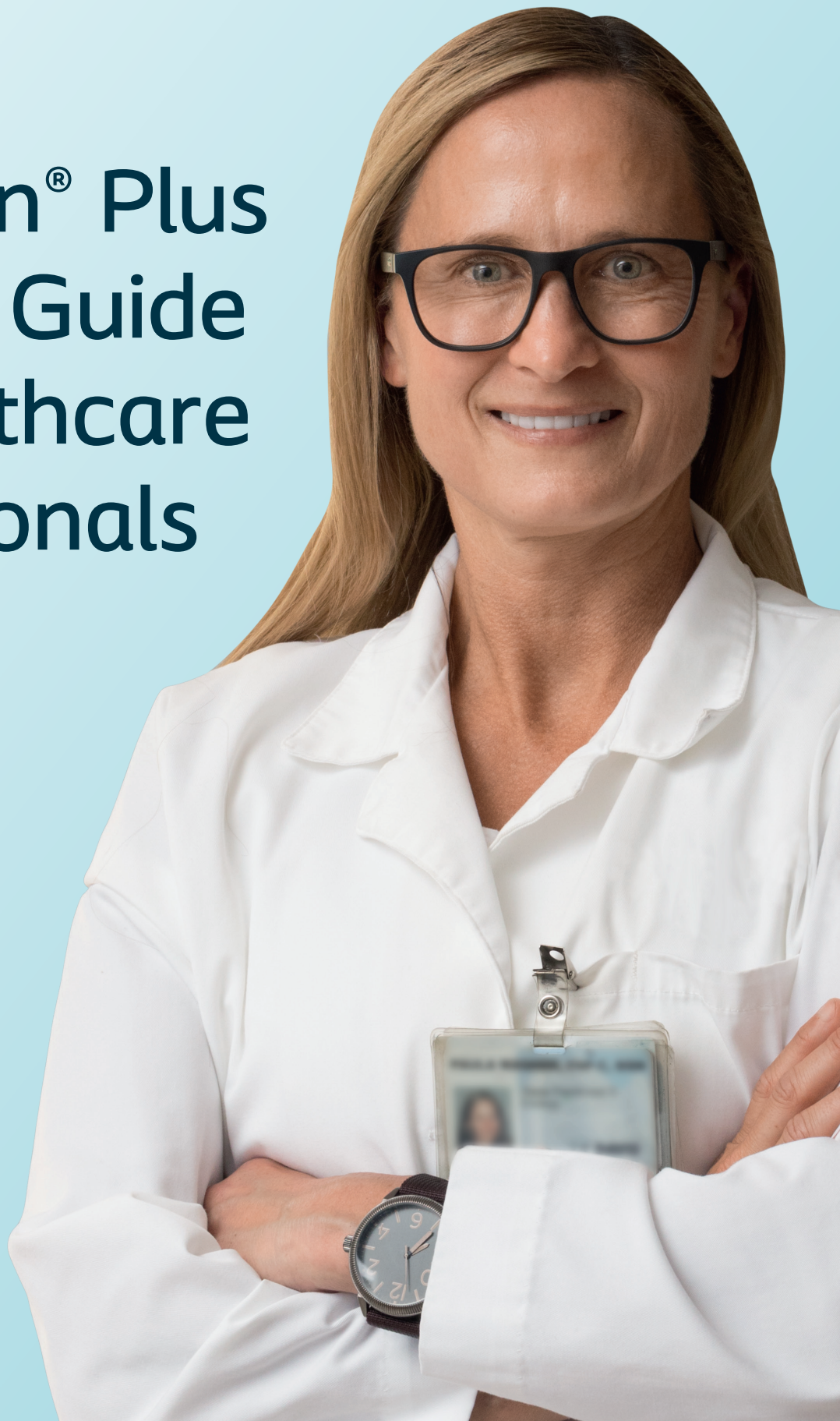


# Peristeen® Plus Training Guide for Healthcare Professionals





*"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 user who received compensation from Coloplast to provide this information.





# Introduction

This training guide was written for healthcare professionals (HCPs) who want to learn how to select, train and support patients confidently and effectively in the use of Peristeen® Plus.

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

While transanal irrigation has been proven to be effective for many patients<sup>1</sup> the initial outcome 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 transanal irrigations at home. Establishing a personalized routine is an important first step to achieving effective and predictable bowel management in the long term. *Coloplast and our dedicated Coloplast Care team of Peristeen Plus experts are here for you and your patients every step of the way.*

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# A recognized treatment for bowel control

Transanal irrigation (TAI) with Peristeen® Plus assists the evacuation of feces by introducing water into the rectum and descending colon. Water is subsequently evacuated into the toilet along with the feces from the descending colon, sigmoid colon and rectum.<sup>1</sup>

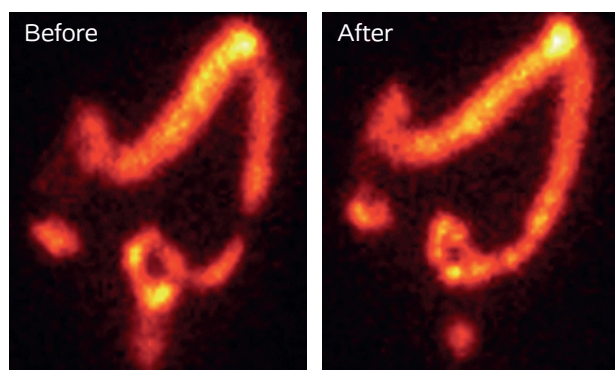
Various studies conducted with individuals with neurogenic bowel dysfunction (NBD) using Peristeen with balloon catheter suggest that Peristeen may increase independence with bowel care, and take less time than conservative bowel management procedures.<sup>2,3</sup> In addition, using Peristeen with balloon catheter is associated with fewer urinary tract infections than conservative bowel management.<sup>2</sup>

