

# 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, Peristeen user*

## Preface

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

**Patients must be trained to use Peristeen Plus 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 Peristeen Plus 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 Coloplast® Charter patient support programme can help and strengthen over time. **Coloplast is here for you and your patients every step of the way**.

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# 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 paediatric 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.<sup>1,2</sup> In addition, Peristeen is associated with significantly fewer urinary tract infections than conservative bowel management,<sup>1</sup> which may potentially lead to cost savings for the healthcare system.<sup>3</sup> In 2018, following an extensive review of clinical and health economic evidence, Peristeen was recommended by NICE – the National Institute for Health and Care Excellence – as a technology that can benefit adults and children with bowel dysfunction.<sup>4</sup>

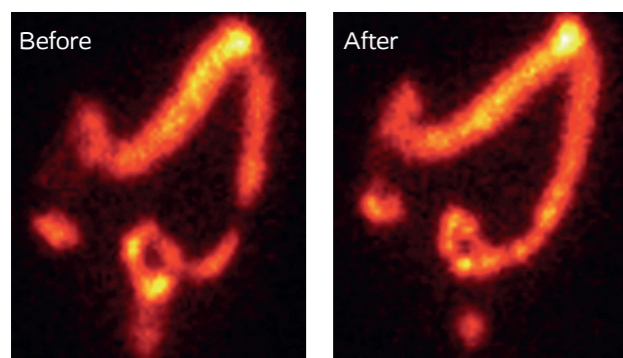
TAI with Peristeen Plus assists the evacuation of faeces by introducing water into the rectum and colon via the anus. The water is subsequently evacuated into the toilet together with the faeces from the lower and descending colon.<sup>5</sup>

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.<sup>6</sup>

## A clinically proven method for managing constipation and faecal incontinence

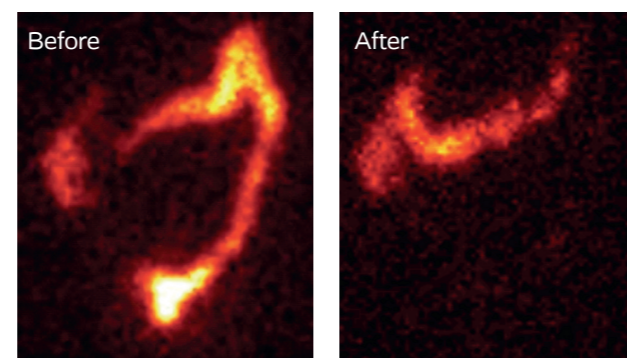
In scintigraphic studies performed in patients with spinal cord injury (SCI) and neurogenic bowel dysfunction, Transanal Irrigation (TAI) has been shown to be effective as a bowel emptying technique.<sup>5</sup> In patients with faecal incontinence, the descending colon and the rectum are emptied, which 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.<sup>1</sup> In patients with chronic constipation, high-volume TAI promotes emptying of most of the descending 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 system

