

Transanal Irrigation System

Instructions for Use

| REF | REF | |
|------|--|--|
| AFLS | Aquaflush Transanal Irrigation Lite/Standard Starter Set | |
| AFLM | Aquaflush Transanal Irrigation Lite/Standard Monthly Set | |
| AFLA | Aquaflush Transanal Irrigation Lite/Standard Size Refill Cones | |
| AFAS | Aquaflush Transanal Irrigation Actif/Pediatric Starter Set | |
| AFAM | Aquaflush Transanal Irrigation Actif/Pediatric Monthly Set | |
| AFSC | Aquaflush Transanal Irrigation Actif/Pediatric Short-Size Refill Cones | |

INDICATIONS FOR USE

The Aquaflush® Transanal Irrigation System is a bowel management device intended to instill body temperature water (95 to 98.6 °F) through a cone delivery into the rectum to assist in the evacuation of stool from the lower and descending colon.

CONTRAINDICATIONS

None

WARNINGS

Consult a physician if any of the following occur:

- · Blood in feces, weight loss, abdominal pain.
- Significant changes in the frequency, color, and consistency of the stools.
- Bowel perforation is an extremely rare but serious and potentially lethal complication to transanal irrigation and will require immediate admission to a hospital, often requiring surgery. Contact your healthcare provider immediately if, during or after transanal irrigation, you experience any of the following symptoms:
 - Severe and sustained abdominal pain or back pain, especially if combined with fever
 - · Sustained anal bleeding

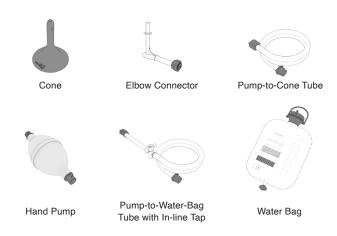
PRECAUTIONS

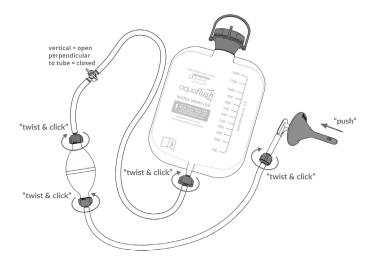
The following list does not rule out transanal irrigation as a bowel management program, but you must discuss your general health with your healthcare provider so that they can ensure that it is the proper treatment for you. For children under the age of five (5), consult a pediatric specialist before starting assisted, transanal irrigation.

- Inflammatory bowel disease (e.g., Crohn's disease or Ulcerative Colitis and Ischaemic Colitis)
- Rectal pain or bleeding (e.g., anal fissure, severe hemorrhoids)
- · Diverticular Disease
- · Autonomic Dysreflexia
- · Recent spinal cord shock following spinal trauma
- Radiation therapy in the abdominal or pelvic region
- · Abdominal or anal surgery polypectomy
- Cancer in the abdominal or pelvic region
- · Long term steroid therapy, Anticoagulant Therapy
- · Coronary Disease
- Pregnancy
- Nursing mothers
- Store the Aquaflush System away from the reach of small children to avoid risk
 of strangulation from tubing, suffocation from plastic bags or choking in the event
 of small components coming loose from the product.
- The Aquaflush Transanal Irrigation System is only intended for use by the person prescribed. A healthcare professional should write the prescription following a thorough patient assessment.
- Refer to the prescription for water installation volume and frequency of use.
- The pump, tubes and water bag are resusable for up to 30 days. The cones are single use.

SYSTEM COMPONENTS AND ASSEMBLY

To assemble, match the colored connectors together and push the cone onto the elbow connector.

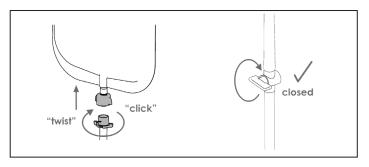




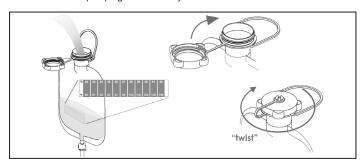
See reverse for STEP-BY-STEP INSTRUCTIONS

STEP-BY-STEP INSTRUCTIONS

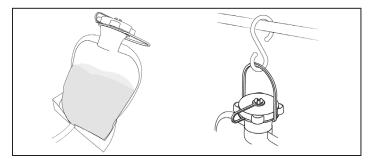
Gather system components and any other supplies for the irrigation session.
 Thoroughly wash and dry hands. Assemble system. Then, ensure the tap head is positioned perpendicular to the tubing as shown.



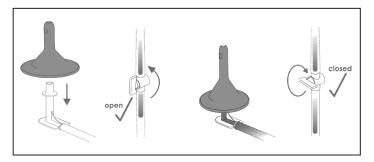
2. Fill the water bag: Unscrew the water bag cap and fill the water bag with body temperature water (95 to 98.6 °F). Note: If the water temperature is too cold, it may cause cramps; if the water temperature is too hot, there is a danger of trauma to the bowel lining. Fold the bag at the water line to expel any air, then close the cap securely; this will help ensure that no air is trapped in the bag and therefore avoid pumping air into the system.



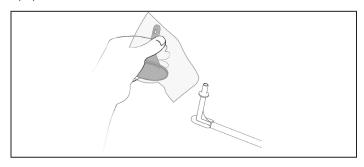
3. Water bag placement: Place the water bag on a flat surface or clean floor using the bag stand provided. The water bag also comes with a built-in hanger & separate 'S' hook. If hanging, locate the water bag above the height of the toilet to avoid getting air into the system.



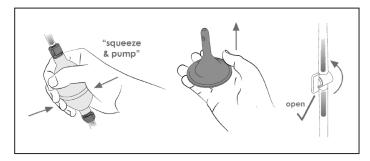
4. Prime the system: Open the tap while holding the cone over the sink or toilet, allowing water to pass through the tubing and pump, and squeeze the pump a few times to release any air bubbles trapped in the tubing/pump. Always prime the system to avoid pumping air into the bowel. Close the tap.



5. Cone placement: Hold the cone with the tubing between your fingers and along the back of your hand. Apply the lubricant to the tip and shaft of the cone. If preferred, apply lubricant to the rectum using a gloved finger. While seated on the toilet, carefully push the cone into the rectum at the correct angle. Hold the cone in position with one hand and then open the tap completely. Consult with your healthcare provider for questions regarding cone placement angle and proper insertion.

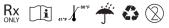


6. Water installation: Gently pump the volume of water advised by your healthcare provider into the rectum by monitoring the volume scale on the water bag. If any discomfort is felt, stop pumping and close the tap immediately. After pumping the prescribed water volume, remove the cone from the rectum and remain seated on the toilet. The bowel may take up to 30 minutes to empty. Following the evacuation, wait about 5 minutes to ensure everything has been expelled.



RECOMMENDED STORAGE CONDITIONS

Store in a clean, dry place at room temperature (41 to 86 °F).



Symbols glossary and additional information available at mtgcatheters.com

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