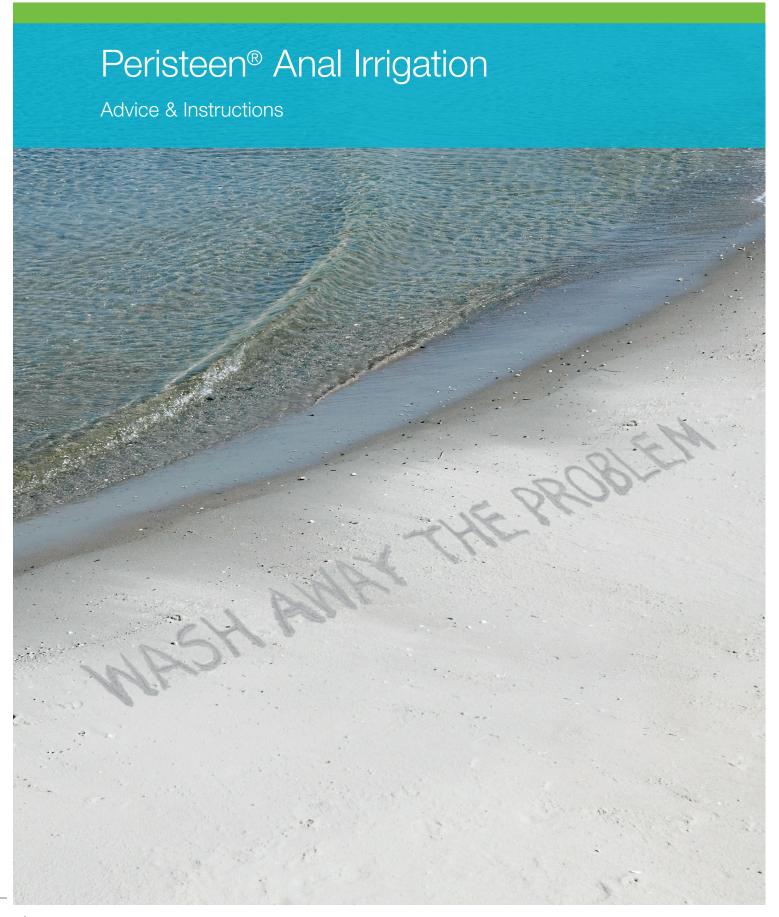
Peristeen®







Contents

| Introduction | 3 |
|---------------------------------|----|
| History | 3 |
| The bowel system | 4 |
| Constipation | 6 |
| Faecal incontinence | 6 |
| Causes of bowel dysfunction | 7 |
| The effect of food and exercise | 8 |
| Anal irrigation | 9 |
| Peristeen Anal Irrigation | 10 |
| Product service life | 11 |
| Frequently Asked Questions | 12 |
| Bowel Diary | 14 |

Introduction

Finding that you no longer have control over your bowels can be frightening and very unpleasant. Obtaining information is difficult as faecal incontinence is still a taboo subject. Yet detailed information can clear up uncertainties and help you deal with your problem.

This information booklet is made especially for people suffering from faecal incontinence, chronic constipation, or for those who spend a long time on the toilet.

The booklet introduces you to the anal irrigation procedure and tells you how to empty your bowels by using water. It also gives you an introduction to the bowel system, constipation and faecal incontinence as well as the causes of bowel dysfunction.

The purpose of the folder is to give you answers to your initial questions and it is intended as a supplement to the training you will receive from your doctor or nurse.

History

The origins of transanal irrigation can be dated as far back as 1500 BC, when the ancient Egyptians recorded the use of colonic irrigation in their medical records.

Since then, bowel irrigation has become a recognized method of treatment for acute constipation and since the 1980s, it has also been used in the prevention of constipation and faecal incontinence.

Over the last ten years, irrigation has become an increasingly used alternative to other methods of bowel management and its benefits have been clinically well documented.

The bowel system

The bowels are part of the digestive system, the primary function of which is to break down the food we eat. The food passes through the stomach and the small intestine (small bowel), where it is broken down and useful components are absorbed into the body. What is left continues to the large intestine (colon and rectum).