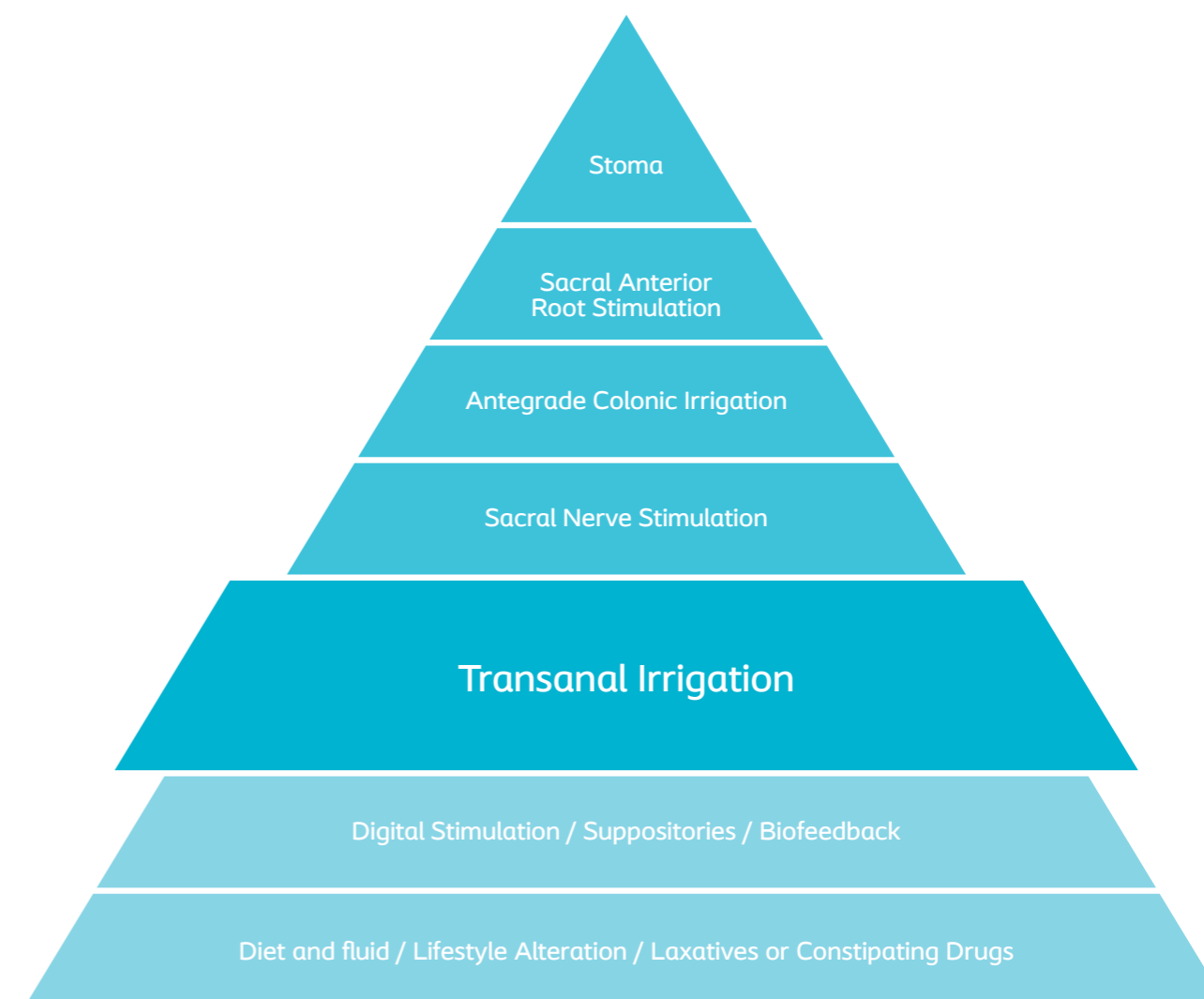


Bowel scintigraphic images of an SCI patient before and after defaecation **using Transanal Irrigation**

## Transanal Irrigation - a recognised long-term standard treatment option

A number of leading global hospitals have adopted balloon catheter transanal irrigation (TAI) as a standard step in their treatment protocol. Long-term use of 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, medication and routines are deemed ineffective or pose too many restrictions to the patient's life.<sup>7</sup>

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.<sup>7</sup> 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 chronic constipation, faecal incontinence and/or time-consuming bowel management procedures. Peristeen Plus can be used by both adults and children over 3 years of age across both neurogenic and functional patient populations.

The system is designed to be easy to handle so that it can be used by a wide range of patients, including those with impaired manual dexterity, helping more patients to regain independence. A smaller size of 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 catheter.

## 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, healthcare professionals 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. 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 healthcare professional 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, 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 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.**

## Bowel perforation

Bowel perforation is an extremely rare but serious and potentially lethal complication of anal irrigation. With the Peristeen system, the estimated rate of bowel perforation in adults is in the order of 1 in 500,000 procedures.<sup>8</sup> In children this rate decreases to 1 in 1 million procedures.<sup>9</sup> Peristeen Plus is equivalent in efficacy and function to Peristeen and is supported by Peristeen's clinical evidence.

Bowel perforation should be suspected if the patient experiences severe or sustained pain in the abdomen or back (sometimes combined with fever), and/or severe or sustained anal bleeding. Peristeen Plus should be stopped immediately and the patient should seek immediate medical help if this occurs.

In order to minimise the risk of perforation, it is crucial to perform the necessary medical assessment on each patient, but also to ensure that patients receive clear instruction and education from you on how to perform the irrigation procedure. The first irrigation must be supervised by a healthcare professional.

# Peristeen Plus for the paediatric population

While most children with constipation and faecal incontinence will respond to structured standard bowel management programmes, some children will prove resistant to these interventions. Transanal irrigation is an effective method of managing bowel dysfunction, even at a young age.<sup>4</sup>

## Assessment

It is essential to carry out a full individual assessment of child suitability prior to commencing irrigation. The following must also be taken into consideration:

- The family dynamics
- The child's emotional and physical compliance
- The child's mobility and setting where irrigation is to be undertaken
- The child's bowel pattern and current regime
- Diet, fluids and medication
- Why other bowel management options have failed

A digital rectal examination (DRE) is not mandatory for paediatrics, however, if anal stenosis or fissure is suspected, it is recommended that a DRE should be performed by an appropriately trained HCP.

Where feasible, assessment and teaching of the procedure should be carried out in the child's own home. This will enable assessment of the child's ability to irrigate in their own toilet or bathroom and the suitability of their home for independent or assisted irrigation. The level of parental involvement will vary from child to child and will require individual assessment.

