

Guideline for Rectal Irrigation for Adults

CONTROLLED DOCUMENT

CATEGORY:	Procedural Document
CLASSIFICATION:	Clinical
PURPOSE	The purpose of this guideline is to support registered practitioners in the teaching of rectal irrigation as a self administered method of bowel management
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Distribution:	
• Essential Reading for:	All registered practitioners who currently undertake the practice of rectal irrigation and all registered practitioners who wish to expand their practice to include this skill.
• Information for:	All clinical staff

## INTRODUCTION

These guidelines are developed for use in running a rectal irrigation clinic. The purpose of the clinic is to teach the patient or carer how to self administer rectal irrigation.

Patients are referred by members of the colorectal team for nurse-led assessment for suitability to use rectal irrigation. They are seen in a specific clinic, the available devices discussed, technique taught and followed up as required.

## EVIDENCE FOR PRACTICE

Rectal irrigation has been available in clinical practice since the late 1980's being used in children with spina bifida (Shandling and Gilmore, 1987). Rectal irrigation is the introduction of warm tap water through the anal canal into the rectum to initiate defaecation. It was initially used in adults with neurogenic bowel dysfunction after conservative management had failed (Briel et al, 1997) but is now used in a wider variety of conditions (Christensen and Krogh, 2010).

Rectal irrigation is reported to benefit some patients with faecal incontinence, evacuatory disorders, rectocele and constipation (Gardiner et al, 2004; Crawshaw et al, 2004). It is possibly more effective in patients with passive soiling than those with urge incontinence secondary to loose stool (Briel et al 1997). Koch et al (2008) found rectal irrigation effective in patients with faecal incontinence and constipation with an overall success rate of over 50%.

In long term follow up of 169 patients over 56 months, rectal irrigation was found to be effective in 44% of patients with faecal incontinence and 62% of patients with defaecatory disorders (Gosselink et al, 2004).

Rectal irrigation has also been found to be effective in treatment of patients with anterior resection syndrome, resulting in improved continence scores and QoL (Rosen et al, 2011; Koch et al, 2009).

NICE recommends rectal irrigation as part of its treatment algorithm for faecal incontinence (NICE, 2007). Rectal irrigation will usually only be tried if other less invasive methods of bowel management have failed to adequately control constipation and/or faecal incontinence. Depending on each individual's assessed symptoms and need this will often include dietary measures, adjusting fluid intake, bowel habit, ensuring toilet access, evacuation techniques, medication and pelvic floor muscle training (Norton & Chelvanayagam 2000; NICE 2007). It is recommended that it is considered in these groups of patients before performing surgery (NICE, 2007, Koch et al, 2008) and can also be used as an additional or salvage treatment after colorectal surgical procedures (Koch et al, 2008; Rosen et al, 2011).

Rectal irrigation has been found in a randomised controlled trial to be effective for both constipation and faecal incontinence in people with spinal cord injury (Christensen et al, 2006). In scintigraphic studies anal irrigation has been found to empty stool as far up as the splenic flexure (Christensen et al 2003).

Two recent systematic reviews concluded that rectal irrigation is a simple treatment option for those with neurogenic bowel dysfunction in whom conservative bowel management has failed (Christensen and Krogh, 2010; Emmanuel, 2010). Rectal irrigation is recommended in the hierarchy of interventions for neurogenic bowel management by the Multidisciplinary Association of Spinal Cord Injury professionals (2012), after conservative management has been unsuccessful.

Rectal irrigation has also been used in a variety of other patients with neurogenic bowel dysfunction. Preziosi et al (2011) found that more than 50% of patients with MS had improvements in function and QoL using rectal irrigation. Various studies have found it effective in managing patients with spina bifida and thus avoiding surgery (Eire et al, 1998; Vande Velde et al, 2007).

Long term effects of using rectal irrigation have been studied by Faaborg et al (2010) in patients with functional bowel disorders. They studied patients who had been irrigating for at least 30 months and found that there was no long term deterioration in anal sphincter function or rectal compliance.

Ideally rectal irrigation is taught to the patient as a self management method of their bowel dysfunction. However this is not always possible and sometimes it is necessary for it to be undertaken by relatives or carers. This is particularly the case in patients with neurogenic bowel dysfunction.

### **Selection of type of irrigation system**

There are currently 5 commercially available systems which are designed for patients with different requirements. They are all available on prescription.

The system recommended by the Colorectal CNS must be designed to suit the patient's capabilities and also to manage the symptoms experienced by the patient. Patient or carer preference must also be taken into account.

The Qufora Mini system is suitable for patients who only need a small amount of water to irrigate. The system can be used with one hand. It is useful for patients who need help to start defaecation, or those who experience post-defaecatory leakage.

The Qufora Cone Toilet system is designed for patients who can sit on a toilet or commode. Water is instilled through a cone inserted into the rectum and held in place during the procedure. It allows instillation of a larger quantity of water and is useful for patients with faecal incontinence and constipation.

The Qufora Balloon Catheter system and Coloplast Peristeen are designed to be used by those unable to hold the cone system in place during irrigation. They both have a rectal balloon catheter which holds the catheter in the rectum while the water is instilled. Again they are designed for use over a toilet. They are often used for those with neurogenic bowel dysfunction and may be used by carers.