Whether the NBD patient experiences fecal incontinence, chronic constipation or both, Peristeen Plus may help re-establish regular and predictable bowel function, while improving confidence and quality of life and minimizing clinical complications.<sup>2</sup>

## Transanal irrigation – a clinically proven method for managing constipation and fecal incontinence

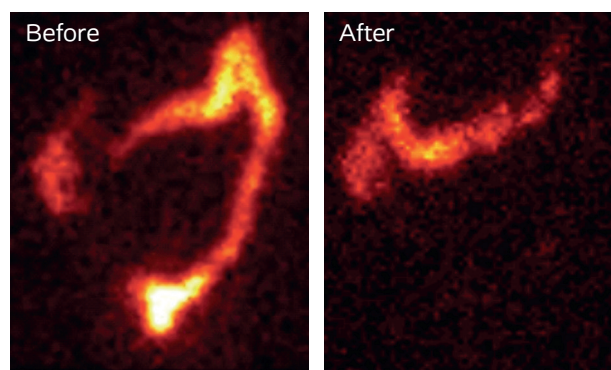
In scintigraphic studies performed in patients with spinal cord injury (SCI) and neurogenic bowel dysfunction, TAI has been shown to be a consistent bowel emptying technique when performed on a regular basis.<sup>1</sup> In patients with chronic constipation, high volume TAI promotes emptying of the rectum and most of the descending colon.

Physiological NBD defecation



Bowel scintigraphic images of an SCI patient before and after defecation **without using transanal irrigation**

Transanal irrigation with a balloon catheter



Bowel scintigraphic images of an SCI patient before and after defecation **using transanal irrigation**<sup>1</sup>

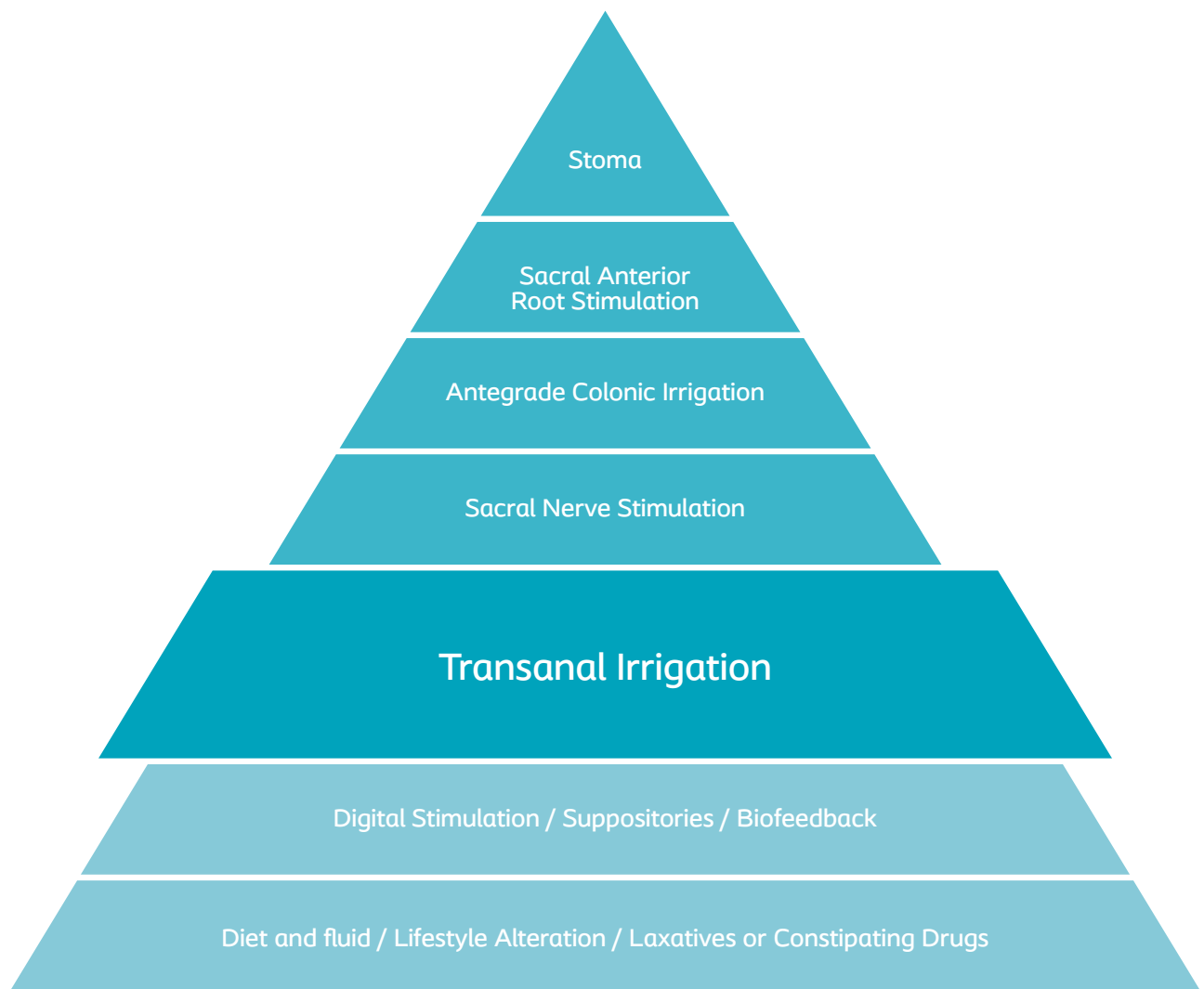
For illustrative purposes only. Performance and experience may vary.



