

*Peristeen® Plus
Training Guide
for Healthcare
Professionals*



Peristeen® Plus

"I remember having tears in my eyes – using Peristeen® was literally the first time I had control over when and where I had a bowel movement."

Sarah,* US

*Sarah is a Peristeen with balloon catheter user who received compensation from Coloplast to provide this information. Sarah has not used the new Peristeen Plus Transanal Irrigation system.



Preface

This training guide is aimed at healthcare professionals (HCPs) who want to learn how to select, train and support patients confidently and effectively in the use of Peristeen Plus – [this booklet will show you how](#).

Patients must start Transanal Irrigation under clinical supervision, but when they are confident to do so, many will successfully use Peristeen Plus without assistance, in the privacy and comfort of their own home.

Because every patient is different, the initial outcomes of Transanal Irrigation can vary from individual to individual. That is why it is important for you to [help patients set the right expectations](#) before they start irrigating at home. [Establishing a personalised routine is an important next step](#) to achieving effective and predictable bowel management in the longer term; something that both you and our patient support programme can help and strengthen over time. [Coloplast is here for you and your patients every step of the way](#).

Contents

Preface	2
A recognised treatment for bowel control	4
Indications, contra-indications, warnings and cautions	6
The Peristeen® Success Package	8
Coloplast® Care	10
Patient Selection, Initiation and Training	12
How to use Peristeen Plus Transanal Irrigation with balloon catheter	14
How to use Peristeen Plus Transanal Irrigation with cone catheter	20
Establishing a personalised routine	27
Additional guidance	30
Peristeen Anal Plug	35

A recognised treatment for bowel control

The new Peristeen® Plus Transanal Irrigation system is an upgraded, easier-to use version of the original Peristeen system. The new Peristeen Plus builds on the evidence-based legacy of Peristeen and is equivalent in efficacy and function.

Various studies of pediatric and adult neurogenic patients suggest that Peristeen may increase independence during bowel care and take less time than conservative bowel management procedures. This way, patients can reduce the total time they need to spend on bowel care.^{1,2} In addition, Peristeen is associated with significantly fewer urinary tract infections than conservative bowel management,¹ which may potentially lead to cost savings for the healthcare system.³

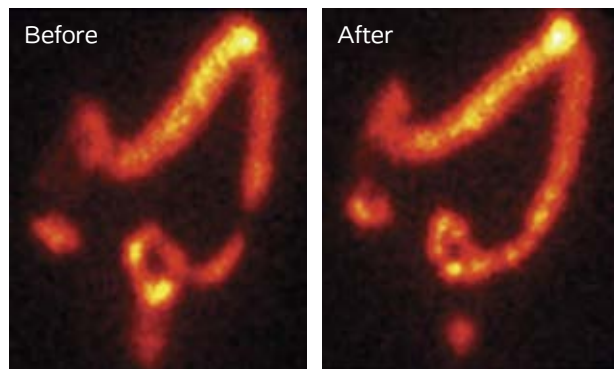
TAI with Peristeen Plus assists the evacuation of faeces by introducing water into the rectum and colon via the anus. The water is subsequently evacuated into the toilet together with the faeces from the lower and descending colon.⁴

Whether the patient experiences faecal incontinence, chronic constipation or both, Peristeen Plus may help re-establish regular and predictable bowel function, thereby improving confidence and quality of life.⁵

Transanal Irrigation – a clinically proven method for managing constipation and faecal incontinence

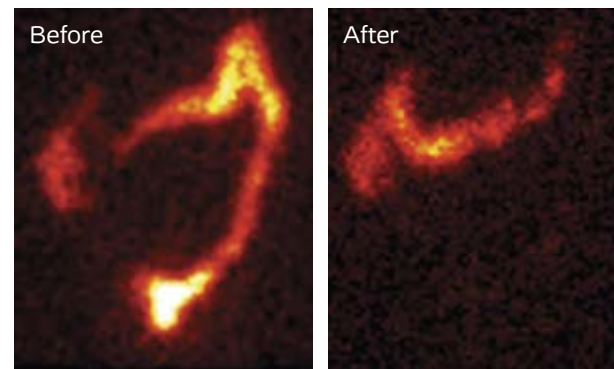
In scintigraphic studies performed in patients with spinal cord injury (SCI) and neurogenic bowel dysfunction, Transanal Irrigation (TAI) has been shown to be effective as a bowel emptying technique.⁴ In patients with faecal incontinence, the left colon and the rectum are emptied, which enables patients to stay continent for up to 2 days. This allows patients to go about their day without the constant fear of having an accident.¹ In patients with chronic constipation, high-volume TAI promotes emptying of most of the left colon and the rectum, therefore helping to prevent blockages.

Physiological defaecation



Bowel scintigraphic images of an SCI patient before and after defaecation **without using Transanal Irrigation**

