

QUICK GUIDE ADULT 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 Classic is intended for transanal irrigation by instilling water up into the lower part of the colon through a rectal catheter.

Indications for use

The Navina Systems are indicated for use for children (2 - <12 years old), adolescents (12 - <18 years old), and transitional adolescents (18 - <21 years old) patients with neurogenic bowel dysfunction, congenital disorders such as Hirschsprung disease or anorectal malformations, fecal incontinence or chronic constipation where less invasive therapies are not successful, as well as, for adults who suffer from fecal incontinence, chronic constipation, and/or time consuming bowel management. Use for pediatric patients is to be performed under the supervision of a trained healthcare professional or adult caregiver. By instilling water up into the lower part of the colon, the Navina Systems promote evacuation of the contents of the colon and rectum.

The Navina Small Rectal Balloon catheter is limited to use for adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults. The Navina Regular Rectal Balloon catheter is limited to use for adults. The Navina Cone catheter is limited to use for children (2 - < 12 years old), adolescent (12 - <18 years old) and transitional adolescent (18 - < 21 years old) patients and adults.

Contraindications

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

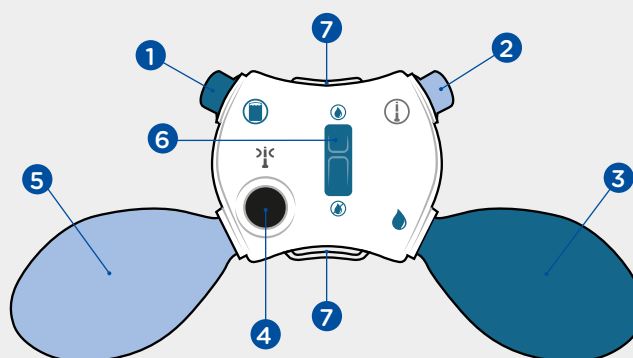
- Known anal or colorectal stenosis
- Active inflammatory bowel disease
- Acute diverticulitis
- Colorectal cancer
- Ischemic colitis
- During spinal cord shock phase
- Complex diverticular disease
- You are within three months of anal or colorectal surgery
- You are within 4 weeks of previous endoscopic polypectomy
- Pregnant women

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



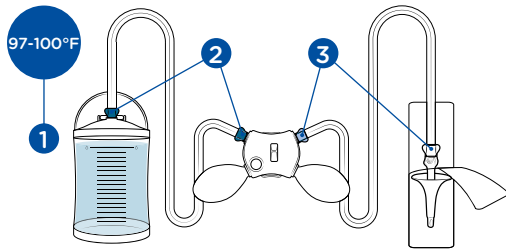
Overview

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 ADULT USE

Preparation & Use

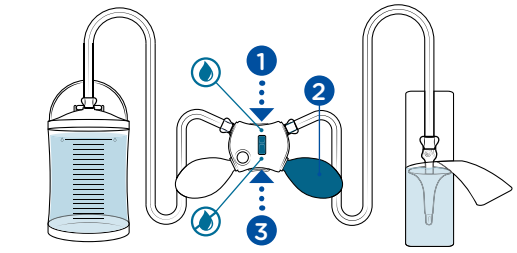
(cone)



1. Preparation

1. Fill water to the 0-mark of the container. Close the lid.
 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.**

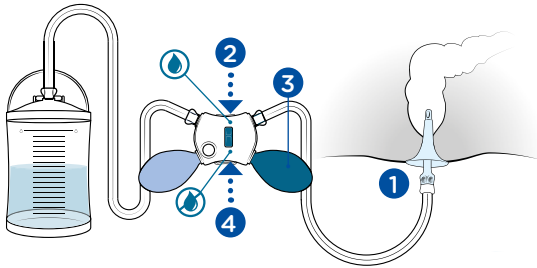
Make sure the safety valve on the lid is not blocked during the procedure.



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.

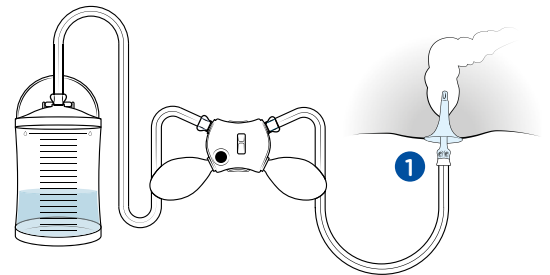
Note: Do not add additional lubricant.



3. Instillation

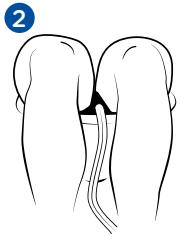
1. Carefully insert the cone, without any force, into the rectum, as far as instructed by your healthcare professional. Hold it in place during the procedure.
2. Open water flow.
3. Instill the water volume, as indicated by your health care provider, using the dark blue pump. Stop or pause the instillation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

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



4. Evacuation

1. Remove cone 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: Check 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.