## Transanal irrigation – a recognized standard treatment option

Globally, hospitals are adapting transanal irrigation (TAI) into their treatment algorithm for neurogenic bowel management based on the clinical trials and positive outcomes being reported. Transanal irrigation is considered for patients with neurogenic bowel dysfunction when other first-line methods of bowel management have failed to adequately control symptoms, or are deemed unsatisfactory, because, they are too time-consuming or are negatively impacting patients' quality of life (QOL).<sup>7</sup>

This step-wise, or pyramid, approach to treating neurogenic bowel dysfunction (NBD), i.e. building from more conservative, first-line interventions (such as diet and laxatives) to second-line treatments like Peristeen® Plus, and ultimately to more invasive surgical treatments, including stoma surgery, has also been incorporated into the 2020 Paralyzed Veterans of America (PVA) Clinical Practice Guideline for Health Care Providers in the Management of Neurogenic Bowel Dysfunction in Adults after Spinal Cord Injury.<sup>8</sup>



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



# Indications, contraindications and cautions

With two catheter lengths to choose from (small and regular), you have options to help your patients achieve long-lasting success with transanal irrigation (TAI). The appropriate catheter size will be determined by the prescribing healthcare professional for each individual starting TAI.

## Indications

Peristeen® Plus Transanal Irrigation system is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon.

Peristeen Plus is indicated for use by children (2 years - <12 years old), adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

## Contraindications

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, radiotherapy to the pelvis, and recent abdomino-perineal surgery
- Active inflammatory bowel disease
- Acute diverticulitis, severe diverticulitis, previous diverticulitis and diverticular abscess
- Chronic symptomatic diverticular disease
- Within 3 months of abdominal, anal or colorectal surgery
- Within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection (EMR) and recent endoscopic sub-mucosal dissection (ESD)
- Severe autonomic dysreflexia
- Ischemic colitis
- During Spinal Cord Shock Phase
- Complex diverticular disease
- In patients who are pregnant and have not used the system before\*

\* If the patient is pregnant and has never used transanal irrigation before, they should not start the irrigation procedure during pregnancy.

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. 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.

***Seek immediate medical assistance if, during or after Peristeen Plus Transanal Irrigation procedure, you experience any of the following:***

- Severe or sustained abdominal pain or back pain, especially if combined with fever
- Severe or sustained anal bleeding
- Blood in the feces
- Rectal pain, and abdominal pain

Re-use of the single-use rectal catheter may create a potential harm to the user. Reprocessing, washing, disinfection and sterilization may compromise product characteristics causing additional risk of physical harm to or infection of the user.

Store the Peristeen Plus Transanal Irrigation system out of reach of small children and supervise children that may be present while you use the system to avoid risk of strangulation with the tubes/straps and suffocation on small parts that may have come loose from the product. Peristeen Plus Transanal Irrigation is not recommended for children below 2 years of age.

Federal Law (USA) restricts this device to sale by or on the order (prescription) of a physician.

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

## Cautions

### Cautions specific to 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 contraindications or cautions.

A physician experienced in the use of Peristeen Plus Transanal Irrigation must evaluate patients prior to starting transanal irrigation. Special attention should be paid to those patients who present with a fragile rectal 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 inflated.

Besides observing the contraindications, 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 hemorrhoids
- Fecal impaction/heavy constipation. If you are heavily constipated (fecally impacted) an initial clean-out of your bowels is mandatory before starting up Peristeen Plus Transanal Irrigation procedure
- Irradiation therapy in the abdominal or pelvic region
- Diverticular disease
- Previous anal or colorectal surgery
- Previous major pelvic surgery
- Mild or moderate autonomic dysreflexia
- Long term corticosteroid therapy
- Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)
- Concurrent use laxatives
- Changed stool pattern such as sudden diarrhea of unknown origin. The cause for diarrhea must be identified
- Rectal medication, since the effect of such medication may be reduced by Peristeen Plus Transanal Irrigation
- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Cancer in the abdominal or pelvic region
- Severe cognitive impairment (unless caregiver is available to supervise/administer)

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



# Patient Selection, Initiation and Training

Before starting Peristeen® Plus Transanal Irrigation, patients must undergo a medical evaluation by a trained healthcare professional to ensure they have no conditions that preclude its use or require further investigation. A digital rectal examination (DRE) must be performed as part of this medical evaluation.

For patients with history of anal, colorectal or pelvic surgery or radiation therapy, an endoscopy, defecography or similar procedure(s) should be used to determine if transanal irrigation is appropriate. Please also refer to a list of precautions and contraindications in this guide or Instructions for Use (IFU) that come with the product to determine if the patient is a suitable candidate for transanal irrigation.

Coloplast has several educational tools available to healthcare professionals with information on patient selection criteria or exclusion considerations. For the Peristeen Plus system, consider using the *Neurogenic Bowel Dysfunction Score*, the *Peristeen Plus Patient Assessment Checklist*, and the *Peristeen Plus Patient Training Checklist* prior to starting a new patient on the therapy and during initial product training.

Ask your Coloplast representative for more information and copies of these helpful tools.



## Peristeen® Plus Patient Assessment Checklist



### Peristeen® Plus Transanal Irrigation System Patient training checklist

Note: This form is intended as a checklist for the clinician during initial Peristeen Plus patient training. It is recommended to provide a copy of this form to the patient for future reference upon completion of the training.

