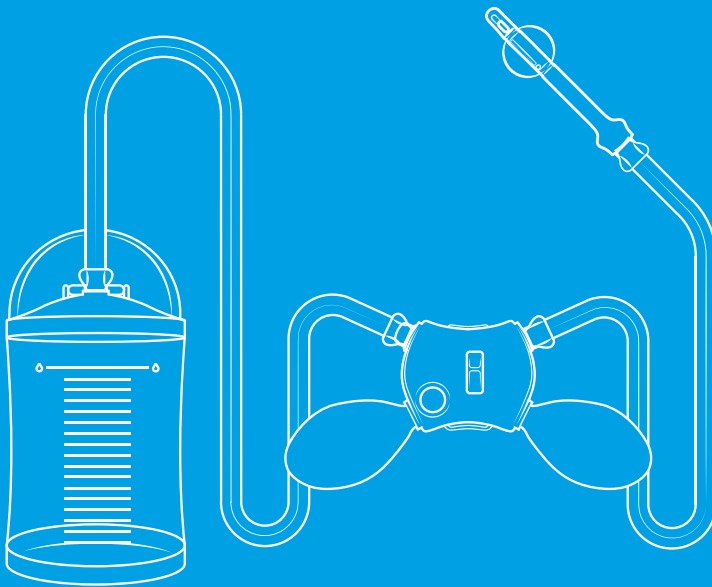




Securing independence

INSTRUCTIONS FOR USE



Navina™ Classic

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IMPORTANT INFORMATION:
Read all instructions before use.
Keep this instruction for further reference.

NAVINA CLASSIC PERSONAL INFORMATION

Navina Classic control unit:

Start date:

Expected date for new control unit:

Personal recommendations from healthcare professional:

TAI frequency:

TAI day and time:

Balloon size:

Recommended

Maximum

Catheter size:

Regular

Small

Water volume:

Bowel medications

(name, dose and frequency):

Other information:

Contact tel #:

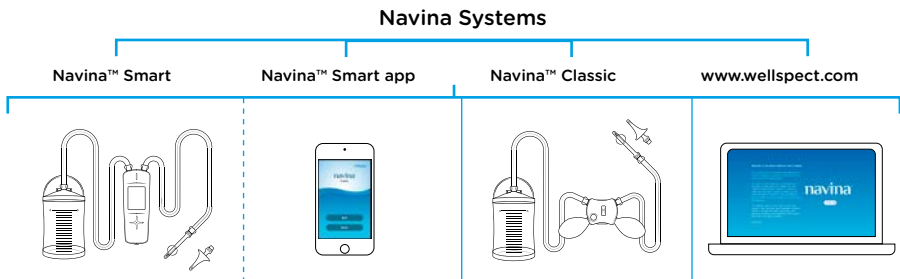
Next follow-up visit:

THANK YOU FOR CHOOSING NAVINA SYSTEMS

Wellspect is proud to present Navina™ Systems – An innovative and user friendly Transanal irrigation (TAI) system. Navina Systems has been developed in close cooperation with users and healthcare professionals, to facilitate TAI and make it available for more people, with different needs. The objective of the treatment is to create a bowel management routine which will facilitate your lifestyle and for many dramatically reduce the time and energy spent on bowel management.

NAVINA SYSTEMS OVERVIEW

The TransAnal Irrigation (TAI) treatment instills water up into the lower part of the colon (through a catheter or a cone), so the peristaltic muscles in the bowel can be triggered and start to evacuate the colon and rectum. The Navina Systems can be used at home, away from home, whilst travelling or in a healthcare setting. TAI with Navina Systems should be carried out while sitting on the toilet. The TAI treatment is very individual and demands patience while the body adapts to the therapy and the optimal personal settings are found (for some it may take 4-12 weeks). If you use Navina Smart, your data can be transferred to and analysed in the Navina™ Smart app. This unique follow-up tool will help you and your healthcare professional to implement a good bowel routine.



Important safeguards

Read all instructions before use!

These instructions are only a reminder and should be seen as complementary to the instructions given by your healthcare professional. They do not replace the need for training with a healthcare professional.

Keep this instruction for further reference.

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

The Navina Systems is indicated to help adults and children from 3 years who suffer from faecal 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).

Precautions

This product is NOT recommended for:

- Pregnant women.

