

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 accidentally 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.

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

A handwritten signature in black ink, appearing to read 'Fayez'.

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

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]