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## Urgent Field Safety Notice

**Commercial name of the affected product: Single-Spiral Soft Platinum J-Coil Hydrophilic Lock**

**FSCA-identifier: FSCA – 2011-03-30**

**Type of action: Recall**

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Date: April 01, 2011

Attention: Chief Executive

### **Details on affected devices:**

**Product name:** Single-Spiral Soft Platinum J-Coil Hydrophilic Lock

**Catalogue number:** DCS-18S-6-50-HL-J

**Lot number:** E2669357

### **Description of the problem:**

Cook Medical has become aware of a labeling issue on a total of 15 Single-Spiral Soft Platinum J-Coil Hydrophilic Lock, Catalogue no.: DCS-18S-6-50-HL-J supplied within the European Union and is conducting a recall on all unused DCS-18S-6-50-HL-J products. Cook Medical has not received any complaints regarding this specific label issue.

Affected devices may have a wrong sticker affixed on the side of the outer package of the product. The main label on the front of the outer package as well as the inner package is correct and corresponds to the product inside the package. The sticker on the side of the outer package may be showing an incorrect length. The sticker may indicate a length of 15mm, while the actual length of the device is 50mm.

Use of the product with a longer length than expected may cause occlusion of a wrong vessel, parent vessel or protrude into it partially with the risks of having blood clots established there. This could potentially harm the patient seriously. If there is uncertainty as whether a DCS-18S-6-50-HL-J has been implanted, please ensure a frequent patient follow-up.

### **Advise on action to be taken by the user:**

1. Please review the attached customer list and quarantine any affected product that remains in your stock.
2. Please complete the attached Customer Response Form, which lists the product and lot

numbers affected and return by fax to Cook Medical marked for the contact person listed below as soon as possible to +45 5686 8696 or alternatively via e-mail to

[WCE-Complaints@CookMedical.com](mailto:WCE-Complaints@CookMedical.com). **This must be done by April 08, 2011 at the latest.**

3. Immediately collect all remaining unused products. The remaining unused products should be returned as soon as possible via DHL quoting Cook Medical's account number: 960 009 561 to arrange pick up.

**Send the unused devices to:**

William Cook Europe Aps  
Att: Annette Lüneborg  
Sandet 6  
DK-4632 Bjaeverskov  
DENMARK

Please reference RA # FSCA-2011-03-30 on the outside of the shipping carton.

Please be advised that the manufacturer will issue credit for all devices returned.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. We have informed the relevant competent authorities.

**Contact reference persons:**

Mette Neiendam Nielsen  
William Cook Europe  
Sandet 6  
DK-4632 Bjaeverskov  
DENMARK  
Tel: +45 5686 8686  
Fax: +45 5686 8696

Annette Lüneborg  
William Cook Europe  
Sandet 6  
DK-4632 Bjaeverskov  
DENMARK

Should you have any questions, please feel free to contact us for more information. We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter.

We look forward to receiving your response.

Best regards,

Annette Lüneborg  
Bjaeverskov, April 01, 2011