Special care must be taken if you have or have had any of the following:

- *Faecal impaction – If you are heavily constipated an initial clean out of the bowel must be performed before starting the irrigation treatment.*
- *Painful anorectal conditions – any condition which may cause pain or bleeding, e.g. anal fissure, anal fistula, third or fourth grade of hemorrhoids.*
- *If you are at risk of autonomic dysreflexia (individuals with spinal cord injury above the sixth vertebra), supervised first irrigation with close follow-up is mandatory.*
- *Severe diverticulosis or diverticular abscess*
- *Irradiation therapy in the abdominal or pelvic region*
- *Previous anal or colorectal surgery*
- *Previous major pelvic surgery*
- *Changed stool pattern such as sudden diarrhea. The cause of diarrhea must be identified.*
- *Increased risk of hemorrhage or using anticoagulant therapy (not including aspirin or clopidogrel).*
- *Long term corticosteroid therapy*
- *Rectal medication, since the effect of the medication may be changed by using anal irrigation.*

Usage

- *The rectal catheter is a single-use product. If reused, Wellspect can not guarantee the functionality nor the safety of the product.*
- *Careful medical history and a digital rectal examination are mandatory.*
- *In the case of previous anal, colorectal or pelvic surgery, an endoscopy or comparable examination should be performed to exclude other additional disorders that would contraindicate the use of TAI.*
- *The first irrigation should be performed under supervision of a healthcare professional.*
- *Make sure to connect the tubes following the instructions, color coding and symbols.*
- *If you have an impaired sensation in your anal area and wish to use the grip rings, make sure a healthcare professional shows you where the ring should be placed on the tube in order to insert the catheter as far as instructed.*
- *Children shall be accompanied by an adult caregiver until the caregiver considers the child able to perform the procedure by themselves.*
- *Only use Navina Systems for its intended use, as described in this instruction manual.*
- *Navina Systems is for a single user and should not be shared with other people.*
- *The Navina catheter regular is for adult use only.*
- *Any serious adverse reaction occurring when using the Navina Systems should be reported to the manufacturer and your local health authority.*
- *Only use Wellspect's original accessories and no modification of this system is allowed.*
- *Check all components for wear or damage before usage. Do not use if damaged.*
- *There are no user-serviceable parts inside the Navina control unit.*
- *Do not attempt to repair the Navina control unit yourself.*
- *Store the Navina System away from the reach of small children.*

Training with healthcare professionals

Navina™ Systems should always be handled with utmost caution.

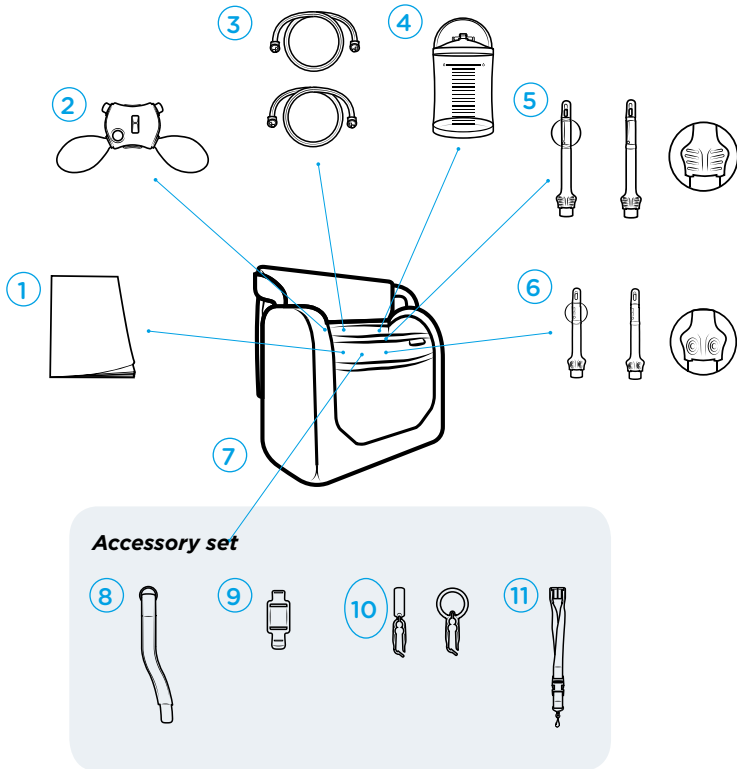
Training sessions in TAI with a healthcare professional specialized in TAI and familiar with the Navina Systems, are mandatory before using Navina Systems independently. After adequate training and recommendations from a healthcare professional, you should be able to handle Navina Systems on your own or with a carer if required. The frequency of treatment varies between individuals and will be recommended by a healthcare professional. It is usual to start using TAI on a daily basis for the first 10-14 days. Gradually you and your bowel will get used to the treatment and then the TAI procedure frequency may possibly be reduced to every second or third day.

Training and education for healthcare professionals and users

For more information, educational and training material about Wellspect, Navina Smart and Navina Classic, please call Wellspect customer service (see contact information) or visit www.wellspect.com.

For frequently asked questions, please consult the Navina section of www.wellspect.com.

COMPONENT LIST



#	Product	#	Product
1.	Navina Classic instructions for use	7.	Navina case
2.	Navina Classic control unit	8.	Navina positioning strap
3.	Navina tube set	9.	Navina Smart control unit positioning clip (Not used with Navina Classic)
4.	Navina water container	10.	Navina grip rings
5.	Navina catheter regular - For adult use only	11.	Navina lanyard
6.	Navina catheter small - From 3 years		

Note: System includes either Navina catheter regular or Navina catheter small.

