

**Attention: distributors and users****15 October 2015**Coloplast A/S  
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Tel: +45 4911 1111  
www.coloplast.com  
CVR-nr. 69749917**URGENT FIELD SAFETY NOTICE****Ref. FRMML-2015-1006-PR30xx & VS30xx****Quarantine and cease use of all batches of the below listed devices:**

- Kiwee® Testicular Implant: REF. PR3001, PR3002, PR3003, PR3004, PR3005
- Vaginal Stent – Inflatable: REF. VS3020, VS3022, VS3024, VS3026

**Tina Gotschalk**  
Vigilance Officer**Description of the problem:**Dir. tel. +45 4911 3339  
dktg@coloplast.com

The EC certificate of all medical devices from the manufacturer Silimed, who is a subcontractor to Coloplast, has been temporarily suspended by their Notified Body, due to particles found at the surface of some breast implants. There is no indication that these issues would pose a threat to the implanted person's safety

The suspension also affects Testicular Implant and Vaginal Stents placed on the market by Coloplast.

In line with recommendations from the Authorities, Coloplast request that all affected devices, with Silimed as point of origin, should be put in quarantine and that use of these devices should be ceased until further notice.

Investigations are still on-going and this notice will be followed by further information as soon as possible.

**Action to be taken by the distributor:**

- Stop distribution of the affected products
- Quarantine the affected products until further notice
- Distribute the FSN to all end-users to whom the devices were sold
- Fill out and return the attached "confirmation of receipt of FSN"

**Action to be taken by the user:**

- Cease implantation of the affected products
- Quarantine the affected products until further notice
- Fill out and return the attached "confirmation of receipt of FSN"

**Product information**

The Testicular Implant is indicated in cases of aesthetic construction in cases of absence of testicles and sex reassignment surgery; and reconstruction surgery, in cases of

congenital malformations, trauma and diseases of the testicles, for example, epididymitis and orchitis, after testicular or prostate cancer, atrophy generated by traumas or torsion.

The Vaginal Stent is used in surgical or non-surgical reparatory and/or constructive procedures of the vagina, with the purpose of maintaining the dimensions of the neo-vagina, providing appropriate conformation and dilation.

### **Transmission of this Field Safety Notice**

Please forward this message to relevant persons in your organization.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

In addition, if you have further distributed these products, please notify the consignees at once of this notification.

Your notification to your customers should be enhanced by including a copy of this notification letter.

This notification should be carried out to the user level. Your assistance is appreciated and necessary.

The undersigned confirms that this notice has been notified to the appropriate Competent Authorities.

If you have any questions, please contact us at:

#### **Contact details:**

Manufacturer: Coloplast Ltd

Address: First Floor  
Nene Hall  
Lynch Wood  
Peterborough Business Park  
PE2 6FX

Contact person: Cara McKay

E-mail: [gbcma@coloplast.com](mailto:gbcma@coloplast.com)

Telephone: 01733 392042

Yours sincerely,



Tina Gotschalk

FSN ref.: FRMML-2015-1006 - PR30xx &amp; VS30xx

**Confirmation of receipt of the FSN**

Please fill out the form and send it to the email address given below - even if you do not have the products on your stock please fill out the document.

E-mail: [gbsurgery@coloplast.com](mailto:gbsurgery@coloplast.com)**Quarantined product:****Kiwee® Testicular Implant:**

	Item number				
	PR3001	PR3002	PR3003	PR3004	PR3005
Volume in your possession to quarantine					

**Vaginal Stent - Inflatable:**

	Item number			
	VS3020	VS3022	VS3024	VS3026
Volume in your possession to quarantine				

 We have checked all the stocks and the products concerned are not on stock.

Name of customer: \_\_\_\_\_

Name / Profession: \_\_\_\_\_

Date / Signature:

**Please return the confirmation of receipt no later than: 02-11-2015**