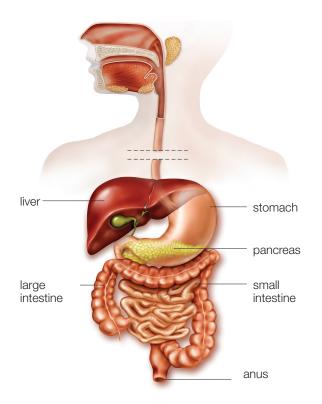
The large intestine receives a liquid mixture of digested food and juices from the small intestine. The main function of the large intestine is to absorb water and salts and to store the waste products (faeces) before they are transported to the rectum. The large intestine receives about 1,500 ml of small intestine content a day and converts this into 150-200 ml of faecal matter. The bowel absorbs the remainder.

On average it takes 1-3 days for food to pass through the entire digestive tract, though this can vary greatly from person to person. The time it takes for food to pass through the digestive system is called the transit time.

The large intestine has two muscles, which make peristaltic movements when contracting. With the aid of peristalsis, faeces is moved from the large intestine into the rectum. Peristalsis is affected by a number of factors such as diet, posture and exercise.

Peristaltic movements

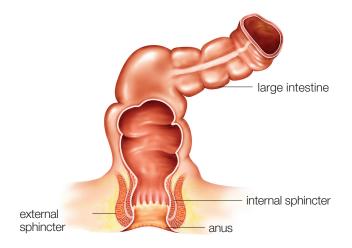
Peristaltic movements (also called peristalsis) are wavelike muscular contractions that transport digested food through the intestines to the rectum. The two colon muscles; one longitudinal muscle along the colon and one circular muscle around the colon, make the contractions.



There are two sphincters in the rectum affecting the evacuation; the internal and the external sphincter. The function of the anal sphincters is to maintain continence and prevent leakage.

Once the rectum receives faeces from the large intestine, it is registered by a set of nerve endings. These nerve endings send a signal to the brain informing that the rectum is full and that it is time to go to the toilet. At this point you can choose to wait for a more suitable time. If you wait too long however, the urge will disappear and the faeces will be forced back into the large intestine.

When you decide to go to the toilet, you activate the defecation reflex by relaxing the external sphincter. Typically, the presence of approx. 150 ml of faeces will result in a reflex relaxation of the internal sphincter. The external sphincter relaxes and the faeces are expelled with the aid of gravity and muscle contractions in the rectum.



Sphincters

There are two sphincters in the rectum controlling the defecation process.

The internal sphincter is an extension of the colon musculature and is controlled by reflex when the rectum is full, i.e. we cannot consciously control it.

The external sphincter can be controlled consciously by the brain.

Constipation

Constipation and faecal incontinence are both symptoms of bowel dysfunction and can be experienced at the same time.

Bowel function and defecation habits vary from one person to another. Some have daily bowel movements, others every second or third day. Due to the extensive variation in the normal defecation pattern, it is difficult to offer a clear definition of constipation.

Constipation occurs when the bowel's peristaltic movements are reduced. This prolongs transit time in the large intestine and more fluid is absorbed from the faeces than with normal transit time, resulting in hard and lumpy stools. This will often result in general discomfort and in some cases disturbed bladder-emptying patterns.

Constipation is generally perceived as:

- Fewer than three defecations a week.
- Prolonged lavatory visits with straining and soreness in the rectum.
- Hard, sparse and lumpy stools.

Changes in digestive and bowel movement patterns will therefore be perceived differently depending on what one is accustomed to.

Faecal incontinence

Faecal incontinence can be defined as lack of control of bowel evacuation resulting in involuntary defecation. Anal incontinence also includes incontinence for air (flatus).

In many cases, faecal incontinence occurs as the result of insufficient sensation in the rectal region. In other words, you do not register the urge to defecate. At the same time, control of the internal and external sphincters may be entirely or partially lacking.

