Urgent FIELD SAFETY NOTICE

Device: Terumo® Radifocus Guide Wire M – Remote Likelihood Of Incidental Compromised Package Integrity

Reference: FSN 1502 2015-05

Action: Return / Re-inspection

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

Description of the problem

Terumo Europe has become aware through its internal investigation of a remote risk for incidental occurrence of compromised packaging integrity in a defined population of Terumo® Radifocus Guide Wire M (Vascular and Non-Vascular).

The investigation conclusion indicates an increased trend of internal non conformities related to the pouch sealing process in a specified period. An incidental increased curling of the pouch raw materials could potentially lead to improperly sealed pouch in the production process. Although the improperly sealed pouches were detected in production and non-conformities were raised and resolved, it is not completely excluded in this specified period that a faulty sealed pouch could still have escaped the inspections.

Although a part of the affected population was previously released to the market being conform to specifications, the investigation could not fully rule out a remote likelihood of an incidental occurrence of individual package(s) in the suspected population possibly not properly sealed. A possible defect, if existing, is likely visible before use and the device labelling including the instructions for use does address this specific risk by providing the following warning/precautions: *"Do not use if package is damaged"* and *" Do not use if the unit package or the guide wire is broken or soiled".*

However, 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

This action is limited to the item codes and lots as detailed in annex I.

Potential hazard

The possibility of an incidental packaging integrity being impacted is remote. The defect is likely detectable before use regardless of the current existing provision on the device labeling. The possibility of a compromised device being used is considered extremely unlikely. In the circumstances of such scenario, accidental use of a compromised device may result in health consequences for the patient, such as infection.

Corrective actions

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

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

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) Your Terumo Europe 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

MD Vigilance Expert
Terumo Europe NV –
Leuven, Belgium

Annex I - Details on affected devices

Product code	Description	Affected lot numbers
NV-GA25153M	Terumo® Guide Wire M Non-Vascular	1502239
NV-GA35403M	Terumo® Guide Wire M Non-Vascular	1502028
NV-GA38153M	Terumo® Guide Wire M Non-Vascular	1502241
NV-GS35153M	Terumo® Guide Wire M Non-Vascular	1502238
NV-GS35263M	Terumo® Guide Wire M Non-Vascular	1502035
NV-GS35403M	Terumo® Guide Wire M Non-Vascular	1501219
NV-GS35453M	Terumo® Guide Wire M Non-Vascular	1501233
NV-PA35403M	Terumo® Guide Wire M Non-Vascular	1502150
NV-PS35153M	Terumo® Guide Wire M Non-Vascular	1502230
NV-PS35153M1	Terumo® Guide Wire M Non-Vascular	1501353, 1502227
NV-PS35183M	Terumo® Guide Wire M Non-Vascular	1503139
NV-PS38153M	Terumo® Guide Wire M Non-Vascular	1502036
RF-GA18053M	Terumo® Radifocus Guide Wire M	1502242
RF-GA18153M	Terumo® Radifocus Guide Wire M	1502029
RF-GA18183M	Terumo® Radifocus Guide Wire M	1502136
RF-GA25183M	Terumo® Radifocus Guide Wire M	1502151
RF-GA25263M	Terumo® Radifocus Guide Wire M	1502037
RF-GA35053M	Terumo® Radifocus Guide Wire M	1502030, 1502031, 1502139, 1502311
RF-GA35083M	Terumo® Radifocus Guide Wire M	1502032, 1502033, 1502140, 1502312
RF-GA35181M	Terumo® Radifocus Guide Wire M	1502143
RF-GA35223M	Terumo® Radifocus Guide Wire M	1502134
RF-GA38263M	Terumo® Radifocus Guide Wire M	1502320
RF-GS18183M	Terumo® Radifocus Guide Wire M	1502154
RF-GS32153M	Terumo® Radifocus Guide Wire M	1502039
RF-GS35155M	Terumo® Radifocus Guide Wire M	1502040
RF-GS35183M	Terumo® Radifocus Guide Wire M	1501355
RF-GS35223M	Terumo® Radifocus Guide Wire M	1501249
RF-GS35261M	Terumo® Radifocus Guide Wire M	1502041
RF-PA18153M	Terumo® Radifocus Guide Wire M	1502159
RF-PA35083M	Terumo® Radifocus Guide Wire M	1501228, 1501229
RF-PA35263M	Terumo® Radifocus Guide Wire M	1501354, 1502303
RF-PA35303M	Terumo® Radifocus Guide Wire M	1502244, 1503041
RF-PS35453M	Terumo® Radifocus Guide Wire M	1502246, 1503042
RF-PS38153M	Terumo® Radifocus Guide Wire M	1502045

Field Safety Notice - CUSTOMER REPLY FORM

Device: Terumo® Radifocus Guide Wire M – Remote Likelihood Of Incidental Compromised Package Integrity

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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 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	

FSN1502A [EN]