COOK

Cook Ireland Limited
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Limerick, Ireland.
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Urgent Field Safety Notice

Commercial name of the affected product: Vital-Port® Mini Titanium Detached Silicone Catheter Infusion Port
FSCA-identifier: 2013C0001
Type of action: Field Safety Corrective Action

Date: 08/01/2013

Attention: Chief Executive

Details on affected devices:

Vital-Port® Mini Titanium Detached Silicone Catheter Infusion Port

IP-S5116W-MPIS-NT
IP-5116
IP-5116W
IP-S5116
IP-S5116W
IP-S5016

Please see attached list for the affected products/lots.

Description of the problem:

In cooperation with the Dusseldorf District Council, Cook Vascular Inc. has initiated a recall of six specific Catalog numbers of our Mini Vital Ports from the German market. The devices are indicated for use in patient therapy requiring repeated vascular access, for injecting or infusion therapy and/or blood sampling.

We have received information that in rare cases if the catheter is placed in a manner that does not follow a smooth course into the vein, or there is an abrupt directional change in the catheter, there may be an increased risk of catheter fracture for the implanted catheter.

If the catheter placement is in the upper two thirds of the upper arm, patients may be at increased risk of catheter fracture and the physician should consider whether the catheter is still necessary, and if it is, weigh the relative risks and benefits of replacing the catheter versus leaving the current catheter in place, even though it may have some increased risk of fracture.

Our records indicate your facility has received one or more of the affected products. If you are a distributor of these products, any further distribution with these specific Catalog numbers should cease and your customers should be notified immediately.

Advise on action to be taken by the user:

1. Please review the attached list and quarantine any affected product that remains in your stock.
2. Immediately collect all remaining unused products. The remaining unused products should be returned as soon as possible via DHL quoting Cook Ireland's account number: 952049139 to arrange pick up.

Send the removed devices to:

Cook Medical EUDC GmbH
Robert-Koch-Strasse2
52499 Baesweiler
Germany

Please attach the enclosed Recall Product Return Form referencing RA # 2013C0001 to the outside of the shipping carton.

Credit will be provided for the returned devices.

3. Where an affected device has been implanted in a patient, and catheter placement is in the upper two thirds of the upper arm, please assess whether the catheter may need to be explanted.

4. Please complete the attached Reply Form, which lists the product and lot numbers affected and return via email to **European.Complaints@CookMedical.com** or alternatively by fax to Cook Ireland marked for the attention of European Complaints / Customer Quality Assurance soon as possible to +353 61334441.

Transmission of this Field Safety Notice:

This notice needs to be passed on 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.

Contact reference person:

Emmett Devereux,
Director of Quality and Regulatory Affairs
COOK Ireland**,**
O'Halloran Road,
National Technology Park,
Limerick,
IRELAND.

Or

Annemarie Beglin
Customer Quality Supervisor,
COOK Ireland**,**
O'Halloran Road,
National Technology Park,
Limerick,
IRELAND.
tel +353 61 334440
fax +353 61 334441

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

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter. We look forward to your response.

COOK VASCULAR INCORPORATED
1186 MONTGOMERY LANE
VANDERGRIFT, PA 15690-6065 U.S.A.
PHONE: 724.845.8621 TOLL FREE: 800.245.4715
WWW.COOKMEDICAL.COM

Dear Doctor,

According to our records you are currently using Cook Medical's Peripheral Mini Titanium Vital-Port®. We would like to thank you for choosing Vital-Port devices for your patients. We would also like to notify you of some important information in this product's Instructions for Use (IFU) that relates to catheter placement and risk of catheter separation.

Mini Titanium Vital-Port catheters may be placed in the upper arm. However, catheter damage may occur if the catheter does not enter the venous system in the lower third of the upper arm and distal to the vein's passage through the deep or brachial fascia. Additionally, to minimize the risk of catheter separation, the catheter needs to follow a smooth course into the vein without abrupt directional changes which may result in catheter kinkage. To address these important topics, please take note of the following information contained in the warning section of this product's IFU:

"*Introduction of the catheter into the subclavian vein using the standard percutaneous techniques may subject the catheter to periodic compression forces with the narrow costoclavicular space between the clavicle and the first rib. Reported complications from repeated subclavian compression include catheter pinch-off syndrome, catheter fracture, and catheter shear followed by embolization of the distal portion.*"

"To avoid catheter damage to a vascular access system implanted peripherally in the upper arm, position the catheter so that it enters the venous system in the lower third of the upper arm and below the vein's passage through the deep or brachial fascia. Following insertion, confirm that the catheter follows a smooth course into the vein and that no abrupt directional changes are present."

These important considerations will help to assure an ongoing low incidence of catheter separation when used in accordance to these recommended placement suggestions. A diagram that depicts these placement recommendations is also enclosed as an attachment to this letter.

Consideration for patient aftercare:

If the catheter placement is in the upper two thirds of the upper arm, patients may be at increased risk of catheter fracture and the physician should consider whether the catheter is still necessary, if it is, weigh the relative risks and benefits of replacing the catheter versus leaving the current catheter in place, even though it may have some increased risk of fracture.

Please notify Cook Vascular if catheter placement has a potential risk of separation, due to placement in the upper two thirds of the upper arm.

Additionally a new warning is being added to the Vital-Port IFU:

WARNING: Failure to adequately anchor the port to the fascia increases the risk of catheter fracture and /or disconnection which could result in catheter migration.

Should you have any questions about these recommendations or experience any device related difficulties, please call us or contact your local representative for immediate assistance. Contact information can be found at http://www.cookmedical.com/contact.do.

Sincerely,
Cook

[redacted]

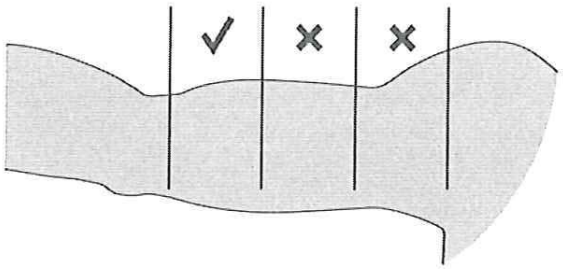
Vice President, Cook Vascular

WARNING:

Failure to adequately anchor the port to the fascia increases the risk of catheter fracture and /or disconnection which could result in catheter migration.

WARNING – Peripheral Implanted Port

To avoid catheter damage to a vascular access system implanted peripherally in the upper arm, position the catheter so that it enters the venous access system in the lower third of the upper arm and below the vein's passage through the deep or brachial fascia.



Abrupt directional changes may result in catheter fracture and subsequent possible embolization. A radiographic confirmation of the catheter insertion should be made to ensure that the catheter is not being pinched."