Transanal Irrigation with a balloon catheter

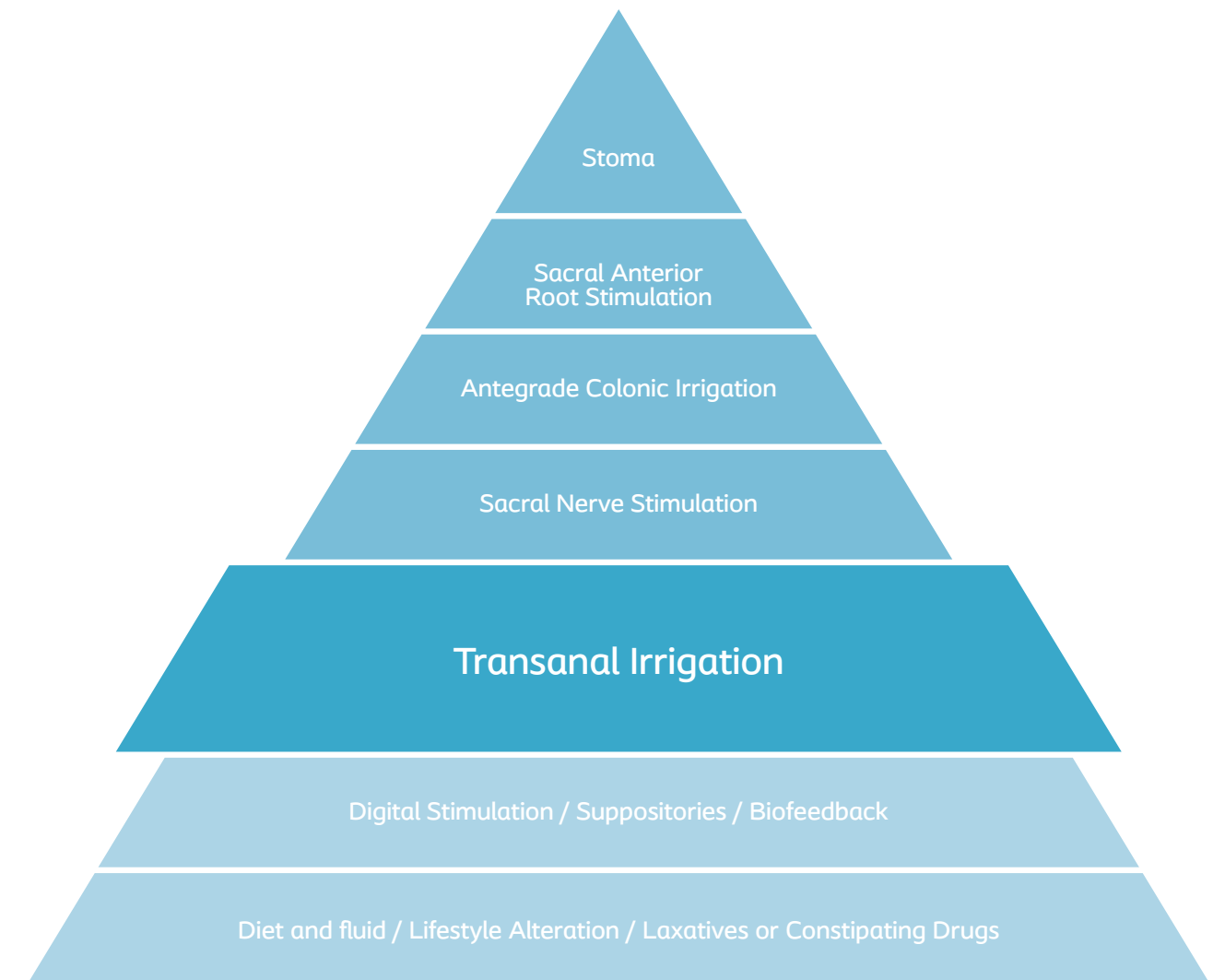


Bowel scintigraphic images of an SCI patient before and after defaecation **using Transanal Irrigation**

Transanal Irrigation – a recognised standard treatment option

A number of leading global hospitals have adopted Transanal Irrigation (TAI) as a standard step in their treatment protocol. TAI is usually recommended if other first-line methods of bowel management have failed to adequately control symptoms, or are deemed unsatisfactory because, for example, it is too time-consuming or poses too many restrictions to the patient's life.⁶

In 2013, an international consensus review conducted by 12 medical specialists from a range of disciplines with experience in prescribing and monitoring patients using Transanal Irrigation, put together a treatment pyramid for managing bowel dysfunction.⁶ The review places Transanal Irrigation as the next treatment option following conservative treatment, such as diet, laxatives, or suppositories.



Treatment pyramid for the management of bowel dysfunction, as proposed by Emmanuel et al. 2013

Indications, contra-indications, warnings and cautions

Peristeen® Plus is indicated to manage symptoms of faecal incontinence, chronic constipation and/or time-consuming bowel management procedures.

The Peristeen Plus system can be used by a wide range of patients. With two catheter types to choose from, you have more options to help your patients achieve long-lasting success with TAI.

Peristeen Plus with balloon catheter can be used by both adults and children above 3 years of age. The balloon catheter has been designed with neurogenic patients in mind. The balloon enables your patients to perform irrigation without having to hold the catheter during the procedure. A smaller size of the balloon catheter is available for children over the age of 3, which can also be used by adults if it is deemed by the healthcare professional to be more suitable than the regular balloon catheter.

Peristeen Plus with cone catheter can be used by both adults and children above 3 years of age. The cone catheter is designed with LARS patients in mind, using input from colorectal surgeons and nurses regarding shape, curvature, length and flexibility.

Contra-indications

Peristeen Plus Transanal Irrigation must **not** be used in the following situations as the mechanical obstruction or the weakened tissue in the colon caused by any of the below would increase the risk of bowel perforation, trauma or bleeding:

- Known anal or colorectal stenosis
- Colorectal cancer (active/recurrent)
- Within 3 months of anal or colorectal surgery
- Within 4 weeks of endoscopic polypectomy
- Ischaemic colitis
- Acute inflammatory bowel disease
- Acute diverticulitis

Since the list is not exhaustive, the physician/healthcare professional should always consider individual patient factors as well.

Warnings

Peristeen Plus Transanal Irrigation procedure should always be carried out with caution. Ensure the balloon catheter size (regular or small) indicated on the packaging matches the catheter size recommended by the healthcare professional. Do not use force when inserting the catheter (balloon or cone). 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.

The patient should seek immediate medical assistance if, during or after the procedure, he/she experiences any of the following:

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

Re-use and/or washing or disinfection of the coated balloon catheter is not recommended as it may compromise product characteristics causing additional risk of bowel perforation.

The Peristeen® Plus Transanal Irrigation system should be stored out of reach of small children, and children that are present while the system is used should be supervised to avoid risk of strangulation with the tubes/straps or suffocation on small parts that may have come loose from the product.

Cautions

Peristeen Plus Transanal Irrigation is not recommended for current or planned pregnancy as the product has not been evaluated in this patient population.

Cautions specific for Healthcare Professionals

Prior to the first Peristeen Plus 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 contra-indications, warnings or cautions. A physician experienced in the use of Peristeen Plus 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 Plus Transanal Irrigation procedure with a cone or balloon catheter, including how much the balloon shall be (if at all) inflated.

Besides observing the contra-indications and warnings, 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
- Faecal impaction/heavy constipation. If the patient is heavily constipated (faecally impacted) an initial clean-out of his/her bowels is mandatory before starting Peristeen Plus 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 transanal irrigation

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

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

The Peristeen® Success Package

Just providing the product is not enough

TAI requires a comprehensive, integrated approach. It's very important for the patient to become comfortable and confident with the TAI procedure. And it's just as important for you to have the tools to guide your patients.

The Peristeen Success Package is specially designed to smooth the way to a fulfilling life with TAI

Peristeen
Success
Package



- Effective product solutions
- Tools and guidance to bowel professionals supporting TAI clinical best practices
- Routine-building and emotional support for users, tailored to the TAI learning curve and individual user needs.

