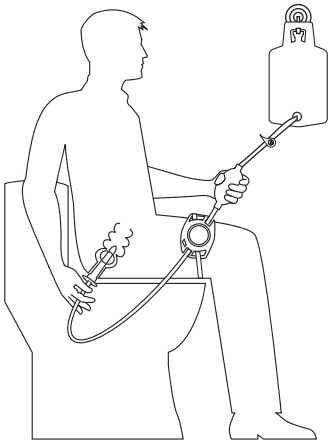


Qufora® IrriSedo Klick Instructions for Use



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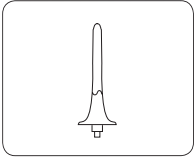


Qufora A/S
Gydevang 28-30
DK-3450 Allerød
Denmark

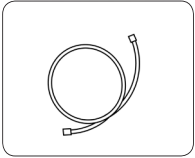
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Explaining the system

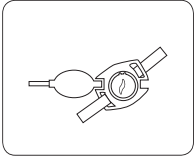
System components



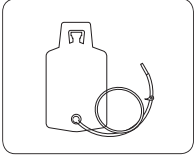
Rectal catheter with a hydrophilic coating and a water inflated balloon
- the catheter is single use



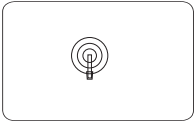
Click tube
- can be used 15 times



Pump and control unit with fixation strap
- can be used 90 times

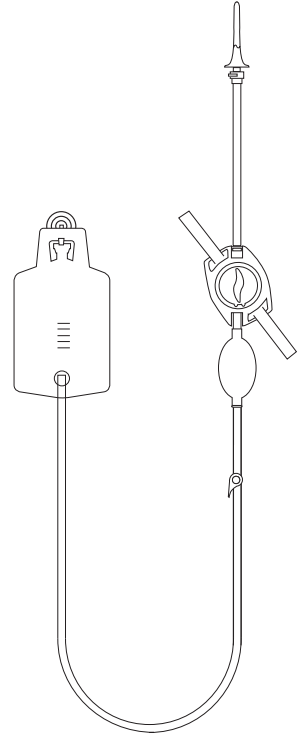


Water bag - 1500 ml with a tube and a valve
- can be used 15 times








Hook
to hang the water bag on
- can only be used on a clean and smooth surface

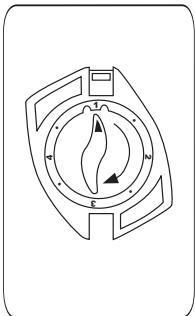
System when assembled



The control unit

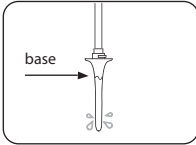
The system works by turning the control unit step by step in a 1-2-3-4 clockwise position.

- Position:**
-  Use pump to prepare the system. Fill up tubes, pump and catheter with water, this empties the systems of air
 -  When the catheter is in the rectum, use the pump to inflate the balloon and create a water tight seal
 -  Use pump or gravity to instill water into the rectum
 -  The balloon will deflate and the catheter can be removed from the rectum
 -  Turning the pointer to a **dot** will pause the system and stop the flow of water.

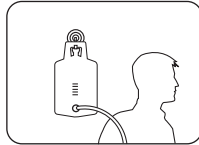


3 Using the system

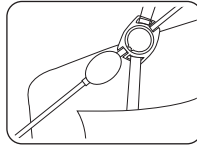
11. Wet the catheter up to its base with tap water. It is now lubricated and ready to use.
12. Hang or place the water bag no higher than shoulder height relative to your sitting position. You may use the supplied hook to hang the water bag on the wall. Now you are able to instill water by using gravity or pump.
13. Sit on or over the toilet. If required, fasten the control unit to your thigh or wheelchair, using the velcro straps.
14. Carefully insert the catheter into the rectum, supporting the catheter at its base.



