



Clinisupplies

 HR HealthCare

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in United States of America



Aquaflush®

EN: Transanal Irrigation Systems

ES: Sistema de irrigación transanal

EN: Instructions for Use

ES: Instrucciones de uso



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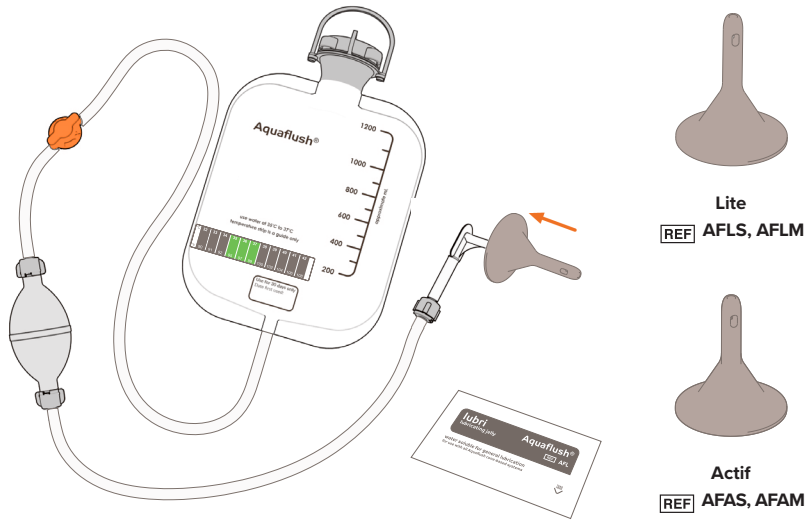
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REF AFLS, AFAS, AFLM, AFAM,

Thank you for choosing Aquaflush®. Aquaflush® Transanal Irrigation (TAI) System is designed to be a simple and effective way for you to control your bowel management routine.

Please read this document carefully, including the warnings and precautions. If you have any questions, please contact us at HR HealthCare or discuss any concerns with your healthcare professional.



INDICATIONS FOR USE

Aquaflush® Transanal Irrigation System must only be used by the person that it is prescribed for following a thorough assessment by a healthcare professional.

INTENDED USE

This device is intended to be used by people with chronic constipation, chronic fecal incontinence, incomplete emptying, or neurological bowel dysfunction.

CONTRAINDICATIONS

Caution: The following list does not rule out transanal irrigation as a bowel management program, but you should have consulted a healthcare professional to ensure that the system is right for you. Children under 5 must be reviewed by a pediatric specialist before starting 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
- Recent colonic biopsy or endoscopic polypectomy
- Cancer in the abdominal or pelvic region
- Long term steroid therapy, Anticoagulant Therapy
- Pregnancy
- Nursing mothers

ADVERSE EVENTS

Any serious incident that has occurred with this device should be reported to the manufacturer and competent authority.

WARNINGS AND PRECAUTIONS

You must consult a healthcare professional if any of the following occur:

- Blood in the feces, weight loss or abdominal pain
- Significant changes in the frequency, colour and consistency of the stool

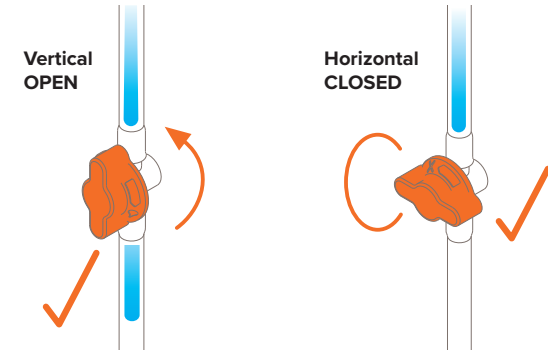
Rare occurrence: Bowel perforation is extremely rare but is serious and life threatening if it occurs and will require urgent attention. If you experience any of the following symptoms during or after transanal irrigation, contact your healthcare professional immediately:

- Severe and sustained abdominal pain or back pain, especially if combined with fever
- Sustained bleeding

