

QUICK GUIDE CHILD USE (cone)

Note: Read the entire instruction for use. Empty your bladder before irrigation. Follow the instructions given by your healthcare professional.

A training session with a healthcare professional specialized in TAI and familiar with the Navina Systems is mandatory before using the Navina Classic system.

Intended use

The Navina Systems is intended for Transanal Irrigation by instilling water up into the lower part of the colon through a rectal catheter.

Indications for use

Navina Systems is indicated to help adults and children from 3 years who suffer from fecal incontinence, chronic constipation and/or time-consuming bowel management. By instilling water up into the lower part of the colon, the peristaltic muscles in the bowel can be triggered and start to evacuate the content of the lower colon and rectum.

Contraindications

Do NOT use Navina Systems if you have one or more of the following:

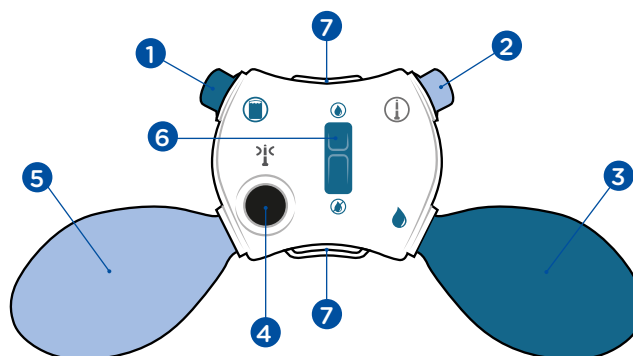
- Known anal or colorectal stenosis
- Active inflammatory bowel disease
- Acute diverticulitis
- Colorectal cancer
- Ischemic colitis
- You are within three months of anal or colorectal surgery
- You are within 4 weeks of previous endoscopic polypectomy

As the list may not be exhaustive, healthcare professionals will always consider individual user factors as well.

Warning!

Seek medical care immediately if you experience severe or sustained abdominal pain, back pain or rectal bleeding during or after anal irrigation. Bowel perforation is a very rare (1 out of 500,000 irrigations or 0.0002 %) yet extremely serious complication of TAI. It is a medical emergency and requires immediate medical attention. Symptoms of bowel perforation include severe or sustained abdominal or back pain or significant rectal bleeding (not just smearing of blood on the rectal catheter which is very common and is not a concern).

Navina Classic control unit



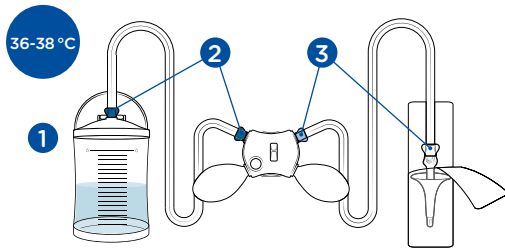
Overview

1. Connector to the water container
2. Connector to the rectal cone
3. Dark blue pump to instill water
4. Black button to deflate the catheter balloon (N/A)
5. Light blue pump to inflate the catheter balloon (N/A)
6. Switch to open/close water flow
7. Loops to attach the position strap or the lanyard, if desired

QUICK GUIDE CHILD USE

Preparation & Use

(cone)

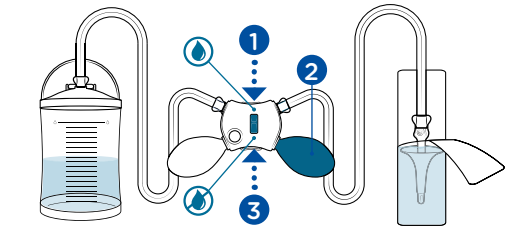


1. Preparation

1. Fill the container with water to the level given by your healthcare professional + max 200 ml extra for activating the cone surface (making it slippery)
2. Connect the water container tube between water container and control unit (dark blue).
3. Connect the cone tube between control unit and cone (light blue/white).

Note: Follow color coding and symbols. Use luke warm and clean water only.

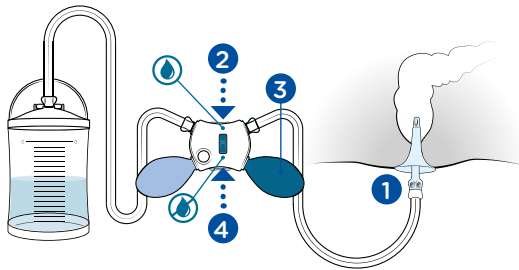
Make sure the safety valve on the lid is not blocked during the procedure.



2. Activation

1. Make sure water flow is opened.
2. Pump water with the dark blue pump until it covers 3/4 of the cone, making it slippery.
3. Close water flow.

Note: Do not add additional lubricant.



3. Instillation

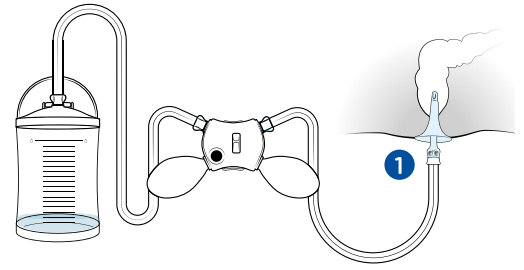
Find the position that is best for the child, this can be bending over with knees bent or sitting on the toilet or crouching.

1. Carefully insert the cone, without any force, into the rectum until the cone fits comfortably, as instructed by your healthcare professional. Hold it in place during the procedure.
2. Open water flow.
3. Instill the water volume, as indicated by your health care provider, using the dark blue pump. Stop or pause the instillation at any time by releasing the pump and closing the water flow.

Note: Monitor the child's face during instillation, for signs of distress or discomfort. Stop or pause if it is uncomfortable for the child.

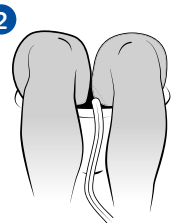
4. Close water flow.

Note: Never insert cone with force. If experiencing resistance, remove cone, and follow see instructions for use trouble shooting section. If resistance continues, stop using irrigation and seek help from a health care professional.



4. Evacuation

1. Remove catheter gently.
2. Allow bowel to empty. If needed to start emptying, relax for 10-15 minutes, lean forward, cough or massage abdomen.



5. Disassembly

1. Open water container lid.
2. Disconnect tubes from control unit.
3. Empty water from tubes.
4. Open water flow and empty water from control unit.
5. Disconnect the single use cone and dispose as household waste. It must not be reused and not flushed down the toilet.
6. Disconnect tube from water container and empty water.
7. Clean and dry the tubing, water container and control unit with a cloth and mild soapy water.

Note: Tick a box in the usage calendar (see instructions for use) after each use to keep track of when to exchange the water container and tube set.

