COOK®

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product:

- **Cook Vital-Port® Vascular Access System**

Manufacturer: Cook Incorporated, P.O. Box 489, 750 Daniels Way, Bloomington, Indiana 47402, US
Cook Reference Number: 2017FA0019
Type of action: Field Safety Corrective Action

Date: 29th November 2017

Attention: Chief Executive / Risk Management / Purchasing

Details on affected devices:

PRODUCT Brand Name	Reference Part number	GPN	LOT NUMBER
Vital-Port Vascular Access System Titanium Power Injectable Single-Chamber Systems	IP-7110 IP-S7010 IP-S7110 IP-S9010 IP-S9110	G20254 G26434 G26436 G26438 G26440	All Lots
Vital-Port Vascular Access System Standard, Petite and Mini Titanium and MRI Single-Chamber Systems	IP-5112-N IP-5112-NC IP-5116 IP-5116-N IP-5118-N IP-5118-NC IP-6018 IP-6113 IP-7112 IP-9112 IP-S5016 IP-S5018 IP-S5116 IP-S5116-MPIS-NT IP-S5116-N IP-S5116W IP-S5116W-MPIS-NT IP-S5118 IP-S5118-N IP-S6010 IP-S6012 IP-S6013 IP-S6018 IP-S6110 IP-S6112 IP-S6113 IP-S6113-MPIS-NT IP-S6118	G46543 G26539 G26468 G46544 G46545 G26540 G26510 G26424 G19803 G19769 G26469 G26507 G26470 G50864 G46546 G26472 G26489 G26509 G46547 G26430 G26458 G26431 G26511 G26432 G26449 G26433 G50860 G26513	All Lots

	IP-S6118-MPIS-NT IP-S7012 IP-S7112 IP-S9012 IP-S9112	G50861 G26435 G26437 G26439 G26441	
Vital-Port Vascular Access System Standard and Petite Titanium Dual-Chamber Systems	IP-S1021 IP-S1121 IP-S7029 IP-S7129 IP-S7129-MPIS-NT	G26428 G26429 G26502 G26504 G50863	All Lots

Description of the problem:

Cook Medical is initiating a voluntary recall of the products listed above. During testing of the non-coring needle, it was identified that the non-coring needle provided with the Cook Vital-Port® Vascular Access System (Vital-Port) may cut or dislodge a core or sliver of material from the Vital-Port septum when the non-coring needle is inserted into the Vital-Port. This needle is used on the initial implant of the Vital-Port. Vital-Port products that have been successfully placed in patients are not impacted by this recall.

Potential adverse events that may occur are unwanted side effects from silicone cores or slivers that may embolize into the patients' bloodstream. In addition, medications may leak from the port, resulting in inadequate delivery of the medication and potential injury to the surrounding tissues.

There have been no adverse event reports from septum leakage or a silicone sliver pushed into the patient associated with these products to date.

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 and quarantine the affected products.

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.

   The Product to be returned 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 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:

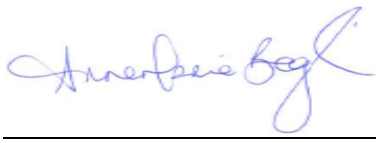
Thomas Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe ApS
Sandet 6, DK-4632 Bjaeverskov, Denmark

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

