

# Urgent FIELD SAFETY NOTICE

Device: **Terumo® Destination® Renal Guiding Sheath**  
Reference: **FSN 1503 2015-11**  
Action: **Return**

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

## 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 labeled 5 cm 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
RSR01	Destination® Renal Guiding Sheath	RN19

Please refer to the box label and/or the pouch label for the Product code, Description, and Lot Number information. Only the specific product/lot 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 cancellation.

## 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 lot.
- 3) Indicate the number of unused units from the referred lot 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

A handwritten signature in blue ink, appearing to read "Nathalie Gérard".

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Nathalie Gérard  
MD Vigilance Specialist  
Terumo Europe N.V.  
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## Field Safety Notice - CUSTOMER REPLY FORM

Device: **Terumo® Destination® Renal Guiding Sheath**

Reference: **FSN 1503 2015-11**

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

To:

E-mail/Telefax:

Hospital Name		
City		
Country		
<p>Our records indicate that you have received devices from the suspected lot.</p>		
<p>By completion and return of this form, I am confirming receipt, reading and acting on this Safety Notice:</p> <p><input type="checkbox"/> We have no physical inventory from the affected population.</p> <p><input type="checkbox"/> We have the following unused affected units ready to return:</p>		
Reference	Lot	Number of units ready to return
RSR01	RN19	
Person Responding [Please Print]		
Title		
Phone Number		
Signature		
Date		

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