Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

Attention: distributors and users

15 October 2015

Coloplast A/S
Holtedam 1
3050 Humlebæk
Denmark
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:

Tina Gotschalk
Vigilance Officer

Dir. tel. +45 4911 3339
dktg@coloplast.com

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

Description of the problem:

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
Telephone:01733 392042

Yours sincerely,

Tina Gotschalk
Tina Gotschalk

FSN ref.: FRMML-2015-1006 - PR30xx & 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

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