

Instructions for use

Qufora IrriSedo MiniGo

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

Indications for using transanal/rectal irrigation

The Qufora IrriSedo MiniGo is used to help manage faecal incontinence and/or constipation conditions. For example:

- Passive faecal incontinence
- Post defaecation seepage
- Rectocele
- Incomplete evacuation
- Evacuation difficulties
- Low anterior resection syndrome

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

For the best results Qufora IrriSedo MiniGo 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 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 transanal/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, considering the size and shape of the device delivering the water. For children the approval should be from a healthcare professional specialised in paediatric care
- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Active perianal sepsis (fistula or abscess)
- 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 radiotherapy
- Known diverticular disease
- Long term steroid therapy
- Anti-coagulant 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

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 soft pump can be used up to 1 month. Should discolouration develop within the recommended usage time, the soft pump 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 MiniGo 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.



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 **Qufora® IrriSedo MiniGo**



Qufora A/S
Gydevang 28-30
3450 Allerød
Denmark

Tel: +45 88 300 592
Fax: +45 88 300 593
info@qufora.com
www.qufora.com

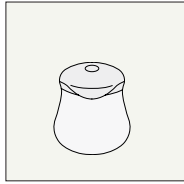
 **Qufora®**

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Explaining the Qufora IrriSedo MiniGo components

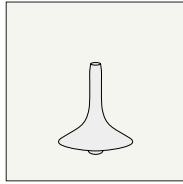
Soft pump



A soft pump (180 ml) with a flip lid that connects to the cone.

The pump can be used up to 1 month

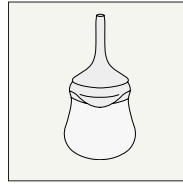
Cone



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

The rectal cone is single-use

Assembled



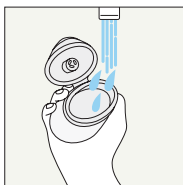
The lid has a one-way valve, so the pump can be squeezed more than once, without air or water being sucked back into the pump during use. For this reason, the pump will stay compressed until the lid is opened.

Filling Qufora IrriSedo MiniGo with water

1. Wash and dry your hands.
2. Open the lid and fill the pump up to the inner rim with luke warm tap water (36-38° C) by holding it under the tap with the lid open.
3. Once the pump is filled to the inner rim hold onto the top part of the pump and press down on the lid until you hear the click sound.
4. Open the cone pouch at the perforated line. Whilst the cone is still in the pouch press the cone firmly to the small round opening on the lid to assemble your system.
5. Attach the empty pouch to a surface using the sticky area on the back of the pouch.
6. To activate the hydrophilic coating on the cone, wet the cone with water up to its base. Gently squeeze the pump until water comes out of the cone tip to remove the air. It is now ready to use.



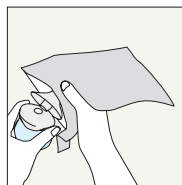
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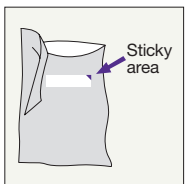
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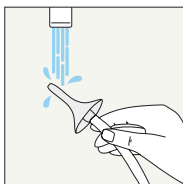
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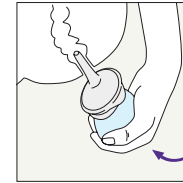
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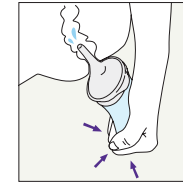
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Using Qufora IrriSedo MiniGo

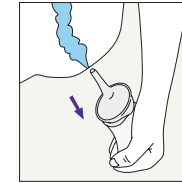
7. Sit on or over the toilet. Carefully guide the cone up to its base into the rectum.
8. Now the cone is in place, gently squeeze the pump to instil water into the rectum. The pump can be squeezed several times to instil the water.
9. Remove the cone from the rectum. Faecal matter and water will be expelled into the toilet.



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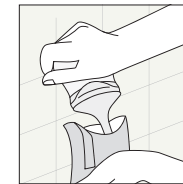
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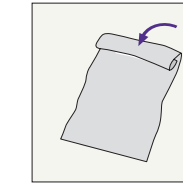
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Emptying and disassembling Qufora IrriSedo MiniGo

10. Place the used cone into the pouch and separate the two parts.
11. 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.



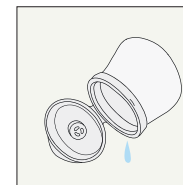
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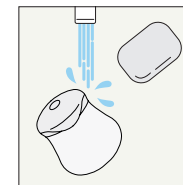
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Cleaning and storing after use

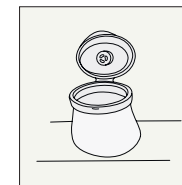
12. Open the lid of the pump to ensure that any residual water is emptied.
13. Re-close the lid to clean the outside of the pump with mild soapy luke warm water, rinse and dry.
14. For storage leave the lid open and keep the pump out of direct sunlight in a dry and ventilated place between 0 and 30° C.
15. Wash and dry your hands.



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Note: Please use Qufora IrriSedo MiniGo as advised by your healthcare professional.