During the assessment, equipment already available in the child's home or required to facilitate irrigation should be considered. Assessment by an occupational therapist may identify helpful adaptations.

## Informed consent

Irrigation is an invasive procedure and as such informed consent must be obtained from the patient or parent/guardian prior to commencing the procedure. This should follow local policy on whether this needs to be written or verbal consent. Either way, the discussion should always be documented and the child and person with parental responsibility's consent recorded.

## Record keeping

It is essential to keep accurate records, including:

- The reasons for selecting irrigation for the child
- Discussions held with the child and/or parents/carer about risks and benefits
- Information and instructions given to the child/parent/carer (number of pumps to inflate the balloon, recommended water volume, continued laxative use)
- Informed consent to use irrigation
- Communication with the primary care team
- Any adverse events reported
- Plans for follow-up and monitoring (suggest frequent contact initially, either by telephone or visit - continue to maintain at least 6 monthly clinical contact once irrigation is settled and working well)

## Establishing a successful routine

Children and their families/carers will require frequent supervision and support, especially during the first few weeks as they establish their new bowel management routine with Peristeen Plus. It is important that this support continues until they are able to carry out the procedure confidently and a successful irrigation routine is in place.

# Peristeen Plus is supported by Peristeen's clinical evidence

There is a substantial body of evidence showing the Peristeen system is an effective method of managing bowel dysfunction in both children and adults. Peristeen Plus is supported by Peristeen's clinical evidence. Peristeen has also been shown to be a cost-effective bowel management technique, compared with other options.<sup>10</sup>

## Summary

Peristeen has the most comprehensive clinical data of any transanal irrigation device with more than 30 clinical studies undertaken using Peristeen. It is proven to:

- ✓ Reduce episodes of faecal incontinence
- ✓ Reduce UTIs
- ✓ Reduce carer dependence
- ✓ Reduce time spent on bowel management
- ✓ Reduce hospitalisations
- ✓ Reduce surgical interventions
- ✓ Improve bowel scores
- ✓ Improve Quality of Life (EQ-5D)



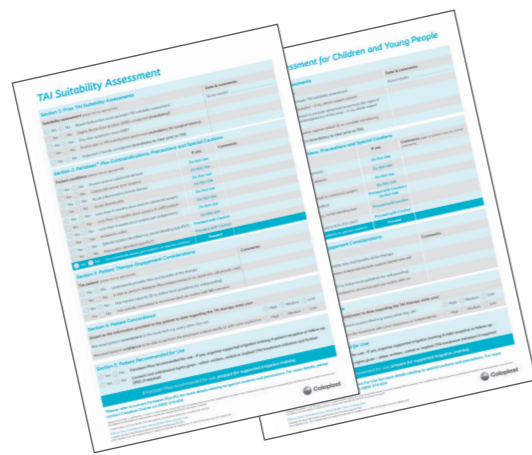
# Patient selection, initiation and training

Before starting Peristeen Plus, patients must undergo a medical evaluation by a qualified healthcare professional to ensure they have no conditions that preclude its use or require further investigation. A digital rectal examination (DRE) is considered mandatory for adults as part of this medical evaluation.

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

In case of history of anal, colorectal or pelvic surgery, and/or radiation therapy, an endoscopy, defecography, or comparable procedure(s) should be used to determine whether the patient's bowel could withstand the Peristeen Plus Transanal Irrigation procedure, including how much the balloon shall be inflated (if at all).

As with all therapies, Peristeen Plus may not be suitable for everyone and in order to facilitate and assist in the work of patient selection and exclusion, Coloplast has developed a TAI Suitability Assessment that you can use prior to starting a new patient on the therapy. A TAI Suitability Assessment for Children and Young People is also available.



Ask your Peristeen Advisor for more information and copies of the appropriate TAI Suitability Assessment as they are complementary to this guide.

## Setting the right expectations

Prior to starting Peristeen Plus for the first time, please take time to describe the procedure to your patient (and their carer, if appropriate), 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 some, it can take up to 12 weeks or more for the treatment to settle down and become routine.**<sup>7</sup>

The patient should be observed closely during their first irrigation for any signs of dizziness, fainting, nausea, abdominal or rectal discomfort. It is important to explain that they may experience some mild abdominal discomfort or tummy ache as the water is instilled which will resolve as soon as the water has been released.

## Training and first irrigation

**It is recommended that a patient's first irrigation with Peristeen Plus is supervised by a healthcare professional to ensure correct, safe and optimal use of the product.**

**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.**

After appropriate training, the majority of people will be able to use Peristeen Plus without the aid of a healthcare professional or carer. However, if the patient is unable to perform the procedure independently, it is important to also involve and train the patient's caregiver who will be in charge of helping or performing the irrigation on the patient.