Navina Systems components and disposal

Warning: If the components are used more times or for a longer period than indicated in the table below, Wellspect cannot guarantee the functionality nor the safety of the product.

#	Product	Number of uses
1.	<i>Navina Classic instructions for use</i>	
2.	<i>Navina Classic control unit</i>	<i>100 uses</i>
3.	<i>Navina tube set</i>	<i>100 uses</i>
4.	<i>Navina water container</i>	<i>15 uses</i>
5.	<i>Navina catheter regular - only for adult use</i>	<i>Single use only</i>
6.	<i>Navina catheter small</i>	<i>Single use only</i>
7.	<i>Navina case</i>	
8.	<i>Navina positioning strap</i>	
9.	<i>Navina Smart control unit positioning clip</i>	
10.	<i>Navina grip rings</i>	
11.	<i>Navina lanyard</i>	

Disposal

All Navina Classic components should be disposed as household waste.

Note: None of the components of the Navina Classic system are manufactured with latex, PVC and phthalates except the two pumps of the Navina Classic control unit which are manufactured without latex and phthalates.

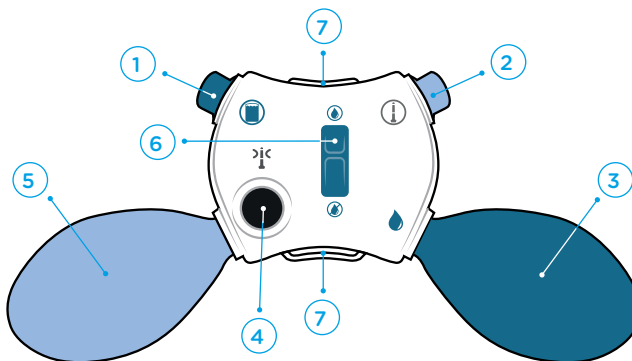
NAVINA CLASSIC CONTROL UNIT

With the Navina Classic control unit you control the inflation of the balloon and instillation of water during the TAI procedure with the help of two manual pumps. With training and recommendations from your healthcare professional and after an initial adaptation period with Navina Classic, you will learn how much you should inflate the balloon and how much and how fast you should instill the water, for optimal personalized results. i.e. how many times and how fast you should press the pumps on the control unit for each operation.

Please read the instructions carefully and keep this manual close to hand.

Overview

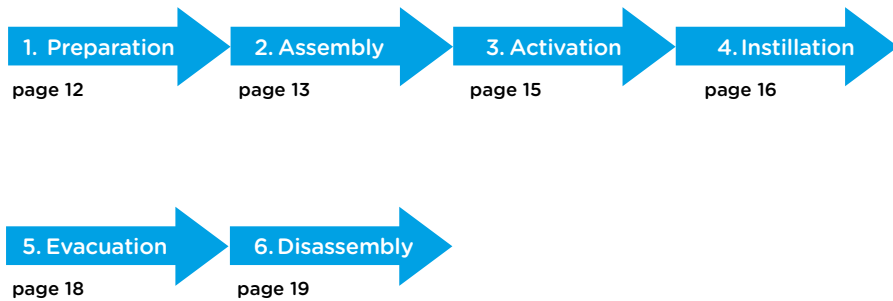
1. Connector to the water container
2. Connector to the rectal catheter
3. Dark blue pump to instill water
4. Black button to deflate the catheter balloon
5. Light blue pump to inflate the catheter balloon
6. Switch to open/close water flow
7. Loops to attach the position strap or the lanyard, if desired



HANDLING PROCEDURE

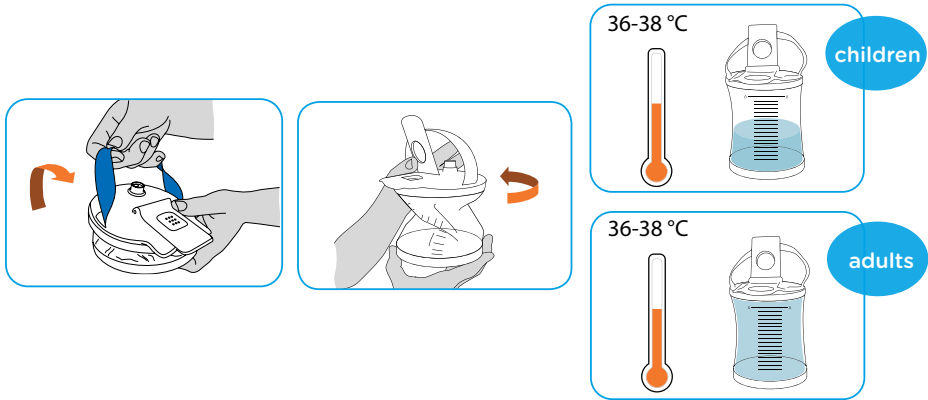
Read the entire instruction. Empty your bladder before irrigation.
Follow the instructions given by a healthcare professional.