Chronic constipation, in which the rectum wall is severely over-stretched, may result in faecal incontinence as the normal defecation reflexes are deactivated by the chronic stretch. At the same time, fluid passes around the faecal mass in the bowel. Often the internal sphincter has reduced function because it is expanded and liquid stoolmixed with dry and hard stool may pass.

Causes of bowel dysfunction

There are many causes of bowel dysfunction and reasons for initiating anal irrigation. The most frequent reasons are mentioned below. In order to receive appropriate and effective treatment, a diagnosis from your health care professional is essential.

Neurological disorders

The defecation mechanism, i.e. the nerves that send a signal to your brain telling you when you need to go to the toilet, may be impaired due to a medical condition or disease, such as a spinal cord injury, spina bifida, multiple sclerosis, parkinson's disease, apoplexia, alzheimer's disease or brain tumour.

Sensory disorders

The sensory function of the rectal mucosa may be impaired. This can occur after surgery, as a result of colitis, compaction, rectal prolapse or as a result of surgical correction of congenital absence or abnormality of the anal opening (anal atresia).

Muscular disorders

There can be damage to the sphincter muscle due to external injuries, tumours or their surgical removal, perineal tear from a vaginal birth, straining from constipation or rectal prolapse.

Psychological/psychiatric disorders

Bowel dysfunction can result from psychoses, depression, depersonalisation or role conflicts (in children and adults) as well as a result of sexual abuse.

Reduced tissue elasticity

This is more frequent in old age or after multiple births.



7

The effect of food and exercise

Food plays an important role in managing your bowels. It is important to find the right balance of stool consistency to avoid constipation on the one hand, and liquid stool, which increases the risk of faecal incontinence, on the other.

Dietary fibres generally soften stool and reduce passage time. Too much fibre, however, can worsen symptoms of bloating and stomach pain.

It is worth noting that some food and liquids such as coffee and artificial sweeteners have a mild laxative effect. It is always important to drink plenty of fluids. Finally physical exercise has a mechanical effect on the bowels, which improves peristalsis, i.e. bowel movements.

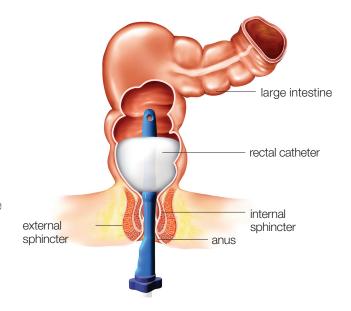


Anal irrigation

Anal irrigation is a procedure for emptying the bowels and is an alternative to other methods such as laxatives, suppositories, manual evacuation and stimulation. Anal irrigation helps prevent both constipation and faecal incontinence as well as reduces the time spent on the toilet. Anal irrigation should only be carried out on a doctor's or nurse's order.

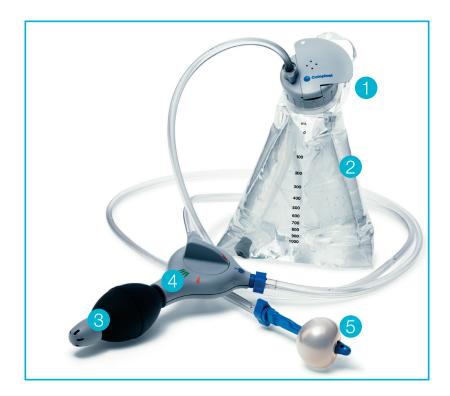
Anal irrigation is performed by introducing room temperature water into the rectum using a rectal catheter, while sitting on the toilet. The water fills up the large intestine and causes the faeces to move onwards in the bowel. After introducing the appropriate amount of water into the bowels, water and stools are emptied into the toilet.

Anal irrigation cleans the descending part of the bowel efficiently thus preventing faecal incontinence and the insertion of water results in a mass movement preventing constipation. It also reduces the risk of faecal incontinence episodes between irrigations and reduces the time spent on bowel management.



Peristeen Anal Irrigation

Peristeen Anal Irrigation is designed to make it easy to empty your bowel effectively and securely.