#### PATIENT INFORMATION

Name \_\_\_\_\_ Date of birth \_\_\_\_\_  
Date of training \_\_\_\_\_ Training clinician name \_\_\_\_\_  
Name of facility \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_

Completed	Action	Clinician initials
<input type="checkbox"/>	I have reviewed the precautions, contraindications and potential complications with the patient and/or caregiver, and Instructions for Use.	
<input type="checkbox"/>	I have reviewed information with the patient/caregiver on how to safely use Peristeen Plus.	
<input type="checkbox"/>	I have demonstrated to the patient/caregiver on how to safely use Peristeen Plus.	
<input type="checkbox"/>	I have provided the patient/caregiver with information on Coloplast® Care program and have reviewed the privacy statement listed on the Care enrollment form.	
<input type="checkbox"/>	Per clinician guidance, the following should be used for Peristeen Plus _____ mL water _____ pumps in balloon Catheter size: _____ small _____ standard	

Before starting Peristeen Plus, patients must undergo a medical evaluation by a qualified healthcare professional to ensure they have no conditions that preclude using transanal irrigation or require further investigation. Transanal irrigation with Peristeen Plus should always be performed with care. Prior to the first transanal irrigation with Peristeen Plus, a bowel clean-out should be carried out as prescribed by your physician. A digital rectal examination is also mandatory to check for any potential issues.

**Contraindications:** Transanal irrigation must not be used in the following situations: (Check any that apply.)

- Yes No
- ☐ Known anal or colorectal stenosis
  - ☐ Colorectal cancer (active/recurrent), radiotherapy to the pelvis, and recent abdomino-perineal surgery
  - ☐ Active inflammatory bowel disease
  - ☐ Acute diverticulitis, severe diverticulitis, previous diverticulitis and diverticular abscess
  - ☐ Chronic symptomatic diverticular disease
  - ☐ Complex diverticular disease
  - ☐ Within 3 months of abdominal, anal or colorectal surgery
  - ☐ Within 4 weeks of endoscopic polypectomy, recent colon biopsy, recent endoscopic mucosal resection (EMR) and recent endoscopic sub-mucosal dissection (ESD)
  - ☐ Severe autonomic dysreflexia
  - ☐ Ischemic colitis
  - ☐ During spinal cord shock phase
  - ☐ In patients who are pregnant and have not used the system before\*

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

\*If the patient is pregnant and has never used transanal irrigation before, they should not start the irrigation procedure during pregnancy.

**Precautions:** Special caution must be shown if you have or have had any of the following: (Check any that apply.)

- Yes No
- ☐ Any anorectal condition, which may cause pain or bleeding e.g. anal fissure, anal fistula or third or fourth degree hemorrhoids
  - ☐ Fecal impaction/heavy constipation. If you are heavily constipated (fecally impacted) an initial clean-out of your bowels is mandatory before starting up transanal irrigation procedure
  - ☐ Irradiation therapy in the abdominal or pelvic region
  - ☐ Diverticular disease
  - ☐ Previous anal or colorectal surgery
  - ☐ Previous major pelvic surgery
  - ☐ Mild or moderate autonomic dysreflexia
  - ☐ Long term corticosteroid therapy
  - ☐ Bleeding diathesis or anticoagulant therapy (not including aspirin or clopidogrel)
  - ☐ Concurrent use laxatives
  - ☐ Changed stool patterns such as sudden diarrhea of unknown origin. The cause for diarrhea must be identified
  - ☐ Rectal medication, since the effect of such medication may be reduced by transanal irrigation
  - ☐ Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
  - ☐ Cancer in the abdominal or pelvic region
  - ☐ Severe cognitive impairment (unless caregiver is available to supervise/administer)

Notes: \_\_\_\_\_

**Warning:** Transanal irrigation procedure should always be carried out with caution. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery. Possible symptoms of bowel perforation:

- Severe or continued pain in the abdomen or back area, especially if fever and/or severe anal bleeding are present
- Rectal pain and abdominal pain
- Blood in feces

If any of these symptoms occur, contact your healthcare provider or urgent care immediately as it may require admission to the hospital and surgery if bowel perforation is confirmed.

## Setting the right expectations

Prior to starting Peristeen® Plus for the first time, please take time to describe the procedure to your patient, 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 personalized 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 be successful and patients to have control of their bowel movements. Compliance with clinical recommendations is critical.

You may consider recommending to your patient that a bowel diary can be a good way of keeping track of progress during this period. Patients will receive a bowel diary, as well as other helpful information, as part of the Peristeen Plus welcome packet. Please ask your Coloplast representative for copies of the Peristeen Plus welcome packet to provide to your patients before or during initial training to help set goals and manage expectations.

In order to further support patients in their routine-building with Peristeen Plus, it is helpful to enroll them in Coloplast Care, a patient support program for Peristeen Plus users. You can read more about Coloplast Care on page 25.

Date / Time (mm/dd/yyyy)	Method: Peristeen Plus / Laxative / Other	Water (ml) / pump(s) (ml)	Bowel type (1-7)	Accidents since last irrigation	Outcome (☺☺☺)	Comments	Notes on diet	Irrigation duration (minutes)
	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			
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	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			
	Per / Lax / Other	/			☺☺			

28 | Finding a routine

## 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 patients will be able to use Peristeen Plus without the aid of a caregiver. However, if the patient is unable to perform the procedure independently (for instance, small children or patients with a high degree of physical impairment), it is important to also involve and train the patient's caregiver who will be in charge of helping or performing the irrigation for the patient.

Subsequent irrigations should be followed up by consultations, in-person or by phone, until the patient has fully adapted the procedure to meet their individual needs and until they feel confident to continue the procedure independently. Coloplast Care Advisors are also available by phone, and trained to help users troubleshoot day-to-day questions, referring them back to their healthcare provider when they encounter clinical questions or issues.

