

QUICK GUIDE ADULT USE Charging & Settings (catheter)

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 Smart system.

Intended use

The Navina Smart 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

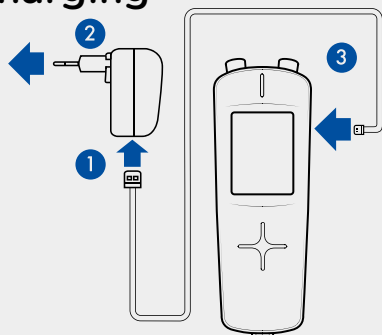
Do NOT use Navina Systems if you have one or more of the following:

- 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).

Charging

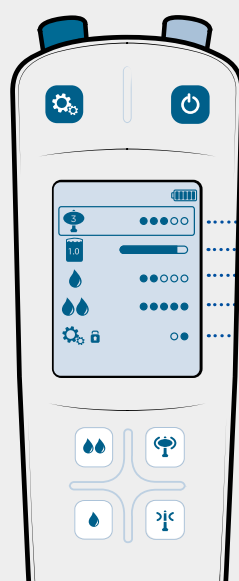


1. Plug the cable into the power adapter
2. Plug the power adapter into a power supply
3. Plug the cable into the Navina Smart control unit

Please note: Charge the Navina Smart control unit fully before first use. The power adapter must not be used in the bathroom or with water

1. Christensen P, Krogh K, Perrouin-Verbe B, et al. Global audit on bowel perforations related to transanal irrigation. Tech Coloproctol. Feb 2016;20(2):109-115

Settings



- 🔘 Turn on Navina Smart control unit. The On/off button also indicates battery charge.
- ⚙️ Enter and exit settings.
- 👆 / 👇 Select flow rates (up/down).
- 👉 / 👈 Select balloon size (+/-).
- 1 Select maximum balloon size. For the small catheter only settings 1-3 shall be used.
- 2 Select maximum water volume to instill.
- 3 Select flow rate for button: 📄
- 4 Select flow rate for button: 📄
- 5 Select pin code if desired.

Transfer data



1. Turn on the Navina Smart control unit and stay on the welcome page.
2. Open the Navina Smart app.
3. The first time, you will have to confirm the control unit identity to pair it with your app.
4. Select Synchronize in the app's main menu.
5. The Navina Smart control unit will be turned off automatically once the data is transferred.
6. Rate the new irrigation uploaded in the app.

Navina™ Smart

QUICK GUIDE ADULT USE

Preparation & Use

(catheter)

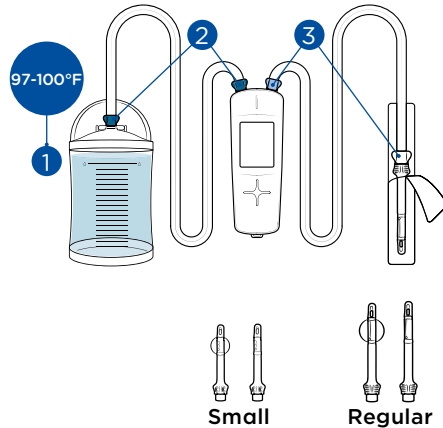
Note: Make sure that the control unit is charged and parameters set before starting on this page.

1. Preparation










1. Fill water to the upper mark of the container and close the lid.
2. Connect the water container tube between water container and control unit (dark blue).
3. Connect the catheter tube between control unit and catheter (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.

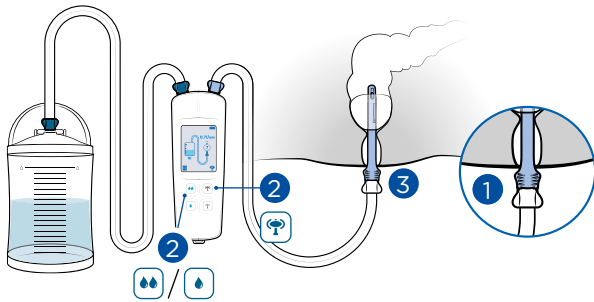





2. Activation

1. Turn on the Navina Smart control unit by pressing .
2. Press any button to go to the activation mode  /  /  / .
3. Press and hold  /  to pump water until the catheter is covered with water (making it slippery) and the  icon appears on the screen.
4. Press  when you are ready to insert the catheter to proceed to the instillation mode.

Note: Do not add additional lubricant.

3. Instillation

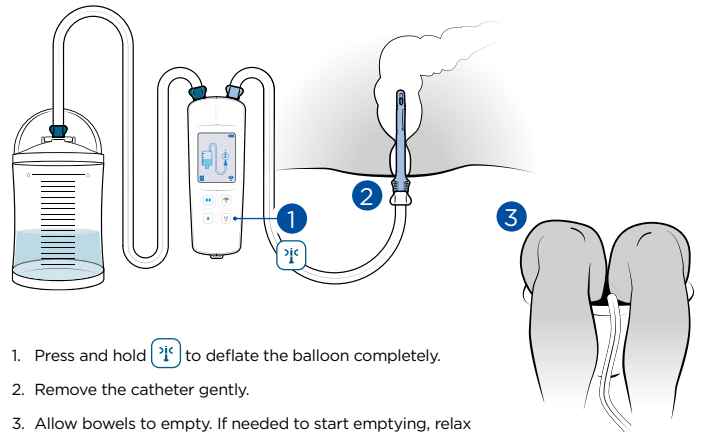



1. Insert the rectal catheter according to your healthcare professional's instruction.
2. Press and hold  to inflate the catheter balloon until the desired balloon size is reached. If repositioning of catheter is needed, deflate balloon completely first.
3. Gently pull the catheter slightly down to seal the rectum.
4. Instill water by pressing  / .

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

Do not turn off the control unit.

4. Evacuation



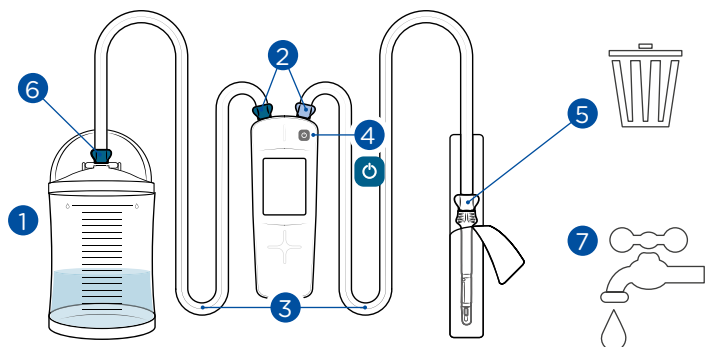
1. Press and hold  to deflate the balloon completely.
2. Remove the catheter gently.
3. Allow bowels to empty. If needed to start emptying, relax for 10-15 minutes, lean forward, cough or massage abdomen.

Do not turn off the control unit.

5. Disassembly

1. Open the water container lid.
2. Disconnect the tubes from control unit.
3. Empty water from the tubes.
4. Turn off the Navina Smart control unit and empty water from the control unit.
5. Disconnect the **single use catheter** and dispose as household waste. It must not be reused and not flushed down the toilet.
6. Disconnect the tube from water container and empty water.
7. Clean and dry the tubing and water container with a cloth and mild soapy water. The control unit must only be wiped clean.

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.



Transfer data

see instructions on opposite side