The Coloplast toolkit for bowel professionals

Tools and materials you can request to support you:

- Summary of evidence, Adult
- Summary of evidence, Paediatric
- NICE Guidance
- NICE Guidance brochure
- MENTOR Tool (SCI patients)
- Patient Assessment Checklist
- HCP Guide
- How to use video, Peristeen Plus balloon catheter
- How to use video, Peristeen Plus cone catheter
- Initiation booklet, Adult
- Initiation booklet, Paediatric
- Step by step guide, Adult (A4)
- Step-by-step guide, Adult (A5)
- Step-by-step guide, Paediatric (A4)
- Coloplast® Care

Tools and materials you can request to support your patients:

- How to use video, Peristeen balloon catheter
- How to use video, Peristeen cone catheter
- Initiation booklet, Adult
- Initiation booklet, Paediatric
- Coloplast Care website
- My Peristeen Check
- Wheelmate app
- Step-by-step guide, Adult (A5)
- Step-by-step guide, Paediatric (A5)
- Step-by-step guide, Cone (A4)
- Coloplast Care

The Peristeen® Success Package:

The path to lasting success with TAI



Coloplast® Care

Coloplast Care is here to help your patients succeed with Peristeen® Plus

We provide your patients with personalised support and practical advice on their path to better bowel control.

Coloplast Care is a free programme designed to help Peristeen Plus users get the most out of the product. It is especially useful if your patient is just starting out with the treatment. Not only do we proactively reach out to Care members to ensure they are succeeding with the product, we also provide them with inspiration and peer advice to help master their lives with Peristeen Plus. Remember, if any of your patients have clinical concerns, we always redirect them back to their healthcare professional.

This is how it works:



How to sign your patients up for Coloplast Care:

You can sign your patients up by filling out and sending in our healthcare professional sign-up form or the patient can sign themselves up:

1. By speaking with our Coloplast Care advisers on the phone: + xxx
2. By filling in the sign-up form on the back of the initiation booklet
3. By sending a text message with the word 'Peristeen' to xxxxxx

Thereafter, a Coloplast Care adviser will reach out to your patient to complete the sign-up.

Note: Please ask your sales representative for copies of the initiation booklet and HCP sign-up forms.



Patient selection, initiation and training

Before starting Peristeen® Plus, the healthcare professional must perform a medical evaluation of the patient, as well as a digital rectal examination (DRE).

Please refer to the previous pages of this guide and the Instructions for use (IFU) document to determine if the patient is a suitable candidate for the transanal irrigation procedure.

In order to facilitate and assist in the work of patient selection and exclusion, Coloplast provides a Peristeen Plus Patient Assessment Checklist, that you can use prior to starting a new patient on the therapy.

Ask your Coloplast representative for more information and copies of the Peristeen Plus Patient Assessment Checklist, as it is complementary to this guide.

Peristeen® Plus Patient Assessment Checklist

Patient Name _____ Date _____

Contra-indications
Peristeen Plus must not be used in the following situations:

- Known anal or colorectal stenosis Yes No
- Colorectal cancer (active/recurrent) Yes No
- Within 3 months of anal or colorectal surgery Yes No
- Within 4 weeks of endoscopic polypectomy Yes No
- Ischaemic colitis Yes No
- Acute inflammatory bowel disease Yes No
- Acute diverticulitis Yes No

Peristeen Plus is not recommended for:

- Children under the age of 3 years Yes No
- Current or planned pregnancy or nursing women Yes No

Cautions
Special caution for any of the following:

- Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, anal fistula or 3rd/4th degree haemorrhoids Yes No
- Faecal impaction/heavy constipation, if constipated (especially impacted) on initial clean-out of the bowels is mandatory before starting up Peristeen Plus Transanal Irrigation procedure Yes No
- Irradiation therapy in the abdominal or pelvic region Yes No
- Severe diverticulitis or diverticular abscess Yes No
- Previous anal or colorectal surgery Yes No
- Previous major pelvic surgery Yes No
- Severe autonomic dysreflexia Yes No
- Long term corticosteroid therapy Yes No
- Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel) Yes No
- Changed stool pattern such as sudden diarrhoea of unknown origin. The cause for diarrhoea must be identified Yes No
- Rectal medication, since the effect of such medication may be reduced by Transanal Irrigation Yes No

Patient information

- Review of medical history and digital rectal examination (mandatory for all) Yes No
- Results/Comments _____
- Does the patient have fragile bowel anatomy – previous anal, colorectal or pelvic surgery, and/or radiation therapy? Yes No
- If yes, has an endoscopy, defecography, or comparable examination been conducted to determine whether the patient's bowel could withstand Peristeen Plus TAI procedure? Yes No
- Does the patient understand the possible risks and benefits of Peristeen Plus, and agree to initiate the therapy? Yes No
- Is the patient able to perform Peristeen Plus independently? Yes No
- If not, does the patient have a carer(s) who will support with Peristeen Plus? Yes No
- Who is the carer? _____
- Will the carer require training? Yes No

Peristeen Plus Recommended for Use
If the patient is found suitable to initiate treatment with Peristeen Plus, consent for to initiate the appropriate training and follow-up. The patient's or a caregiver must be supervised by a healthcare professional.

Coloplast

Setting the right expectations

Prior to starting Peristeen® Plus for the first time, please take time to describe the procedure to your patients, answer any questions, seek their acceptance, and help manage their expectations. To avoid potential disappointment or concern that irrigation does not work for them, explain that an initial period of adjustment is perfectly normal and is required to establish their personalised routine. It can work successfully for individuals within a few days, but for others it may take up to 12 weeks to establish a reliable and effective routine.⁶

You may consider recommending a diary to your patients as a way of keeping track of progress during this period (see below). Patients will receive a diary, as well as practical information, as part of the Peristeen Plus Initiation Booklet. Please ask your Coloplast representative for copies of this booklet. It can be used during the initial training to help set goals and manage expectations.

In order to further support patients in their initiation and routine-building with Peristeen Plus, it is helpful to enroll them, or advise them to enroll in Coloplast® Care. This is Coloplast's patient support program and today 9 out of 10 users appreciate the availability of patient support programme when starting bowel irrigation. You can read more about Coloplast Care on page 10.

Date / time dd/mm hh:mm	Method: Peristeen Plus / Laxatives / Other	Water (ml) / Air pumps (no)*	Irrigation duration (minutes)	Bristol type (1-7)	Accidents since last irrigation	Outcome 😊 😐 😞	Comments	Notes on diet
3 / 12 10 : 35	Per / Lax / Other	700 / 3	25	4	None	😊	Good irrigation with no water leakage	Had a lot of fibre, nuts and seeds
/ / : :	Per / Lax / Other	/				😊		
/ / : :	Per / Lax / Other	/				😊		
/ / : :	Per / Lax / Other	/				😊		
/ / : :	Per / Lax / Other	/				😊		

Training and first irrigation

A healthcare professional must supervise the first use of Peristeen Plus for any patient to ensure correct, safe and optimal use of the product.

After proper training, many people will be able to use Peristeen Plus without the aid of a helper. However, if the patient is unable to perform the procedure independently (for instance small children or patients with a high degree of disability), it is important to involve and train the patient's caregiver who will be in charge of helping or performing the irrigation on the patient.