Overview



1. Preparation

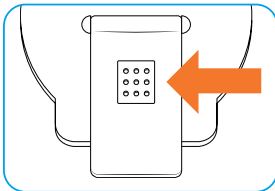
1. Open the lid of the water container.
2. Unwrap the water container by releasing the handle and expanding the container.
3. **Children:** Fill the container with lukewarm clean tap or bottled water to the level given by your healthcare professional + max 200 ml for activating the catheter's slippery surface.
Adults: Fill the container with lukewarm clean tap or bottled water to the upper mark of the the container.



4. Gently close the lid of the container until it clicks. Different ways of doing this are illustrated below.



IMPORTANT: Make sure that the safety valve on the lid is not blocked during the whole TAI procedure.

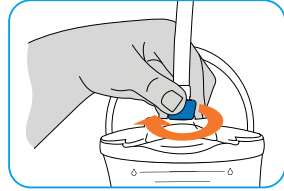



5. Place the container wherever is most convenient during the TAI procedure; standing on the floor, hanging by the handle or placed on a shelf or in the sink.

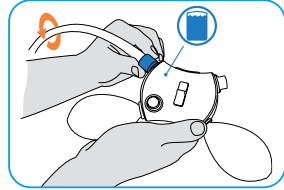
IMPORTANT: If the container is hanged, be sure to place the handle **behind** the tube.


2. Assembly

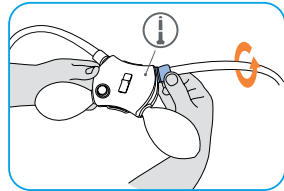
1. Connect the tube with **dark blue** connectors to the **dark blue** connector on the water container. Lock the connection by turning it clockwise until it stops.



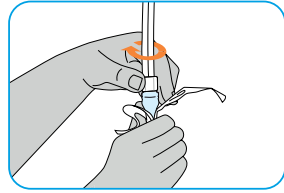
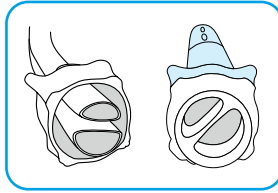
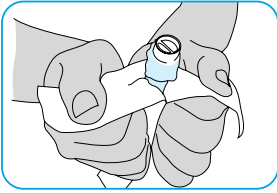
2. Connect the other end of the tube with **dark blue** connectors, to the **dark blue** connector with the  symbol on the Navina Classic control unit. Lock the connection by turning it clockwise until it stops.



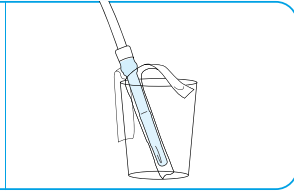
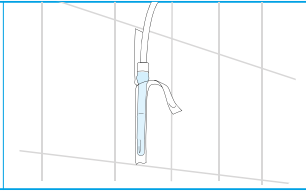
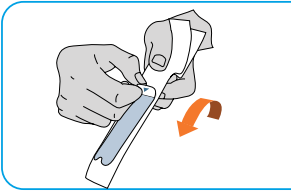
3. Connect the tube with the **light blue** connector to the **light blue** connection and the  symbol on the Navina Classic control unit. Lock the connection by turning it clockwise until it stops.




4. Peel the catheter packaging open **2-3 cm** to expose the rectal catheter connection. Do **not** remove the catheter from the packaging.
5. Attach the tube with the **white** connection to the catheter. The connection is half-moon shaped to help connect it correctly. Lock the connection by turning it clockwise until it stops.



6. Attach the packaging to a vertical surface by the adhesive patch, place it in the sink or in a tall glass to keep the incoming water remain in the package.
7. Ensure that the placement of the catheter is within easy reach when seated on the toilet.

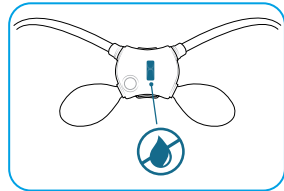
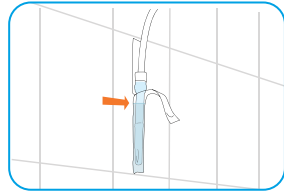
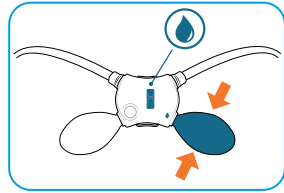


3. Activation of the hydrophilic surface of the catheter

1. Make sure the water flow is open. The water flow is open when you can see this  symbol above the blue switch.
2. Use the dark blue pump to start the water flow. This will empty the tubes of air and activate the hydrophilic surface on the catheter making it slippery.

Note: Do not add any additional lubricant.

3. Close the water flow when the water has reached $\frac{3}{4}$ of the length of the catheter



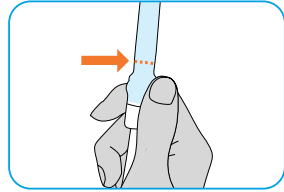
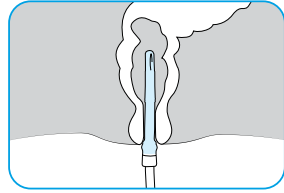
4. Instillation

Insert the rectal catheter

1. Make sure not to block the flow in the tubes in any way, e.g. by sitting on them.
2. Remove the catheter from its packaging. Keep the package for the disposal of the catheter.
3. Hold the catheter's handle as instructed by a healthcare professional.

