Urgent FIELD SAFETY NOTICE

Device: Terumo® Destination® Guiding Sheath
Reference: FSN 1503 - Supplement 2016-04
Action: Return

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

This letter is to inform you that Terumo Medical Corporation has expanded the scope of the Voluntary Recall for Destination® products originally announced in November 2015 (Terumo Europe's letter reference FSN1503, issued in November 2015) to include the additional products referenced in the table below.

Description of the problem

Terumo Medical Corporation has initiated a Voluntary Recall of the Terumo Medical Destination® products listed in this letter.

Terumo Medical Corporation is initiating this recall based on internal investigation and testing that revealed the distal end of certain lots of Terumo Medical Destination® products may not contain the labelled length of coating. While there have been no complaints or patient related incidents reported, the lack of coating could render it difficult to navigate the device to the target vasculature.

Details on affected device

Reference	Product Description	Lot Number
RSC03	Destination® Carotid Guiding Sheath 6 Fr, 90cm, TBV Valve	RL17
		RM29
RSC07	Destination® Carotid Guiding Sheath 6 Fr, 90cm, CCV Valve	RL24
		RM01

Please refer to the box label and/or the pouch label for the Product code, Description, and Lot Number information. Only the specific products/lots listed above are affected by this recall. No other Terumo Medical product distributed by Terumo Europe N.V. is involved in this voluntary device recall.

Potential hazard

An injury from the usage of the product without coating is not expected.The lack of coating could render it difficult to navigate the device to the target vasculature and may result in procedure delay or cancelation.

Corrective action

Involved customers are alerted about the issue and asked to stop using the suspected lot and to return the remaining units in their inventory.

Customer instructions

1) Review this Field Safety Notice, and assure that all users are aware of this notice.
2) Stop using the units of the suspected referred codes/lots.
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 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

Nathalie Gérard
MD Vigilance Specialist
Terumo Europe N.V.

Field Safety Notice - CUSTOMER REPLY FORM

Device: Terumo® Destination® Guiding Sheath

Reference: FSN 1503 - Supplement 2016-04

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

To:

E-mail/Telefax:

Customer number	
Hospital Name	
City	
Country	

Our records indicate that you have received devices from the suspected codes/ 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	

FSN1503A-supplement [EN]