Before starting Peristeen Plus, thorough bowel clean-out is recommended, especially for patients who are heavily constipated (fecal impaction). This is for safety reasons and to provide the basis for a successful outcome. Impaction in the rectum or colon may cause difficulty for the insertion of the catheter and the instillation of the irrigation water. It can also increase discomfort, the chance of catheter expulsion and adverse events or technical problems.<sup>7,10</sup>



# The Peristeen® Plus Success Package

Just providing the product is not enough

Transanal irrigation (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 Plus Success Package is specially designed to pave the way to a fulfilling life with TAI

## Peristeen Plus 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

### Introduction to TAI and Peristeen Plus

- PM-18891 TAI with Peristeen Plus – Intro  
PM-18826 TAI with Peristeen Plus – For predictable bowel management

### Peristeen Plus Process and Coverage

- PM-18824 Peristeen Plus Process Summary:  
"Guiding HCPs and patients to success"

### Patient Assessment and Training

- PM-18756 Neurogenic Bowel Dysfunction (NBD) Score – Pediatric  
PM-18755 Neurogenic Bowel Dysfunction (NBD) Score – Adult  
PM-18828 Peristeen Plus Patient Assessment Checklist  
PM-18823 Peristeen Plus Training Day Tips  
PM-17965 Peristeen Plus HCP Training Guide

### Welcome Kits

- PM-18864 Peristeen Plus Welcome Packet – Pediatric (EN)  
PM-18955 Peristeen Plus Welcome Packet – Pediatric (SP)  
PM-18878 Peristeen Plus Welcome Packet – Adult (EN)  
PM-18956 Peristeen Plus Welcome Packet – Adult (SP)

### Videos



Peristeen Plus  
Animation: Upgrades  
from Peristeen (EN)



Peristeen Plus  
Animation: Upgrades  
from Peristeen (SP)



Peristeen Plus  
Introduction:  
Easy to Use (EN)



Peristeen Plus  
Introduction:  
Easy to Use (SP)



Peristeen Plus  
Scintigraphic (EN)



Peristeen Plus  
How-to-Use – HCP  
(EN)



Peristeen Plus  
How-to-Use –  
Pediatric (EN)



Peristeen Plus  
How-to-Use –  
Pediatric (SP)



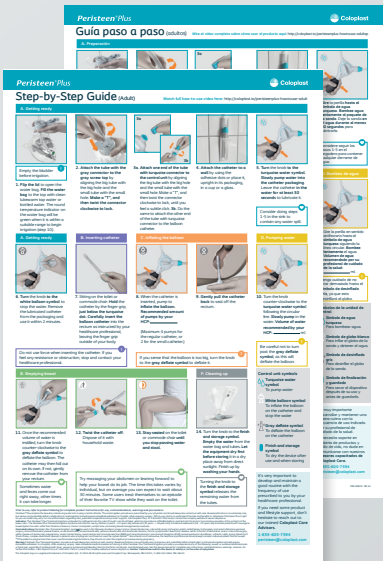
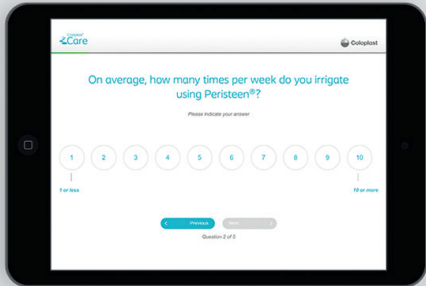
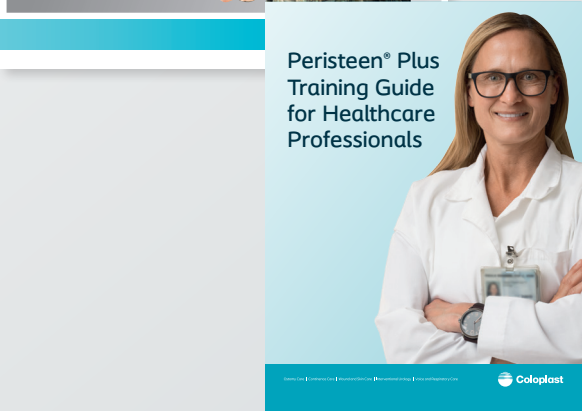
Peristeen Plus  
How-to-Use – Adult  
(EN)



Peristeen Plus  
How-to-Use – Adult  
(SP)

# The Peristeen® Plus Success Package:

## A path to lasting success with TAI







# How to use Peristeen® Plus Transanal Irrigation system with balloon catheter


This how-to-use guide has been modified and condensed from the Instructions for Use (IFU). If you are new to Peristeen Plus or wish to read the full version, it is important to consult the IFU directly and other product information before the first patient training.


It is helpful that you do the initial training with your patient using the Peristeen Plus welcome kit. Versions for pediatric and adult patients are available. Please ask your Coloplast representative for copies to provide to your patients.

## Control unit symbols

 Turquoise water symbol

 Gray 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**  
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  
\*available for new Care enrollments and upon request

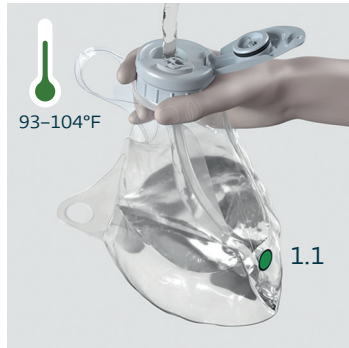


## Product codes

29152	System without a catheter (excl toiletry bag)	  	1 control unit / 1 water bag with lid / 2 leg straps (1 pack) / 1 tube
29142	Accessory unit - Regular**		15 rectal catheters <b>Regular</b> / 1 water bag (no lid)
29149	Accessory unit - Small**		15 rectal catheters <b>Small</b> / 1 water bag (no lid)
29125	Tube**		2 tubes with blue connectors - available at no cost through Coloplast Care program

\*\*Peristeen Plus catheters and tubes are not compatible with Peristeen, and vice versa

Transanal Irrigation with Peristeen® Plus is most commonly carried out while sitting on the toilet. 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 water 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:** The system is not meant to be used with any additives.