- 1. Screw top (including lid) to connect control unit to water bag.
- 2. Bag for water.
- 3. Pump for activating balloon and pumping water.
- 4. Control unit for regulation of air and water.
- 5. Pre-coated rectal catheter with balloon.

Product service life

Once you have received proper training from your doctor or nurse, it is easy to start using Peristeen Anal Irrigation on your own. The system is simple to use; below is a description of each part and its recommended use.



Rectal catheter is for single use only

The rectal catheter has a hydrophilic coating only guaranteed to work once. Also for hygienic reasons the rectal catheter should be discarded after irrigation.



Water bag works approximately 15 times

The water bag can be used for 1 month when irrigating every other day (equals approx. 15 irrigations). The pressure inside the water bag wears out the material of the bag.



Control unit, lid and tubes work approximately 90 times

The control unit, lid and tubes can be used for 6 months when irrigating every other day (equals approx. 90 irrigations). Due to wear and tear Coloplast cannot guarantee a longer service life.

Frequently Asked Questions

Who can perform anal irrigation?

Anal irrigation is for people who suffer from faecal incontinence, chronic constipation or have to spend a long time on bowel management procedures. You must be examined by a health care professional and receive professional instruction before starting the irrigation procedure to eliminate serious diseases or conditions. After receiving instruction and training, the majority will be able to perform anal irrigation on their own.

How often should I irrigate?

Anal irrigation should be carried out every or every other day or as recommended by your doctor or nurse.

How long does the irrigation take?

The time used for irrigation is individual. When using anal irrigation you use approx. 30-45 minutes on bowel management daily.

How much water should I use?

The required amount of water is individual and your doctor or nurse will tell you how much water to use. An average procedure normally calls for a volume of 500 ml-1 litre of water. You should not increase the amount of water uncritically since the bowel may retain it and release it over time in small amounts.

Why is the temperature of the water important?

The water should be room temperature. If it is too hot, it may harm the delicate lining of the rectum; if it is too cold, cramps may occur.

How quickly should I pump the water?

If the water is pumped too quickly into the bowel, you may experience discomfort such as sweating, dizziness or stomach ache. We recommend one pump per second.

Can I stop the irrigation if I want a break?

In case of discomfort and you feel the need for a break, stop the water flow and wait until the discomfort ceases. When you are ready, resume pumping. If the discomfort does not disappear, contact your health care professional immediately.

What should I do if water seeps into the toilet?

If water seeps past the balloon and into the toilet there is no need to change the irrigation procedure if the irrigation still works.

You can stop the pumping of water, wait for a while and fill some more water into the bowel. Make sure the catheter is placed in the correct position right above the sphincters. If water still seeps into the toilet, you can fill more air into the balloon and resume pumping water into the bowel.

What should I do if the irrigation water and/ or faeces do not come out (no emptying)?

You may be heavily constipated and a clean out of the bowel is necessary. Contact your health care professional for assistance.

The reason could also be that you have not had enough to drink and are dehydrated, so the bowel has absorbed the irrigation water. Try irrigating once more using the normal amount of water and remember to drink more water. If another attempt at irrigation does not help, contact your doctor or nurse.

What if I experience leakage after irrigation?

If you experience leakage after irrigation you might have used too much water. Make sure to use the amount of water recommended by your health care professional. You can also try to stay a little longer at the toilet. Contact your health care professional if you continue experiencing leakage.

What if I experience defecation between irrigations?

If you experience defecation between irrigations, the cause may be insufficient emptying after irrigation due to constipation or hard stools. Contact your health care professional for different solutions, e.g. frequency of irrigation, amount of water and/or medication.

How do I store my Peristeen Anal Irrigation system?

The system and the rectal catheters should be stored at room temperature (max. 25° Celsius) and away from direct sunlight. Ensure the tubing is not kinked when stored.

How do I clean my Peristeen Anal Irrigation system?

The tube can be cleaned by turning the knob on the control unit to the water symbol and pump the excess water out of the tube.

