

**Cook Medical Europe**

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Urgent Field Safety Notice

Commercial name of the affected product: TIPSS-200 Transjugular Intrahepatic Portosystemic Shunt Procedure Pack

Manufacturer: William Cook Europe Aps, Sandet 6, 4632 Bjaeverskov, Denmark

Cook Reference Number: 2017FA0003

Type of action: Field Safety Corrective Action

Date: 14 February 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Catalog Identifier	Lot Number
Transjugular Intrahepatic Portosystemic Shunt Procedure Pack	TIPSS-200	E3496885

Description of the problem:

Cook Medical is initiating a voluntary recall of the procedure pack Transjugular Intrahepatic Portosystemic Shunt (TIPSS-200) labelled with the lot number E3496885.

The Procedure Pack consists, among others, of the balloon catheters ATB5-35-80-8-4.0 and ATB5-35-80-10-4.0, and is intended for percutaneous transjugular intrahepatic portosystemic shunting to establish a tract inside the liver parenchyma and thus connecting a large hepatic vein with a main portal vein branch.

Based on two complaints of the same lot, we found that this lot was packed incorrectly as it contained balloon catheters of the same size - either two ATB5-35-80-8-4.0 or two ATB5-35-80-10-4.0 instead of one of each.

The balloon catheters are used for dilation of the parenchyma tract by introducing an 8 mm balloon catheter and/or secondly introducing the 10 mm balloon.

Potential adverse events that may occur as a result of missing one of the balloon sizes are overdilation compared to the stent size and increased risk of encephalopathy.

This notice is directed to you because our records indicate that you have received the Transjugular Intrahepatic Portosystemic Shunt (TIPSS-200) labelled with the lot number E3496885.

Advise on action to be taken by the user:

1. Immediately collect all remaining affected products 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 devices 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 Customer Relations 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 on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Marianne Høy
Manager, Support
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

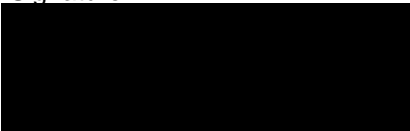
Or

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.

Signature



Annemarie Beglin
Quality Systems Manager