If a patient is heavily constipated (faecal impaction), it is necessary to thoroughly clean out their bowels before starting Peristeen Plus. This is for reasons of safety and to provide the basis for a successful outcome; impaction in the rectum or colon may cause difficulty or make impossible the insertion of the catheter and the instillation of the irrigation water, increase discomfort, catheter expulsion and the chance of adverse events or technical problems.<sup>7,9</sup>

## Introducing Peristeen Plus and the first irrigation to children

Preparing the child and parents prior to commencing irrigation is essential to gain the commitment required and also to ensure they understand the expected outcomes of the irrigation. **The child and parent must be made aware that it can take several weeks to establish a good routine.** The use of age appropriate visual aids and materials, a practical demonstration and a discussion about all the practicalities of the procedure should precede the irrigation being performed.

Allowing the child to 'play' and familiarise themselves with the Peristeen Plus equipment prior to undertaking the first full procedure is an effective way of introducing the system to them. For anxious children, letting them practice the insertion of the rectal catheter can reduce their anxiety. Also allowing them to be in control of the balloon inflation and water installation at the beginning can give them confidence to proceed with the procedure.

Older children and parents may find the instructional step by step training video helpful. The level of parental involvement will vary from child to child and will require individual assessment. If possible, the training should be undertaken where the procedure is to be carried out. More than one teaching session is often needed and each teaching session may take between one to two hours.

The procedure will normally take place while sitting on a toilet or commode. It is important that the child is able to sit comfortably in the correct position so that their feet are flat and their knees slightly higher than their hips – a step and seat reducer may be necessary. For some children with additional needs an assessment by an occupational therapist may be helpful to ensure the correct toileting equipment is in place, such as adapted seating and handrails. Specialised equipment such as soft toilet seats are also available.

Supervision by an appropriately qualified healthcare professional is an integral part of introducing Peristeen Plus to all children. For some this may be the HCP being just outside the bathroom door, rather than in the room, but they should be present.

The child should be observed closely during the procedure for any signs of dizziness, fainting, nausea, abdominal or rectal discomfort. It is important to explain to the child they may experience some mild tummy ache as the water is instilled which will resolve as soon as the water has been released.

## Tracking progress whilst establishing a routine





You may consider recommending a diary to your patient as a way of keeping track of progress during this period. Patients will receive a diary, as well as practical information, as part of the Coloplast Charter Welcome Pack. Please ask your Peristeen Advisor for copies of this booklet. It can be used during initial training, to help set goals and manage expectations.

In order to further support patients with Peristeen Plus, it is helpful to enroll them or advise them to enroll in Coloplast Charter, a patient support programme specific for Peristeen Plus users. You can read more about Coloplast Charter on page 28.

# How to use Peristeen Plus Transanal Irrigation

This how-to-use guide has been modified from the Peristeen Plus Instructions for Use (IFU) booklet. If you are new to Peristeen Plus or wish to read the full version, please consult the IFU directly.

## Control unit symbols

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

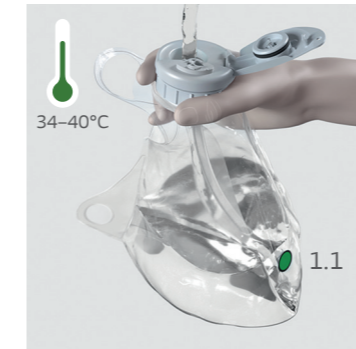
1. **Screw top (including lid)**  
Replace after 90 uses  
*Remember to keep the lid when you change the water bag*
2. **Water bag with water temperature indicator**  
Replace after 15 uses
3. **Control unit**  
Replace after 90 uses
- 3a. **Pump for inflating balloon and pumping water**
- 3b. **Dial 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



\*Peristeen Plus is also available without the toiletry bag to help reduce our environmental footprint

## Preparation

Transanal Irrigation with Peristeen Plus is most commonly carried out while sitting on the toilet. Please advise your patients to empty their bladder before starting the irrigation.



### 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.

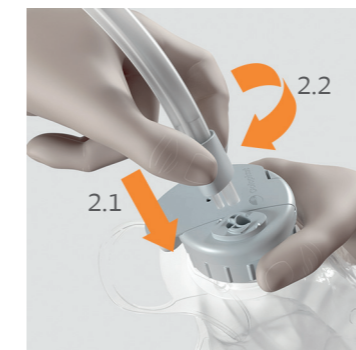
**Note:** Do not add any additives to the water.