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

4. Carefully insert the catheter, without any force. Your healthcare professional will instruct you how far to insert the catheter. Maximum insertable length should not be exceeded.



IMPORTANT: Never insert the catheter with force. If experiencing resistance when inserting the catheter, remove the catheter and make sure that your rectum is empty. Digital evacuation may be needed to ensure that the catheter can be safely and correctly inserted. This is particularly important during the early use of the System. When well established, your rectum will usually be empty when conducting TAI. However, if resistance continues do not force the catheter into the rectum. Stop using the irrigation. Seek help from a healthcare professional.

Note: Grip rings are available as a handling aid, see Accessories for more information about the grip rings and other accessories available.


Inflate balloon

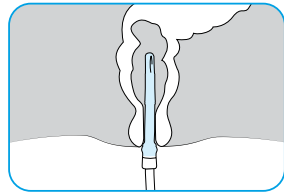
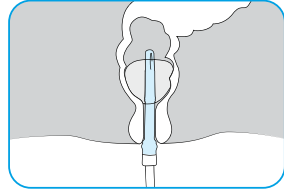
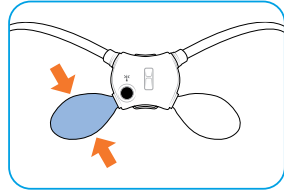
Children: Monitor the child's face during inflation, for signs of distress or discomfort. Stop or pause if it is uncomfortable for the child.

1. Use the light blue pump on the Navina Classic control unit to inflate the balloon. Stop the inflation at any time by releasing the pump.
2. Inflate the balloon up to the size advised by a healthcare professional.
3. Gently pull the catheter slightly down to seal off the rectum.

IMPORTANT: Do not over inflate the catheter balloon as this may cause the balloon to burst.


- Never use more than **5 pumps** when you are using the **regular** catheter.
- Never use more than **2 pumps** when you are using the **small** catheter.

Note: If you need to adjust the position of the catheter, you can deflate the balloon by pressing  and then reposition the catheter. The balloon should not be inflated more than 2 times.

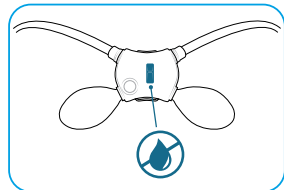
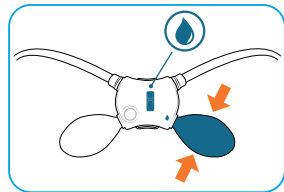


Instill water

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


1. Open the water flow. The water flow is open when you can see this  symbol above the blue switch.
2. Use the dark blue pump to instill the volume of water into your bowel indicated by a healthcare professional.
3. Stop or pause the instillation at any time by releasing the pump and closing the water flow with the blue switch.

Note: The speed at which water is instilled varies depending on how fast you pump. Pumping with full pump capacity every 5 to 10 second gives a flow rate of approximately 300-500 ml/min. By using the scale on the water container you can check the amount of instilled water.

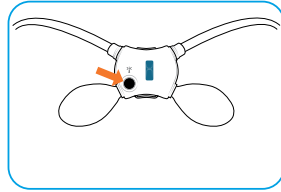


5. Evacuation

Remove catheter

1. Press and hold  until the balloon is totally empty.
2. The catheter may slide out by itself. If not, pull out the catheter gently.
3. Rest the catheter on the inside of the toilet or place it back in the packaging.

IMPORTANT: Do not remove the catheter before the balloon is completely deflated, may take 10 seconds.

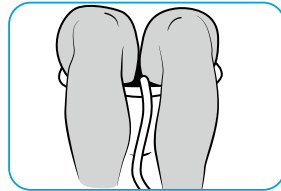


Evacuation

If the colon does not start to empty on its own, relax for 10-15 minutes and then try to lean forward, cough, perform abdominal massage or move the upper body to start the emptying process. The evacuation time is individual and can vary from one day to another.

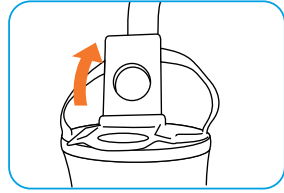
Ensure a comfortable position on the toilet (with a footstool if feet do not touch the ground) to promote pelvic floor relaxation.

IMPORTANT: In case the balloon cannot be deflated, detach the tube either from the catheter side or from the Navina Classic control unit. This will deflate the balloon immediately.

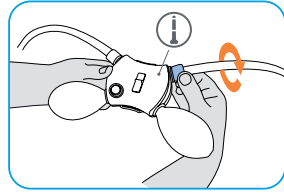


6. Disassembling and cleaning

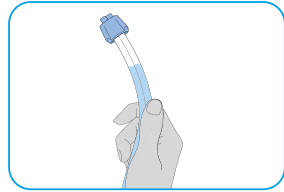
1. Open the lid of the water container to minimize the pressure in the System.