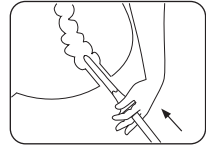
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12

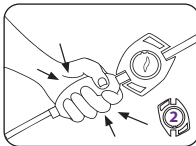


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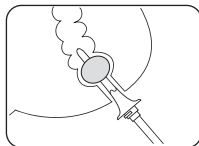


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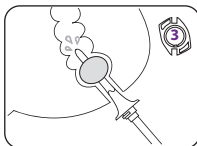
15. Turn the control unit clockwise to position 2. Squeeze the pump once or twice (maximum of four complete pumps) to inflate the balloon with water (15a) until the catheter holds in the bowel by itself (15b). Your healthcare professional will advise you on this.
16. Turn the control unit clockwise to position 3. Water can now be instilled into the bowel or you can let the water flow into the bowel using gravity. If you need to stop the flow turn the control unit to the dot between 3 and 4. To resume irrigation, turn the control unit back to position 3.
17. The amount of water flowing into the bowel can be monitored by using the scale on the water bag. Your healthcare professional will advise you on how much water to use, on average 300-500 ml (less for children). Do not use more than 1000 ml unless your healthcare professional indicates this. If you feel any discomfort, do not instill more water into the bowel. Stop the flow by turning the control unit to the dot between 3 and 4.



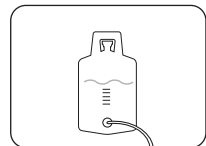
15a



15b

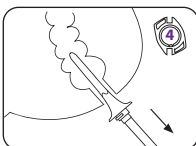


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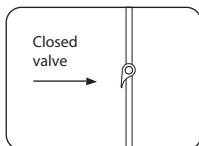


17

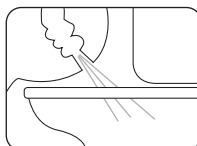
18. When you have instilled the required amount of water into the bowel, turn the control unit clockwise to position 4. The balloon will now deflate and the catheter can be carefully removed from the rectum.
19. Close the valve on the water bag tube (lever is parallel to the tube).
20. Water and faecal matter will now be expelled. If this does not happen immediately, try coughing or leaning forward.
21. Click the used catheter into the grey pouch by pressing the purple button. Hold the tube upwards to prevent water spillage. The pouch can be folded and sealed using the sticky area, then disposed of in household waste.



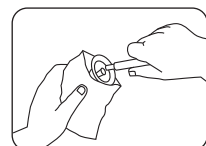
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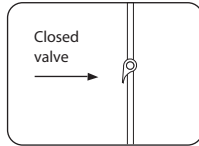
Instructions for use

1 Preparing the system for use

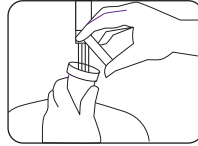
1. Wash and dry your hands.
2. Before you start, make sure the valve on the water bag tube is closed - lever is parallel to the tube.
3. Open the lid on the water bag and fill the water bag with the amount of luke warm tap water advised by your healthcare professional. Please note you need an extra 300 ml for preparing your system. Close the lid on the water bag.
4. Connect the water bag tube to the pump.
5. Connect the click tube to the control unit - when you hear a click it is connected.



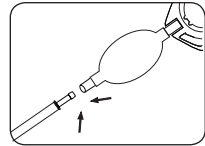
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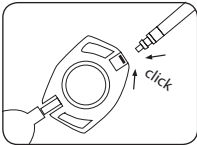
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3



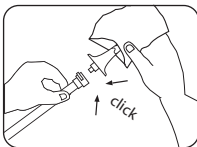
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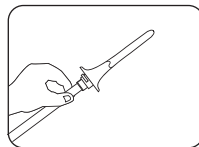
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2 Filling the system with water

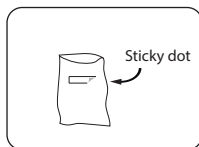
6. Open the grey catheter pouch and connect the catheter to the click tube while leaving the catheter in the pouch - when you hear a click it is connected (6a). Take the catheter out without touching the hydrophillic coating (6b).
7. Attach the catheter pouch to a surface somewhere near the toilet, using the sticky dot.
8. Turn the control unit to position 1.
9. Hold the pump with the control unit pointing upwards (9a) and open the valve on the water bag tube (9b). Squeeze until the pump is full of water so that no air is left and water comes out of the catheter (9c).
10. Pause the system by turning the control unit to the dot position between 1 and 2.