#### 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

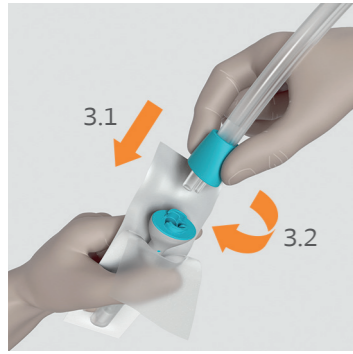
Attach the tube with the grey connector to the grey screw top by aligning the big tube with the big hole and the small tube with the small hole.

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

Attach the control unit and tubing to the thigh using the strap for extra stability, if required.

Place the water bag on the floor within reach.





### 3. Connect the 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 approx. 2-3cm 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.

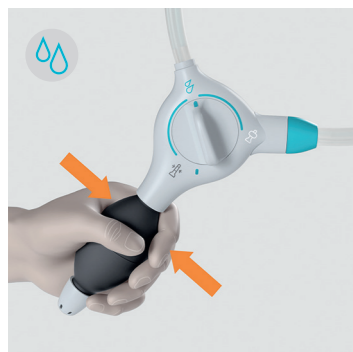
**Warning:**

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



### 4. Prepare balloon catheter

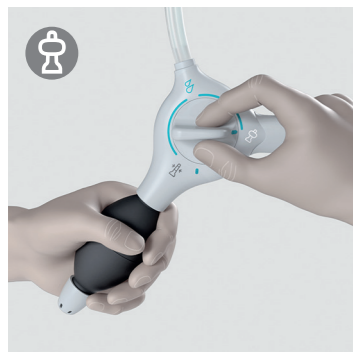
The catheter packaging can be fixed to a vertical surface by using the adhesive dots or alternatively placed upright in a suitable container such as a glass or in the sink.



### 5. Lubricate balloon catheter in water

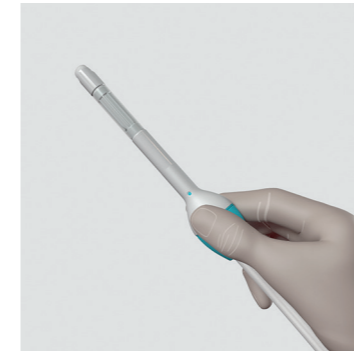
Turn the dial to the **Turquoise water symbol** (water drop icon).

Carefully pump (2-3 pumps) until the water fills the catheter packaging to activate the catheter's self-lubricating coating.



Turn the dial to the **White balloon symbol** (balloon icon) to stop the water. Wait at least 30 seconds and then remove the now lubricated catheter from the packaging and use it immediately.

**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. The finger grip is the first part of the catheter with the widest diameter.

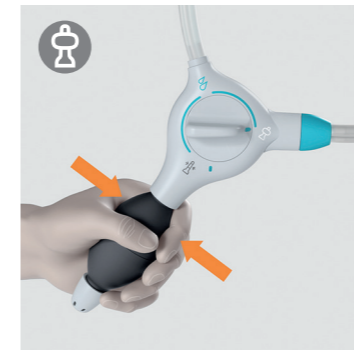
Carefully insert the balloon catheter into the rectum without using force, leaving the finger grip outside of the body.

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

- **For children, if the child is able to stand unsupported**, insertion of the catheter is best carried out with the child standing next to the toilet. This can involve standing directly in front of the toilet facing away and leaning slightly forward or standing to the side of the toilet, depending on the space available.
- **If the child is unable to stand**, position the child on a bed or changing mat for insertion of the catheter and inflation of the balloon. The child can then be lifted on the toilet or commode using a hoist and toileting sling if necessary.

**Warning:**

Do not use force when inserting the balloon catheter.



### 7. Inflate the balloon

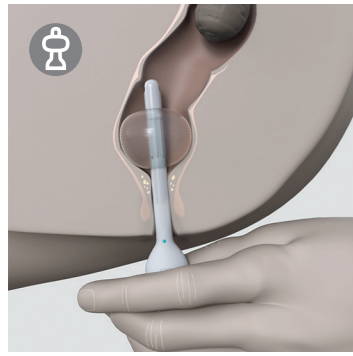
**Balloon size**

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.

It is important to work with individual patients to find the right number of pumps - it is helpful to record in writing the amount of pumps you recommend they use. **In the case of children**, the actual number of pumps will depend on whether the child or adult is carrying out the procedure; the child may have to pump slightly more to fully inflate the balloon.



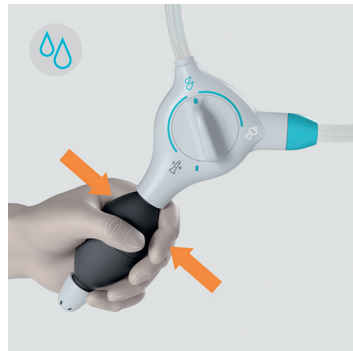
### Inflate balloon

Turn the dial to the **White balloon symbol** (🕒) to inflate the balloon. Once inflated, the patient should gently pull the catheter down so that it feels secure.