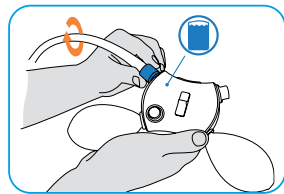
2. Remove the **light blue** connection from the Navina Classic control unit.



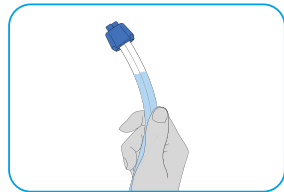
3. Empty the tube of water.
 - If the catheter is hanging in the toilet, raise the tube to empty water.
 - If the catheter is in the packaging, empty the water through the **light blue** connector.



4. Remove the tube with the **dark blue** connection from the Navina Classic control unit.

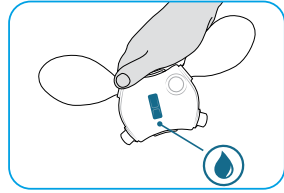


5. Raise the tube so that the remaining water flows back to the water container.

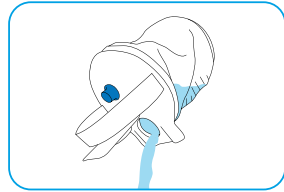
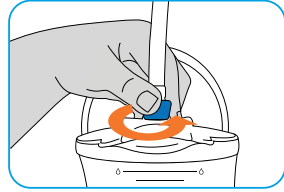


6. Open the water flow.
7. Turn the unit upside down over the toilet or sink to empty any remaining water.

Note: Pressing the pumps can help making sure the last drops of water come out of the control unit.

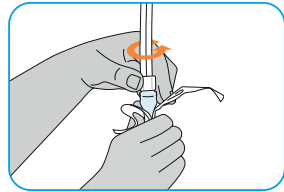


8. Remove the **dark blue** connection from the water container and empty the remaining water.



9. Hold the tube with the **white** connection and place the catheter back in its packaging, if not already there, and disconnect it from the tube.
10. Dispose of the single use catheter and packaging with the household waste.

IMPORTANT: Do not flush the catheter down the toilet.



11. Clean and dry the remaining parts of the System with a cloth and mild soapy water.

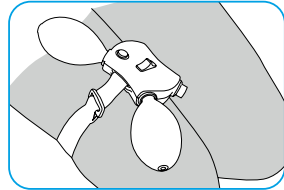
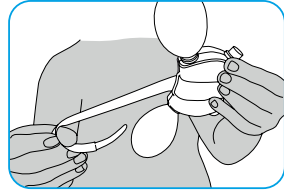
ACCESSORIES

The accessories provides easier use and are included with the Navina Classic System. An accessory set can be ordered separately if a replacement is needed.

The positioning strap

To facilitate handling, the Navina Classic control unit can be attached to where suitable, for example your thigh, with the help of the positioning strap.

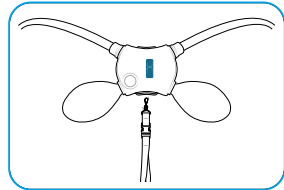
1. Thread the **positioning strap** with the velcro facing down through the loops on the Navina Classic control unit.
2. Adjust the length of the **positioning strap** by folding the strap over itself and fixing it with the velcro.
3. Place the **control unit** facing upwards and secure the **positioning strap**.



The lanyard

The lanyard let's the control unit hang around your neck.

1. Thread the small loop through the bottom of the Navina Classic control unit and pass the connection through the thread loop.
2. Attach the connection on the **lanyard**.
3. Hang the **lanyard** around the neck.

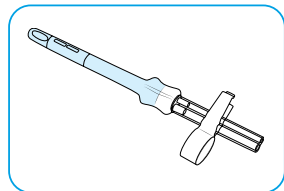
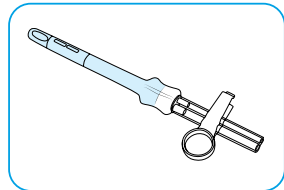


The grip rings

There are two different grip rings to facilitate the handling of the rectal catheter.

1. Place one of the rings (vertical or horizontal) on the catheter tube, close to the rectal catheter connector. Press until it clicks to secure the **grip ring** in place.