### Water temperature

The water should be 93–104°F, with body temperature being optimal. Water that is too hot may harm the delicate lining of the bowel. Water that is too cold 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



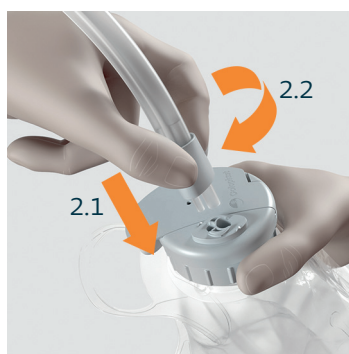
Suitable for irrigation



Too hot

Proceed with the irrigation when the indicator is green.

If in doubt or not able to distinguish the colors, run the water over your wrist to feel if it is body temperature.



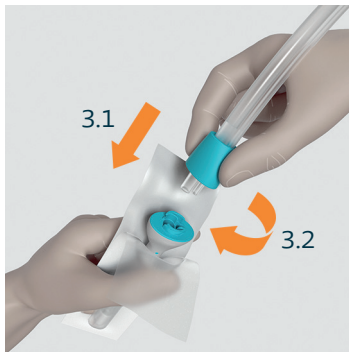
## 2. Connect tube to water bag

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

Push them together (2.1), make a “T” and then twist the connector clockwise until locked (2.2).

Place the water bag on the floor within reach.





### 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.

Make a “T”, and then twist the connector clockwise to lock, until you hear and feel a subtle click.

Check catheter expiration 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).

Make a “T”, and then twist the connector clockwise to lock (3.2) , until you hear and feel a subtle click.

**Warning:** Make sure the catheter size indicated in the packaging matches the catheter size recommended by the healthcare professional. Using the wrong size catheter may cause damage to the bowel wall.

**Note:** Do not inflate the balloon on the rectal catheter without having activated the coating (See Step 5).



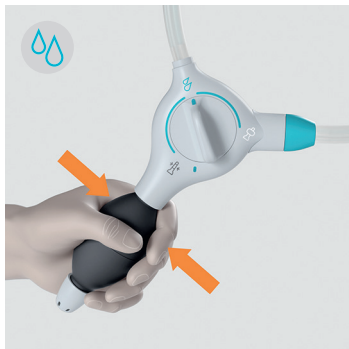
### 4. Prepare balloon catheter

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

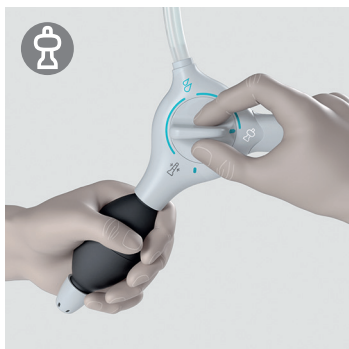
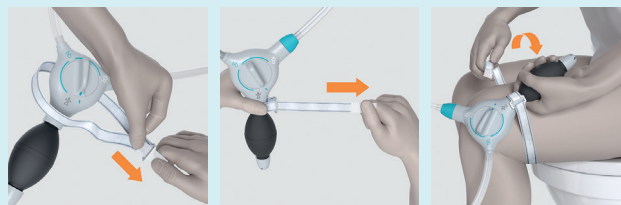
### 5. Lubricate balloon catheter in water

Turn the knob to the **turquoise water symbol** 

**Slowly pump water into the catheter packaging** (2-3 pumps). Leave the catheter **in water for at least 30 seconds** to lubricate it.



**Note: if needed, attach the control unit to the patient's thigh.** First, slide the strap through the buckle and pull tight. Then, **fit the pump to the thigh** using the VELCRO® brand strap.



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.



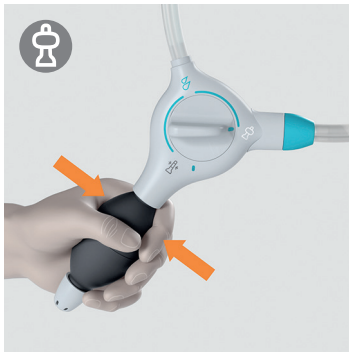
## 6. Insert balloon catheter

Hold the balloon catheter by the finger grip, just below the turquoise dot.

Carefully insert the balloon catheter into the rectum, as instructed by your healthcare professional, leaving the finger grip outside of the body.

### Warning:

Do not use force when inserting the balloon catheter. If you feel any resistance or obstruction, stop.



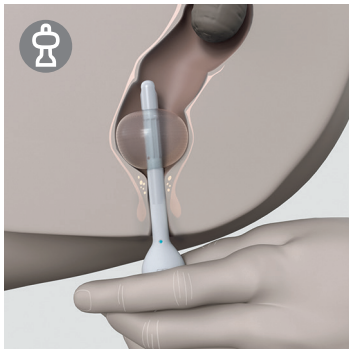
## 7. Inflate balloon

### Balloon size

It is up to the healthcare professional to advise how much to inflate the balloon, bearing in mind the recommendation 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

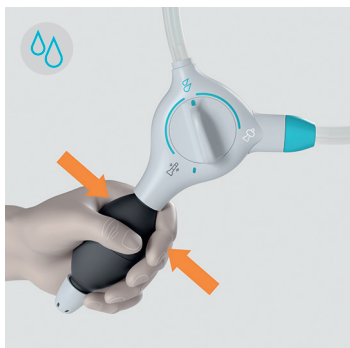
When the catheter is inserted, turn the knob to the **white balloon symbol** (⚙️) to inflate the balloon. Gently pull the catheter back to seal-off the rectum.

If the patient senses that the balloon is too big, turn the knob to the **gray 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 counter-clockwise to the **turquoise water symbol**  following the circular line. Avoid turning past the **gray 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.

