

Вих.№274 від «30» листопада 2017 року

Державна Служба України з лікарських засобів
та контролю за наркотиками

Товариство з обмеженою відповідальністю «КАМСАБ», яке знаходиться за адресою: вулиця Євгена Сверстюка,19, к.503, м. Київ, Україна, 02660, що є уповноваженим представником на території України виробника Cook Medical Europe (Ірландія) висловлює Вам свою повагу та надає інформацію щодо повідомлення від виробника Cook Medical Europe (Ірландія) про відкликання продуктів Cook Vital-Port® судинної системи оцінки (Vital-Port) у зв'язку з дефектом мембрани порту. Детальна інформація зазначена у зверненні виробника, що додається.

На даний час Група європейських експертів із забезпечення якості замовників в даний час здійснює заходи з корегувальних дій на місцях від імені Cook Inc., що стосуються продуктів Cook Vital-Port® судинної системи оцінки (Vital-Port).

Додатки:

1. Копія повідомлення від виробника Cook Medical Europe (Ірландія) від 29/11/2017
2. Копія повідомлення-звернення з ціллю інформування щодо відкликання даного товару із зазначенням партій продукції з ринку.

Директор



Герейханов К.Г.



COOK®

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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

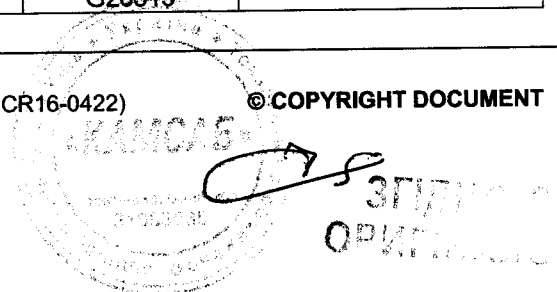
Type of action: Field Safety Corrective Action

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



	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 Assess 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:

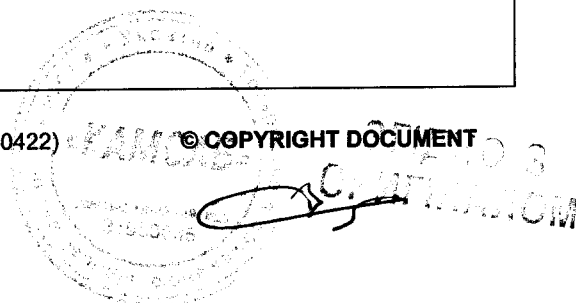
1. Immediately collect all remaining affected products as per the specified lot listing from your inventory and quarantine the affected products.
2. Please complete the enclosed Customer Response Form. Where product is indicated as being returned, our Customer Services department will contact you to 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:

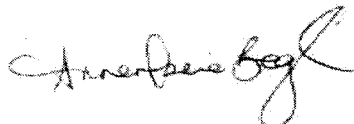
Thomas Kirk
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Or

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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

