

Instructions for use



Qufora® IrriSedo Flow



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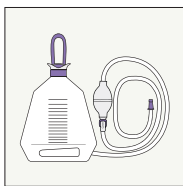
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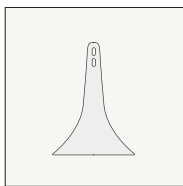
Explaining the Qufora IrriSedo Flow components

Water bag with pump and flow regulator



A water bag with a pump and integrated water flow regulator. The water bag holds up to 1500 ml of water.

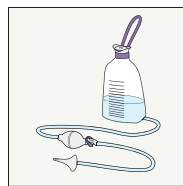
Flow cone



A flow cone with a hydrophilic coating that is activated with water.

The flow cone is single-use

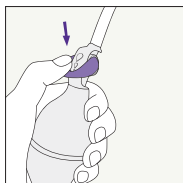
Assembled



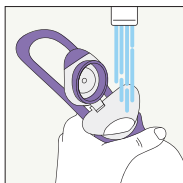
System including water

Filling Qufora IrriSedo Flow with water

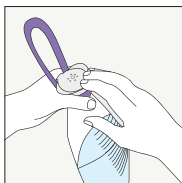
1. Wash and dry your hands.
2. Make sure the water flow regulator is closed (2a).
Hold onto the neck of the water bag and fill the water bag with luke warm tap water (36-38° C) by holding it under the tap with the lid open (you will need more water than you need for your irrigation to prepare your system, approximately 100-300 ml water) (2b).
3. Once the water bag is filled with the required amount of water, continue to hold onto the neck of the water bag and press down on the lid until it is closed.
4. The water bag can be placed anywhere between floor and shoulder height. 4a) It can be placed on the floor or, 4b) hanging by the handle.
5. Open the cone pouch at the perforated line. Whilst the cone is still in the pouch press the cone firmly onto the tube connector to assemble your system.
6. Attach the empty pouch to a surface using the sticky area on the back of the pouch.
7. To prepare the system with water when hanging, hold the pump so the water flow regulator is at the top. Now open the water flow regulator. When placing the water bag on the floor, follow as above and squeeze the pump. When you see the water coming out of the cone, close the water flow regulator. The system is now ready for use.
8. Hold the cone under the tap or dip it in water for a few seconds to activate the hydrophilic coating.



2a



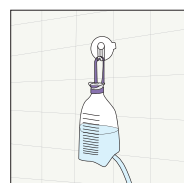
2b



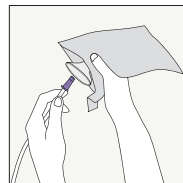
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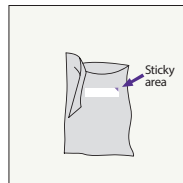
4a



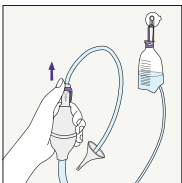
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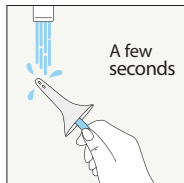
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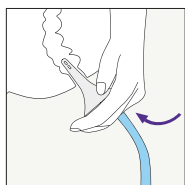
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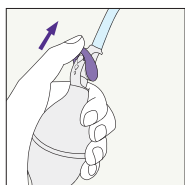
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Using Qufora IrriSedo Flow

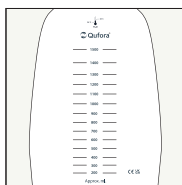
9. Sit on or over the toilet. Carefully guide the cone up to its base into the rectum.
10. Continue to hold the cone in place, open the water flow regulator to instil water into the rectum. If the water bag is placed lower than the toilet seat, squeeze the pump to instil water into the rectum.
11. The amount of water flowing into the bowel can be monitored by using the scale on the water bag. Your healthcare professional will guide you regarding the amount of water to use for your irrigation. A general guide is 500 ml (this will vary for children) however this may be more or less depending on your requirement. If you feel any discomfort, do not instil more water into the bowel.
12. Remove the cone from the rectum. Faecal matter and water will be expelled into the toilet. If advised by your healthcare professional the procedure can be repeated.



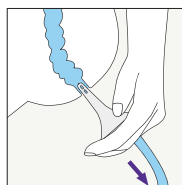
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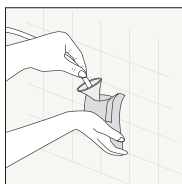
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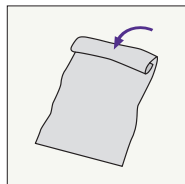
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Emptying and disassembling Qufora IrriSedo Flow

13. Place the used cone into the pouch and separate the two parts.
14. The pouch can be folded and sealed using the sticky area, then disposed of in household waste. Please note that the cone is single-use only and must not be used again.



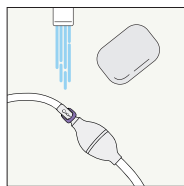
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Cleaning and storing after use

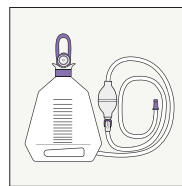
15. Clean the outside of the pump with luke warm water, rinse and dry.
16. Empty the water bag and hang it to dry with the lid open.
17. For storage leave the lid open and keep the water bag with the pump and water flow regulator out of direct sunlight in a dry and ventilated place between 0° and 30° C.
18. Wash and dry your hands.



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Please note: Please use Qufora IrriSedo Flow only as advised by your healthcare professional.

Instructions for use

Qufora IrriSedo Flow

Using the Qufora IrriSedo Flow makes it possible to perform transanal/rectal irrigation. Please read both pages of this instructions for use before using the Qufora IrriSedo Flow.

Indications for using transanal/rectal irrigation

The Qufora IrriSedo Flow is intended for adults and children 3 years and above to help manage faecal incontinence and/or constipation conditions.

For example:

- Low anterior resection syndrome
- Urge faecal incontinence/urgency
- Constipation (slow transit/idiopathic/ opioid induced/IBS-C)
- Neurogenic (spinal cord injury, upper/lower motor neurone/MS parkinson's/spina bifida/cauda equina)

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

For the best results Qufora IrriSedo Flow should be used daily or as advised by your healthcare professional.

Before starting transanal/rectal irrigation

Use only after assessment and training from a qualified healthcare professional. A digital rectal examination is mandatory prior to your first irrigation. You should be supervised by an experienced healthcare professional during your first irrigation.

Transanal/rectal 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.

Please note:

Transanal/rectal irrigation is not recommended for:

- Pregnancy or planned pregnancy or breastfeeding
- Children under 3 years of age

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

- 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
- Diarrhoea of unknown aetiology
- Faecal impaction/rectal constipation
- Severe autonomic dysreflexia
- Severe diverticulosis or diverticular abscess
- Abdominal or pelvic irradiation
- 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

Seek medical attention if the following is experienced during or after transanal/rectal irrigation:

- Sustained or severe bleeding from the rectum
- Sustained or severe abdominal or back pain, with or without fever

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

Please observe

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

Please contact your healthcare professional for further advice.

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

Recommended usage time

The water bag with pump and water flow regulator can be used 30 times (equal to 1 month usage time*). Should discoloration develop within the recommended usage time, the water bag with pump and water flow regulator should be replaced.

The cone is for single-use only

If the cone is reused, there is a risk of adverse effects to the product and the health of the patient, 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.

If any serious incident has occurred you should contact your healthcare professional who will liaise with Qufora A/S and the competent authority.

Handling and storage

Qufora IrriSedo Flow 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.

Please find further information about this product on www.qufora.com.

*when used for irrigation every day.

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