



FIELD SAFETY NOTICE

To Users of Peristeen Anal Irrigation System

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UPDATE OF INSTRUCTIONS FOR USE (IFU) PERISTEEN ANAL IRRIGATION SYSTEM

Coloplast ref no DKMIF-20100825-1000

In order to improve the safety of the end-users, Coloplast has issued an updated version of the Instructions for Use.

The updated version has been distributed on the English market from April 2010. The update does not imply any changes to the irrigation procedure by the end-user, but further highlights the precautions connected to the use of product.

The following information has been updated:

- "Warnings", "Contraindications" and "Precautions" have been highlighted
- The following warnings have been included:
 - 1. This product contains phthalates
 - 2. You should not reuse the catheter
- Bowel perforation has been highlighted in "Precautions"
- Use of small catheter and regular catheter has been described and pumping of the balloon specified
- The following have been added: Do not use Peristeen system with other users and Do not use lubricants

Please visit Coloplast's website to learn more about Peristeen Anal Irrigation System (address: www.coloplast.co.uk) or contact our Customer Service (0800 132 787 – Charter Healthcare customers or 01733 398989 for trade customers) for more information

FSN PERISTEEN

Customer Care

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