

Medical Device Alert

Ref: MDA/2014/007 Issued: 26 February 2014 at 16:00

Device

Peristeen anal irrigation system
manufactured by Coloplast Limited.



Problem

Risk of using transanal irrigation inappropriately.

The manufacturer has updated the instructions for use including changes to the indications, contraindications, precautions and warning sections. More detailed instructions for patient examination before starting transanal irrigation have been added.

The MHRA is issuing this MDA to help bring the changes to the attention of the relevant healthcare professionals, suppliers and end users.

Action by

All clinical staff who assess end users before starting transanal irrigation, and train and monitor end users.
Staff with responsibility for the procurement and supply of these products.
End users of this device.

CAS deadlines

Action underway: 19 March 2014

Action complete: 09 April 2014

Note: These deadlines are for systems to be in place to take action.

Action

Be aware of the [Field Safety Notice](#) that Coloplast issued in January 2014.

Familiarise yourself with the updated instructions for use.

Review existing end users to ensure that they are aware of these changes and that the device remains suitable for their use.

Amend local protocols that relate to the use of the Peristeen anal irrigation device to reflect these changes.

Contact

Manufacturer
Martin Beynon
Medical Marketing Director
Coloplast
Tel: 01733 392 000
Email: gbmrb@coloplast.com

Device

The instructions for use have been updated in response to publication of the review article 'Consensus review of best practice of transanal irrigation in adults'.

<http://www.nature.com/doifinder/10.1038/sc.2013.86>

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- 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
- Community children's nurses
- Community hospitals
- Community nurses
- Continence advisors
- District nurses
- Gastroenterology departments
- Health visitors
- Hospital at home units
- Medical directors
- Paediatricians
- Palliative care teams
- Purchasing managers
- Risk managers
- School nurses
- Supplies managers

NHS England area teams

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

- Community pharmacists
- General practitioners
- Practice managers
- Practice 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. Independent healthcare providers and social care providers can 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

Manufacturer

Martin Beynon
Medical Marketing Director
Coloplast
Tel: 01733 392 000
Email: gbmr@coloplast.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/007** or **2014/001/016/081/001**

Technical aspects

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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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722 Email: nss.irc@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 5801 Email: Haz-Aic@wales.gsi.gov.uk

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Addressees may take copies for distribution within their own organisations

Appendix

Peristeen[®]



Anal Irrigation



PERISTEEN ANAL IRRIGATION



1. Screw top.
(Incl. lid) to connect control unit to water bag. Lid should be replaced after 90 uses (equals 6 months' use*)
2. Water bag.
Water bag should be replaced after 15 uses (equals 1 month's use*)
3. Pump for activating balloon and flushing water.
Pump should be replaced after 90 uses (equals 6 months' use*)
4. Control unit for regulation of air and water.
Control unit should be replaced after 90 uses (equals 6 months' use*)
5. Coated rectal catheter with balloon for insertion into the rectum.
The rectal catheter is for single use only.

*When irrigating every other day.

Product codes

	Product code			
Peristeen Anal Irrigation	29121		System	1 control unit 2 rectal catheters 1 bag 2 straps
	29122		Accessory unit	15 rectal catheters 1 bag
	29123*		Rectal catheter	10 rectal catheters
	29124		Strap	10 set of 2 straps
	29125		Tube	2 tubes with blue connectors
	29126*		System	1 control unit 2 rectal catheters Small 1 bag 2 straps
	29127*		Accessory unit	15 rectal catheters Small 1 bag
	29128*		Rectal catheter	10 rectal catheters Small
	29129*		System without a catheter	1 control unit 1 bag 2 straps
* Not available in all countries				
Coloplast A/S Holtedam 1 3050 Humlebaek Denmark		23315269, V17 The Coloplast logo is a registered trademark of Coloplast A/S. © [2013-11-18] All rights reserved Coloplast A/S, 3050 Humlebaek, Denmark.		

INDICATION

Peristeen Anal Irrigation is intended to instil water into the colon through a rectal catheter with an inflatable balloon; the catheter is inserted into the rectum to promote the evacuation of the contents in the lower colon of patients who suffer from faecal incontinence, chronic constipation and/or the need for time-consuming bowel management procedures.

Please read all of the instruction including warnings, contra-indications and precautions before performing Peristeen Anal Irrigation procedure.

