

To Whom it may concern

11 July 2013
DKTMD/dktmd

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CVR-nr. 69749917

FIELD SAFETY NOTICE ref. no. FRSBU-2013-07-03 YN2813

RECALL

Coloplast recalls the Connectable Pusher CH/FR 4.8 / 75 cm REF YN2813 included in the following kits (EC marked following MDD 93/42/EEC article 12):

VORTEK® Double Loop Ureteral Stent Open/Open With Connectable Pusher
VORTEK® Hydro-Coated Double Loop Ureteral Stents

Thuy Maria Duong
Vigilance Officer

Catalogue number: BCFA531002, ACB1B51002, ACB1B71002, BCFA551002, ACB1521002, ACB1531002, ACB1541002, ACB1551002, ACB1562020, ACB1B01002, ACB1B11002, ACB1B21002, ACB1B31002, ACB1B41002, ACB2531002, ACB9521002, BCFA541002, BCFA571002, BCFG531002, BCFG541002, BCFG551002

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Lot numbers: 3691418, 3691386, 3692086, 3691387, 3691413, 3699728, 3701017, 3730548, 3730549, 3730550, 3701018, 3705165, 3730555, 3701022, 3730556, 3701023, 3730557, 3730558, 3705144, 3717507, 3730651, 3705147, 3728026, 3730680, 3700379, 3727029, 3731759, 3709109, 3731761, 3699743, 3699744, 3700388, 3701081, 3699745

Background information and scope of the recall

The connectable pusher is used to place the double loop ureteral stent (JJ). This device consist of two parts; an internal and external pusher tube.

Coloplast have detected some sliding impairment in between internal/external pusher tubes following material composition modification.

Safety concerns.

This may induce a potential functionality failure of this device, generating the need of using another set by the surgeon with limited patient risk.

Even though we received no complaint from this material batch, as a preventive measure we decide to recall all finished products made with this material batch.

This recall concerns all batch numbers of kits mentioned above.

Advice on action to be taken by the user:

The customers affected by this recall are kindly advised to return any product covered by the list above to the distribution centre of Coloplast Champlan. All expenses will be refunded by Coloplast. Please see address below.

Customer Care
Trade Team
Coloplast Ltd
Nene Hall, Peterborough Business Park
Peterborough, PE2 6FX
United Kingdom

Please contact Supply Chain Customer Service for assistance

e-mail: gb_trade@coloplast.com
phone: 01733 368989

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.

Yours sincerely,



Thuy Maria Duong