Subsequent irrigations should be followed up by consultations, in-person or by telephone, until the patient has fully adapted the procedure to meet their individual needs and until they feel confident to continue the procedure independently.

If a patient is heavily constipated (faecal impaction), it is necessary to thoroughly clean out their bowels before starting Peristeen Plus. This is for safety reasons and to provide the basis for a successful outcome. Impaction in the rectum or colon may cause difficulties when it comes to inserting the catheter and instilling the irrigation water. It can also increase discomfort, the chance of catheter expulsion and adverse events or technical problems.^{6,7}



How to use Peristeen® Plus Transanal Irrigation with balloon catheter

This how-to-use guide has been modified from the Instructions-for-use (IFU) leaflet. If you are new to Peristeen Plus or wish to read the full version, please consult the IFU directly. It is helpful that you do the initial training with your patient using the Peristeen Plus Initiation Booklet. Please ask your Coloplast representative for copies of this booklet.

1. **Screw top (including lid)**
Replace after 90 uses
Remember to keep the lid when you change the water bag
2. **Water bag incl. temperature indicator**
Replace after 15 uses
3. **Control unit**
Replace after 90 uses
- 3a. **Pump for inflating balloon and pumping water**
- 3b. **Knob for regulating air and water**
4. **Tubes**
Replace after 90 uses
5. **Coated rectal balloon catheters**
Single-use only
6. **Straps**
Replace when elasticity weakens
7. **Toiletry bag***
For system storage

To ease the irrigation, please advise your patients to empty their bladder before starting.



1. Fill water bag completely

Flip the lid to open the water bag. Fill the water bag to the top with clean tap or bottled water. The bag must be filled completely to function properly and to stand on the floor. Close the lid by clicking it into place.

Note: Do not add any additives to the water.

Water temperature

The water should be lukewarm (34–40°C); too hot water may harm the delicate lining of the bowel, too cold water may cause stomach cramps. For suitable water temperature range, see the round temperature indicator (1.1) on the front of the water bag.



Too cold



Suitable for irrigation



Too hot

Proceed with the irrigation when the indicator is green. If in doubt or not able to distinguish the colours, run the water over your wrist to feel if it is lukewarm.

2. Connect tube to water bag

Attach the tube with the grey connector to the grey screw top by aligning the big tube with the big hole and the small tube with the small hole.

Push them together (2.1) and turn the connector clockwise until locked (2.2).

Place the water bag on the floor within reach.



Control unit symbols

	Turquoise water symbol		Grey deflate symbol
	White balloon symbol		Finish and storage symbol



* Not provided with every system



3. Connect balloon catheter

Attach one end of the tube with turquoise connector to the control unit by aligning the big tube with the big hole and the small tube with the small hole.

Twist the connector clockwise until locked.

Check catheter expiry date on packaging.

Open the catheter packaging to the turquoise dot on the catheter. Attach the other end of the tube with turquoise connector to the balloon catheter (3.1).

Twist the connector clockwise until locked (3.2). Do not inflate the balloon yet.

Warning:

Ensure the catheter size (regular or small) indicated on the packaging matches the catheter size recommended by the healthcare professional.



4. Prepare balloon catheter

Fix the catheter to a wall by using the adhesive dots or place it in its packaging in a cup or a glass.



5. Lubricate balloon catheter in water

Turn the knob to the **Turquoise water symbol** 

Carefully pump until the water fills the catheter packaging to lubricate the catheter.



Turn the knob to the **White balloon symbol**  to stop the water. Wait 30 seconds.

Remove the lubricated catheter from the packaging and use it within 2 minutes.

Note: Do not use any other lubricants on the balloon catheter as this might damage the balloon.



6. Insert balloon catheter

Hold the balloon catheter by the finger grip under the turquoise dot.

Carefully insert the balloon catheter into the rectum, leaving the finger grip outside of the body.

The healthcare professional shall instruct the patient how to insert the balloon catheter.

Warning:

Do not use force when inserting the balloon catheter.



7. Inflate balloon


Balloon size


The healthcare professional shall advise how much to inflate the balloon. It is recommended to inflate the 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 to avoid bursting the balloon.

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

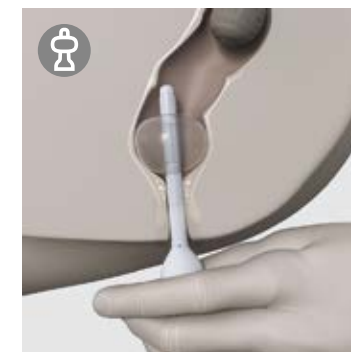
Inflate balloon

Turn the knob to the **White balloon symbol**  to inflate the balloon. Gently pull the catheter back to seal-off the rectum.

If the patient senses that the balloon is too big, turn the knob to the **Grey deflate symbol**  to deflate it.



If the patient experiences problems, advise them to contact their healthcare professional.

Note: A full pump consists of squeezing the pump completely until its inner walls touch each other.







8. Pump water

Turn the knob anti-clockwise to the **Turquoise water symbol**  following the circular line. Avoid turning past the **Grey deflate symbol** , as this will deflate the balloon.



Pump the water slowly into the bowel until the required amount of water is reached. The healthcare professional shall guide the patient on how much water to use.

Note: If the balloon needs more air, turn the knob clockwise to the **White balloon symbol**  and pump one more time. Turn the knob back to the **Turquoise water symbol**  and resume irrigation.

In case of pain or discomfort during irrigation


Pain or discomfort can occur if the water is pumped too quickly or is not lukewarm (34–40°C).

Turn the knob to the **White balloon symbol**  to stop the water and wait until the pain or discomfort ceases.

When the patient is ready, turn the knob back to the **Turquoise water symbol**  and resume pumping water. If the pain or discomfort continues, turn the knob to the **Grey deflate symbol** , remove the catheter and advise the patient to contact their healthcare professional immediately.



9. Remove and dispose of catheter

When the recommended amount of water has been instilled, turn the knob anti-clockwise to the **Grey deflate symbol**  to deflate the balloon.

When completely deflated, gently remove the balloon catheter from the rectum.



Unlock the balloon catheter and dispose of it in accordance with local guidelines, e.g. with normal household waste.

Do not flush it down the toilet.

Do not move away from the toilet.



10. Emptying bowel

Soon the bowel will start to empty itself. If nothing happens, advise the patient to press, cough, do abdominal massage or move the upper part of the body to activate the emptying process.

The time needed for the bowels to empty is individual, but on average it takes 30 minutes.




