

Urgent FIELD SAFETY NOTICE

Device: **Radifocus® Introducer II, Radifocus® Introducer II M coat and Glidesheath Slender™**

Issue: **Potential loss of package integrity that may compromise the sterility of the product**

Reference: **FSN 1701 2017-05**

Action: **Return**

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

DESCRIPTION OF THE PROBLEM

Terumo Corporation (headquartered in Japan) is conducting a global, voluntary recall of selected lots of Radifocus Introducer II, Radifocus Introducer II M coat and Glidesheath Slender, which are used to support transradial or transfemoral intervention procedures.

The reason for the recall is a potential loss of package integrity that may compromise the sterility of the product. This issue was identified by Terumo during a routine inspection when an incomplete seal of the kit's peel pouch was observed.

DETAILS ON AFFECTED DEVICE

For the list of affected devices (item and lot number combination) see **ANNEX I**.

POTENTIAL HAZARD

There have been no customer complaints or reported patient injuries associated to this issue. The potential defect rate is estimated to be less than 0.02%. The potential for patient harm is also low given the nature of the defect and impact on product performance. Sterility tests performed on products showing compromised package integrity, were all negative (= no growth of microorganisms).

We are committed to patient health and safety in all that we do and have elected to take this voluntary recall (field removal) as a precautionary measure.

CORRECTIVE ACTION

Terumo is alerting the involved customers about the issue, requesting that they stop using the suspected population and to return the remaining units in their inventory.

CUSTOMER INSTRUCTIONS

- 1) Review this Field Safety Notice and ensure that all users are aware of this notice.
- 2) Immediately identify and segregate all remaining unused units of items and lots listed in Annex I.
- 3) Indicate the number of unused units from the attached list 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 collection of the product and customer service will arrange a credit note, if applicable.

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
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Sales Support team UK- email: Sales.Support@terumo-europe.com

A handwritten signature in blue ink, appearing to read "Fien Aerts".

Fien Aerts
VP Regulatory & Quality
Terumo Europe NV
Leuven, Belgium

Annex I - Details on affected devices (page 1/4)

Product code	Description	Affected lot numbers
RS*A10K10SQ	Radifocus® Introducer II	161101, 161207
RS*A11K10SQ	Radifocus® Introducer II	161129, 161207, 170113, 170116
RS*A40G05SQ	Radifocus® Introducer II	161122, 161202, 170112
RS*A40G07SQ	Radifocus® Introducer II	161117
RS*A40K10AQ	Radifocus® Introducer II	161118
RS*A50G07SQ	Radifocus® Introducer II	170109
RS*A50K10SQ	Radifocus® Introducer II	161212
RS*A60G05SQ	Radifocus® Introducer II	161031, 161130
RS*A60G07SQ	Radifocus® Introducer II	170109
RS*A70K10SQ	Radifocus® Introducer II	161031
RS*A90K10SQ	Radifocus® Introducer II	161109, 161202, 170109, 170202
RS*B10K10MQ	Radifocus® Introducer II	161213
RS*B10N10MQ	Radifocus® Introducer II	161128, 161208, 170110
RS*B10N25AQ	Radifocus® Introducer II	161104
RS*B11K10MQ	Radifocus® Introducer II	161107, 161209, 170116
RS*B11N10MQ	Radifocus® Introducer II	161114, 161212, 170201, 170202
RS*B11N10SQ	Radifocus® Introducer II	161111, 161212, 170113
RS*B11N25AQ	Radifocus® Introducer II	161115, 161212
RS*B40G07SQ	Radifocus® Introducer II	161202
RS*B40K10AQ	Radifocus® Introducer II	161209
RS*B50G07SQ	Radifocus® Introducer II	161201
RS*B60N10MQ	Radifocus® Introducer II	161125, 161222
RS*B90K10MQ	Radifocus® Introducer II	161102, 161201
RS*B90N10MQ	Radifocus® Introducer II	161103, 161206
RS*B90N10SQ	Radifocus® Introducer II	161111, 161206, 170113
RS*B90N25AQ	Radifocus® Introducer II	161108, 161202, 170110
RS*R50N10MQ	Radifocus® Introducer II	161124
RS*R60N10MQ	Radifocus® Introducer II	161129, 161213
RS*R80N10MQ	Radifocus® Introducer II	161207
RS*R90N10MQ	Radifocus® Introducer II	161108, 161121, 161205, 170201