*IMPORTANT: If you have an impaired sensation in your anal area and wish to use the **grip ring**, make sure a healthcare professional shows you where the ring should be placed on the tube in order to insert the catheter as far as instructed.*



SIGNS AND SYMBOLS



Manufacturer



Reference number. Article number representing the product when ordering



Lot number



Use by



Single use



Consult instructions for use



Caution



US federal law restricts this device to sale by or on the order of a physician



Single patient, multiple use

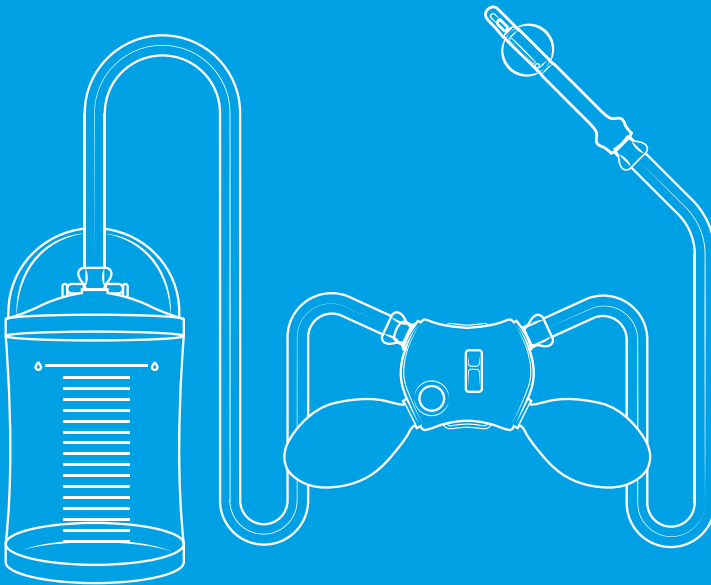


Medical device



Securing independence

Navina™ Classic Quick guide



Navina™ Classic

QUICK GUIDE

Read the entire instruction for use. Empty your bladder before irrigation.

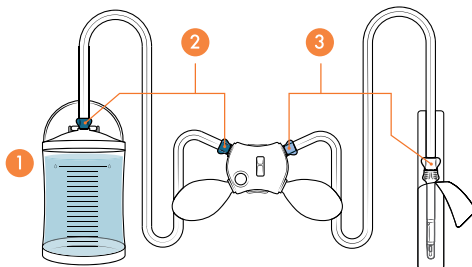
Follow the instructions given by your healthcare professional.

For detailed information on performing the procedure on children, consult pages 12-20.



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

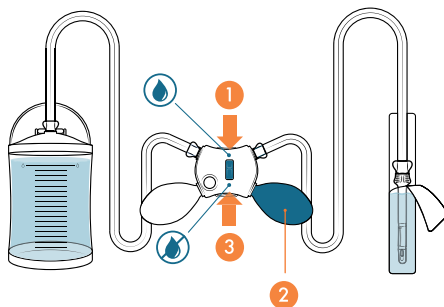
1. Preparation

1. Fill the water container.
 - a) Adults: Fill to the upper mark
 - b) Children: Fill to the level instructed by your healthcare professional + max 200 ml.
2. Connect the water container tube between the water container and the control unit (dark blue).
3. Connect the catheter tube between the control unit and the catheter (light blue/white).





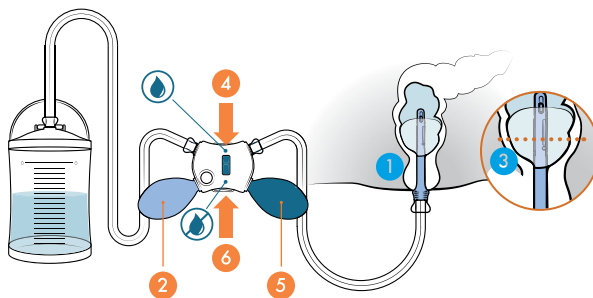
2. Activation

1. Make sure that water can flow through the connections. The water can flow when you see this symbol  above the blue switch on the control unit.
2. Pump water with dark blue pump until the catheter tube is immersed in water.
3. Close the water flow (the water flow is closed when you can see this  symbol below the blue switch).



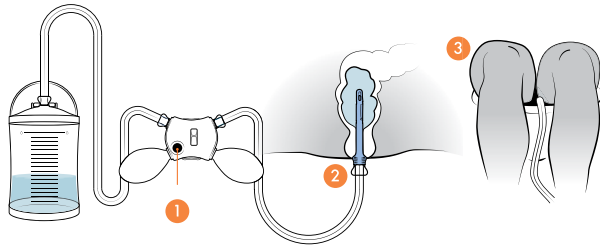
3. Instillation

1. Insert the rectal catheter according to your healthcare professional's instruction.
2. Inflate the balloon with the light blue pump.
3. Gently pull catheter slightly down to seal the rectum.
4. Open the water flow .
5. Instill water with the dark blue pump.
6. Close the water flow .




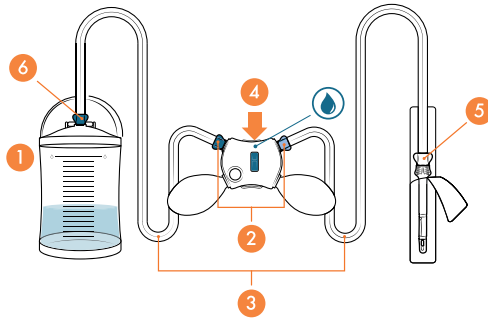
4. Evacuation

1. Deflate the balloon by pressing the black button.
2. Remove the catheter.
3. Allow bowels to empty.



5. Disassembly

1. Open the water container lid.
2. Disconnect the tubes from the control unit.
3. Empty water from the tubes.
4. Open the water flow  and empty water from control unit.
5. Disconnect the catheter and dispose in household waste.
6. Disconnect the tube from the water container and empty water.
7. Rinse, clean and dry system.