It is vital for your safety that you consult a physician/health care professional specialised in Peristeen Anal Irrigation before performing the irrigation procedure.

A careful medical history should be taken to explore any of the potential contraindications or precautions. Prior to your first Peristeen Anal Irrigation a digital rectal examination is mandatory. In case of previous anal, colorectal or pelvic surgery, endoscopy or comparable examination should be performed to exclude comorbidity.

You must receive thorough instructions from a health care professional before using this product.

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

The small catheter, labelled with a smiley, is intended for children.
The regular catheter is intended for adults.

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.

CONTRA-INDICATIONS

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

- Known anal or colorectal stenosis.
- Colorectal cancer.
- Acute inflammatory bowel disease.
- Acute diverticulitis.
- Within 3 months of anal or colorectal surgery.
- Within 4 weeks of endoscopic polypectomy.
- Ischaemic colitis.
- Since the list is not exhaustive, the physician/health care professional should always consider individual patient factors as well.

INFORMATION

Coloplast accepts no liability for any injury or loss that may arise if this product is used in a manner contrary to Coloplast's current recommendations.

PRECAUTIONS

Always consult a health care professional specialised in Peristeen Anal Irrigation before you perform the procedure.

Peristeen Anal Irrigation is not recommended for:

- Children below 3 years of age.
- Current or planned pregnancy or nursing women.

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

- Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, anal fistula or third or fourth degree haemorrhoids.
- Faecal impaction/heavy constipation. If you are heavily constipated (faecally impacted) an initial clean-out of your bowels is mandatory before starting up Peristeen Anal Irrigation procedure.
- Irradiation therapy in the abdominal or pelvic region.
- Severe diverticulosis or diverticular abscess.
- Previous anal or colorectal surgery.
- Previous major pelvic surgery.
- Severe autonomic dysreflexia.
- Long term corticosteroid therapy.
- Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel).
- Changed stool pattern such as sudden diarrhoea of unknown origin. The cause for diarrhoea must be identified.
- Rectal medication, since the effect of such medication may be reduced by Peristeen Anal Irrigation.

For hygienic reasons the Peristeen Anal Irrigation system is for single patient use only.

FREQUENTLY ASKED QUESTIONS

What should I do if irrigation water and/or faeces do not come out (no emptying)?

Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up or abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.



Should I use lubricant on the rectal catheter?

No. The rectal catheter is pre-coated with a lubricant, which is activated when water is added to the catheter packaging (see step 5 for more details). Adding extra lubricant may damage the balloon.

Why is the temperature of the water important?

The water should be lukewarm (36-38°C). If it is too hot, it may harm the delicate lining of the bowel and if it is too cold, stomach cramps may occur.

Can I stop the irrigation if I want a break?

If you feel the need for a break, turn the knob on the control unit to the balloon symbol . When you are ready, turn the knob back to the water symbol  and resume pumping.

Can I re-use the rectal catheter?

The rectal catheter is intended for single use only and should be disposed with normal household waste. Do not flush the catheter down the toilet.

What kind of water should I use when on holiday?

If you do not have access to clean tap water, then use bottled water.


How do I change the water bag?

Remove the grey screw top from the bag and screw it onto a replacement bag. Avoid kinking the suction pipe placed on the grey screw top.

How do I clean my Peristeen Anal Irrigation system?

Apart from the single use catheter all the components can be washed in mild soapy water. It is possible to replace the tube with the blue connector if it becomes soiled.

How should my Peristeen Anal Irrigation system be stored?

The system and the rectal catheter should be stored at room temperature (recommended between 15-25°C) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol . Also ensure that tubes are not kinked and that the system is kept away from sharp objects.

WARNINGS

Peristeen Anal Irrigation procedure should always be carried out with caution. 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 physician immediately, if during or after Peristeen Anal Irrigation you experience any of the following:

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



DBP

This product contains phthalates and should neither be used by children nor pregnant or nursing women without consulting a health care professional. Contains or presence of phthalate: dibutyl phthalate (DBP)

Reuse of the single use product may create a potential harm to the user. Reprocessing, washing, disinfection and sterilisation may compromise product characteristics causing additional risk of physical harm to or infection of the user.

HOW TO USE

Preparation

Peristeen Anal irrigation is most commonly carried out while sitting on the toilet. Empty the bladder before irrigation.