The Qufora Bed system is a closed irrigation system especially for patients who are unable to sit on a toilet or commode and therefore need their bowel management to be carried out on the bed. The catheter directs the water into the rectum and the return water is collected hygienically in the collection bag. All systems have single use only cones or catheters and are designed to use warm tap water.

## CONSENT

Although formal written consent is not required for minor procedures, verbal consent for the procedure of rectal irrigation must be obtained where possible and this must be documented in the patient's notes. For further information regarding consent and mental capacity please refer to the following documents:

- Department of Health Reference Guide to Consent for Examination or Treatment (2009).
- The Trust's Policy and Procedural document for consent to examination or treatment (current version).
- Mental Capacity Act (2005).

This method of bowel management should be discussed with the patient and carers prior to starting and written information provided so that the patient is able to make an informed choice. All the suitable available systems should be demonstrated and the final choice must take into account the patient or carer's preference.

## INDICATIONS

Patients for consideration of rectal irrigation will be referred by other members of the colorectal team, and also other practitioners eg the Continence Advisor or the Clinical Nurse Specialist for MS.

Patients that are suitable for rectal irrigation are those with:

Neurogenic bowel dysfunction:

- Spinal cord injury
- Spina bifida
- Multiple sclerosis
- Cauda equina

Chronic constipation:

- Outlet obstruction
- Slow transit constipation

Faecal incontinence:

- Urge incontinence

Passive incontinence

Post defaecatory leakage:

Rectocele

Prolapse

Anterior resection syndrome

Post surgical bowel dysfunction

## CONTRAINDICATIONS

Rectal irrigation is contraindicated if:

1. The patient has capacity but does not give consent for rectal irrigation
2. The patient has known obstruction of the large bowel due to strictures or tumours.
3. The patient has acute active inflammatory bowel disease
4. The patient has acute active diverticulitis
5. The patient has complex diverticular disease (ie fistulae and/or abscesses)
6. The patient has had recent abdominal or anal surgery (in the last 3 months)
7. The patient has severe cognitive impairment.
8. The patient has had a recent colonic biopsy (in the last month).

## LIMITATIONS TO PRACTICE

Rectal irrigation should be used with caution and after discussion with the colorectal consultant surgeon in the following groups of patients:

1. Spinal cord injury above T6 (monitor for autonomic dysreflexia) until it is clear that the technique is well tolerated and does not provoke autonomic dysreflexia
2. Unstable metabolic conditions (frail, known renal disease or liver disease: may need to monitor electrolytes).
3. Under 18 years old (consult paediatric consultant and use saline for younger children).

4. An inability to perform the procedure independently or comply with the protocol in the absence of close involvement of carers. (e.g. due to physical disability, cognitive impairment, major mental/emotional disorder).
5. Anorectal conditions that could cause pain or bleeding during the procedure (e.g. third degree haemorrhoids, anal fissure).
6. Pregnant or planning pregnancy (women).
7. Active perianal sepsis.
9. Use of rectal medications for other diseases.
10. Congestive cardiac failure.
11. Long term steroid therapy
12. Altered stool habit together with bleeding per rectum.
13. Had pelvic radiotherapy.
14. Autonomic dysreflexia.

If the Colorectal CNS has concerns about an individual patient and their suitability for rectal irrigation the case must be discussed in the functional bowel MDT meeting which is held monthly.

If the Colorectal CNS is concerned about an individual patient's condition they must refer the patient to the appropriate medical practitioner for advice on any further action to be taken, and this must be recorded in the patient's notes.

## **RISKS**

A systematic review performed by Emmanuel (2010) found that rectal irrigation has a safe overall profile with few and rarer adverse events.

The major risk with rectal irrigation is perforation of the bowel: incidence is less than 1 in 100,000 ( Biering-Sorensen et al, 2009), but this risk is cumulative. The patient must be informed of the risk before agreeing to start irrigation, and instructed in signs and symptoms of perforation (MDA 2011/002, Jan 2011). The risk must be balanced against the risks of other interventions and the benefits to the individual patient.

**If the patient suffers from acute, severe and sustained abdominal pain or back pain and/or heavy rectal bleeding they should seek medical advice immediately.**

If the patient has a spinal injury of T6 or above they are at risk of developing autonomic dysreflexia, although the incidence is less than when using

conventional methods (Christensen and Krogh, 2010). For this reason the first irrigation should be undertaken with someone present – ideally in the clinic with the Colorectal CNS. For patients at risk of autonomic dysreflexia they must have their medication to hand before commencing the procedure (usually Nifedipine capsules).

The minor side effects which may be encountered include the following:

Worsened faecal incontinence due to leakage of irrigation fluid

Minor discomfort or abdominal cramps usually only present until bowel emptying completed

Nausea

Dizziness

Headache

Minor rectal or anal bleeding.

The appropriate Health and Safety risk assessments must have been completed for the clinical area.

## **CRITERIA FOR COMPETENCE**

1. Colorectal CNSs must have undertaken education and training recognised by their line manager in relation to rectal irrigation.
2. Evidence of satisfactory supervised practice must be provided by the Colorectal CNS as witnessed by a practitioner who is already competent in rectal irrigation. (Appendix 1)
3. The number of supervised practices required will reflect the individual Colorectal CNSs learning needs.
4. Evidence of competence must be provided and a copy kept in the Colorectal CNSs personal file and in the ward or department where the skill is practised. (Appendix 2)
5. The Colorectal CNS must provide evidence of competence in the safe handling, use and maintenance of all types of rectal irrigation equipment used.
6. Colorectal CNSs new to the Trust, who have been performing the skill elsewhere, must read and understand this protocol. Evidence of appropriate education and competence must be provided and checked by the CNS for Functional Bowel before undertaking rectal irrigation at the Trust. The decision whether the registered practitioner needs to complete Trust training and competence will be at the discretion of the practitioner's line manager.