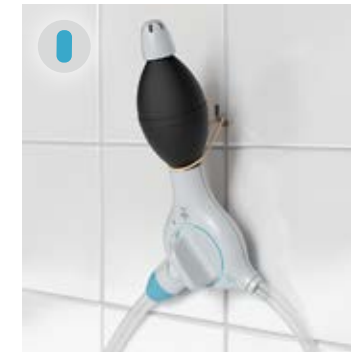
11. Empty and dry system

Unlock the connector from the lid of the water bag.

Flip the lid to open the water bag and pour excess water out.

Keep the lid open and leave the water bag upside down to dry for at least 1 hour.

Drain the rest of the system, by placing the control unit with connected tubes over the sink and turn the knob to the **Finish and storage symbol** .



Hang the control unit, including tubes, upside down (e.g. by using a rubber band) and leave to dry for at least 1 hour.


Afterwards, all components should be stored at room temperature and out of direct sunlight, e.g. in the toiletry bag. Ensure the tubes are not kinked and the system and all its parts are kept away from sharp objects.

12. Clean system

Apart from the single use balloon catheter, all components can be washed in mild soapy water when needed. The strap can be washed at 60°C and hung to dry.

It is not necessary to disassemble the system before cleaning the external surfaces. The balloon catheter shall not be connected when cleaning the system.

The internal surfaces of the components can be cleaned using the following procedure:

- A.** Flip the lid to open the water bag and fill it to the top with mild soapy water. Close the lid by clicking it into place. Turn the knob to the **Turquoise water symbol**  and pump the water through the tubing into a sink until the water bag is empty.
- B.** Repeat this procedure twice with clean tap water to remove soap remains. Then, unlock the connector from the lid and follow the drying procedure as in section "11. Empty and dry system".





The tube with the turquoise connector can be replaced if it becomes soiled.

 Always consult the 'Instructions for use' (IFU) included with the product prior to the first use.

How to use Peristeen® Plus Transanal Irrigation with cone catheter

This how-to-use guide has been modified from the IFU. If you are new to Peristeen Plus or wish to read the full version, please consult the IFU directly. It is helpful that you do the initial training with your patient using the Peristeen Plus Initiation Booklet. Please ask your Coloplast representative for copies of this booklet.

Control unit symbols

-  Turquoise water symbol
-  White water stop symbol
-  Grey deflate symbol – not used with cone catheter!
-  Finish and storage symbol

1. **Screw top (including lid)**
Replace after 90 uses
Remember to keep the lid when you change the water bag
2. **Water bag incl. temperature indicator**
Replace after 15 uses
3. **Control unit**
Replace after 90 uses
- 3a. **Pump for pumping water**
Replace after 90 uses
- 3b. **Knob for regulating water**
4. **Tubes**
Replace after 90 uses
5. **Coated rectal cone catheters**
Single-use only
6. **Straps**
Replace when elasticity weakens
7. **Toiletry bag***
For system storage

To ease the irrigation, please advise your patients to empty their bladder before starting.



1. Fill water bag completely

Flip the lid to open the water bag. Fill the water bag to the top with clean tap or bottled water. The bag must be filled completely to function properly and to stand on the floor. Close the lid by clicking it into place.

Note: Do not add any additives to the water.

Water temperature

The water should be lukewarm (34–40°C); too hot water may harm the delicate lining of the bowel, too cold water may cause stomach cramps. For suitable water temperature range see the round temperature indicator (1.1) on the front of the water bag.



Proceed with the irrigation when the indicator is green. If in doubt or not able to distinguish the colours, run the water over your wrist to feel if it is lukewarm.

2. Connect tube to water bag

Attach the tube with the grey connector to the grey screw top by aligning the big tube with the big hole and the small tube with the small hole.

Push them together (2.1) and turn the connector clockwise until locked (2.2).

Place the water bag on the floor within reach.



* Not provided with every system



3. Lubricate cone catheter in water

Check cone catheter expiry date on packaging.

Remove the cone catheter from its packaging and place it in a cup with clean tap water or bottled water.

The cone catheter must be covered by water as indicated on the picture for the lubricant to be activated.

Wait 30 seconds.

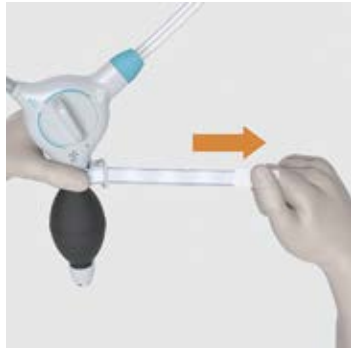
Note: Do not use any other lubricants on the cone catheter.



4. Fasten control unit

While the lubricant is being activated, attach the control unit to the thigh by using the strap.

Place the strap around the base of the pump.



Slide the strap through the buckle and pull tight.



Fit the pump to your thigh and adjust the strap for a comfortable fit.



5. Connect cone catheter

Attach one end of the tube with turquoise connector to the control unit by aligning the big tube with the big hole and the small tube with the small hole.

Twist the connector clockwise until locked.


Attach the other end of the tube with turquoise connector to the cone catheter (5.1).

Twist the connector clockwise until locked (5.2).

Use the cone catheter within 2 minutes.



6. Fill tubes with water

Turn the knob to the **Turquoise water symbol**  and pump until the water flows from the cone catheter.

To avoid spilling water place the cone catheter over a cup, water container or sink.



Turn the knob to the **White water stop symbol**  to stop the water.



7. Insert cone catheter

Hold the cone catheter by the finger grip.

Carefully insert the cone catheter into the rectum as instructed by your healthcare professional.

Hold the cone catheter in place during the irrigation. You can either hold it by the finger grip or below the cone base.

Warning:

Do not use force. Insert the cone leaving the cone baseplate outside of your body.



8. Pump water


Turn the knob to the **Turquoise water symbol** .

Pump the water slowly into the bowel until the required amount of water is reached. Your healthcare professional will guide you on how much water to use.

In case of pain or discomfort during irrigation

Pain or discomfort can occur if the water is pumped too quickly or not lukewarm (34–40°C).


Turn the knob to the **White water stop symbol**  to stop the water and wait until the pain or discomfort ceases.

When you are ready, turn the knob back to the **Turquoise water symbol**  and resume pumping water.

If the pain or discomfort continues, remove the cone catheter and contact your healthcare professional immediately.



9. Remove and dispose of cone catheter

When the recommended amount of water has been instilled, turn the knob to **White water stop symbol**  to stop the water.



Gently remove the cone catheter from the rectum.



Unlock the cone catheter and dispose of it in accordance with local guidelines, e.g. with normal household waste.

Do not flush it down the toilet.



10. Emptying bowel

Remove the control unit from the thigh.

Do not move away from the toilet.



Soon the bowel will start to empty itself. If nothing happens, try to press, cough, do abdominal massage or move the upper part of the body to activate the emptying process.

