

To Whom it may concern

12. Oktober 2017Coloplast A/S
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CVR-Nr. 69749917

URGENT FIELD SAFETY NOTICE

Ref. FRMML-2015-1006-PR30xx & VS30xx**Voluntary withdrawal 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

Sukhjit Gill Køfer
Vigilanzbeauftragte**LOT numbers:** applicable to all batches of all aforementioned medical devices

Vigilance@coloplast.com

Beschreibung des Problems:

The EC certificate for all medical devices made by manufacturer Silimed (n° G1 15 08 86183 006) has been temporarily suspended by their Notified body - TÜV Product Service SUD (identification n°0123), due to particles found at the surface of some implants. There is no indication that these issues would pose a threat to the implanted person's safety.

This voluntary withdraw affects Testicular Implants and Vaginal Stents placed on the market by Coloplast that have been in quarantine following the initial Field Safety Notice (FSN) since October, 2015.

In line with the recommendations from the Authorities, Coloplast requests that all affected devices, with Silimed as point of origin, should be withdrawn.

Action to be taken by the distributors:

The distributors affected by this voluntary withdraw are kindly advised to:

- Return any product covered by the list above to the address mentioned below.
- Fill out and return the attached „Confirmation of receipt of FSN“

Action to be taken by the users:

The customers affected by this voluntary withdraw are kindly advised to:

- Return any product covered by the list above to the address mentioned below.
- Distribute the FSN to all end-users who received the devices.
- Fill out and return the attached „Confirmation of receipt of FSN“

Coloplast Distribution GmbH
Retourenabteilung / Herr Scharnberg
Rückruf Urologie: Silimed
Werner-Schröder-Straße 1
21035 Hamburg

All expenses will be refunded by Coloplast.

Please contact Ms. Kyra Sievert at Supply Chain Customer Service for assistance.

E-Mail: service@coloplast.com

Phone: 040 669807-77

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 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 this product, please notify the consignees at once of this notification.

Your notification to your customers may 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:

Subsidiary: Coloplast GmbH

Address: Kuehnstraße 75, 22045 Hamburg

Contact person: Ms. Kyra Sievert

E-Mail: service@coloplast.com

Telephone: 040 669807-77

Yours sincerely,

██████████

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: service@coloplast.com

I acknowledge receipt of the Coloplast Field Safety Notice.

Voluntary withdrawn product:

Kiwee® Testicular Implant

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

Vaginal Stent - inflatable:

	Item number			
	VS3020	VS3022	VS3024	VS3026
Volume in your possession to return to Coloplast				

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

Name of customer: _____

Profession / Title / Department: _____

Name des Hospital / City: _____

Date / Signature:

Please return the confirmation of receipt no later than: November 15th 2017