7. In accordance with codes of professional practice, the registered practitioner has a responsibility to recognise, and to work within, the limits of their competence. In addition, the registered practitioner has a responsibility to practise within the boundaries of the current evidence based practice and in line with up to date Trust and national policies and procedural documents. Evidence of continuing professional development and maintenance of skill level will be required and confirmed at the registered practitioner's annual appraisal by the registered practitioner's line manager.

A list of practitioners competent to perform this skill must be kept by the line manager.

## CLINICAL INCIDENT REPORTING AND MANAGEMENT

Any untoward incidents and near misses must be dealt with by the appropriate management team. An incident form must be completed and in addition the Risk Management Team must be notified by telephone of any Serious Incidents Requiring Investigation (SIRI).

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## PROTOCOL SUBMISSION DETAILS

Protocol prepared / reviewed\* (\*delete as appropriate) by:

Detail members of the team who developed the protocol (Involve appropriate staff depending upon where the protocol will be practised and by whom; e.g. medical staff, allied health professionals, registered nurses, pharmacist, health and safety advisors)

Name	Title
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Education Package developed/ reviewed by: (if appropriate)

Protocol submitted to and approved by:

(The titles may alter depending on nature of the protocol if it is multidisciplinary or Trust wide)

Executive Chief Nurse	.....
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Date:	.....
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Executive Medical Director	.....
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Date:	.....
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Head of Service/ Associate Director for Allied Health Professionals/Associate Director of Health Care Scientists/Associate Director of Nursing, Division.....

Date:	.....
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Matron/Senior Practitioner	.....
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Date:	.....
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Clinical Service Lead	.....
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Date:	.....
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**UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST**  
**EVIDENCE OF SUPERVISED PRACTICE**

o become a competent practitioner, it is the responsibility of each **practitioner (specify job title/role)** to undertake supervised practice in order to perform **EXPANDED PRACTICE PROTOCOL TITLE** in a safe and skilled manner.

Name of **Practitioner (specify job title/role)**: .....

DATE	DETAILS OF <b>PROCEDURE</b>	SATISFACTORY STANDARD MET	COMMENTS	PRINT NAME, SIGNATURE & DESIGNATION
	<i>If required:</i> Provide example of detail to include when completing this form	Yes / No	<i>If required:</i> Provide example of detail to include when completing this form	
		Yes / No		
		Yes / No		
		Yes / No		
		Yes / No		
		Yes / No		

		Yes / No		
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**UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST**  
**CRITERIA FOR COMPETENCE**

**ND COMPETENCE: EXPANDED PRACTICE PROTOCOL TITLE**

ate(s) of Education and supervised practice: .....

ame of **Practitioner** (print): ..... (specify job title/role) Clinical Area / Department: .....

ame of Supervisor (print): .....

Element of Competence To Be Achieved	Date Achieved	<b>Practitioner Sign</b> (specify job title/role)	Supervisor Sign
Discuss and identify · indications, · contraindications · limitations or rectal irrigation according to these guidelines.			
Provide evidence of competence in rectal irrigation			
Demonstrate understanding of different systems and their use			
Demonstrate competence in selection of the most appropriate device with the patient			
Discuss accountability in relation to the NMC Code: Standards of conduct, performance and ethics for nurses and midwives (2008).			
Demonstrate maintenance of the patient's privacy and dignity throughout the procedure.			
Demonstrate a working knowledge of the Trust's policy for consent to examination or treatment.			

Element of Competence To Be Achieved	Date Achieved	<b>Practitioner Sign</b>	Supervisor Sign
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		(specify job title/role)	
Demonstrate a working knowledge of the <i>Mental Capacity Act</i> .			
Demonstrate accurate provision of information pre and post procedure in a way that the patient understands.			
Demonstrate involvement of the patient in decision making about their care and treatment.			
Demonstrate application of the Trust Principles for carers.			
Demonstrate competence in teaching use of the appropriate rectal irrigation system, and assessment of patient understanding and technique.			
Demonstrate the safe use of rectal irrigation system in accordance with manufacturers instructions for use (see Appendix) Qufora mini Qufora toilet system Qufora Balloon system Coloplast Peristeen Qufora bed system			
Demonstrate safe infection control practices throughout the procedure. To include: <ul style="list-style-type: none"> <li>Standard precautions</li> <li>Aseptic non touch technique (where applicable)</li> </ul>			
Demonstrate accurate record keeping.			
Discuss any health and safety issues in relation to this expanded practice			
Demonstrate an understanding of the incident reporting process.			

I declare that I have expanded my knowledge and skills and undertake to practice with accountability for my decisions and actions.  
I have read and understood the protocol for **EXPANDED PRACTICE PROTOCOL TITLE**

**Signature of Practitioner:** ..... **Print name:**.....  
(specify job title/role)

ate: .....

declare that I have supervised this practitioner (please specify job title/role) and found her/him to be competent as judged by the above criteria.

