Urgent FIELD SAFETY NOTICE

Device: **Terumo® Hypodermic NEOLUS Needle – Incidental Compromised Package Integrity**
Reference: **FSN 1905 2019-09**
Action: **Return**

Attention: Chief of Hospital, Clinics, Pharmacy & Medical staff

Description of the problem

Terumo Europe has become aware through its internal investigation of a risk for incidental occurrences of compromised packaging integrity, potentially compromising the product sterility, in a defined population of Terumo® Hypodermic NEOLUS Needle.

The conclusion of the current investigation indicates that in a specified period, a temporary technical issue on the packaging line caused pressure on the blister film. This resulted in occasional damages of the film, potentially impacting the integrity of the blister in the affected population.

Although a portion of the affected population was previously released to the market being conform to specifications, the investigation could not fully rule out potential occurrences of individual affected packages in this population.

Terumo Europe is voluntarily conducting this Field Safety Corrective Action for the affected device population as a precautionary measure.

There is no reported complaint from the market regarding this issue.

Details on affected devices

Product code	Description	Affected lot numbers
NN-2525R	Terumo® Hypodermic NEOLUS Needle	1907005
NN-2525R	Terumo® Hypodermic NEOLUS Needle	1907006
NN-2316R	Terumo® Hypodermic NEOLUS Needle	1907007
NN-2525R	Terumo® Hypodermic NEOLUS Needle	1907009
NN-2316R	Terumo® Hypodermic NEOLUS Needle	1908002
NN-2525R	Terumo® Hypodermic NEOLUS Needle	1906012
NN-2525R	Terumo® Hypodermic NEOLUS Needle	1906013

Potential hazard

The possibility of a compromised device being used is considered low. Accidental use of a compromised device may occasionally result in health consequences for the patient, such as infection.

Corrective actions

Terumo Europe has been implementing corrective actions assuring elimination of such remote defect.

Terumo Europe is alerting its involved customers about the issue, and is asking to immediately identify, segregate and return the remaining units in their inventory to Terumo Europe.

Customer instructions

1) Review this Field Safety Notice and assure that all users are aware of this notice.
2) Immediately identify and segregate the units of the suspected device population.
3) Indicate the number of unused units from the referred codes/lots 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.
4) The company representative will contact you to organize immediate pick-up and provide 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.

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

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

***Field Safety Notice* - CUSTOMER REPLY FORM**

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

E-mail/Telefax:

Hospital/Customer Name	
City	
Country	

Our records indicate that you have received devices from the suspected lots.

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	

FSN1905A [EN]