URGENT FIELD SAFETY NOTICE

Device: **TERUMO® SYRINGE - 30 ML-LUER LOCK/CENTRIC**

Reference: **FSN1203**

Action: **Device Removal**

Attention: Chief of Hospital & Clinics, Medical staff

DESCRIPTION OF THE PROBLEM & REASON FOR CORRECTION

Terumo Corporation has recently received three complaints for items SS-30LZ (equivalent to SS*30LZ1, SS*30LE1) from Japanese customers that no injection can be made with Terumo syringe when it is used with Sureplug®.

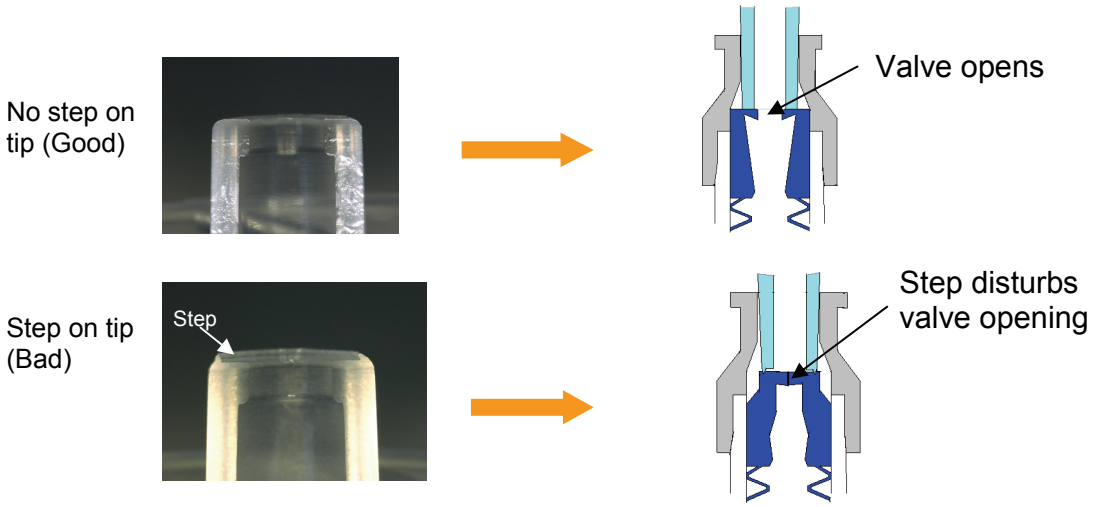
Terumo Corporation's investigation has determined that this malfunction is due to very small difference in tip shape in the affected population compared to the standard product according to the factory specifications.

This only happens if affected syringes are used in combination with Sureplug® or equivalent devices (e.g. SmartSite) having the same structure. No problems have been reported when the syringe is used in other applications according to the intended use.

Terumo Corporation started a voluntary recall of affected lots in Japan on Aug. 31. 2012 due to risk of no injection under the mechanism mentioned below.

Mechanism

In order to assure stable opening of Sureplug® or equivalent devices having the same structure, Terumo controls syringe tip shape precisely. At this time, mould tool adjustment of barrel was accidentally wrong.



PATIENT HAZARD

It is possible that no infusion can be made with the syringe when it is used in combination with Sureplug® or equivalent devices having the same structure. We have judged that serious health injury will not occur by the affected lots for following reasons:

- It is perceivable when it happens
- This device is used by professional medical staff.

Please note that this problem happens only if the affected products are used with Sureplug® or equivalent devices having the same structure.

No report on health injury from Japan or overseas for the affected lots have been reported.

CORRECTIVE ACTION

Terumo Corporation has eliminated and corrected the root cause in production.
As a precautionary measure, Terumo Corporation is issuing a voluntary recall of the affected population in case affected syringe may be used with Sureplug® or equivalent devices having the same structure.

DETAILS ON AFFECTED DEVICES

Reference	Description	Lot number Range
SS*30LE1	TERUMO® SYRINGE - 30 ml-Luer Lock/Centric	120525J, 120609J, 120610J, 120611J

Note: code SS*30LE1 is the product distributed by Terumo Europe N.V.

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 lots on the related reply form and return this form as quickly as possible to the fax number indicated on the form.

(3) Your local Terumo Europe representative will contact you to organize the pick up, compensation and provide replacement.

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

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

Organisation (to be completed by the sales or dealer)
Contact name (function)
Contact phone, mobile, email

[redacted]
MD Vigilance Expert
Regulatory Affairs
Terumo Europe NV
Leuven, Belgium

Field Safety Notice - CUSTOMER REPLY FORM

Device: **TERUMO® SYRINGE - 30 ML-LUER LOCK/CENTRIC**

Reference: **FSN1203**

Please complete, sign and fax this back: To:

Telefax:

Hospital Name	
City	
Country	

Our records indicate that you have received affected Terumo syringes.

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 of the referred syringes.

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

Reference	Lot	Number of units ready to return
SS*30LE1		

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1203A [EN]