



NAVINA FOR
CHILDREN
Securing freedom
for families

Navina™

A brighter future for children with bowel dysfunction

When the bowel works, life works. But what about when it doesn't? For children living with bowel dysfunction, feeling uncomfortable, afraid of accidents and embarrassment can be part of everyday life. On top of that, a disproportionate amount of time might be spent on bowel management and on the toilet trying to poop.

Our wish is for all children to feel well and confident, and we believe bowel management shouldn't take away quality time from the child, nor the family as a whole.

Our contribution is The Navina System, a transanal irrigation system developed specifically for children.



TAI is a good solution for children – and their families

Transanal irrigation (TAI), also known as bowel irrigation, is a long-term solution for many children and families living with bowel dysfunction. TAI can restore a healthy bowel routine and well-being using only lukewarm water. Furthermore, TAI helps children regain control of when and where to go to the toilet. With this comes increased confidence and more time to do

the things they want to do. Older children and teenagers can often learn to perform the procedure themselves, giving them more independence and confidence. A more predictable bowel-emptying routine can make caregivers feel more secure and confident about their child being away at school or with friends. When at home, TAI can save a lot of time and effort.

Studies confirm our belief

- TAI is an effective treatment in children and young people with constipation or bowel leakage as a result of neurogenic bowel.¹
- TAI reduces bowel leakage and fecal soiling.^{2, 3, 4}
- TAI improves family satisfaction with the child's bowel management.¹
- TAI in children improves Quality of Life.^{2, 3, 4, 5}
- TAI reduces time spent on bowel management compared to conservative bowel management.³
- TAI improves patient independence.^{6,7}

Navina Irrigation System: The only irrigation system with electronic or manual control

The Navina Irrigation System has high user satisfaction and is considered easy and effective to use. The Navina Irrigation System consists of an electronic unit Navina Smart as well as a manual unit Navina Classic.

It also includes a tube set, water container and rectal catheter and cone, fully interchangeable. Whatever your patient needs or prefers there is a solution.

But the real game changer for TAI in children is probably the electronic Smart control, which ensures that the therapy is consistent in its performance every time.

To facilitate the training period and beyond, we have developed a range of Navina educational materials and accessories. All together it means we offer a complete assortment of products and material for both children and adults.



Navina Smart:

Electronic handling with personal settings

Navina Smart is an electronic TAI system developed for a safe and predictable TAI procedure to give children and their caregivers better control. The electronic control unit is user-friendly and comes with built-in safety for maximum balloon size, water quantity and flow rate. Levels are set by you as a healthcare professional, and ensures that each irrigation is the

same, regardless of who performs it. Navina Smart automatically detects and rejects used catheters for safety and hygiene. All-in-all, the Navina Smart is safe for children and efficient for families in a home environment. Precise, safe and controlled irrigation with just the touch of a button.

Tubing

Color-coded connectors. Easy to assemble, grip and clean.

Disposable catheter or cone

Catheter with a durable⁸ and flexible balloon. A cone for those who cannot tolerate a catheter with balloon.

Smart control

Intuitive, easy-touch buttons and large display.



Water container

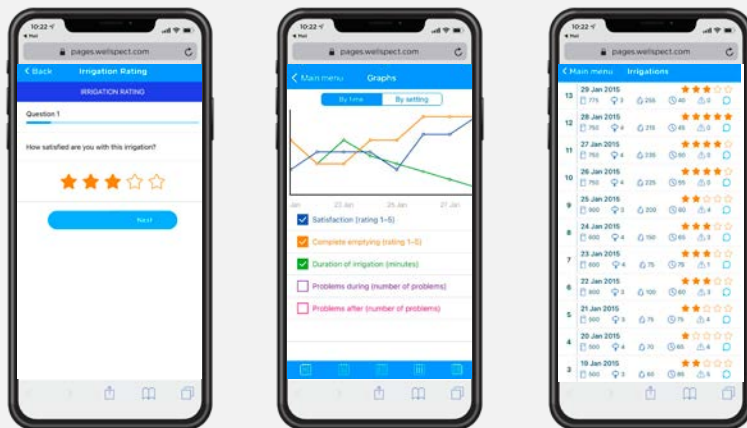
Collapsible. Double scale. Easy to open and close.

Note: Catheter, cone, tubing and water container are the same for both Navina Smart and Navina Classic.

Navina Smart app: Monitor procedures and progress

The Navina Smart app is a good tool to monitor treatment progress and satisfaction. It can be reassuring for caregivers to follow the child's progress. Settings and treatment data (balloon size, water volume, water flow rate and duration time), can be transferred to the app after each completed irrigation procedure and paired with the child's satisfaction rating.

For you as a healthcare professional, it means more control and patient involvement, quality data for progress analysis and treatment recommendations, and more efficient follow-up meetings. In short: much better than a manual bowel diary. For caregivers and children it can mean motivation and quicker results.



Disposable catheter and cone

The Navina Irrigation System works with both catheter and cone.

- Hydrophilic catheter suitable for children
- Flexible and durable⁸ balloon seals the rectum throughout treatment.
- Hydrophilic cone designed to fit snugly against the bottom
- Soft and pliable material makes them easy to grip.



Note: Catheter, cone, tubing and water container are the same for both Navina Smart and Navina Classic.

Navina Classic:

Easy and convenient manual pumping

Navina Classic offers easy manual pumping, large intuitive controls and color-coded water and air inflation pumps for clear understanding. It comes

with a flexible and durable⁸ balloon, and a sturdy water container. Navina Classic is the perfect choice when manual irrigation is preferred.



Classic control

Intuitive with color coded pumps. Easy to teach and learn.

Important information

Intended use

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

Indications for use

Navina Irrigation System is indicated to help adults and children from 2 years who suffer from bowel leakage, chronic constipation and/or time-consuming bowel care.

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 Irrigation System 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
- Pregnant women

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

Warning

Bowel perforation is a very rare (1 of 500,000 irrigations or 0.0002 %⁹) 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).

References

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7. Lopez Pereira P et al. J Pediatr Urol. Apr 2010;6(2):134-138
8. Sigvardsson S and Gränfors M, 28th ESPU Congress. 2017, Poster S19-10
9. Christensen et al. Tech Coloproctol. Feb 2016;20(2):109-115

At Wellspect we develop innovative continence care solutions that improve quality of life for people with bladder and bowel problems. We inspire our users to build self-confidence and independence as well as good health and well-being. We have been leading the industry for over 40 years with our product brands LoFric[®] and Navina[™]. We always aim to minimize the environmental impact of our products and passionately strive to become climate neutral. We work together with users and healthcare professionals to improve clinical outcome in a sustainable way, now and for the future.

Wellspect. A Real Difference.

For more information about our products and services, please visit Wellspect.com.

Join the conversation on LinkedIn, Twitter, Facebook and Instagram.

wellspect.us

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Navina irrigation system

Intended use

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

Indications

The Navina Irrigation System is indicated to help adults and children from 2 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 Irrigation System 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
- Pregnant women

As the list may not be exhaustive, healthcare professionals will always consider individual user factors as well. Before use see Instructions for Use.

Symbols glossary



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