If the patient senses that the balloon is too big, turn the dial 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 dial 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 (one pump every 5-10 seconds) into the bowel until the required amount of water is reached. The healthcare professional shall guide the patient on how much water to use.

The amount of water needed is individual and you will have to help your patient to find the optimal amount for them. Usually 300-1000ml is sufficient for adults. **For children**, 10-20ml/kg is recommended.<sup>9</sup> For more information regarding the amount of water required to effectively empty the bowel, please see page 24.

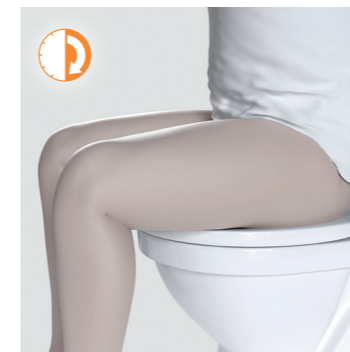
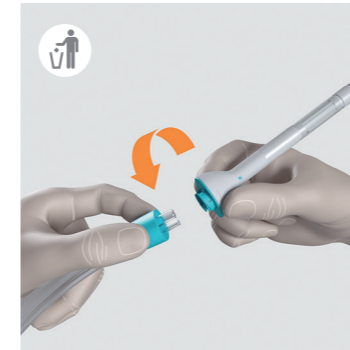
**Note:** If the balloon needs more air, turn the dial clockwise to the **White balloon symbol** (🕒) and pump one more time. Turn the dial back to the **Turquoise water symbol** (💧) and resume irrigation.

### 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 dial to the **White balloon symbol** (🕒) to stop the water and wait until the pain or discomfort ceases.

When the patient is ready, turn the dial back to the **Turquoise water symbol** (💧) and resume pumping water. If the pain or discomfort continues, turn the dial 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 dial anti-clockwise to the **Grey deflate symbol** (🕒) to deflate the balloon.

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

Often the catheter will slide out by itself; if not, gently pull the catheter.

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, the patient should not strain but try coughing or moving/applying gentle pressure or do abdominal massage in a right to left movement to the upper part of their body to activate the emptying process.

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

New users may need to stay on the toilet longer, until they can be sure they have passed all of the water and stool. As they get to know how their body responds, this time can be reduced accordingly.




## 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 dial 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 should 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 dial 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 above 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.

# Peristeen Plus order codes

| Order code | Name   | Content  |  |
|------------|--|--|--|
| 29140      | Peristeen Plus system <b>Regular</b> (inc. toiletry bag) | 1 control unit / 2 balloon catheters <b>Regular</b> / 1 water bag (inc. screw top) / 2 straps (1 pack) / 1 tube / 1 toiletry bag |   |
| 29141      | Peristeen Plus system <b>Regular</b> (exc. toiletry bag) | 1 control unit / 2 balloon catheters <b>Regular</b> / 1 water bag (inc. screw top) / 2 straps (1 pack) / 1 tube                  |   |
| 29142      | Peristeen Plus accessory unit <b>Regular</b>             | 15 balloon catheters <b>Regular</b> / 1 water bag (exc. screw top)   |   |
| 29143      | Peristeen Plus catheter <b>Regular</b>                   | 10 balloon catheters <b>Regular</b>  |   |
| 29147      | Peristeen Plus system <b>Small</b> (inc. toiletry bag)   | 1 control unit / 2 balloon catheters <b>Small</b> / 1 water bag (inc. screw top) 2 straps (1 pack) / 1 tube / 1 toiletry bag     |   |
| 29148      | Peristeen Plus system <b>Small</b> (exc. toilet bag)     | 1 control unit / 2 balloon catheters <b>Small</b> / 1 water bag (inc. screw top) 2 straps (1 pack) / 1 tube                      |   |
| 29149      | Peristeen Plus accessory unit <b>Small</b>               | 15 balloon catheters <b>Small</b> / 1 water bag (exc. screw top)   |   |
| 29150      | Peristeen Plus catheter <b>Small</b>                     | 10 balloon catheters <b>Small</b>  |   |
| 29145      | Peristeen Plus strap                                     | 10 sets of 2 straps  |   |
| 29146      | Peristeen Plus tube                                      | 2 tubes with turquoise connectors  |  |



## Establishing a personalised routine

Bodies are different, and bowels can take time to adapt to a new treatment. For those reasons, our Coloplast Charter programme provides patients with specialist advice as well as hints and tips to make the adjustment as quick and smooth as possible.

