



- 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. Control unit.**  
3a. Pump for inflating balloon and pumping water.  
3b. Knob for regulating air and water.  
Control unit should be replaced after 90 uses (equals 6 months' use\*)
  - 4. Coated rectal catheter with balloon for insertion into the rectum.**  
The rectal catheter is for single use only.
- \*When irrigating every other day.

Please read all the instructions provided here before using Peristeen Transanal Irrigation for the first time.



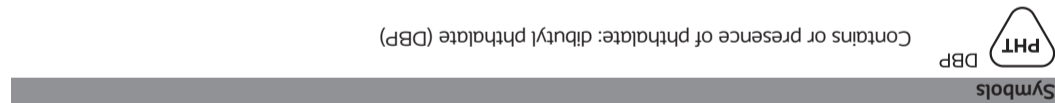
Product codes

29121	System		1 control unit 2 rectal catheters <b>Regular</b> 1 water bag 2 straps 1 tube
29122	Accessory unit		15 rectal catheters <b>Regular</b> 1 water bag
29123*	Rectal catheter		10 rectal catheters <b>Regular</b>
29124	Strap		10 set of 2 straps
29125	Tube		2 tubes with blue connectors
29126*	System		1 control unit 2 rectal catheters <b>Small</b> 1 water bag 2 straps 1 tube
29127*	Accessory unit		15 rectal catheters <b>Small</b> 1 water bag
29128*	Rectal catheter		10 rectal catheters <b>Small</b>
29129*	System without a catheter		1 control unit 1 water bag 2 straps

\* Not available in all countries



IFU Master Peristeen Transanal Irrigation Version 3  
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2018-05-30



Contains or presence of phthalate: dibutyl phthalate (DBP)

To receive further information as well as training material for Peristeen Transanal Irrigation, please access [www.coloplast.com](http://www.coloplast.com) for contact information.

The patient must receive thorough instructions from a health care professional before using this product. The patient's first irrigation must be supervised by a health care professional.

A health care professional trained in the use of Peristeen Transanal Irrigation must determine the appropriate catheter and balloon size for patients eligible to the Peristeen Transanal Irrigation procedure.

- Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, anal fistula or third or fourth degree hemorrhoids
- Faecal impaction/heavy constipation. If you are heavily constipated (faecally impacted) an initial clean-out of your bowels is mandatory before starting up Peristeen Transanal 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 Transanal Irrigation

Besides observing the contraindications, special caution must be shown if the patient has or has had any of the following:

A physician experienced in the use of Peristeen Transanal Irrigation must evaluate patients who may have a fragile bowel anatomy (for instance, due to previous anal, colorectal or pelvic surgery and/or radiation therapy). Endoscopy, defecography or comparable procedures should be used to determine whether the patient's bowel could withstand the Peristeen Transanal Irrigation procedure, including how much the balloon shall be (if at all) inflated. Prior to the first Peristeen Transanal Irrigation procedure, a careful review of the patient's medical history as well as a digital rectal examination must be performed to explore any potential contraindications or precautions.

Cautions specific for Health Care Professionals

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.

**Cautions specific for Patients**

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

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.

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

Coloplast's current recommendations.

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

Peristeen Transanal Irrigation is not recommended for:

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

Re-use of the single use rectal catheter 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.

The coating of the single use rectal catheters contains phthalates and should not be used by children, pregnant women or nursing women without consulting a healthcare professional.

**Seek for immediate medical assistance if during or after Peristeen 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

Peristeen Transanal Irrigation procedure should always be carried out with caution. Bowel perforation is an extremely rare, but serious and potentially lethal complication to transanal irrigation and will require immediate admission to hospital, often requiring surgery.

Peristeen Transanal 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

Peristeen Transanal 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.

- The small catheter, labelled with a smiley, is normally used by children.
- The regular catheter is normally used by adults.

The rectal balloon catheter is available in two sizes:

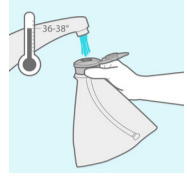
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Indications

## How to use

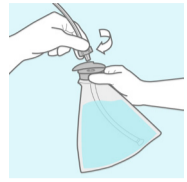
### Preparation

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

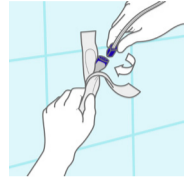


1. Open the lid and fill the bag to the top with lukewarm water (36-38 °C). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

**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.



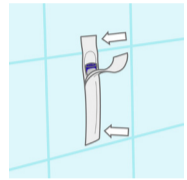
3. Open the catheter packaging 2 to 3 cm. Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connector locks.



**Note:** Make sure the catheter size indicated in the packaging matches the catheter size recommended by your health care professional. Using the wrong size catheter may cause damage to the bowel wall.

**Note:** Make sure that the catheter's expiry date indicated in the packaging has not been exceeded.

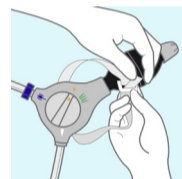
**Note:** Do not inflate the balloon on the rectal catheter without having activated the coating (see step 5 for more details).