Signature of Supervisor: ..... Print name:.....

ate: .....

A copy of this record should be placed in the practitioner's (specify job title/role) personal file, a copy must be stored in the clinical area by the line manager, and a copy can be retained by the individual for their Professional Portfolio.



# Procedure for Teaching Rectal Irrigation

## EQUIPMENT

Irrigation kit  
Single use catheter or cone  
1000 mls tepid tap water  
Single use disposable non sterile gloves  
Single use disposable apron  
Water soluble lubricating gel  
Tissues/wipes  
Waste bag  
Access to toilet/commode  
Hand washing facilities

## PROCEDURE ACTION

Verbally confirm the identity of the patient by asking for their full name and date of birth. If client unable to confirm, check identity with family/carer  
Introduce yourself as a staff member and any colleagues involved at the contact  
Ensure verbal consent for the presence of any other third party is obtained  
Explain procedure to patient including risks and benefits and gain valid consent.  
Establish that the patient has no known allergies, check in patients health records and also ask patient/family of known allergies  
Obtain valid consent and document in patients health records  
Follow Trust Consent Policy if unable to gain consent, to demonstrate treatment is in patients best interests  
Clarify if the patient requires a formal chaperone

Ask the patient if they wish to use the toilet prior to undertaking the procedure.

Prepare the environment i.e. commode, toilet

Decontaminate hands prior to procedure

Apply single use disposable apron

Apply single use disposable non-sterile gloves

Clean the skin as required (when visibly soiled)  
Instruct patient in use of specific device as per IFU (see appendix)

## RATIONALE

To avoid mistaken identity

To promote mutual respect and put client at their ease

Students for example, as the client has the choice to refuse

To ensure client understands procedure and relevant risks

To reduce risk of allergic reactions

To gain co-operation and patients agreement to care

Needs to be in discussion with other members of the team, carers, G.P and in spinal cord injured patients, their spinal injury centre

It is the patient's choice to have a chaperone if wanted. Discuss with line manger if nurse considers a chaperone is needed as part of risk assessment

For comfort of the patient

To facilitate easy access for defecation ensuring privacy and dignity

To reduce the risk of transfer of transient micro-organisms on the healthcare workers hands

To protect clothing or uniform from contamination and potential transfer of micro-organisms

To protect hands from contamination with organic matter and transfer of micro-organisms

To prevent skin excoriation and promote comfort

Ensure that device used as per manufacturers instructions

Water and stool should start to pass into the toilet very soon after the cone/catheter is removed. Advise the patient to AVOID THE TEMPTATION TO STRAIN. It can take 10 – 20 minutes for the bowel to stop emptying.

Clean and dry the anal area.

Dispose of single use catheter or cone

Empty any remaining water from the bag and tubing

On completion of procedure remove and dispose of PPE to comply with waste management policy

Decontaminate hands following removal of Personal Protective Equipment

Clean reusable equipment (if required) in line with Trust policy and manufacturers instructions.

Record information in patients health records, this should include:- • Valid consent • If a chaperone was required • Reason for rectal Irrigation procedure • Date and time • Review date to assess the need for next procedure • Report any comments/ concerns made by the patient

Demonstrates procedure has been successful

Avoids complications post procedure

To prevent skin excoriation and promote comfort

To prevent cross infection and environmental

To allow transport home

To prevent cross infection and environmental contamination

To remove any accumulation of transient and resident skin flora that may have built up under gloves and possible contamination following removal of PPE

Decontamination of medical equipment is essential for the effective delivery of patient care.

To record patient care given, provide seamless care and comply with health records policy

# Instructions for use



## Qufora Rectal Irrigation System

Using the Qufora Irrigation System makes it possible to perform rectal irrigation.  
Please read both pages of this instruction before using the Qufora Irrigation System.

### Application

The Qufora Irrigation System is used to prevent chronic faecal incontinence and/or constipation or for those who spend a long time on bowel management. It should be used regularly - usually daily or every other day to provide the best effect.

### Before starting rectal irrigation

Use irrigation only after assessment and approval by a doctor or a qualified healthcare professional. You should be supervised by a qualified health care professional the first time you irrigate.

### Indications for using rectal irrigation

Individuals with the following conditions and symptoms may benefit:

- Neurogenic bowel dysfunction, e.g. spinal cord injury, spinabifida and multiple sclerosis.
- Chronic constipation.
- Chronic faecal incontinence.

Within these groups some individuals may require support of a carer to perform the procedure.

### Use rectal irrigation only after careful discussion with relevant medical practitioner under the following circumstances (relative contraindications):

- Pregnancy
- Children under 3 years of age, considering the size and shape of the device delivering the water. For children the approval should be from a qualified medical practitioner specialised in paediatric care.
- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).
- Active perianal sepsis (fistula or abscess).
- Rectal or colonic surgical anastomosis within the past 6 months.
- Diarrhoea of unknown aetiology.
- Faecal impaction/ rectal constipation.
- Past pelvic radiotherapy.
- Known diverticular disease.
- Long term steroid therapy.
- Anticoagulant therapy.
- Low blood sodium.
- Pelvic malignancy.
- Colonic biopsy within the past 3 months.
- Use of rectal medications for other diseases which may be diluted by irrigation.
- Congestive cardiac failure.

- Anal surgery within the past 6 months.