The time needed for the bowels to empty is individual, but on average it takes 30 minutes.



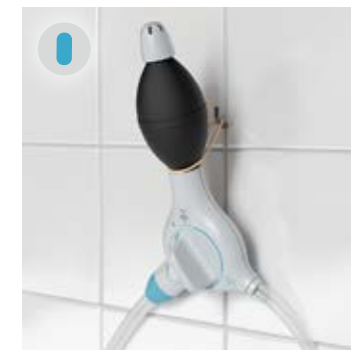
11. Empty and dry system

Unlock the connector from the lid of the water bag.

Flip the lid to open the water bag and pour excess water out.

Keep the lid open and leave the water bag upside down to dry for at least 1 hour.

Drain the rest of the system, by placing the control unit with connected tubes over the sink and turn the knob to the Finish and storage symbol.



Hang the control unit, including tubes, upside down (e.g. by using a rubber band) and leave to dry for at least 1 hour.

Afterwards, all components should be stored at room temperature and out of direct sunlight, e.g. in the toiletry bag. Ensure the tubes are not kinked and the system and all its parts are kept away from sharp objects.

12. Clean system

Apart from the single use cone catheter, all components can be washed in mild soapy water when needed. The strap can be washed at 60°C and hung to dry.

It is not necessary to disassemble the system before cleaning the external surfaces. The cone catheter shall not be connected when cleaning the system. The internal surfaces of the components can be cleaned by following the procedure described in details on page 19 of this Guide and in the Instructions-for-use document.

"With Peristeen®, it takes some time to adjust what works for your body, but you just need to be patient."

Bob,* US

Establishing a personalised routine

Bodies are different, and bowels can take time to adapt to a new treatment. For those reasons, our Coloplast® Care programme offers an initiation booklet containing general advice as well as tips and tricks to make the adjustment as quick and smooth as possible.

You can learn more about how Coloplast Care can support your patient on page 10.

If your patient is new to Peristeen® Plus, please advise them it is common to have to adjust the irrigation routine a few times to get it right. Some trial and adaptation will be required to optimise the process and establish their personalised routine, both for the irrigation process and the clean-up afterwards. This should be considered in the context of the longer-term benefits and time that can be saved with Peristeen Plus, as it may take up to 12 weeks to adapt to the routine.⁶

There are several parameters that can be adjusted in consultation with a healthcare professional, if required:

1. Amount of water used for irrigation
2. Frequency of irrigation
3. Pharmaceutical intake
4. Amount of air for the balloon catheter

*Bob is a Peristeen with balloon catheter user who received compensation from Coloplast to provide this information. Bob has not used the new Peristeen Plus Transanal Irrigation system.

1. Amount of water for irrigation

The volume of water required to effectively empty the bowel depends on several factors including the patient's bowel condition, their diet, and the frequency of irrigation.

When first using Peristeen® Plus in adults, the volume of water will usually begin at 300-500 ml. Over the next few weeks, this volume can be gradually increased up to to 1 litre, or until the individual feels they are completely empty and have no accidents between irrigations. With regard to the amount of water that can be instilled in children, an international expert recommendation establishes 10-20 ml of water per kg of ideal body weight, up to a maximum of 1 litre.⁷

If soiling occurs between irrigations try:

- Advising the patient to stay on the toilet a little longer to allow complete emptying of the bowel
- Reducing the volume of water
- Two half volume irrigations (e.g. two 250 ml irrigations instead of one 500 ml irrigation)
- Peristeen Anal Plug may help if the problem persists (read more on [page 35](#))

If irrigation water is not expelled after sitting on the toilet for 20 to 30 minutes, try some abdominal movements to increase intra-abdominal pressure, such as coughing, abdominal massage or standing up. If water is still not expelled, the patient may be impacted and a clean-out of the bowel may be necessary. The patient may also be dehydrated, so advise the patient to drink more fluid and repeat the irrigation the following day.⁷

The recommended rate for pumping water into the bowel is 200-300 ml/minute for adults. One pump of water every 5-10 seconds is an acceptable rate. It will usually take less than 5 minutes to instil the water. Pumping water into the bowel too quickly may cause discomfort, sweating, dizziness and stomach pain.⁷ If this occurs, the procedure can be paused at any time and resumed when the discomfort has passed and the patient feels ready. If the discomfort does not pass, the irrigation should be stopped and the patient's usual bowel care routine followed to achieve emptying. Peristeen Plus can be tried again at a later point in time.

Water for irrigation should be lukewarm (34-40°C). If the water is too hot, it may damage the mucosa lining of the bowel. If it is too cold, it may trigger reflexes and increase spasms that cause discomfort and/or expulsion of the catheter. Plain tap water is recommended. Bottled water can be used when regular drinking tap water is not recommended. Adding substances to the irrigation water has not shown to have documented benefits.

2. Frequency of irrigation

For patients who are new to Peristeen Plus, it is recommended to irrigate on a daily basis. After 1 or 2 weeks, some patients find that irrigation can be tried every second day. As the frequency of irrigation decreases, it may be necessary to adjust other parameters; for example, the volume of water may need to be increased to achieve complete emptying. Some patients will find it necessary to irrigate every day but eventually most patients settle into a routine of irrigation every other day.

Conducting irrigation at approximately the same time each day seems to work best for most people, but it is not essential. Eating and drinking stimulate the gastrocolic reflexes of the bowel, so conducting irrigation about 30 minutes after a meal may synchronise the irrigation with the natural activity of the bowel and achieve a better emptying.⁷ The most convenient time can be chosen by the patient to fit in with their daily routine.

3. Pharmaceutical intake

Use of medications that affect bowel function and stool consistency such as laxatives and bulking agents can also be adapted to optimise bowel management with Peristeen® Plus. If a patient is taking laxatives before starting irrigation, it is usually advisable for them to continue these at the same dose initially. A gradual reduction in laxatives can be attempted while monitoring for continued effectiveness. Some patients are able to gradually reduce or completely stop taking laxatives once a successful bowel irrigation routine has been achieved.⁷



For patients using balloon catheter only

4. Amount of air in the catheter balloon

It is recommended to inflate the rectal balloon only as much as considered necessary for preventing leakage during irrigation. The required number of pumps will vary between individuals depending on the condition of the individual's sphincters and rectum:

- Typically 1 to 3 pumps is sufficient for the **regular** catheter (maximum 4 pumps)
- Typically 1 pump for the **small** catheter (maximum 2 pumps).

Therefore, it is important to work with individual patients to find the right number of pumps. For some patients, the HCP can determine that the patient shall use the catheter without pumping the balloon at all.