1. Open the lid and fill the bag to the top with lukewarm water (36-38 °C). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

Note: Use clean tap water. If you do not have access to clean tap water use bottled water. Do not add any additives to the water.



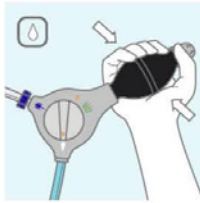
2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it 90° clockwise.





3. Open the catheter packaging 2 to 3 cm. Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connector locks.



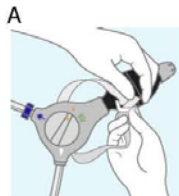
4. Fix the catheter packaging to a vertical surface by using the adhesive dots.



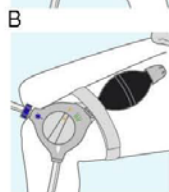
5. Turn the knob on the control unit to the water symbol  and pump water into the catheter packaging (2 to 3 pumps) to ensure lubrication of the catheter.

Turn the knob on the control unit to the balloon symbol  to stop the water flow. Wait 30 seconds. Remove the lubricated catheter from the packaging and use it immediately.

Note: For extra stability when pumping, you can attach the control unit to the thigh by using the strap.




A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight.

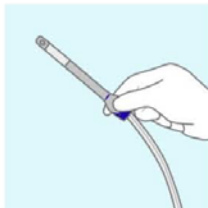


B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

Insertion of rectal catheter



6. Ensure the knob on the control unit is pointing to the balloon symbol . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force.



Note: When inserting the catheter, hold it by the finger grip and insert it as far as the finger grip will allow (up to the blue line). The finger grip is the widest part of the catheter.

Inflation of balloon





7. Your health care professional shall advise you how many times to pump. It is recommended to inflate the rectal balloon only as much as considered necessary for preventing leakage during irrigation.




Gently pull the catheter back to seal off the rectum.



Note: Do not overinflate the balloon to avoid balloon burst. For adults three pumps are usually sufficient. If you experience leakage pump one more time (in total maximum four times). For the small catheter, one pump is usually sufficient. If you experience any leakage, pump one more time (in total maximum two times). If you have problems, contact your health care professional.



Note: If you sense that the balloon is too big, turn the knob to the air symbol  to deflate it. When ready turn to the balloon symbol  to inflate the balloon once again.

Insertion of water




8. Turn the knob on the control unit anti-clockwise to the water symbol . Pump the water slowly into the bowel at a rate of 200-300 ml/minute for adults until the required amount of water is reached. The amount of water needed is individual but usually 500-1000 ml. is sufficient. Your health care professional will guide you on how much water to use. For children please consult a health care professional specialised in Peristeen Anal irrigation.

Note: If an additional pump is needed (note, step 7) turn the knob on the control unit clockwise to the balloon symbol  and pump one more time. Turn the knob anti-clockwise to the water symbol  and resume irrigation.

Note: Discomfort can occur if the water is not at body temperature or inserted too quickly. In case of discomfort, turn the knob of the control unit to the balloon symbol  to stop the water flow and wait until it ceases. Ensure that the water is not too cold and/or inserted too quickly. When you are ready, turn the knob back to the water symbol  and resume pumping. If the discomfort/pain continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

Removal of rectal catheter

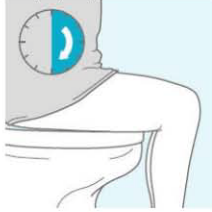


9. Turn the knob on the control unit anti-clockwise to the air symbol  to deflate the balloon. Often the catheter will slide out by itself, if not, pull the catheter gently.

Note: Do not remove the catheter before the balloon is completely deflated.

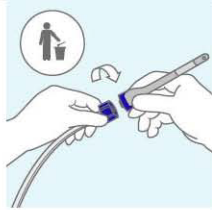
Note: For the most efficient result remove the catheter immediately after the balloon has deflated.

Emptying



10. Soon the colon will start to empty itself. If nothing happens, try to press, cough, do abdominal massage or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.


Disposal



11. Unlock the connectors from the lid and the catheter. Discard the single use catheter and dispose it with normal household waste. Do not flush the catheter down the toilet.



12. Pour excess water out of the bag.

When storing the system, turn the knob on the control unit anti-clockwise to the finish symbol . When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the toilet bag and that the system and all its parts are kept away from sharp objects.