Urgent FIELD SAFETY NOTICE

Device: **Terumo® ACCUFORCE® PTCA Dilatation Catheter (ϕ2.5mm)**

Issue: **Low likelihood of balloon burst below RBP in a specific device population**

Reference: FSN 1508 2016-03

Action: Return

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

DESCRIPTION OF THE PROBLEM

Terumo Corporation has initiated a Voluntary Recall of the specific population of Terumo® ACCUFORCE® PTCA Dilatation Catheter (ϕ2.5mm) listed in this letter.

Terumo Corporation is initiating this recall based on internal investigation and testing that revealed a low likelihood of potential balloon burst below **R**ated **B**urst **P**ressure (RBP) in the referred suspected device population.

The affected lots were previously released to the market being in compliance with the product acceptance and release criteria. However, the current investigation, including further testing and trend review, could not exclude incidental occurrence of potentially compromised units in these lots.

There have been no related complaints and the risk of patient harm is considered remote. However, Terumo Corporation is conducting this voluntary action as a precautionary measure having the potential of a limited number of units in the suspected population not meeting product specification.

DETAILS ON AFFECTED DEVICE

Reference	Product Description	Lot Number
DC-RM2512HHW	PTCA DILATATION CATHETER (RX) ACCUFORCE® 2.5 x 12 mm, catheter effective length 145 cm	160114
DC-RM2515HHW	PTCA DILATATION CATHETER (RX) ACCUFORCE® 2.5 x 15 mm catheter effective length 145 cm	160107, 160118, 160125
DC-RM2520HHW	PTCA DILATATION CATHETER (RX) ACCUFORCE® 2.5 x 20 mm, catheter effective length 145 cm	160121

POTENTIAL HAZARD

Based on confirmed testing data and clinical experience in the circumstances of a balloon burst, this typically occurs longitudinally in the balloon seam along the partial or full balloon length. Therefore, there is minimal risk that part of the balloon could be separated or be left in patient's coronary artery. Furthermore, a longitudinal balloon burst occurs instantaneously with an immediate and broadly spread pressure release pattern resulting in negligible risk of damaging the vessel.

CORRECTIVE ACTION

Involved customers are alerted about the issue, asked to 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 the units of the suspected device population.

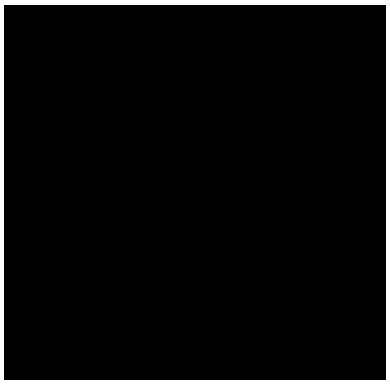
3) Indicate the number of unused units from the referred codes/lots on the related reply form and return this form as quickly as possible to the e-mail address or the fax number indicated on the form.

4) Your Terumo Europe representative will contact you to organize immediate collection of the product and customer service will arrange a credit note.

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



Field Safety Notice - CUSTOMER REPLY FORM

Device: **Terumo® ACCUFORCE® PTCA Dilatation Catheter (ϕ2.5mm)**

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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.

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	

FSN1508A [EN]