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Product code	Description	Affected lot numbers
RS+A40G07SQ	Radifocus® Introducer II	161124
RS+A40G10SQ	Radifocus® Introducer II	161125
RS+A40K10AQ	Radifocus® Introducer II	161121
RS+A50G07SQ	Radifocus® Introducer II	161125, 161212
RS+A50K10SQ	Radifocus® Introducer II	161128
RS+A60G07SQ	Radifocus® Introducer II	161206
RS+A60K10AQ	Radifocus® Introducer II	161126
RS+A60K10SQ	Radifocus® Introducer II	161126, 161209
RS+A70K10SQ	Radifocus® Introducer II	161124
RS+A80K10SQ	Radifocus® Introducer II	161128
RS+B40K10AQ	Radifocus® Introducer II	161121
RS+B40K10MQ	Radifocus® Introducer II	161122, 161209
RS+B40K10SQ	Radifocus® Introducer II	161123
RS+B50K10MQ	Radifocus® Introducer II	161123, 161214
RS+B50N10MQ	Radifocus® Introducer II	161128, 161206
RS+B50N10SQ	Radifocus® Introducer II	161126
RS+B50N25AQ	Radifocus® Introducer II	161126
RS+B60G07SQ	Radifocus® Introducer II	161122
RS+B60K10MQ	Radifocus® Introducer II	161129, 161212, 161214
RS+B60N10MQ	Radifocus® Introducer II	161115, 161130, 161210
RS+B60N10SQ	Radifocus® Introducer II	161130
RS+B60N25AQ	Radifocus® Introducer II	161129
RS+B70K10MQ	Radifocus® Introducer II	161123, 161206
RS+B70N10MQ	Radifocus® Introducer II	161124
RS+B70N10SQ	Radifocus® Introducer II	161124
RS+B70N25AQ	Radifocus® Introducer II	161125
RS+B80K10MQ	Radifocus® Introducer II	161126
RS+B80N10MQ	Radifocus® Introducer II	161128
RS+B80N10SQ	Radifocus® Introducer II	161128
RS+B80N25AQ	Radifocus® Introducer II	161129
RS+R40K10MQ	Radifocus® Introducer II	161122
RS+R50N10MQ	Radifocus® Introducer II	161126
RS+R60N10MQ	Radifocus® Introducer II	161130, 161203
RS+R70N10MQ	Radifocus® Introducer II	161125, 161212
RS+R80N10MQ	Radifocus® Introducer II	161128

Annex I - Details on affected devices (page 3/4)