USAGE CALENDAR

Tick a box in the chart after each use to keep track of when to exchange the control unit, water container and tube set.

You will receive a new chart with every order of Navina Classic System which should coincide with the maximum 100 uses.

- New rectal catheter every time you irrigate.
- Change water container after every 15th use.
- New control unit and tube set after 100 uses.

Start date:

<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10
<input type="checkbox"/> 11	<input type="checkbox"/> 12	<input type="checkbox"/> 13	<input type="checkbox"/> 14	<input checked="" type="checkbox"/> 15	<input type="checkbox"/> 16	<input type="checkbox"/> 17	<input type="checkbox"/> 18	<input type="checkbox"/> 19	<input type="checkbox"/> 20
<input type="checkbox"/> 21	<input type="checkbox"/> 22	<input type="checkbox"/> 23	<input type="checkbox"/> 24	<input type="checkbox"/> 25	<input type="checkbox"/> 26	<input type="checkbox"/> 27	<input type="checkbox"/> 28	<input type="checkbox"/> 29	<input checked="" type="checkbox"/> 30
<input type="checkbox"/> 31	<input type="checkbox"/> 32	<input type="checkbox"/> 33	<input type="checkbox"/> 34	<input type="checkbox"/> 35	<input type="checkbox"/> 36	<input type="checkbox"/> 37	<input type="checkbox"/> 38	<input type="checkbox"/> 39	<input type="checkbox"/> 40
<input type="checkbox"/> 41	<input type="checkbox"/> 42	<input type="checkbox"/> 43	<input type="checkbox"/> 44	<input checked="" type="checkbox"/> 45	<input type="checkbox"/> 46	<input type="checkbox"/> 47	<input type="checkbox"/> 48	<input type="checkbox"/> 49	<input type="checkbox"/> 50
<input type="checkbox"/> 51	<input type="checkbox"/> 52	<input type="checkbox"/> 53	<input type="checkbox"/> 54	<input type="checkbox"/> 55	<input type="checkbox"/> 56	<input type="checkbox"/> 57	<input type="checkbox"/> 58	<input type="checkbox"/> 59	<input checked="" type="checkbox"/> 60
<input type="checkbox"/> 61	<input type="checkbox"/> 62	<input type="checkbox"/> 63	<input type="checkbox"/> 64	<input type="checkbox"/> 65	<input type="checkbox"/> 66	<input type="checkbox"/> 67	<input type="checkbox"/> 68	<input type="checkbox"/> 69	<input type="checkbox"/> 70
<input type="checkbox"/> 71	<input type="checkbox"/> 72	<input type="checkbox"/> 73	<input type="checkbox"/> 74	<input checked="" type="checkbox"/> 75	<input type="checkbox"/> 76	<input type="checkbox"/> 77	<input type="checkbox"/> 79	<input type="checkbox"/> 79	<input type="checkbox"/> 80
<input type="checkbox"/> 81	<input type="checkbox"/> 82	<input type="checkbox"/> 83	<input type="checkbox"/> 84	<input type="checkbox"/> 85	<input type="checkbox"/> 86	<input type="checkbox"/> 87	<input type="checkbox"/> 88	<input type="checkbox"/> 89	<input checked="" type="checkbox"/> 90
<input type="checkbox"/> 91	<input type="checkbox"/> 92	<input type="checkbox"/> 93	<input type="checkbox"/> 94	<input type="checkbox"/> 95	<input type="checkbox"/> 96	<input type="checkbox"/> 97	<input type="checkbox"/> 98	<input type="checkbox"/> 99	<input checked="" type="checkbox"/> 100

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www.wellspect.com.au

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NAVINA CLASSIC SYSTEM



2931EN-D

69005 Navina Classic System Regular - For adult use only

1 Navina Classic control unit
1 Water container

69007 Navina Classic System Small



1 Tube set
2 Rectal catheters (Regular or Small)
1 Accessory set
1 Navina case

69006 Navina Classic System Regular refill - For adult use only

1 Navina Classic control unit
1 Water container

69008 Navina Classic System Small refill



1 Tube set
2 Rectal catheters (Regular or Small)

69003 Consumable set Regular - For adult use only

1 Water container
15 Rectal catheters (Regular or Small)

69004 Consumable set Small



68940 Rectal catheter set Regular - For adult use only

10 Rectal catheters (Regular or Small)

68943 Rectal catheter set Small



69011 Tube set



1 Catheter tube
1 Water container tube

69012 Accessory set



2 Grip rings (1 vertical, 1 horizontal)
1 Lanyard
1 Positioning strap
1 Navina Smart positioning clip
(not used with Navina Classic)

69013 Navina Classic control unit



1 Navina Classic control unit

wellspect.com



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