STEP-BY-STEP INSTRUCTIONS

1. Before you start: Wash your hands thoroughly and ensure you have everything you need close by. Start by ensuring the orange tap on the tube is in the horizontal closed position as shown in the diagram below and the silicone cone has been attached to the 'elbow' connector. (Figure 1)

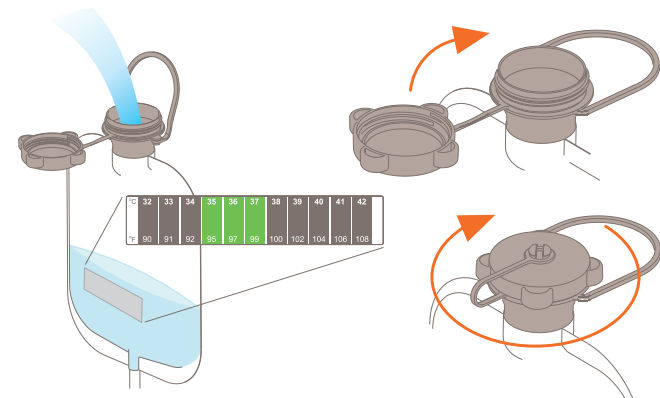
Figure 1



2. Preparing your system for use: Unscrew the waterbag cap and fill the bag with water at a temperature between 35°C to 37°C (95°F to 98°F), which is close to body temperature. (Do not use cold or hot water). Fold the bag at the water line to remove any trapped air before securely closing the cap. This process ensures that no air is trapped in the bag, preventing the risk of pumping air into the system. It is important you do not pump air into the bowel. (Figure 2)

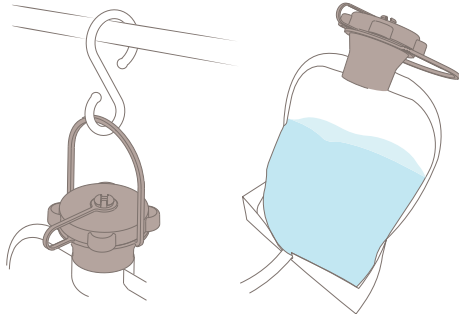
User Tip: The temperature gauge on the bag will indicate when the water in the correct range.

Figure 2



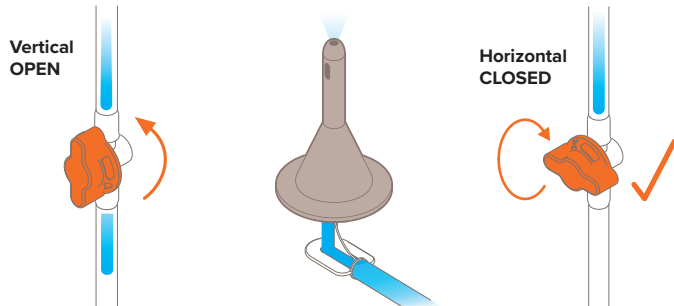
3. Place the waterbag on a flat surface or on the floor using the Aquaflush® Bag Stand provided or hang it above shoulder height using the built-in hanger with an 'S' hook. The hanging option uses gravity, allowing the system to free flow without the need for a pump and should be hung above the height of the toilet to avoid getting air into the system. You can only free flow if the water bag is above the height of the person doing the irrigation. (Figure 3)

Figure 3



4. Removing air from the system: Hold the cone over the sink, open the orange tap into the vertical open position (see diagram) and allow the water to pass through the tubing and into the pump. Squeeze the pump a few times to clear any air in the system before use. Turn the orange tap back into the horizontal closed position. Now your Aquaflush® System is ready for use. (Figure 4)