### Irrigation should not be used under the following circumstances (absolute contraindications):

- Acute active inflammatory bowel disease.
- Known obstructing rectal or colonic mass stricture or tumour.
- Diverticulitis or complex diverticular disease (diverticular abscess or rupture).
- Anal surgery within the past 3 weeks or haemorrhoid banding within the past 6 weeks.

### Warning

Perforation of the bowel wall is extremely rare. However it is a serious and potentially lethal complication of rectal irrigation. Should this occur, immediate medical attention is required.

### Seek medical attention if the following is experienced after rectal irrigation:

- Sustained and severe bleeding from the rectum.
- Sustained and severe abdominal or back pain along with a fever.

If the single use items of the product are reused, there is a risk of unwanted effects that can influence the function of the product and the health of the patient, the caregivers and third persons.

The 'PHT' symbol indicates that the product contains phthalates. This should be considered especially when used for children and pregnant or breast feeding women.

### Please observe

Rectal irrigation can be associated with passing sensations of bowel discomfort, nausea, shivering, fatigue, sweating, headache and light bleeding from the rectum.

By following the recommended water volumes and water temperatures the bowel electrolyte balance is unlikely to be affected.

### Recommended usage time and cleaning

**Water bag/pump/tubes:** Rinse in clean water and the wash the outside with mild hand soap.

**Water bag:** remove the lid, empty the

bag, open the valve on the tube and hang the parts to dry.

**Water bag/pump/tubes:** can be used up to 1 month or until discoloration occurs.

Cones, catheters and collection bags are single use item.

### Liability

MBH-International A/S accepts no liability for any injury or other loss that may arise if this product is used in any way contrary to the recommendations of MBH-International A/S.

### Handling and storage

Qufora Irrigation System should be stored at temperatures between 0 and 25° C. Protect the product from direct sunlight and do not expose to heavy pressure.

The product should be kept out of reach of children.

Further information about this product can be found on [www.mbh-international.com](http://www.mbh-international.com).

Please read both pages

## Qufora Rectal Irrigation Mini System

### How to use the mini system.

#### The system comprises:

- A soft rectal cone.
- A hand pump that connects to the cone. The hand pump can contain 90 ml. of water.

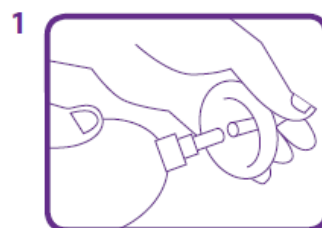
**Note:** The hand pump has a set of one way valves so water can only enter the pump from the bottom and flow out from the top where the clear connector is.

Use irrigation only after assessment and approval by a qualified health care professional.

#### To use the system, follow the instructions:

- 1 Assemble mini system is by pushing the cone and the hand pump together (**fig.1**).
- 2 Fill clean water (36 – 38 °C) into a clean bowel or open container.
- 3 Lubricate the tip of the cone with a water based lubricant.
- 4 The hand pump is filled with water by compressing the pump, submerging the free end of the pump in the warm water and releasing the pump to draw the water into the pump (**fig. 2**).
- 5 Hold the pump vertical with the cone pointing upwards to avoid water running out from the cone.
- 6 To fill the pump cavity completely, carefully compress the pump again until water seeps from the cone tip and release the pump with the free end in water. The mini system is now ready for use.
- 7 Seated on the toilet, carefully guide the cone into the rectum (**fig. 3**). While the cone is held in place gently compress the pump to pressure the water into the rectum.
- 8 Compress the pump as much as possible to utilise as much water as possible.
- 9 Withdraw the pump. Because of the one-way valve there is no reflux of soiled water into the pump. Faecal matter and water will flush into the toilet (**fig 4**).
- 10 The procedure can be repeated by repeating step 4 – 9.
- 11 Pull cone and pump apart, wipe clean the pump with mild soap (**fig. 5**). Dispose of cone by putting it into a disposal bag before putting it in the household waste. Do not flush into the toilet. Wash your hands to complete the procedure.

To gain faecal continence or to resolve constipation, irrigation should be used routinely on a daily or bi-daily basis.



Learn more at [mbh-international.com](http://mbh-international.com)

#### Manufacturer

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IFYmini UK 013013 01

# Instructions for use



## Qufora Rectal Irrigation System

Using the Qufora Irrigation System makes it possible to perform rectal irrigation.  
Please read both pages of this instruction before using the Qufora Irrigation System.

### Application

The Qufora Irrigation System is used to prevent chronic faecal incontinence and/or constipation or for those who spend a long time on bowel management. It should be used regularly - usually daily or every other day to provide the best effect.

### Before starting rectal irrigation

Use irrigation only after assessment and approval by a doctor or a qualified healthcare professional. You should be supervised by a qualified health care professional the first time you irrigate.

### Indications for using rectal irrigation

Individuals with the following conditions and symptoms may benefit:

- Neurogenic bowel dysfunction, e.g. spinal cord injury, spinobifida and multiple sclerosis.
- Chronic constipation.
- Chronic faecal incontinence.

Within these groups some individuals may require support of a carer to perform the procedure.