4. The catheter packaging can be fixed to a vertical surface by using the adhesive dots.

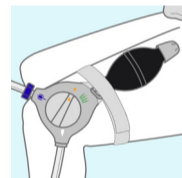


5. Turn the knob on the control unit to the water symbol  and pump water into the catheter packaging (2 to 3 pumps) to ensure lubrication of the catheter. Turn the knob on the control unit to the balloon symbol  to stop the water flow. Wait 30 seconds. Remove the lubricated catheter from the packaging and use it immediately.

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

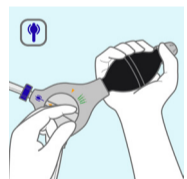



A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight.

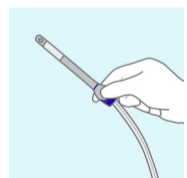


B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

### Insertion of rectal catheter



6. Ensure the knob on the control unit is pointing to the balloon symbol. 



7. Hold on to the rectal catheter by the finger grip, the wide part of the catheter. Your fingertips must only just touch the blue line. Carefully insert the catheter into the rectum as instructed by your healthcare professional. Do not use force. Insert the catheter just to the blue line – leaving the finger grip outside of your body.

### Inflation of balloon



8. The health care professional shall advise how much to inflate the balloon. It is recommended to inflate the rectal balloon only as much as considered necessary for preventing leakage during irrigation.

For regular catheter size, one to three full pumps are usually sufficient to prevent leakage. Do not exceed a maximum of four full pumps in order to avoid balloon burst.

For small catheter size, one full pump is usually sufficient to prevent leakage. Do not exceed a maximum of two full pumps in order to avoid balloon burst.

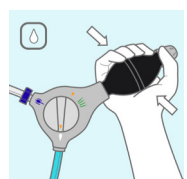
If you sense that the balloon is too big, turn the knob to the air symbol  to deflate it. When ready turn to the balloon symbol  to inflate the balloon once again.


Gently pull the catheter back to seal off the rectum.

If you have problems, contact your health care professional.



**Note:** A full pump consists of squeezing the rubber bulb until its two opposite internal walls can be felt as touching one another.



### Pumping of water



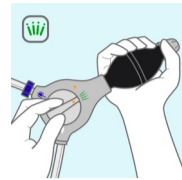
9. Turn the knob on the control unit anti-clockwise to the water symbol.  Pump the water slowly into the bowel until the required amount of water is reached. Your health care professional will guide you on how much water to use.


**Note for health care professionals:** The amount of water needed is individual. For adults, 300-1000 ml is usually sufficient. For children, 10-20 ml per ideal body weight in kilograms is recommended.

**Note:** If an additional pump is needed (note, step 8) 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 pumped 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 neither too cold nor pumped 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



10. 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.

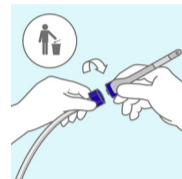
**Note:** For the most efficient result, remove the catheter immediately after the balloon has deflated.

### Emptying



11. Soon the bowel 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 30 minutes.

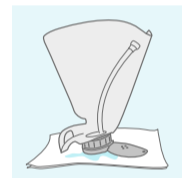
### Disposal and drying



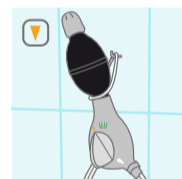
12. Unlock the connectors from the lid and the catheter. Discard the single use catheter and dispose it with normal household waste. Do not flush the catheter down the toilet.




13. Open the water bag lid and pour excess water out of the bag.



14. Keep the lid open and store it in a dry place for at least 1 hour. If possible, keep the water bag upside down while drying.



15. Hang the control unit, including the tubes, upside down (e.g. by using a rubber band) to dry for at least 1 hour before storing it away from sunlight in the toilet bag. It is important to turn the knob on the control unit counter clockwise to the finish symbol  before it is hung to dry.

After allowing it to dry for at least 1 hour the control unit, the tubes, and the water bag should be stored at room temperature (recommended between 15-25°C) and out of direct sunlight, preferably in the toilet bag. Ensure the tubes are not kinked and that the system and all its parts are kept away from sharp objects.

### Cleaning of the system

16. Apart from the single use catheter, all the components can be washed in mild soapy water. The tube with the blue connector can be replaced if it becomes soiled.

It is not necessary to disassemble the system before cleaning the external surfaces.

The internal surfaces of the tubes, control unit and water bag lid including the suction pipe can be cleaned by the following procedure:

Unlock the connector from the catheter.

A. Open the lid and fill the bag to the top with mild soapy water. As the bag unfolds, the water level will fall and refilling is necessary. The bag must be filled completely to function properly. Close the lid by clicking it into place. Turn the knob on the control unit to the water symbol and start pumping the water through the tubing and into a sink or similar. Continue until the water bag is emptied.

B. Repeat this procedure twice with clean tap water to remove soap remains. After the last rinsing, unlock the connector from the lid and follow the normal drying procedure as described in section for Disposal and drying.

### Frequently asked questions



#### 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 often do I change the water bag? And how do I do it?

The water bag needs to be replaced by a new one every 15 uses. Remember to keep the screw top (including the lid) as this is not supplied with a new water bag (item 29122 and 29127). When replacing 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.