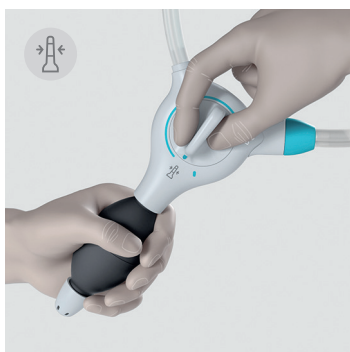
**Note:** If the balloon needs more air, turn the knob clockwise to the **white balloon symbol**  and pump one more time. Turn the knob back to the **turquoise water symbol**  and resume irrigation.

### In case of pain or discomfort during irrigation


Pain or discomfort can occur if the water is pumped too quickly or is not lukewarm.

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 **gray deflate symbol** , remove the catheter and advise the patient to contact their healthcare professional immediately.



## 9. Remove and dispose of catheter

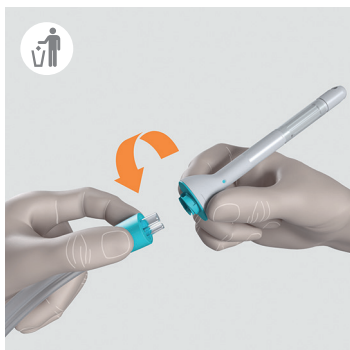
When the recommended amount of water has been instilled, turn the knob anti-clockwise to the **Gray deflate symbol**  to deflate the balloon.

The catheter may fall out on its own. If it does not, wait until it's completely deflated, then gently remove the balloon catheter from the rectum.

Unlock the balloon catheter and dispose of it with normal household waste.

If the control unit was attached to the patient's thigh, you may remove it at this time. Do not move away from the toilet.

Do not flush it down the toilet.



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



## 10. Emptying bowel

Soon the bowel will start to empty itself. **Patient should remain seated on the toilet until they stop passing water and stool.**

**Note:** If nothing happens, the patient should try to press, cough, do abdominal massage or move the upper part of their body to activate emptying process. Drainage time varies by individual, and can take around 30 to 47 minutes to complete the entire irrigation process.<sup>2</sup>



## 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** (blue circle with a white dot).

Hang the control unit, including tubes, upside down and leave to dry for at least 1 hour.

**Let the equipment dry first before storing** it in a dry place at room temperature and out of direct sunlight. Be careful not to kink the tubes.

## 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 140°F 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** (blue circle with a white dot) 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.



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

Bob\*, US







# Establishing a personalized routine

Bodies are different, and it can take time to adapt to a new treatment. To help during this initial adjustment period, Coloplast Care program offers general advice as well as helpful tips to make the adjustment quick and smooth as possible. For more information about Coloplast Care, talk to your local Coloplast representative or send a brief Coloplast Care Enrollment Form to [peristeen@coloplast.com](mailto:peristeen@coloplast.com) to enroll your patients into this program.

If your patients are 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 optimize the process and establish their individual routines, both for the irrigation process and the clean up afterwards. This should be considered in the context of the long-term benefits and time that can be saved with Peristeen Plus, as it may take up to 12 weeks to adapt to the routine.<sup>7</sup>

There are several parameters that may need to be adjusted per consultation with the 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

## 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. This volume can be gradually increased up to 1 liter, 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 liter.<sup>10</sup>

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)

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>7</sup>

The recommended rate for pumping water into the bowel is 200-300 ml/minute for adults. Pumping water into the bowel too quickly may cause discomfort, sweating, dizziness and stomach pain.<sup>7</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 a later point in time.

Water should be at body temperature. 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 cause spasms that result in 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 no documented benefit.

## 2. Frequency of irrigation

For patients who are new to Peristeen Plus, it is recommended to irrigate on a daily basis. Over time, some patients find that irrigation can be tried every other 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. Patients should consult with their healthcare provider before changing any prescribed parameters, such as frequency of irrigation or the volume of water.

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 synchronize the irrigation with the natural activity of the bowel and achieve a better emptying.<sup>7</sup> The most convenient time can be chosen by the patient to fit in with their daily routine.

### 3. Pharmaceutical intake



Some healthcare professionals may consider the use of medications that affect bowel function and stool consistency, such as laxatives and bulking agents, which can also be adapted to optimize bowel management with Peristeen® Plus. Some patients may be able to gradually reduce or completely stop taking laxatives per consultation with healthcare professional once a successful bowel irrigation routine has been achieved.<sup>9</sup>

### 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)

Work with individual patients to find the right number of pumps, from the first training. For some patients, the healthcare professional can determine that the patient may 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 dial on the control unit to the balloon symbol  to inflate the balloon and then back to the 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. In rare cases, the balloon can burst during irrigation. Patients should be warned of this possibility before they start irrigating for the first time.

To reduce the risk of the balloon 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 lower resection), the need for inflating the balloon, and in that case how much, is determined after the necessary endoscopic or equivalent investigations.

Note: Peristeen Plus Transanal Irrigation must not be used within 3 months of abdominal, anal or colorectal surgery. See the device manual for complete user instructions, contraindications, warnings, precautions and potential complications/adverse events.



# Helpful Hints

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

## Observation

## Adaptation

### GETTING READY

Placing the water bag in a high position

It is not more effective to place the water bag in a high position – it is preferable to place the bag on the floor.

Adding substances (e.g. salt, chamomile tea, olive oil etc.) to the water

No advantages are reported.

### INSERTING CATHETER

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 consult with your healthcare provider to treat accordingly. You could also try to adjust the direction slightly backwards after the tip of the catheter has been inserted. Base insertion off of digital rectal evaluation (DRE) completed by healthcare professional, and assess positioning on the toilet. Do not use force with insertion.

### INFLATING BALLOON

Balloon does not fully inflate with recommended number of pumps

It's important to recommend pumps based on each patient's individual hand strength. Some patients may require more pumps to get to one full pump.

