

Hitna OBAVIJEST O MOGUĆOJ NEISPRAVNOSTI MEDICINSKOG PROIZVODA

Uređaj: **Radifocus® Introducer II, Radifocus® Introducer II M Coat i Glidesheath Slender™**
Problem: **Mogući gubitak integriteta pakiranja koji može ugroziti sterilnost proizvoda**
Kataloški broj: **FSN 1701 2017-05**
Radnja: **Povrat**

Primatelji: Ravnatelj bolnice, laboratorij za kateterizaciju, zdravstvene ustanove i medicinsko osoblje

OPIS PROBLEMA

Tvrtka Terumo Corporation (sa sjedištem u Japanu) provodi globalni, dobrovoljni opoziv određenih serija uvodnica Radifocus Introducer II, Radifocus Introducer II M Coat i Glidesheath Slender, koje se upotrebljavaju u transradijalnim i transfemoralnim intervencijskim postupcima.

Razlog za opoziv moguće je narušavanje integriteta pakiranja koje može ugroziti sterilnost proizvoda. Postojanje tog problema tvrtka Terumo utvrdila je tijekom redovitog pregleda kad je uočeno nepotpuno zatvaranje samoljepive vrećice kompleta.

POJEDINOSTI O UREĐAJU NA KOJI SE OBAVIJEST ODNOSI

Popis uređaja na koje se obavijest odnosi (kombinacija kataloškog broja i broja serije) potražite u **DODATKU I.**

MOGUĆE OPASNOSTI

Nema pritužbi klijenata ni prijavljenih ozljeda pacijenata povezanih s tim problemom. Procjenjuje se da je stopa potencijalnog oštećenja manja od 0,02 %. Niska je i mogućnost štete za pacijenta s obzirom na prirodu oštećenja i učinak na performanse proizvoda. Svi su testovi sterilnosti izvedeni na proizvodima s narušenim integritetom pakiranja bili negativni (= bez rasta mikroorganizama).

Posvećeni smo zdravlju i sigurnosti pacijenata u svemu što radimo i odlučili smo pokrenuti ovaj dobrovoljni opoziv (povrat) kao mjeru opreza.

KOREKTIVNA RADNJA

Tvrtka Terumo upozorava na problem korisnike na koje se to odnosi, tražeći da prestanu upotrebljavati sumnjive proizvode i vrte preostale jedinice koje se nalaze u njihovu inventaru.

UPUTE ZA KUPCE

- 1) Pregledajte ovu obavijest o mogućoj neispravnosti medicinskog proizvoda i sve korisnike upoznajte sa sadržajem obavijesti.
- 2) Odmah pronađite i odvojite sve preostale neupotrijebljene jedinice proizvoda i serije navedene u Dodatku I.
- 3) Na pripadajućem obrascu za povrat navedite broj neupotrijebljenih jedinica s priloženog popisa i obrazac što prije pošaljite na adresu e-pošte ili broj faksa naveden na obrascu.

- 4) Predstavnik tvrtke Terumo Europe kontaktirat će vas kako bi organizirao trenutachno prikupljanje proizvoda, a služba za korisnike napraviti će odobrenje, ako je potrebno.

Potvrđujemo da je ova *Obavijest o mogućoj neispravnosti medicinskog proizvoda* poslana i nadležnom tijelu vaše države.

Za sva eventualna pitanja ili poteškoće obratite se nama ili svom lokalnom predstavniku tvrtke Terumo.

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

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

Dodatak I – Pojediniosti o uređajima na koje se obavijest odnosi
(stranica 1/4)

Šifra proizvoda	Opis	Brojevi serija na koje se obavijest odnosi
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

Dodatak I – Pojediniosti o uređajima na koje se obavijest odnosi
(stranica 2/4)

Šifra proizvoda	Opis	Brojevi serija na koje se obavijest odnosi
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
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Dodatak I – Pojediniosti o uređajima na koje se obavijest odnosi (stranica 3/4)

Šifra proizvoda	Opis	Brojevi serija na koje se obavijest odnosi
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

Dodatak I – Pojediniosti o uređajima na koje se obavijest odnosi
(stranica 4/4)

Šifra proizvoda	Opis	Brojevi serija na koje se obavijest odnosi
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

