

## Product description

Peristeen Light consists of a reusable water container, a tube and a single use catheter.

## Intended purpose

The product is intended to help manage faecal incontinence and/or constipation.

The product can be used by adults and children aged 3 years and older.

## Indications

The product is indicated for patients suffering from faecal incontinence, chronic constipation and/or time-consuming bowel management procedures.

## Contra-indications

Transanal irrigation procedures must not be carried out in the following situations as the mechanical obstruction or the weakened tissue in the rectum caused by any of the below would increase the risk of bowel perforation, trauma or bleeding:

- Known anal stenosis.
- Colorectal cancer (active/recurrent).
- Within 3 months of anastomotic colorectal surgery.
- Ischaemic colitis.
- Active inflammatory bowel disease.
- Acute diverticulitis and diverticular abscess.
- Since the list is not exhaustive, the physician/health care professional should always consider individual patient factors as well.

## Warnings

Transanal irrigation procedures must be carried out with caution. Bowel perforation is an extremely rare, but serious and severe complication.

Seek immediate medical assistance if during or after the transanal irrigation procedure you experience any of the following:

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

## Cautions

Use only after assessment from a healthcare professional. Special caution must be shown if the patient has or has 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.
- Within 3 months of irradiation therapy in the abdominal or pelvic region and cessation of proctitis
- Severe diverticulosis.
- Previous anal or colorectal surgery - close monitoring is recommended during initiation of therapy.
- Within 3 months of anal surgery.
- Within 4 weeks of endoscopic polypectomy.
- Within 3 months of radical prostatectomy.
- Risk of uncontrolled autonomic dysreflexia.
- Change of stool pattern (e.g., sudden diarrhea) (if so, consider investigating for primary causes).

For an existing user transanal irrigation may be continued with caution. Starting transanal irrigation during pregnancy is not recommended.

Do not use if package is damaged, as the product may be compromised.

The product is not made with natural rubber latex, however rare contamination with trace amounts of natural rubber latex during manufacturing or packaging may occur, potentially leading to allergic reactions in patients with known or suspected allergies to natural rubber latex.

Store your Peristeen Light system out of reach of small children and supervise children that may be present while you use the system to avoid risk of strangulation with the tubes and suffocation on small parts that may have come loose from the product

## Information

Re-use of the Peristeen Light catheter is not recommended as cross contamination may occur, potentially leading to infection.

Reprocessing, disinfection and/or sterilisation may compromise product characteristics, causing additional risk of physical harm or infection to the user.

The catheters packaging contains safety information about the product and should be kept for the lifetime of the catheters.

The water container and tube are for single patient use and can be used up to 30 times. After each use, follow the instructions in the 'Empty, dry and storage' section.

Side-effects related to transanal irrigation may include passing sensations of bowel discomfort, nausea, shivering, fatigue, sweating, headache, and mild bleeding.

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.

## How to use

To ease the irrigation, empty the bladder before starting.



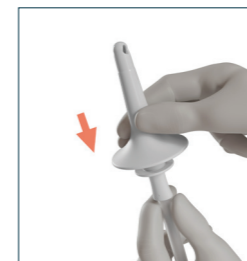
### Fill water container

Open lid and fill up the water container with lukewarm tap or bottled water (between 34°C and 40°C). Too hot water may harm the delicate lining of the bowel, too cold water may cause stomach cramps.

Close lid.

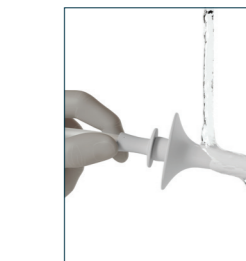
### Attach catheter to tube

Take the catheter out of the packaging and attach it to the tube.



### Attach tube to lid

Attach the other end of the tube to the lid.



### Lubricate catheter

Hold the catheter under running water (tap or bottled water) for a minimum of 2 seconds to activate the coating.

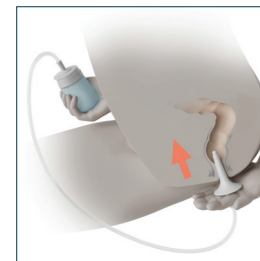
Start using the product within 2 minutes.

Note: Do not use other lubricants on the catheter.



### Remove air

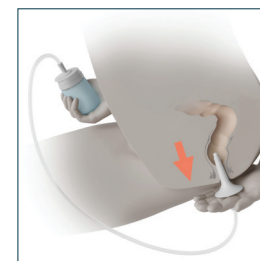
To remove the air in the catheter and tube, slowly squeeze the water container until water comes out of the catheter tip.



### Insert and irrigate

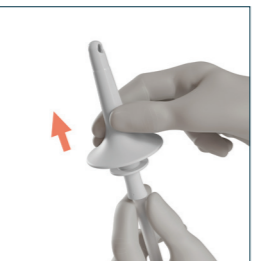
Hold the water container and carefully insert the catheter into the rectum until the base of catheter is touching your body.

To begin irrigation, gently squeeze the water container to instill water into the rectum.



### Emptying bowel

Remove the catheter. Faeces and water will be expelled into the toilet.



### Disassemble product

To detach the catheter from the tube, hold it with toilet paper (or similar) and pull it off.

Detach the tube from the lid.

Dispose of the catheter.



### Empty, dry and storage

Remove residual water from the water container and tube.

Use water and mild soap on the external surfaces of the water container and tube.

Dry with a towel or similar. Store the water container with the lid open and hang the tube to dry.

Keep out of reach of children.

Wash and dry your hands.

### Reporting of incidents

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

### Disposal

The catheter is intended for single use only and should be disposed of in accordance with local guidelines, e.g., with normal household waste.

The water container and tube are intended for multiple use and should be disposed of after 30 uses in accordance with local guidelines, e.g., with normal household waste.

Do not flush the product down the toilet.

### Explanation of symbols

**MD** Medical device

**CE** Indicates that the product is in compliance with European legislation for medical devices

**REF** Catalogue number

**Hourglass** Use-by date (YYYY-MM-DD)

**LOT** Batch code

**Factory** Date of manufacture (YYYY-MM-DD)

**Factory** Manufacturer

**Information** Consult instruction for use

**No re-use** Do not re-use

**Multiple use** Indicates a medical device that may be used multiple times (multiple procedures) on a single patient

**No latex** Not made with natural rubber latex

**No damage** Do not use if package is damaged and consult instructions for use

**UDI** Indicates a carrier that contains Unique Device Identifier information

**No sun/heat** Keep away from sunlight and heat

**Up arrow** This way up

**Recycling** Recyclable packaging

**CE** Coloplast A/S  
Høttedam 1  
3050 Humlebaek  
Denmark

en  
**Instructions for use**  
Please read the following instructions carefully.

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# Peristeen® Light

## Transanal Irrigation



## Peristeen® Light