Product code	Description	Affected lot numbers
RM*AF5G10HQW	Radifocus® Introducer II M Coat	161103
RM*AF5J10SQW	Radifocus® Introducer II M Coat	161108, 161216
RM*AF5J16SQW	Radifocus® Introducer II M Coat	161111, 161125
RM*AF5J25SQW	Radifocus® Introducer II M Coat	161115, 161214
RM*AF6J10SQW	Radifocus® Introducer II M Coat	161021, 161024, 161107, 161121 161122, 161123, 161202, 161216 170109, 170110, 170119, 170120 170123, 170124, 170125
RM*AF6J25SQW	Radifocus® Introducer II M Coat	161114, 161129, 161130, 161213 161228, 170223, 170224, 170302
RM*RF5F10PQ	Radifocus® Introducer II M Coat	161024, 161109, 161128, 161214 170126, 170201
RM*RF5F16PQ	Radifocus® Introducer II M Coat	161114, 161212
RM*RF5F25PQ	Radifocus® Introducer II M Coat	161114
RM*RF5J10PQ	Radifocus® Introducer II M Coat	161110, 161209, 170112
RM*RF5J16PQ	Radifocus® Introducer II M Coat	161115, 161213, 170113
RM*RF5J25PQ	Radifocus® Introducer II M Coat	161111, 161130, 161209, 170116
RM*RF6F10PQ	Radifocus® Introducer II M Coat	161025, 161026, 161027, 161028 161111, 161223, 161226, 170113 170202, 170203, 170208
RM*RF6F16PQ	Radifocus® Introducer II M Coat	161027, 161108, 161130
RM*RF6F25PQ	Radifocus® Introducer II M Coat	161031, 161110, 161212, 161226 170130, 170131, 170208
RM*RF6J10PQ	Radifocus® Introducer II M Coat	161109, 161213, 161219, 170131
RM*RF6J16PQ	Radifocus® Introducer II M Coat	161028, 161115, 161128, 161209 170118
RM*RF6J25PQ	Radifocus® Introducer II M Coat	161031, 161102, 161209, 161228 170127

Annex I - Details on affected devices (page 4/4)

Product code	Description	Affected lot numbers
RM*ES5F10SQR	Glidesheath Slender™	161108, 161202, 170110
RM*ES5J10SQ	Glidesheath Slender™	161103, 161118, 161201
RM*ES6F10SQR	Glidesheath Slender™	161021, 161109, 161128
RM*ES6J10HQS	Glidesheath Slender™	161124, 170116, 170202
RM*ES6J10PQ	Glidesheath Slender™	161109, 161125, 161205
RM*ES6J10SQ	Glidesheath Slender™	161223
RM*ES6J16HQS	Glidesheath Slender™	170111, 170206, 170307
RM*ES6J16PQ	Glidesheath Slender™	161128
RM*ES6J16SQ	Glidesheath Slender™	161110, 161125
RM*ES7F10SQR	Glidesheath Slender™	161115
RM*RS5C10PQ	Glidesheath Slender™	161104, 161123, 161124, 161201 170120, 170201
RM*RS5F10PQ	Glidesheath Slender™	161107, 161201, 161227, 170127 170201
RM*RS5F16PQ	Glidesheath Slender™	161108, 170202
RM*RS6C10PQ	Glidesheath Slender™	161024, 161111, 161214
RM*RS6F10PQ	Glidesheath Slender™	161024, 161025, 161101, 161104 161107, 161116, 161117, 161118 161121, 161122, 161123, 161202 161215, 161216, 161219, 161220 161221, 161222, 161223, 170110 170111, 170112, 170117, 170118 170119, 170120, 170125, 170126 170203
RM*RS6F16PQ	Glidesheath Slender™	161031, 161110, 161114 161213
RM*RS6J10PQ	Glidesheath Slender™	161028, 161108, 161111 161115, 161208, 161209 170112, 170113, 170127 170130, 170131
RM*RS6J16PQ	Glidesheath Slender™	161026, 161114, 161128 161207, 170125
RM*RS7F10PQ	Glidesheath Slender™	161031, 161109, 161209 161212
RM*RS7F16PQ	Glidesheath Slender™	161115, 161129
RM*RS7J10PQ	Glidesheath Slender™	161129
RM*RS7J16PQ	Glidesheath Slender™	161114, 161130

Field Safety Notice - CUSTOMER REPLY FORM

Device: **Radifocus® Introducer II, Radifocus® Introducer II M coat and Glidesheath Slender™**

Issue: **Potential loss of package integrity that may compromise the sterility of the product**

Reference: **FSN 1701 2017-05**

Action: **Return**

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

To:

E-mail/Telefax:

Client number	
Hospital Name	
City	
Country	

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

Hospital own inventory		
Reference	Lot	Number of units

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1701A [EN]