Insufficient air can cause water to leak or the catheter to slide out of the rectum. If water leaks during the procedure, try pumping one more time to a maximum of 4 pumps in total for the regular catheter and 2 pumps for the smaller catheter (remember to turn the knob on the control unit to the **White balloon symbol**  to inflate the balloon and then back to the **Turquoise water symbol**  to resume irrigation).

Conversely, too much air can cause the balloon to be expelled. If this happens, repeat the procedure using a little less air. The frequency of expulsions often decreases as a patient becomes used to the procedure.

The balloon is designed to burst in case of over-inflation and therefore a burst inside the rectum during irrigation can occur in rare cases. Patients should be warned of this possibility before they start, so that they do not panic, as it can be loud.

To reduce the risk of bursting, do not over inflate the balloon.



4.1. Inflation: additional considerations

Please use the following notes to guide the amount of air pumped into the balloon when using the regular balloon catheter (further adaptation may be required):

- For patients with low sphincter tone, it may be necessary to pump the balloon 3 or 4 times to achieve a good seal. If the catheter still slides out of the rectum after 4 pumps, it may be supported by holding it in place with the hand.
- Conversely, for patients with strong anorectal reflexes (hypertonic sphincter), it may be better to limit the inflation, since reflex expulsion of the balloon can happen after only 1 or 2 pumps.
- For patients with a history of anorectal surgery (for instance those with an anastomosis after low anterior resection), the need for inflating the balloon, and in that case how much, is determined after the necessary endoscopic or equivalent investigations.

Additional guidance

A period of adaptation must be expected to tailor the treatment to each individual – this is an important first step towards effective long-term bowel management with Peristeen® Plus. If, when using Peristeen Plus, you encounter any of the following situations, try adapting the treatment as recommended below.





Observation	Adjustment
The catheter will not pass easily into the anus	Check whether there is a spastic reaction of the anal canal while introducing the catheter. Check for hard, impacted stools and treat accordingly by means of oral or rectal medication and/or a digital evacuation of stool. You could also try to adjust the direction slightly backwards after the tip of the catheter has been inserted. Do not use force.
Difficulty irrigating water into the rectum	Check for blocking of the in-flow of water in the rectum. Be aware if faeces are present in the lower rectum, the user should consider irrigating more frequently or adjusting the irrigation procedure. ⁶ A clean-out of the lower rectum may be suggested (i.e. by using a gloved finger) before resuming irrigation.
Water is not expelled during irrigation	Try abdominal movement, cough, abdominal massage or standing up. If water is still not expelled, the patient may be constipated and a clean-out of the bowel may be necessary. The patient may also be dehydrated. Ensure the patient is adequately hydrated and repeat the irrigation the following day.
The patient experiences abdominal cramps when water is pumped into the rectum	Try pumping the water more slowly and/or pause for a minute and wait until the cramping eases. Check that water is not too cold. It should be lukewarm (34-40°C).
The patient experiences discomfort, sweating and/or dizziness when water is pumped into the rectum	Pause the irrigation. Turn the knob to the White balloon symbol  [White water stop symbol if using the system with cone catheter] to stop the water flow and wait until the discomfort ceases. When the patient is ready, turn the knob back to the Turquoise water symbol  and resume pumping. If the discomfort is severe and/or does not resolve, urgent medical attention is necessary due to a risk of autonomic dysreflexia or a bowel perforation.
Spots of blood are seen on the catheter	Occasional bright red spots of blood are not a cause for concern and could be due to hemorrhoids or other anal conditions. However, urgent medical attention is required if the patient experiences sudden sustained bleeding. ⁶ The origin of any anal bleeding should be investigated, especially in the first months of using Peristeen Plus.

No faeces are passed from the rectum after the catheter is removed	The patient could be heavily constipated in which case the block should be cleared before repeating irrigation, and a laxative may be required. If the patient has previously had good results with transanal irrigation, and there's no stool present, the frequency of irrigation can be reduced.
There is leakage after the irrigation is finished	Advise the patient to stand, wriggle, sit down again and brace. Return to the toilet and try again after 30-60 minutes. Try titrating the water volume up or down or repeat the irrigation twice using half the volume of water each time. For neurogenic patients, try digital stimulation after emptying.
The patient has a bowel movement between irrigations or does not feel empty	Try irrigating more frequently or repeat the irrigation. This may also require increasing the amount of water for irrigation.
Placing the water bag in a high position	The water bag should be placed on the floor within reach and should not be elevated. Peristeen® Plus system is not intended as a gravity-dependent system, i.e. water must be pumped into the colon with the aid from the control unit hand pump.
Adding substances (e.g. salt, camomile chamomile tea, olive oil etc.) to the water	No advantages are reported.
Laxative/bulking agents	If a patient is taking laxatives/bulking agents before starting irrigation, advise them to continue. Some patients find they are able to gradually reduce the doses of prescribed medications or stop taking laxatives/ bulking agents entirely once bowel emptying with irrigation is well established.
Service life of the Peristeen Plus products parts	The catheter is for single use. The water bag lid and the control unit including tubes should be replaced after 90 uses. The water bag should be replaced after 15 uses. Please remind your patients to keep the screw top, including the lid, as it is not supplied with a new water bag. The straps should be replaced when the elasticity weakens.

Additional guidance



Balloon catheter

Observation	Adjustment
The catheter is expelled when water is pumped into the rectum	Check that the irrigation water is not too cold – it should be lukewarm (34-40°C). Also try pumping the water more slowly. Assess for heavy constipation/impaction and treat accordingly before resuming irrigation.
The catheter is expelled and the balloon is deflated	Check if the balloon has burst during irrigation. Ensure the knob is not turned to the Grey deflate symbol  instead of the Turquoise water symbol  .
Water leaks during the irrigation	Try inflating the balloon further by turning the knob to the White balloon symbol  and pumping one more time (for a maximum of 4 pumps with the regular catheter and 2 pumps with the small catheter). Now, gently pull the catheter back to seal off the rectum. Turn the knob to the Turquoise water symbol  and resume irrigation.
The patient experiences severe or sustained pain in the abdomen or back, with or without fever, and/or sustained anal bleeding	Stop the irrigation immediately. Deflate the balloon and remove the catheter. Urgent medical attention is necessary.
The balloon bursts	The balloon is designed to burst in case of over-inflation, and can occur in rare cases. Patients should be warned of this possibility before they start. To reduce the risk of the balloon bursting, do not over-inflate the balloon.
The catheter is expelled immediately after inflation	The balloon may be stimulating the rectum to contract. Try inflating the balloon more slowly or using less air.


















Cone catheter

Observation	Adaptation
Irrigation water is leaking during the irrigation	Check whether your patient is holding the cone catheter close to the anus and creating a seal using the cone catheter. The patient may need to try different holding positions and see which would work better for them.