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. It is helpful to ensure the patient understands that, at first, 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 the routine.<sup>7</sup>

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. Amount of air in the balloon catheter
4. Medication dosage and intake

## 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 with full bowel capacity, the volume of water will usually begin at 300-500 ml. This volume can be gradually increased up to 1 litre, over the next few weeks, 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.<sup>9</sup> It is important to initially monitor the child's response to the instillation of the water and stop as soon as the child feels uncomfortable. The volume can gradually be increased over time. Sometimes the feeling of fullness can be interpreted as pain by younger children until they become more familiar with the sensation.

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 (split) irrigations (e.g. two 250 ml irrigations instead of one 500 ml irrigation)
- A Peristeen® Anal Plug may help if the problem persists or if the patient has anxiety associated with the perceived risk of soiling (read more on page 30)

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.<sup>9</sup>

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;<sup>9</sup> 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 the next session.

Water 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 the patient is in places where 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. Using Peristeen Plus less frequently than every second day in many cases is not recommended as **Peristeen Plus is most effective when a routine is established.**

Conducting irrigation at approximately the same time each day seems to work best for most people, but it is not essential. Eating and drinking stimulates 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.<sup>9</sup> The most convenient time can be chosen by the patient to fit in with their daily routine.

## 3. Amount of air in the balloon catheter

The function of the balloon is to hold the catheter in place in the rectum; the degree to which the balloon must be inflated, if at all, to achieve this (i.e. the number of pumps of air required) depends on the condition of the individual's sphincters and rectum.

**Most patients using the regular catheter require 1 to 3 pumps of air in the balloon (maximum 4 pumps); for the small catheter, 1 to 2 pumps is usually sufficient (maximum 2 pumps).** It is important to work with individual patients to establish the right number of pumps.

Insufficient air can cause water to leak or the catheter to slide out of the rectum. If a seal is not achieved after 2 pumps and 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 dial 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. Inflate the balloon just enough to ensure the balloon stays in place and a seal is created. For some patients, the healthcare professional can determine that the patient shall use the catheter without pumping the balloon at all.

### 3.1 Inflation: additional considerations

Please use the following notes to guide the amount of air pumped into the balloon when using the regular size 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 lower rectal resection), the need for inflating the balloon, and in that case how much, is determined after the necessary endoscopic or equivalent investigations.
- For the small catheter size, 1 or maximum 2 pumps is recommended.


## 4. Medication dosage and 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. Gradually, 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.<sup>9</sup>

# Additional guidelines

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, any of the following situations are encountered, try adapting the treatment as recommended below.

| Observation  | Adaptation   |
|--|--|
| Water leaks during the irrigation  | Try inflating the balloon further by turning the dial to the <b>White balloon symbol</b>  and pumping one more time (to 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 dial to the <b>Turquoise water symbol</b>  and resume irrigation.   |
| 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 the irrigation 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 dial to the <b>White balloon symbol</b>  to stop the water flow and wait until the discomfort ceases. When the patient is ready, turn the dial back to the <b>Turquoise water symbol</b>  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. |
| 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 by turning the dial to the <b>Grey deflate symbol</b>  and remove the catheter. Consider the possibility of bowel perforation. Urgent medical assessment is necessary.   |
| 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 haemorrhoids or other anal conditions. However, urgent medical attention is required if the patient experiences sudden sustained bleeding. <sup>7</sup> Nevertheless, the origin of any anal bleeding should be investigated, especially in the first months of using Peristeen Plus.   |
| The balloon bursts   | 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. To reduce the risk of bursting, do not over-inflate the balloon (maximum 4 pumps for the Regular catheter and 2 pumps for the Small catheter).  |
| 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.  |
| 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 dial is not turned to the <b>Grey deflate symbol</b>  instead of the <b>Turquoise water symbol</b>  .   |
| 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 faeces in the rectum as it may block the in-flow of water. Be aware that faeces in the lower rectum is a sign that the user should consider irrigating more frequently or adjust the irrigation procedure. <sup>7</sup> A clean-out of the lower rectum may be suggested.  |
| Irrigation water is not expelled  | 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, so advise the patient to drink more fluid and repeat the irrigation the following day.  |
| 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; a laxative may be required. If irrigation had good results previously, there may be no stool present and the frequency of irrigation can be reduced to every other day if the patient is currently on a daily routine.   |
| There is leakage after the irrigation is finished                           | Advise the patient to stand, wriggle, sit down again and brace; 30 to 60 minutes after irrigating – return to toilet and brace. Try using more or less water, or repeating the irrigation twice using half the volume of water each time. For neurogenic patients, try digital stimulation after emptying. Consider using a Peristeen Anal Plug if the problem persists. More information can be found on page 30. |
| The patient has a bowel movement between irrigations or does not feel empty | Check patient is following their suggested routine. Try irrigating more frequently or repeat the irrigation. Increasing the amount of water for irrigation may be required.  |
| Placing the water bag in a high position                                    | Peristeen Plus is not a gravity dependent system and it is therefore no more effective to place the water bag in a high position – it is preferable to place the bag on the floor within reach.  |
| Adding substances (e.g. salt, chamomile tea, olive oil etc.) to the water   | No advantages are documented.  |
| 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 amount or entirely stop taking laxatives/bulking agents once bowel emptying with irrigation is routine.  |
| Service life of the Peristeen Plus products parts                           | The catheter is for a 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 <b>remind your patients to keep the screw top, including the lid</b> , as this is not supplied with a new water bag. The straps should be replaced when the elasticity weakens.  |

