Wellspect®
A REAL DIFFERENCE

QUICK GUIDE ADULT USE

Charging & Settings

(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 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

Navina Smart 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
- You are pregnant

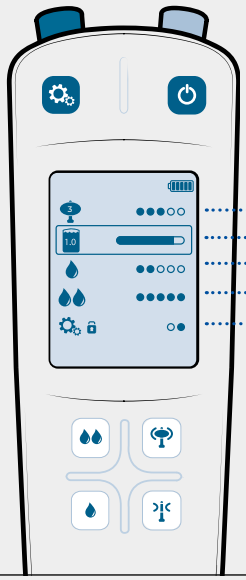
As the list may not be exhaustive, healthcare professionals will always consider individual user factors as well.

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 %[1]) 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).

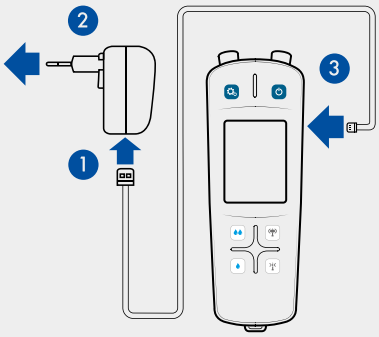
Settings

- Turn on Navina Smart control unit.
- Enter and exit settings.
- / Select flow rates (up/down).
- / Select balloon size (+/–).



1. This setting is not applicable when using a cone.
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.

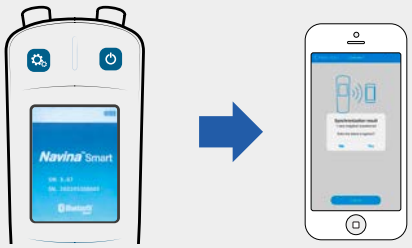
Charging



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.

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 to transfer data.
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.

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

Navina™ Smart

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QUICK GUIDE ADULT USE

Preparation & Use

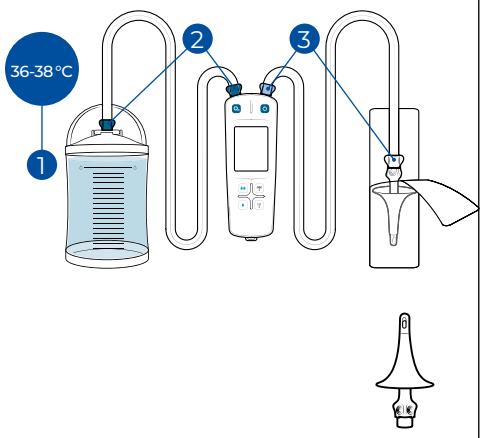
(cone)

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

1. Preparation

1. Fill with 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 cone tube between control unit and cone (light blue/white).

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

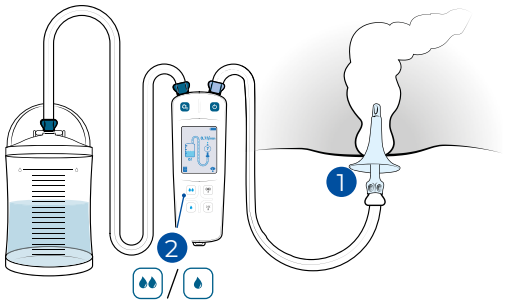


Cone

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 cone is covered with water (making it slippery) and the icon appears on the screen.
4. Press when you are ready to continue to the instillation mode.

Note: Do not add additional lubricant.

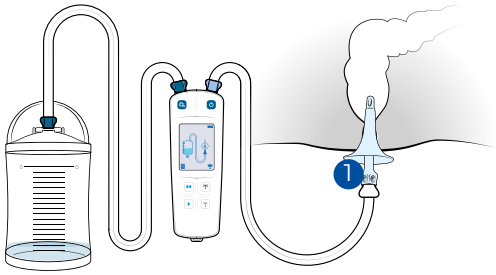


3. Instillation

1. Carefully insert the cone, without any force, as you have been instructed by your healthcare professional. Hold the cone in place during irrigation.
2. Instill water by pressing / .

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

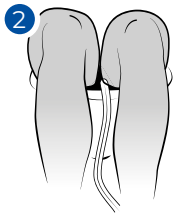
Do not turn off the control unit.



4. Evacuation

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

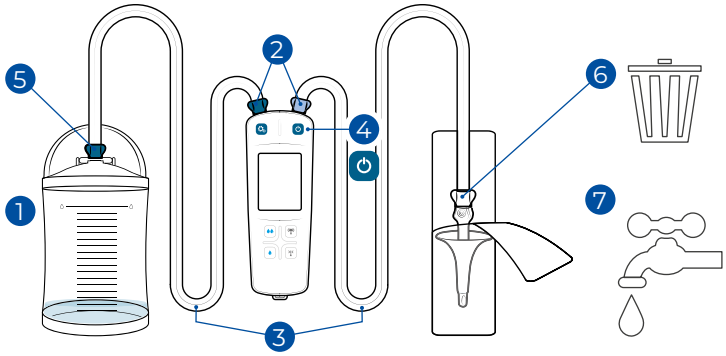
Do not turn off the control unit



5. Disassembly

1. Open the water container lid.
2. Disconnect the tubes from control unit.
3. Empty water from the tubes by raising the disconnected ends.
4. Turn off the Navina Smart control unit and empty water from the control unit.
5. Disconnect the tube from water container and empty the water container.
6. Disconnect the **single use cone** and dispose as household waste. It must not be reused and not flushed down the toilet.
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: 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.



Transfer data

see instructions on opposite side

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