Medical Device Alert

Action

Ref: MDA/2011/002 Issued: 06 January 2011 at 11:30

Device

Peristeen Anal Irrigation System manufactured by Coloplast Limited.



Problem

Bowel perforation is an extremely rare (less than 1 in 100,000 uses) complication to anal irrigation.
Recently, there have been some incidents of bowel perforation following insertion of the rectal catheter, which is part of the anal irrigation system.

Action by

- All clinical staff who use, or care for patients who use, the Peristeen Anal Irrigation system.
- Purchasing staff with responsibility for the procurement and supply of these products.
- Patients who use this device.

Action

Familiarise yourself with the instructions for use (IFU), which have recently been updated.

Ensure that patients (and where appropriate carers):

- have received comprehensive training and are competent in the use of the system before using it unsupervised
- are aware of the risk of bowel perforation, how to recognise the symptoms and actions to be taken.

Before starting Peristeen Anal Irrigation, Coloplast instruct that patients should undergo a medical evaluation by a doctor with appropriate expertise to ensure that they have no conditions that preclude its use or require further investigation.

CAS deadlines

Action underway: 04 February 2011

Action complete: 06 April 2011

Contact

Manufacturer
Sue Frost MPhil, RGN
Senior Market Manager - Peristeen
Coloplast Limited

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Device

The following Peristeen product codes contain rectal catheters:

29121 – Peristeen Anal Irrigation System (contains 2 rectal catheters)
29122 – Accessory Unit (contains 15 rectal catheters and one bag)
29123 – 10 rectal catheters

29126 – Peristeen Anal Irrigation System (contains 2 rectal catheters - small)
29127 – Accessory Unit (contains 15 rectal catheters – small and one bag)
29128 – 10 rectal catheters – small

Problem

Bowel perforation is a rare but serious complication of anal irrigation, which often requires surgery to close the perforation or, if necessary, to form a temporary or permanent colostomy. Complications of bowel perforation such as peritonitis or sepsis can be fatal.

The risk of bowel perforation can be reduced by ensuring that patients are clinically assessed for suitability prior to treatment. Patients and carers should receive comprehensive training to ensure that they are competent in the use of the Peristeen Anal Irrigation System before using it unsupervised. The residual risk of perforation should be balanced against the improvement in bowel function and quality of life for each patient.

The risk of bowel perforation has been highlighted in the manufacturer's revised instructions for use. The MHRA is issuing this Medical Device Alert to bring this issue to wider attention. For information the warnings, contra-indications, precautions and intended use which appear in the most recent IFU for the Peristeen Anal Irrigation System (in packs manufactured after 3 December 2010) are reproduced below:

WARNINGS

Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to hospital, often requiring surgery.

Contact your doctor immediately, if you during or after anal irrigation experience following:

- **Severe and sustained abdominal pain or back pain, especially if combined with fever**
- **Sustained anal bleeding**

PHT DBP

This product contains phthalates and should not be used by either children or pregnant or nursing women without consulting a physician. Contains or presence of phthalate: dibutyl phthalate (DBP)

Reuse of the single use rectal catheter may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

CONTRA-INDICATIONS

Peristeen Anal Irrigation must **not** be used in the following situations:

- Known obstruction of the large bowel due to strictures or tumours.
- Acute inflammatory bowel disease.
- Diverticulitis.
- Complex diverticular disease
- Recent abdominal or anal surgery.

PRECAUTIONS

Always consult a physician before starting up the irrigation procedure. If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure. Please consult your health care professional.

Peristeen Anal Irrigation is not recommended for:

- Children under 3 years of age.
- Pregnant or nursing women.

Special caution must be shown if you have or have had any of the following:

- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).
- Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe haemorrhoids (third or fourth degree haemorrhoids).
- Irradiation therapy in the abdominal or pelvic region.
- Diverticular disease
- Abdominal or anal surgery.
- Recent colonic biopsy.
- Spinal cord shock phase.
- Autonomic dysreflexia.
- Cancer in the abdominal or pelvic region.
- Long term steroid therapy.
- Anticoagulant therapy.
- Changed stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified.
- Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
- Risk factors for ischaemic colitis (atrial fibrillation, coronary artery disease, hypercholesterolaemia).

If any of the above conditions apply to you, anal irrigation must only be initiated after careful investigation and instruction by your health care professional.

When you use anal irrigation you must consult a physician in case of:

- Onset of any the above mentioned conditions.
- Blood in faeces, weight loss, abdominal pain.
- Changes in the frequency, colour and consistency of the stools.

For hygienic reasons the Peristeen Anal Irrigation system must only be used by the same person. Do not share with others.

Intended Use

Peristeen Anal Irrigation is for people who suffer from faecal incontinence, chronic constipation or have to spend a long time on bowel management procedures.

Please read the whole instruction including warnings, contra-indications and precautions before carrying out the anal irrigation procedure.

It is vital for your safety that you consult a physician before starting up the irrigation procedure. We also require that you receive thoroughly instruction from a health care professional before using this product.

Your first irrigation must be supervised by a health care professional.

Before starting the irrigation procedure, please ensure you have identified which catheter size you are using. The product codes can be found on the catheter packaging.

- Small catheter – product code 29128
- Regular catheter – product code 29123

FOR HEALTH CARE PROFESSIONALS

To receive further information as well as training material for **Peristeen** Anal Irrigation, please access www.coloplast.com for contact information.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- OFSTED (Directors of Children's Services) for information
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All wards
- Clinical governance leads
- Colorectal surgeons
- Continence advisors
- Directors of nursing
- Gastroenterologists
- Hospital at home units
- Medical directors
- Paediatricians
- Purchasing managers
- Risk managers
- Spinal units
- Supplies managers
- Theatres

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community children's nurses
- Community hospitals
- Community nurses
- Continence advisors
- District nurses
- General practitioners
- Health visitors
- Palliative care teams
- Practice managers
- Practice nurses
- School nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Education departments for equipment held in schools
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/002** or **2009/011/004/081/001**

Technical aspects
Ainsley Wickens or Catriona Blake
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Clinical aspects
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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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