Adjust to country specific product assortment



Catalogue numbers	Name	Content	
29140	Peristeen Plus system Regular (incl. toiletry bag)	1 control unit / 2 balloon catheters Regular / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube / 1 toiletry bag	
29141	Peristeen Plus system Regular (excl. toiletry bag)	1 control unit / 2 balloon catheters Regular / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube	
29142	Peristeen Plus accessory unit Regular	15 balloon catheters Regular / 1 water bag (excl. screw top)	
291431	Peristeen Plus catheter Regular	10 balloon catheters Regular	
291432	Peristeen Plus catheter Regular	15 balloon catheters Regular	
29147	Peristeen Plus system Small (incl. toiletry bag)	1 control unit / 2 balloon catheters Small / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube / 1 toiletry bag	
29148	Peristeen Plus system Small (excl. toiletry bag)	1 control unit / 2 balloon catheters Small / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube	
29149	Peristeen Plus accessory unit Small	15 balloon catheters Small / 1 water bag (excl. screw top)	
291501	Peristeen Plus catheter Small	10 balloon catheters Small	
291502	Peristeen Plus catheter Small	15 balloon catheters Small	
29151	Peristeen Plus system without catheters (incl. toiletry bag)	1 control unit / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube / 1 toiletry bag	
29152	Peristeen Plus system without catheters (excl. toiletry bag)	1 control unit / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube	
29144	Peristeen Plus water bag	3 water bags (excl. screw top)	
29145	Peristeen Plus strap	10 sets of 2 straps	
29146	Peristeen Plus tube	2 tubes with turquoise connectors	

Adjust to country specific product assortment



Catalogue numbers	Name	Content	
29160	Peristeen Plus system with cone catheter (incl. toiletry bag)	1 control unit / 2 cone catheters / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube / 1 toiletry bag	
29161	Peristeen Plus system with cone catheter (excl. toiletry bag)	1 control unit / 2 cone catheters / 1 water bag (incl. screw top) / 2 straps (1 pack) / 1 tube	
29162	Peristeen Plus cone catheter accessory unit	15 cone catheters / 1 water bag (excl. screw top)	
29163	Peristeen Plus cone catheter	15 cone catheters	
29144	Peristeen Plus water bag	3 water bags (excl. screw top)	
29145	Peristeen Plus strap	10 sets of 2 straps	
29146	Peristeen Plus tube	2 tubes with turquoise connectors	



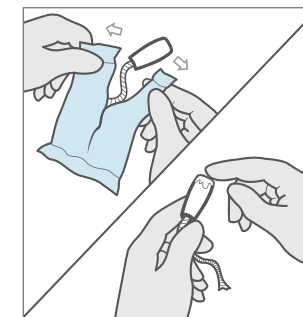
Peristeen® Anal Plug



Simple and discreet

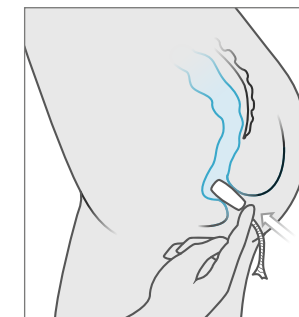
Peristeen Anal Plug functions as an effective barrier to solid faeces in the rectum and is inserted just like a suppository. Designed with a soft foam that expands to the shape of the rectum, it takes the worry out of public or social occasions as well as sports, such as swimming. It can be a great complement to Peristeen Plus Transanal Irrigation.

How to use

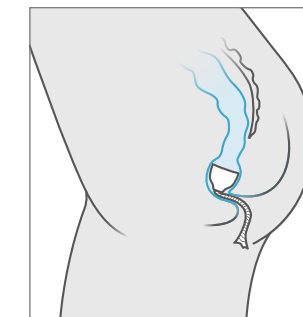


1. Smear a small amount of Peristeen Gel (provided in box) on the tip of the Peristeen Anal Plug.

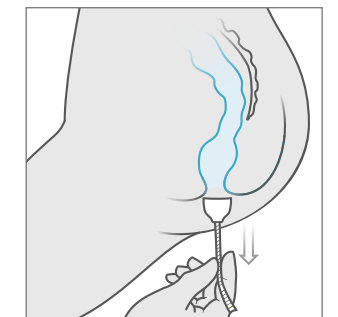
Other lubricants may be used instead.



2. Insert gently into the anus. Ensure entire Peristeen Anal Plug is inserted into the rectum, just inside the anal sphincters. Only the gauze should be visible.



3. Once the Peristeen Anal Plug is in position, it will expand to full size as the film dissolves in the body's natural warmth and moisture. It can remain in the rectum for up to 12 hours.



4. Peristeen Anal Plug can be removed by gently pulling the gauze, which will not trigger an emptying reflex. A fresh plug can be inserted immediately after removal of the old one if required. Dispose of the used plug in a waste bin, not the toilet.

CONTRA-INDICATIONS

Peristeen Anal Plug must not be used if you suffer from:


- Hemorrhoids (3rd and 4th degree)
- Anal stenosis

IMPORTANT

Keep out of reach of children. If placed in the mouth, the Peristeen Anal Plug will expand and may cause choking.

Peristeen Anal Plug

Code	Order code	Size	Units per box
1450	xxxxxxx	Small	20
1451	xxxxxxx	Large	20

 Before use, always consult in full detail the 'Instructions for use' delivered with the products.

Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes Ostomy Care, Continence Care, Wound and Skin Care and Interventional Urology. We operate globally and employ about 12,000 employees.

References

1. Christensen P, Bazzocchi G, Coggrave M, et al. A randomized controlled trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients. *Gastroenterology* 2006;131:738–747.
2. Midrio P, Mosiello G. et al. Peristeen transanal irrigation in paediatric patients with anorectal malformations and spinal cord lesions: a multicentre Italian study. *Colorectal Disease* 2015.
3. Emmanuel A, Kumar G, Christensen P et al. Long-term cost-effectiveness of transanal irrigation in patients with neurogenic bowel dysfunction. *PLOS One* DOI:10.1371/journal.pone.0159394 August 24, 2016.
4. Christensen P, Olsen N, Krogh K, Bacher T, Laurberg S. Scintigraphic assessment of retrograde colonic washout in fecal incontinence and constipation. *Dis Colon Rectum* 2003;46:68–76.
5. Coggrave M et al. MASCIIP Guidelines for management of bowel dysfunction in individuals with central neurological conditions. 2012.
6. Emmanuel et al. Consensus review of best practice of transanal irrigation in adults. *Spinal Cord*. 2013; 51 (732-738).
7. Mosiello G, Marshall D, Rolle U, Crétolle C, Santacruz B, Frischer J and Benninga M. Consensus. Review of Best Practice of Transanal Irrigation in Children. *JPGN* 2017;64: 343–352.