We encourage you to contact us or your local Terumo representative with any questions or concerns.

Terumo UK Ltd or Terumo Europe NV
Tel: +44 01276 480452
Fax: +44 1276 480465
Sales Support team UK
Sales.Support@terumo-europe.com

Fayez Abou Hamad
MD Vigilance Expert
Terumo Europe NV –
Leuven, Belgium

TERUMO

Field Safety Notice - CUSTOMER REPLY FORM

Device: **Terumo Two-Parts Syringe – Occasional Appearance of Lubricant Particles**

Reference: **FSN 1409 2015-03**

Please complete, sign and e-mail or fax this back: To:

E-mail/Telefax:

Hospital Name	
City	
Country	

Our records indicate that you have received affected devices.

By completion and return of this form, I am confirming receipt, reading and acting on this Safety Notice:

☐ We have no physical inventory from the affected population.

☐ We have the following unused affected units ready to return:

Reference	Lot	Number of units ready to return

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1409A [EN]

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Appendix II

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Appendix III

Advisory Corrective Action Response Form

Please acknowledge that you have received, read and understood the actions to be taken by completing the information below.

The completed response form should be immediately returned via fax or email to

Fax: 00353469280110 Email:iarmstrong@arcroyal.ie

I have checked our inventory and found the following number of affected Inflation devices.

Product Number	Lot Number	Quantity left in stock of affected packs

This facility has read and understood the information supplied to us through the advisory notice issued by ArcRoyal in relation Terumo two part Syringe

Facility Name	
Facility Address	
Your Printed name and Title	
Signature and Title	
Phone Number/Fax Number	

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Appendix IV

Certificate of Destruction

I certify that the product(s) listed in the table below have been destroyed and removed from Inventory Records as a result of product Recall Instructions received from ArcRoyal.

Product Number	Lot Number	Qty Destroyed

Authorized Signature:
Name:
Position:
Date:
Destruction of the medical devices listed above was completed on _____