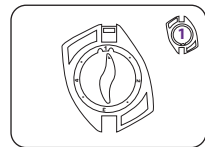
6a



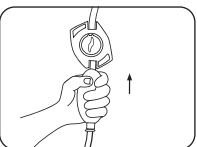
6b



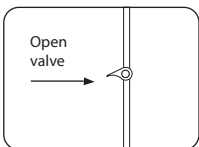
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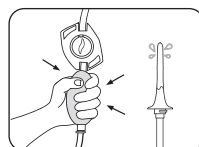
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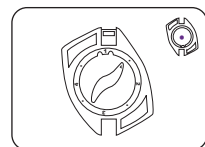
9a



9b



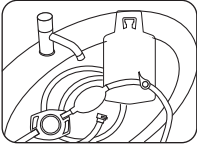
9c



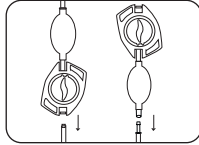
10

4 Emptying and disassembling the system

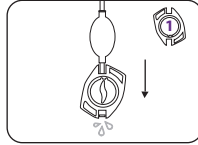
22. Place the system in the sink for emptying, separating and cleaning.
23. Separate the parts by clicking and pulling the connectors apart.
24. Empty the system from water. To empty the control unit and the pump turn the control unit to position 1 and let the water run out through the control unit (24a). To empty the water bag open the valve on the water bag open the valve on the water bag and let the water run through the tube (24b).



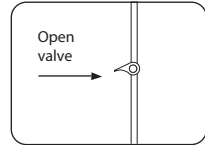
22



23



24a



24b

5 Cleaning and storing after use

25. Clean the outside of the click tube, the water bag and tube with mild soap and water.
26. Hang the system to dry with the water bag lid and the valve on the water bag tube open and leave the control unit in position 1.
27. Wash and dry your hands.
28. Store the product out of direct sunlight in a dry and ventilated place between 0 and 30 C.

Read before use

Qufora® IrriSedo Klick

Using Qufora® IrriSedo Klick makes it possible to perform rectal irrigation. Please read all pages of this instruction before using Qufora® IrriSedo Klick.

Application

Qufora® IrriSedo Klick is intended for adults and children 3 years and above to prevent chronic faecal incontinence and/or constipation. It should be used regularly - usually daily or every other day for the best effect.

Before starting rectal irrigation

Use only after assessment, approval and full instruction by a healthcare professional who is specialised in this procedure. A digital rectal examination is mandatory prior to your first irrigation. You should be supervised by an experienced healthcare professional during your first irrigation.

Indications for using rectal irrigation

Individuals with the following conditions and symptoms may benefit:

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

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

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

- Known anal or colorectal stenosis.
- Colorectal cancer/pelvic malignancy pre surgical removal.
- Acute inflammatory bowel disease.
- Acute diverticulitis.
- Within 3 months of anal or colorectal surgery.
- Within 4 weeks of endoscopic polypectomy.
- Ischaemic colitis.

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

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

- Pregnancy or planned pregnancy or breast feeding.
- Children under 3 years of age.
- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).
- Active perianal sepsis (fistula or abscess, third or fourth degree haemorrhoids).
- Previous rectal or colonic surgery within the past 6 months.
- Diarrhoea of unknown aetiology.
- Faecal impaction/rectal constipation.
- Severe autonomic dysreflexia.
- Severe diverticulosis or diverticular abscess.
- Abdominal or pelvic irradiation.
- Known diverticular disease.
- Long term steroid therapy.
- Anti-coagulant therapy.
- Low blood sodium.
- Previous severe pelvic surgery.
- Colonic biopsy within the past 3 months.
- Use of rectal medications for other diseases which may be diluted by irrigation.
- Congestive cardiac failure.

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 during or after rectal irrigation:

- Bleeding from the rectum.
- Abdominal or back pain, with or without fever.

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 using the water temperature and volumes, recommended by the doctor or healthcare professional, the bowel electrolyte balance is unlikely to be affected.

Recommended usage time (when used routinely every or every other day)

The water bag and the click tube can be used up to 15 times. The pump and control unit can be used up to 90 times.

Should discolouration develop on any part of the system within the recommended usage time, the part should be replaced.

The balloon catheters are single use items.

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 carers and third persons.

Liability

Qufora 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 Qufora A/S.

Handling and storage

Qufora® IrriSedo Klick should be stored at temperatures between 0° C and 30° 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.qufora.com.