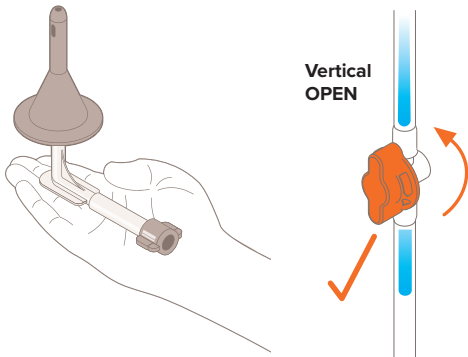
Figure 4



5. Apply the lubricant provided to the tip and shaft of the cone and the anus if required. Sit on the toilet and gently push the cone into the rectum at the correct angle of insertion advised by your healthcare professional. Turn the orange tap to the vertical open position fully. (Figure 5)

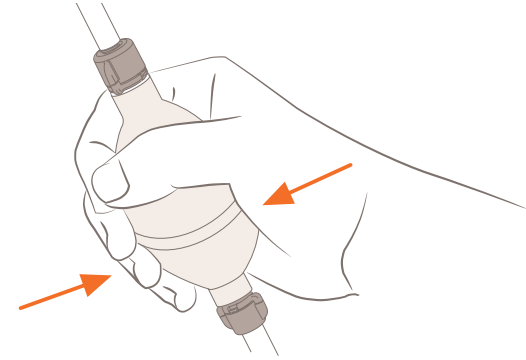
User Tip: If you have difficulty correctly inserting the cone, consult your healthcare professional.

Figure 5



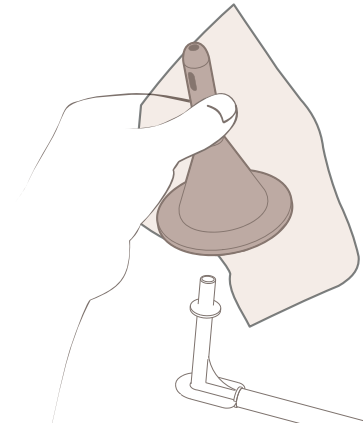
6. Gently pump the volume of water advised by your healthcare professional into the rectum, monitoring the volume scale on the water bag (usually between 300ml to 500ml). (If any discomfort is felt stop pump immediately, close the orange tap to the horizontal position and seek advice from your healthcare professional). When you have finished pumping, turn the orange tap to the horizontal closed position and remove the cone from the rectum. Remain seated on the toilet. Your bowel may take up to 30 minutes to empty, and it is recommended to wait an additional 5 minutes after everything appears to have been expelled. (Figure 6)

Figure 6



7. Using the disposal bag provided, remove the cone from the 'elbow' connector and dispose according to your local authority guidelines. The cone is intended to be used once. Wash the water bag, tubing and pump with mild soapy water and hang to dry ensuring the orange tap is in the vertical open position and the pump is disconnected from the water bag. (Figure 7)

Figure 7



STORAGE AND HANDLING

Cones are single-use, the rest of the system can be used for 30 days.

SAFETY: Ensure you store your 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.

Do not use after the date of expiry, which can be found on the carton label.

	EN: Non-sterile ES: No estéril
	EN: Medical Device ES: Dispositivo médico
	EN: Unique device identifier ES: Identificador único del dispositivo
	EN: Consult instructions for use ES: Consultar las instrucciones de uso
	EN: Keep away from sunlight ES: Mantener fuera de la luz del sol
	EN: Do not use if package is damaged ES: No usar si el producto presenta algún daño.
	EN: Catalogue number ES: Número de catálogo
	EN: Batch code ES: Código de lote
	EN: Date of Manufacture ES: Fecha de facturación
	EN: Use-by date ES: Fecha de caducidad
	EN: Do not re-use ES: No reutilizar

	EN: Box and instructions for use are recyclable ES: La caja y las instrucciones de uso son reciclables.
	EN: Caution ES: Advertencia
	EN: Single patient multiple use ES: Varios usos por parte de un paciente
	EN: Not made with natural rubber latex ES: No contiene látex de caucho natural
	EN: Keep dry ES: Mantener seco
	EN: Manufacturer ES: Fabricante
	EN: Distributor ES: Distribuidor
	EN: Importer ES: Importador
	EN: European conformity mark ES: Marca de conformidad europea
	EN: Authorized representative in the European community ES: Representante autorizado en la Comunidad Europea/Unión Europea

- Enfermedad intestinal inflamatoria (p. ej. Enfermedad de Crohn o colitis ulcerosa y colitis isquémica)
- Dolor rectal o sangrado, p. ej. Fisura anal, hemorroides graves
- Enfermedad diverticular
- Disreflexia autonómica
- Shock espinal reciente tras un trauma medular
- Terapia por radiación en la región abdominal o pélvica
- Cirugía abdominal o anal

EVENTOS ADVERSOS

En caso de incidente grave que resulte del uso de este dispositivo, avise al fabricante o a la autoridad competente.