The catheter is expelled and the balloon is deflated

Check for a burst balloon. Ensure the knob is not turned to the gray deflate  instead of the turquoise water symbol 

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 balloon bursts

The balloon is designed to burst in case of over-inflation, and it can burst during irrigation 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.



A whistling sound is coming from the bag

When too much pressure is built in the water bag, you can hear a whistling noise. The noise comes from the pressure relief valve mounted in the top of the water bag lid and is a safety measure, to ensure that the pressure at which the water flows from the bag is not too high. Pause pumping for a moment, and when resuming, pump at a slower pace.

## PUMPING WATER

The catheter is expelled and the balloon is deflated	Check for a burst balloon. Ensure the knob is not turned to the gray deflate  instead of the turquoise water symbol 
Difficulty irrigating water into the rectum	Check for feces in the rectum as it may block the in-flow of water. Be aware that feces in the lower rectum is a sign that the user should consider irrigation more frequently or adjust the irrigation procedure. A clean out of the lower rectum may be suggested.
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 at body temperature.
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  to stop the water flow and wait until the discomfort ceases. When the patient is ready, turn the dial back to the turquoise water symbol  and resume pumping. If the discomfort is severe and/or does not resolve, urgent medical assessment is necessary. Consider the possibility of autonomic dysreflexia or bowel perforation.

## EMPTYING BOWEL

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. Nevertheless, the origin of any anal bleeding should be investigated, especially in the first months of using Peristeen Plus.
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 feces 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. If irrigation had good results previously, there may be no stool present and the frequency of irrigation can be reduced.
Water leaks during the irrigation	Try inflating the balloon further by turning the knob to the white balloon symbol  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 knob to the turquoise water symbol  and resume irrigation.
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.
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, remove the catheter. Consider the possibility of bowel perforation. Urgent medical assessment is necessary.

## Observation

## Adaptation

### GENERAL

The patient has a bowel movement between irrigations or does not feel empty

Try irrigating more frequently or repeat the irrigation.

Laxative/bulking agents

If a patient is taking laxatives/bulking agents before starting irrigation, 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 lid and the control unit should be replaced after 90 uses. Tube with blue connector should be replaced after 90 uses or when soiled. The water bag should be replaced after 15 uses and remind your patient to keep the screw top, including the lid, as this is not supplied with a new water bag. The straps should be replaced when the elasticity weakens.



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

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

Coloplast Care is a complimentary support program 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. Dedicated Peristeen Plus Advisors proactively reach out to patients enrolled in Coloplast Care to ensure they are succeeding with the product, and provide helpful tips and 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 professionals.

### This is how it works:



### How to enroll your patients in Coloplast Care:

You can enroll patients by submitting Coloplast Care enrollment form for Peristeen Plus to:

#### Coloplast Care

 **1-855-605-7594 / Fax 1-855-676-2594**

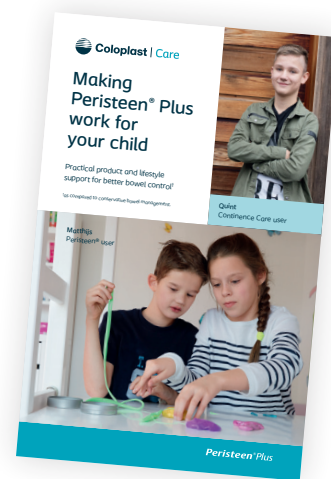
 **peristeen@coloplast.com**

 **[www.coloplastcare.us/bowel](http://www.coloplastcare.us/bowel)**

A Coloplast Care Advisor will send a confirmation email to you and will reach out to your patients to welcome them into the program. We recommend encrypting emails and forms if sending over email.

**Note:** Please ask your local sales representative for copies of the Peristeen Plus Welcome Pack and Coloplast Care enrollment form for Peristeen Plus.

Information from Coloplast Care is for educational purposes only. It is not intended to substitute for professional medical advice and should not be interpreted to contain treatment recommendations.



## Notes

[illegible]

Information from Coloplast Care is for educational purposes only. It is not intended to substitute for professional medical advice and should not be interpreted to contain treatment recommendations.

Prior to use refer to product labeling for complete product instructions for use, contraindications, warnings and precautions.

**Indication:** The Peristeen® Plus Transanal Irrigation System is intended to instill water into the colon through a rectal catheter, which incorporates an inflatable balloon, inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Plus Transanal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Contraindications: Peristeen Plus Transanal Irrigation must not be used in the following situations: known anal or colorectal stenosis, colorectal cancer (active/recurrent), radiotherapy to the pelvis, and recent abdomino-perineal surgery, active inflammatory bowel disease, acute diverticulitis, severe diverticulitis, previous diverticulitis and diverticular abscess, chronic symptomatic diverticular disease, within 3 months of abdominal, anal or colorectal surgery, within 4 weeks of endoscopic polypectomy, recent colonic biopsy, recent endoscopic mucosal resection (EMR) and recent endoscopic sub-mucosal dissection (ESD), severe autonomic dysreflexia, ischemic colitis, during Spinal Cord Shock Phase, complex diverticular disease, in patients who are pregnant and have not used the system before\*. Since the list is not exhaustive, the healthcare professional should always consider individual patient factors as well.

\*If the patient is pregnant and has never used transanal irrigation before, they should not start the irrigation procedure during pregnancy.

**Warnings:** Peristeen Plus Transanal irrigation procedure should always be carried out with caution. Bowel perforation is an extremely rare, but serious and potentially lethal, complication to transanal irrigation and will require immediate admission to a hospital, often requiring surgery. See the device manual for complete user instructions, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Coloplast Corp at 1-855-605-7594 or consult the company website at [www.coloplast.us](http://www.coloplast.us). Caution: Federal law restricts this device to sale by or on the order of a physician.

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