### Use rectal irrigation only after careful discussion with relevant medical practitioner under the following circumstances (relative contraindications):

- Pregnancy
- Children under 3 years of age, considering the size and shape of the device delivering the water. For children the approval should be from a qualified medical practitioner specialised in paediatric care.
- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).
- Active perianal sepsis (fistula or abscess).
- Rectal or colonic surgical anastomosis within the past 6 months.
- Diarrhoea of unknown aetiology.
- Faecal impaction/ rectal constipation.
- Past pelvic radiotherapy.
- Known diverticular disease.
- Long term steroid therapy.
- Anticoagulant therapy.
- Low blood sodium.
- Pelvic malignancy.
- Colonic biopsy within the past 3 months.
- Use of rectal medications for other diseases which may be diluted by irrigation.
- Congestive cardiac failure.

- Anal surgery within the past 6 months.

### Irrigation should not be used under the following circumstances (absolute contraindications):

- Acute active inflammatory bowel disease.
- Known obstructing rectal or colonic mass stricture or tumour.
- Diverticulitis or complex diverticular disease (diverticular abscess or rupture).
- Anal surgery within the past 3 weeks or haemorrhoid banding within the past 6 weeks.

### Warning

Perforation of the bowel wall is extremely rare. However it is a serious and potentially lethal complication of rectal irrigation. Should this occur, immediate medical attention is required.

### Seek medical attention if the following is experienced after rectal irrigation:

- Sustained and severe bleeding from the rectum.
- Sustained and severe abdominal or back pain along with a fever.

If the single use items of the product are reused, there is a risk of unwanted effects that can influence the function of the product and the health of the patient, the caregivers and third persons.

The 'PHT' symbol indicates that the product contains phthalates. This should be considered, especially when used for children and pregnant or breast feeding women.

### Please observe

Rectal irrigation can be associated with passing sensations of bowel discomfort, nausea, shivering, fatigue, sweating, headache and light bleeding from the rectum.

By following the recommended water volumes and water temperatures the bowel electrolyte balance is unlikely to be affected.

### Recommended usage time and cleaning

**Water bag/pump/tubes:** Rinse in clean water and wash the outside with mild hand soap.

**Water bag:** remove the lid, empty the bag, open the valve on the tube and hang the parts to dry.

**Water bag/pump/tubes:** can be used up to 1 month or until discoloration occurs.

Cones, catheters and collection bags are single use item.

### Liability

MBH-International A/S accepts no liability for any injury or other loss that may arise if this product is used in any way contrary to the recommendations of MBH-International A/S.

### Handling and storage

Qufora Irrigation System should be stored at temperatures between 0 and 25° C. Protect the product from direct sunlight and do not expose to heavy pressure.

The product should be kept out of reach of children.

Further information about this product can be found on [www.mbh-international.com](http://www.mbh-international.com).

Please read both pages



## Qufora Rectal Irrigation Cone System

### How to use the cone system

#### The system comprises:

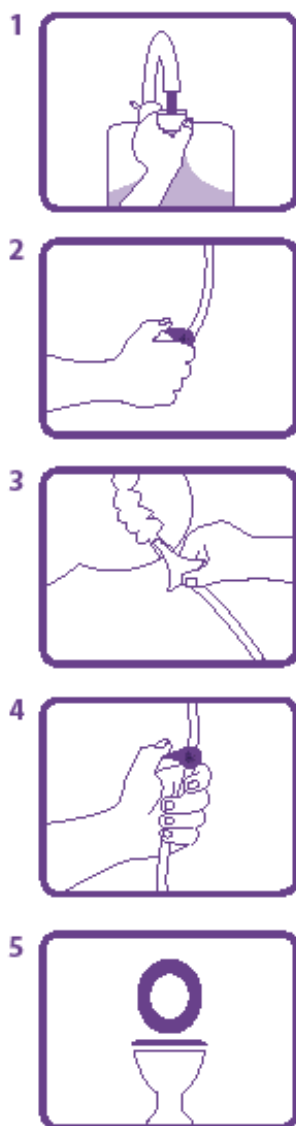
- A water bag that holds 2.5 litres of water fitted with a valve and a pump.
- A soft cone with tube and connector.

Use Irrigation only after examination and approval by a doctor or a qualified healthcare professional.

#### To use the system please follow the instructions:

- 1 Fill the water bag with warm tap water (36°C - 38°C) (fig.1). Hang the water bag no higher than 50 cm above the level of the toilet seat. The length of the tube from the water bag to the valve is 50 cm. Connect the water bag tube to the cone.
- 2 Lubricate the tip of the cone with a water based lubricant. Open the valve (fig. 2) to fill the tube and pump with water and close it again.
- 3 Seated over the toilet, carefully guide the cone into the rectum (fig. 3).
- 4 With the cone held in position with one hand, open the valve. Start by opening the valve about half way (fig. 4). If the water bag is placed lower than the toilet seat, open the valve completely and pump the water into the rectum.
- 5 Allow approximately 300 – 500 ml. (less for children as specified by your healthcare professional) of water to enter the rectum and close the valve. The amount of water can be monitored on the water bag scale. Use max. 1000 ml. per irrigation. If any discomfort is felt, close the valve immediately.
- 6 Close the valve and remove the cone. Water and faecal matter will flush into the toilet (fig 5).
- 7 If necessary the procedure can be repeated by repeating step 3 to 6.
- 8 Pull the cone and tube apart, clean the pump with mild soap. Dispose of cone by placing it into a disposal bag before putting it in the household waste. Do not flush down the toilet. Wash your hands to complete the procedure.

To gain faecal continence or to resolve constipation, irrigation should be used routinely on a daily or bi-daily basis.