ADVERTENCIAS

Debe consultar a un profesional sanitario si observa algunos de los factores siguientes:

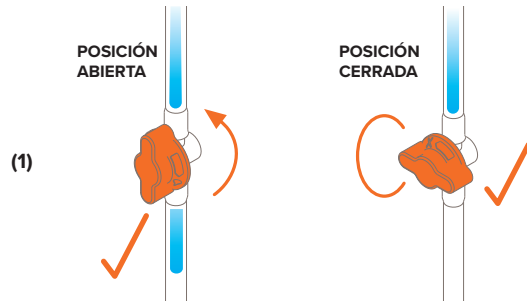
- Sangre en las heces, pérdida de peso o dolor abdominal
- Cambios significativos en la frecuencia, color y consistencia de las heces

Muy poco frecuente: La perforación intestinal es sumamente rara pero es grave y puede resultar mortal si se produce, necesitando atención urgente. Si padece alguno de los síntomas siguientes durante o después de la irrigación transanal, póngase en contacto con su profesional sanitario inmediatamente:

- Dolor abdominal o dolor de espalda severo y continuado, especialmente si también hay fiebre
- Sangrado continuado

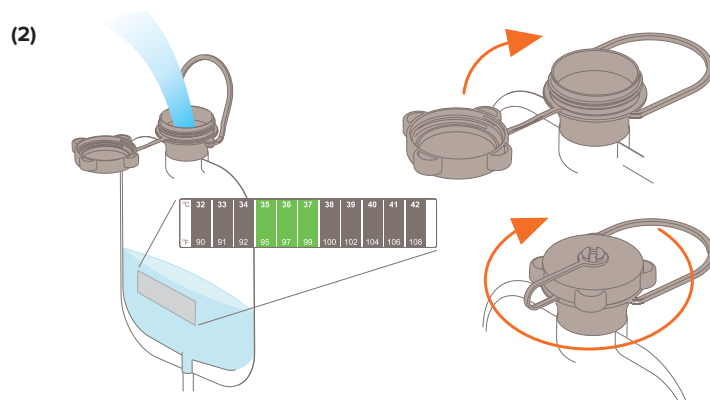
INSTRUCCIONES PASO A PASO

1. Antes de comenzar: Lávese las manos concienzudamente y asegúrese de que tiene cerca todo lo que necesita. Comience por asegurarse de que el tapón naranja del tubo está en posición cerrada, horizontal, como se muestra en el diagrama siguiente y el cono de silicona se ha acoplado al conector de codo. (1)



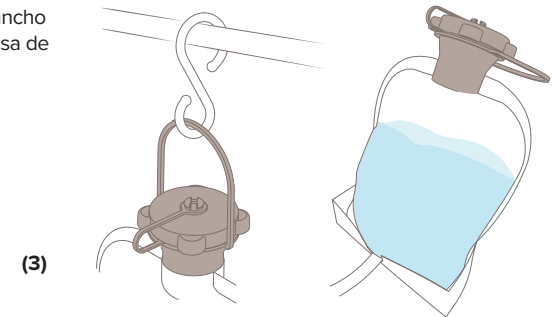
2. Preparación del sistema para su uso: Desenrosque el tapón de la bolsa de agua y rellene la bolsa con agua a una temperatura de entre 35 °C y 37 °C (95 °F y 98 °F). (No use agua fría ni caliente). Doble la bolsa por la línea de agua para eliminar el aire antes de cerrar firmemente el tapón. Este proceso garantiza que no quede aire atrapado en la bolsa, evitando el riesgo de que se bombee aire hacia el sistema. Es importante no bombear aire hacia el intestino.