Alternatively you can change the tube with the blue connectors. The surface of all the components (excluding the single use catheter) can be washed in mild soapy water.

What do I do when travelling?

The bowels absorb water, so when travelling in countries where it is not safe to drink the water, you should use still mineral water or cooled boiled water for irrigation.

Flatulence

Anal irrigation empties the bowel of faeces and flatulence. Experience shows that the release of flatulence from the rectum will be considerably reduced once irrigation is practised regularly.

Adaptation period

An adaptation period of approx. 10 days may be expected. The procedure must be individually adjusted together with your health care professional e.g. regarding the amount of water and air, and the frequency of irrigating.



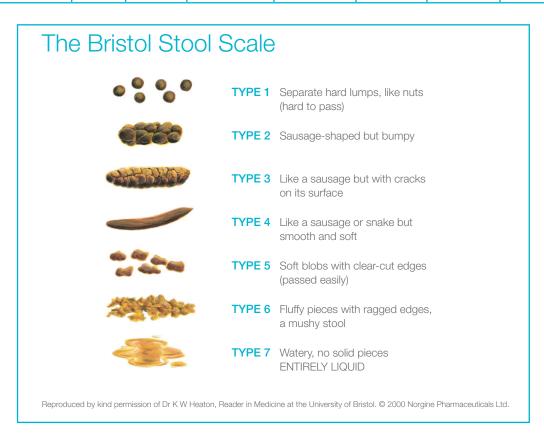
For additional product information, please contact our Consumer Support Team at 1-866-293-6349 or ca conspec@coloplast.com

Bowel Diary

It is important to record your results each time you use Peristeen. This will help on discussions with your doctor/nurse or to provide accurate information if experiencing issues where adjustments may be necessary

| Trained by: | | Date: | |
|-------------|--|-------|--|
| | Name of caregiver who trained on Peristeen | | |

| Date | Time (Start - Finish) | #of pumps | Water (ml) | Consistency (Bristol Scale) | Faecal incontinence | Abdominal pain | Medication | Comments |
|----------|--------------------------|--------------|---------------|--------------------------------|---------------------|----------------|------------|-------------|
| March 18 | 9:00 - 10:15 | 3 | 500 ml | ³ EXAN | APLE NO | No | No | Bowel Empty |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |
| | - | | | | | | | |



14

| Peristeen Anal Irrigation Codes | | | |
|---------------------------------|-------|-----------------|---|
| | 29121 | System | 1 control unit 2 rectal catheters 1 bag 2 straps |
| | 29122 | Accessory unit | 15 rectal catheters 1 bag |
| ļ | 29123 | Rectal Catheter | 10 rectal catheters |
| <u>@</u> | 29124 | Strap | 1 set of 2 straps |
| | 29125 | Tube | 2 tubes with blue connectors |

To order Peristeen or if you have any questions please contact our **Consumer Support Team** at 1-866-293-6349 or email at ca_conspec@coloplast.com



The Coloplast story began back in 1954. Elise Sørensen is a nurse. Her sister Thora has just had an ostomy operation and is afraid to go out, fearing that her stoma might leak in public. Listening to her sister's problems, Elise creates the world's first adhesive ostomy bag. A bag that does not leak, giving Thora – and thousands of people like her – the chance to return to their normal life.

A simple solution with great significance.

Today, our business includes ostomy care, urology and continence care and wound and skin care. But our way of doing business still follows Elise's example: we listen, we learn and we respond with products and services that make life easier for people with intimate healthcare needs.

Ostomy Care Urology & Continence Care Wound & Skin Care



Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare. Our business includes ostomy care, urology and continence care and wound and skin care. We operate globally and employ more than 7,000 people.

The Coloplast logo is a registered trademark of Coloplast Canada. © 2011-04 All rights reserved Coloplast Canada, Mississauga, Canada.

Coloplast Canada 3300 Ridgeway Dr. Unit 12 Mississauga, ON L5L 5Z9 1-877-820-7008

www.coloplast.ca

E0397N