# Coloplast® Charter

## Coloplast Charter is here to help your patients succeed with Peristeen Plus

At Coloplast Charter, we will provide your patients with the support and advice they need to succeed with Peristeen Plus, as well as deliver their products free to their home, so that they can establish the best start to their new bowel management routine.

Coloplast Charter offers a call programme for people who have just started using Peristeen Plus.

### First call (7 days after the patient has received training on Peristeen Plus)

One of our CQC regulated telehealth specialists will call your patient to support them in establishing confidence with the routine you have asked them to follow and set up their ongoing delivery preferences.

We are here to answer any concerns your patient may have about starting to use Peristeen Plus and in the first few months we will schedule follow-up calls to check on how they are doing.

We speak to people who use Peristeen Plus all the time, so we are in a great position to pass on tips, advice and the wisdom of other users' experiences. If we uncover an issue that we can't resolve, we will advise patients to see you as their healthcare professional or their GP.

### The Coloplast Charter programme includes:

- Calls from a CQC regulated and experienced telehealth specialist, to support the training you provided to your patient
- Easy ordering of products online or by phone
- Reliable, flexible and discreet delivery
- Complimentary items to support their routine

## Healthcare Professional support

This dedicated team work alongside your Peristeen Advisor to ensure you get the best service possible from Coloplast Charter.

### Personalised support

To allow you more time to focus on what's important - care for your patients - our experienced team, who you will get to know, will provide:

- Easy registration of new patients to Coloplast Charter
- Efficient resolution of queries and will let you know the outcome

Register your patients to Coloplast Charter by contacting our dedicated Healthcare Professional Support team:

England & Wales: 0800 374 654  
Scotland: 0808 168 3850  
Northern Ireland: 0800 581 220

 [hcp@coloplastcharter.co.uk](mailto:hcp@coloplastcharter.co.uk)



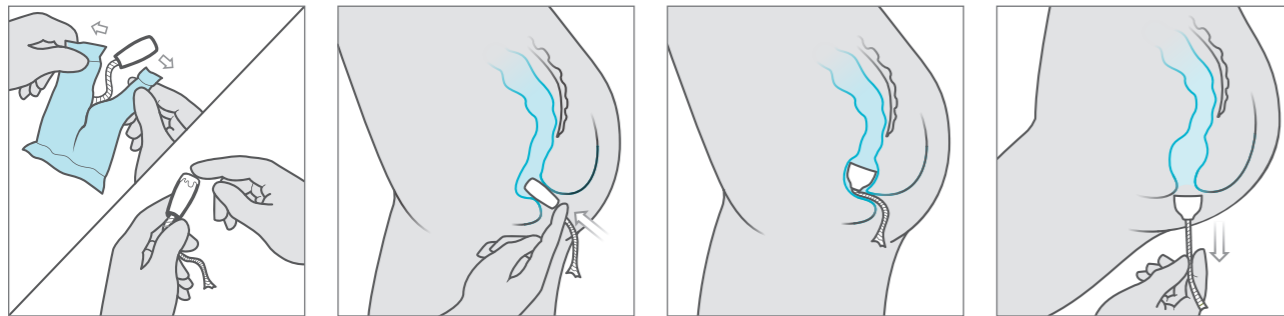
# Peristeen® Anal Plug



## Simple, safe and discreet

Peristeen Anal Plug functions as an effective barrier to faeces in the rectum and is inserted just like a suppository. Designed with a soft foam that expands to the natural shape of the rectum, while still allowing air to pass through, it is safe, hygienic and discreet, bringing security and confidence to users. It can help your patients achieve more predictability and can be a great complement to Peristeen Plus Transanal Irrigation.

## To use



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

### CONTR-AINDICATIONS

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

- Haemorrhoids (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

| Order code | Size         | Units per box |
|------------|--------------|---------------|
| 1450       | Small (37mm) | 20            |
| 1451       | Large (45mm) | 20            |



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

# References

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10. Christensen P et al. Cost-effectiveness of transanal irrigation versus conservative bowel management for spinal cord injury patients. *Spinal Cord* 2009;47:138-143



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 individual needs. We call this intimate healthcare.

Our business includes Ostomy Care, Continence Care, Wound and Skin Care and Urology Care. We operate globally and employ about 11,000 employees.

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