

Instructions for use

Qufora IrriSedo MiniGo Flex

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

Indications for using transanal/rectal irrigation

The Qufora IrriSedo MiniGo Flex is intended for adults and children 3 years and above 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 Flex 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 soft pump can be used 30 times (equal to 1 month usage time*). Should discolouration develop within the recommended usage time, the soft pump should be replaced.

The Cone Flex is for single-use only

If the Cone Flex 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 Flex 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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Qufora® IrriSedo MiniGo Flex



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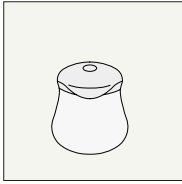


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Explaining the Qufora IrriSedo MiniGo Flex components

Soft pump

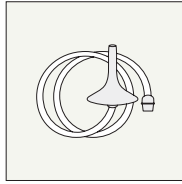


A soft pump (180 ml) with a flip lid that connects to the cone.

The pump can be used 30 times (equal to 1 month usage time*)

*when used for irrigation every day

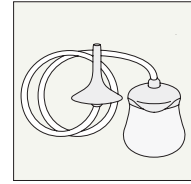
Cone Flex



A rectal cone with integrated flexible tube. The Cone Flex has a hydrophilic coating that is activated with water.

The Cone Flex is single-use

Assembled



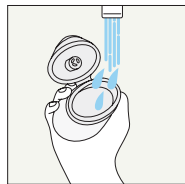
The lid has a one-way valve, so the pump can be squeezed more than once, without air or water being sucked back into the pump during use. For this reason, the pump will stay compressed until the lid is opened.

Filling Qufora IrriSedo MiniGo Flex with water

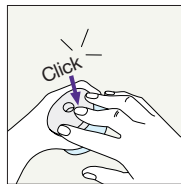
1. Wash and dry your hands.
2. Open the lid and fill the pump up to the inner rim with luke warm tap water (36-38° C) by holding it under the tap with the lid open.
3. Once the pump is filled to the inner rim hold onto the top part of the pump and press down on the lid until you hear the click sound.
4. Open the Cone Flex pouch at the perforated line. Whilst the Cone Flex is still in the pouch press the end of the tube 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 Flex, 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.



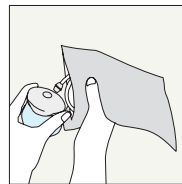
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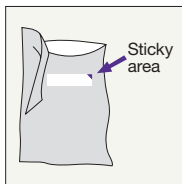
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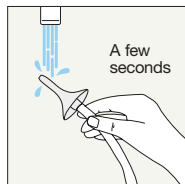
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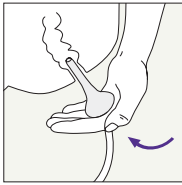
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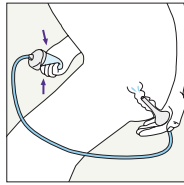
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Using Qufora IrriSedo MiniGo Flex

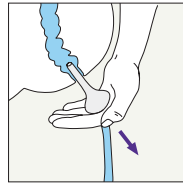
7. Sit on or over the toilet. Carefully guide the Cone Flex up to its base into the rectum.
8. Now the cone is in place, gently squeeze the pump to instil water into the rectum. The pump can be squeezed several times to instil the water.
9. Remove the cone from the rectum. Faecal matter and water will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



7



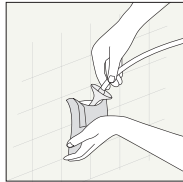
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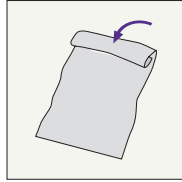
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Emptying and disassembling Qufora IrriSedo MiniGo Flex

10. Place the used Cone Flex 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 Flex is **single-use** only and must **not** be used again.



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Cleaning and storing after use

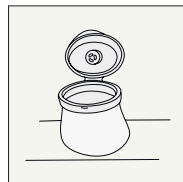
12. Open the lid of the pump to ensure that any residual water is emptied.
13. Re-close the lid to clean the outside of the pump with mild soapy luke warm water, rinse and dry.
14. For storage leave the lid open and keep the pump out of direct sunlight in a dry and ventilated place between 0 and 30°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



12



13



14



15

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