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Fig. cone UK 013073.01



# Instructions for use

## Qufora Rectal Irrigation System

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### Application

The Qufora Irrigation System is used to prevent chronic faecal incontinence and/or constipation or for those who spend a long time on bowel management. It should be used regularly - usually daily or every other day to provide the best effect.

### Before starting rectal irrigation

Use irrigation only after assessment and approval by a doctor or a qualified healthcare professional. You should be supervised by a qualified health care professional the first time you irrigate.

### Indications for using rectal irrigation

Individuals with the following conditions and symptoms may benefit:

- Neurogenic bowel dysfunction, e.g. spinal cord injury, spinabifida and multiple sclerosis.
- Chronic constipation.
- Chronic faecal incontinence.

Within these groups some individuals may require support of a carer to perform the procedure.

### Use rectal irrigation only after careful discussion with relevant medical practitioner under the following circumstances (relative contraindications):

- Pregnancy.
- Children under 3 years of age, considering the size and shape of the device delivering the water. For children the approval should be from a qualified medical practitioner specialised in paediatric care.
- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).
- Active perianal sepsis (fistula or abscess).
- Rectal or colonic surgical anastomosis within the past 6 months.
- Diarrhoea of unknown aetiology.
- Faecal impaction/ rectal constipation.
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- Long term steroid therapy.
- Anticoagulant therapy.
- Low blood sodium.
- Pelvic malignancy.
- Colonic biopsy within the past 3 months.
- Use of rectal medications for other diseases which may be diluted by irrigation.

- Congestive cardiac failure.
- Anal surgery within the past 6 months.

### Irrigation should not be used under the following circumstances (absolute contraindications):

- Acute active inflammatory bowel disease.
- Known obstructing rectal or colonic mass stricture or tumour.
- Diverticulitis or complex diverticular disease (diverticular abscess or rupture).
- Anal surgery within the past 3 weeks or haemorrhoid banding within the past 6 weeks.

### Warning

Perforation of the bowel wall is extremely rare. However it is a serious and potentially lethal complication of rectal irrigation. Should this occur, immediate medical attention is required.

### Seek medical attention if the following is experienced after rectal irrigation:

- Sustained and severe bleeding from the rectum.
- Sustained and severe abdominal or back pain along with a fever.

If the single use items of the product are reused, there is a risk of unwanted effects that can influence the function of the product and the health of the patient, the caregivers and third persons.

The "PHT" symbol indicates that the product contains phthalates. This should be considered especially when used for children and pregnant or breast feeding women.

### Please observe

Rectal irrigation can be associated with passing sensations of bowel discomfort, nausea, shivering, fatigue, sweating, headache and light bleeding from the rectum.

By following the recommended water volumes and water temperatures the bowel electrolyte balance is unlikely to be affected.

### Recommended usage time and cleaning

**Water bag/pump/tubes:** Rinse in clean water and wash the outside with mild hand soap.

**Water bag:** remove the lid, empty the bag, open the valve on the tube and hang the parts to dry.

**Water bag/pump/tubes:** can be used up to 1 month or until discoloration occurs.

Cones, catheters and collection bags are single use item.

### Liability

MBH-International A/S accepts no liability for any injury or other loss that may arise if this product is used in any way contrary to the recommendations of MBH-International A/S.

### Handling and storage

Qufora Irrigation System should be stored at temperatures between 0 and 25° C. Protect the product from direct sunlight and do not expose to heavy pressure.

The product should be kept out of reach of children.

Further information about this product can be found on [www.mbh-international.com](http://www.mbh-international.com).

Please read both pages

## Qufora Rectal Irrigation Balloon System

### How to use the balloon system

#### The system comprises:

- A water bag that holds 2.5 litres with a tube fitted with a valve.
- A pump and control unit.
- A Velcro strap.
- A double lumen tube.
- A rectal catheter with a silicone balloon.

#### The numbers on the control unit indicate the following functions:

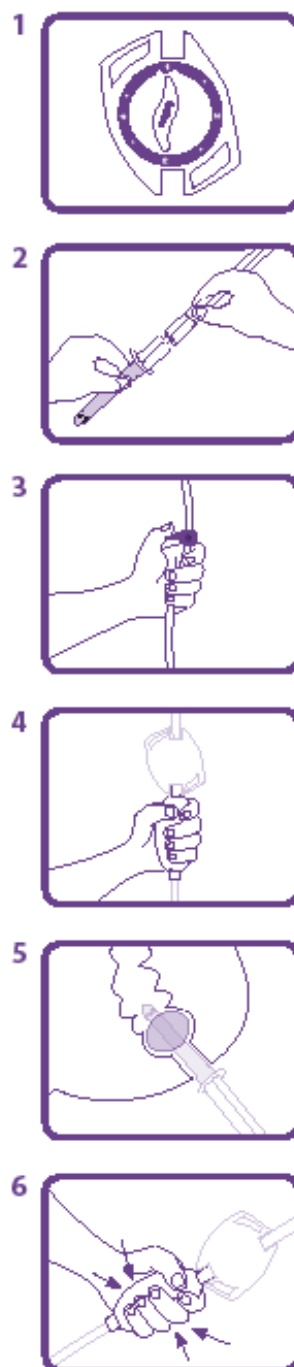
- Position 1** - Fills the tubes with water/dries the system after use.  
**Position 2** - Fills the balloon with water to retain the balloon in the rectum.  
**Position 3** - Water runs through the catheter into the rectum.  
**Position 4** - Water evacuates the balloon to allow the catheter to be extracted.  
Between the numbered positions, 4 "stop positions" are indicated by white dots.

