

**Cook Medical Europe**

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Urgent Field Safety Notice

Commercial name of the affected product: Ring Transjugular Intrahepatic Access Set

Manufacturer : Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US

Cook Reference Number: 2017FA0014

Type of action: Field Safety Corrective Action

Date: 08 August 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Reference Part Number	Global Part Number	Lot Number
Ring Transjugular Intrahepatic Access Set	RTPS-100	G06541	5390640

Description of the problem:

Cook Medical is initiating a voluntary field action of lot 5390640 for RTPS-100. Cook Medical has received complaints that the devices' catheters are the incorrect length.

Potential adverse events if the nonconforming products are used include being unable to puncture the hepatic parenchyma necessitating the replacement of the device or resulting in rescheduled procedure.

The Ring Transjugular Intrahepatic Access Set is intended for transjugular liver access in diagnostic and interventional procedures.

This notice is directed to you because our records indicate that you have received lot 5390640 of the RTPS-100 that have not expired.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products as per the specified lot listing from your inventory.
2. Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Response form.

Product should be addressed to:

Cook Medical EUDC
Robert-Koch-Straße, 2
52499 Baesweiler
GERMANY

Credit will be provided for the returned affected products where applicable.

3. Send the Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61 334441). Do not enclose the response form with the returned product.
4. Please report any adverse event to Cook Medical by contacting our Customer Services Department.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Thomas Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe ApS
Sandet 6, DK-4632 Bjaeverskov, Denmark

Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@cookmedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.



Annemarie Beglin
Quality Systems Manager