Consejo útil: El medidor de temperatura de la bolsa indicará cuándo el agua se encuentra dentro de los valores adecuados.

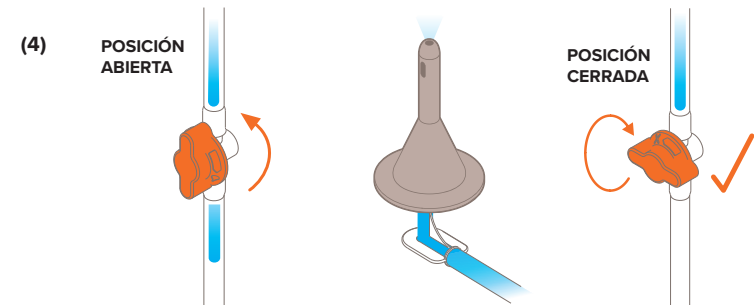


3. Coloque la bolsa de agua sobre una superficie plana o sobre el suelo usando el Soporte para Bolsas Aquaflush® que se suministra, o cuélguela por encima de la altura del hombro usando el colgador incorporado con un gancho en «S»*. La opción de colgar utiliza la gravedad, permitiendo que el sistema fluya libremente sin necesidad de una bomba y deberá colgarse por encima de la altura del inodoro para evitar que entre aire en el sistema. El agua solo fluirá libremente la bolsa si está por encima de la altura de la persona que realiza la irrigación.

*Si necesita un soporte para bolsas o un gancho en «S», póngase en contacto con su empresa de distribución o su proveedor.



4. Extracción de aire del sistema: Sujete el cono sobre el lavabo, abra el tapón naranja en posición abierta, vertical (ver el diagrama) y deje que el agua salga por el tubo hacia la bomba. Presione la bomba unas cuantas veces para eliminar cualquier resto de aire en el sistema antes de su uso. Vuelva a colocar el tapón naranja en posición cerrada, horizontal. Ahora su sistema Aquaflush® está listo para su uso.

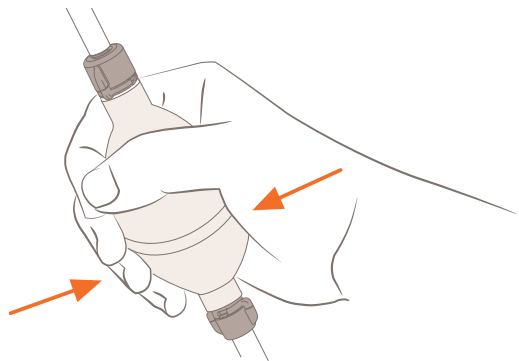


5. Aplique el lubricante que se suministra en la punta y el eje del cono, y en el ano si es necesario. Siéntese en el inodoro y presione suavemente el cono para introducirlo en el recto con el ángulo correcto de inserción que le ha recomendado el profesional sanitario. [Si utiliza un Cono de auto-retención, tire del cono ligeramente para que los pétalos se asienten firmemente en el recto]. Gire el tapón naranja a su posición vertical, totalmente abierta.

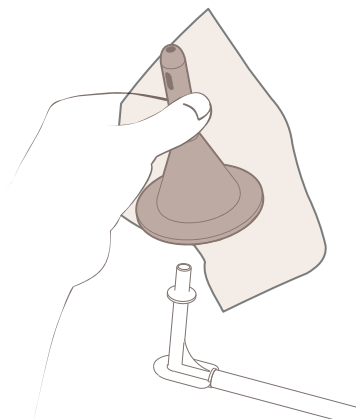
Consejo útil: Si tiene problemas para insertar el cono correctamente, consulte a su profesional sanitario.



(6)



(7)



No utilizar después de la fecha de caducidad, que se encuentra en la etiqueta de la caja.

[illegible]

Bowel care diary

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Bowel care diary

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