Use Irrigation only after assessment and approval by a qualified health care professional.

#### To use the system, please follow the instructions:

- 1 Before use have single use gloves and lubricant within reach. Fill the water bag with warm tap water (36 – 38 °C) and fit the lid. Place the water bag no higher than 50 cm above the toilet seat. The length of the tube from water bag to the valve is 50 cm.
- 2 Push the catheter onto one end for the double lumen tube (Fig. 2) and fit the other end of the tube to the control unit. Turn the control unit to position 1.
- 3 Hold the catheter pointing downwards and the pump vertical and open the valve (Fig. 3). Compress the pump slowly to fill the pump and tubes with water (Fig. 4). Water will run through the catheter. Turn the control unit to position 2, ready to fill the balloon.
- 4 Apply lubricant to the catheter tip and, seated on the toilet, carefully insert the catheter into the rectum (Fig. 5). Use the Velcro strap to fixate the control unit to the thigh.
- 5 The balloon is filled by compressing the pump completely. If the catheter needs to be further secured, compress the pump again.
- 6 Turn the control unit to position 3. Water can now be pumped into the rectum (Fig. 6). Allow approximately 300 to 500 ml (less for children as specified by healthcare professional) to enter the rectum and set the control unit between position 3 and 4. The amount of water can be monitored on the bag scale. Use max. 1000 ml. per irrigation. If any discomfort is felt, do not fill more water into the bowel.
- 7 When the water has been instilled in the bowel, turn the control unit to position 4. The water from the balloon will flow into the rectum and the catheter can be extracted.
- 8 Water and faecal matter will flush into the toilet.
- 9 The procedure can be repeated by repeating step 5 – 8.
- 10 After irrigation wash the outside of the water bag, the control unit and double lumen tube with mild soap. Empty the water bag and hang the double lumen tube and control unit individually to dry with the control unit in position 1 and the lid off the water bag.
- 11 Do not re-use the balloon catheter. It should be disposed of by putting it into a disposal bag before putting it in the household waste. Do not flush down the toilet. Wash your hands to complete the procedure.

To gain faecal continence or to resolve constipation, irrigation should be used routinely on a daily or bi-daily basis.



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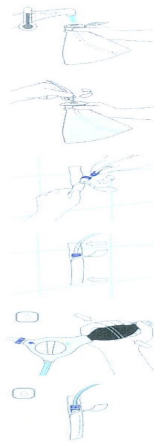
QY balloon UK 013013.01



# Peristeen Irrigation

## Preparation



Anal irrigation is most commonly carried out while sitting on the toilet.



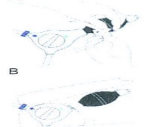
1. Open the lid and fill the bag to the top with lukewarm water (36-38 °C). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.  
**Note:** Use clean tap water. If you do not have access to clean tap water, then we recommend using bottled water. Do not add any additives to the water.
2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it 90° clockwise.

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

4. Fix the catheter packaging to a vertical surface by using the adhesive dots.

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

**Tip:** For extra stability when pumping, you can attach the control unit to the thigh by using the strap:  
Attach the control unit and tubing to the thigh by using the strap:




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

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

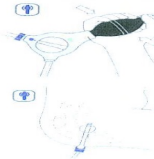
## Insertion of rectal catheter



6. Ensure the knob on the control unit is pointing to the balloon symbol . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force.

When inserting the catheter, hold it by the finger grip and insert it as far as the finger grip will allow (up to the blue line). The finger grip is the widest part of the catheter.



## Inflation of balloon



7. Start pumping gently to inflate the balloon. Your health care professional shall advise you how many times to pump. A few pumps are usually enough.

Gently pull the catheter back to seal off the rectum.

**Note:** Do not overinflate the balloon. The balloon on the small catheter must not be pumped more than twice. The balloon on the regular catheter must not be pumped more than five times.

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

#### Insertion of water



#### Removal of rectal catheter






#### Emptying





#### Conclusion



8. Turn the knob on the control unit anti-clockwise to the water symbol . Pump the water slowly into the bowel at a rate of one pump per second until the required amount of water is reached. Through training with your health care professional, it will become evident how much water to use.

If water leaks, try inflating the balloon further by turning the knob on the control unit clockwise to the balloon symbol  and pump one more time. Turn the knob anti-clockwise to the water symbol  and resume irrigation.

In case of discomfort, turn the knob of the control unit to the balloon symbol  to stop the water flow and wait until it ceases. When you are ready, turn the knob back to the water symbol  and resume pumping. If the discomfort continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

9. Turn the knob on the control unit anti-clockwise to the air symbol  to deflate the balloon. Often the catheter will slide out by itself; if not, pull the catheter gently.


Note: Do not remove the catheter before the balloon is completely deflated.

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

10. Soon the colon will start to empty itself. If nothing happens, try to press, cough or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.

11. Unlock the connectors from the lid and the catheter. Discard the single use catheter.

Pour excess water out of the bag.

When storing the system, turn the knob on the control unit anti-clockwise to the finish symbol . When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the toilet bag and that the system and all its parts are kept away from sharp objects.