

## DEAR PARENT OR CAREGIVER

This guide is about Transanal Irrigation (TAI), also known as bowel irrigation, and has been developed to support you as a parent or caregiver of a child about to undergo the procedure. Our aim is to give you knowledge and insight about how the bowel works and how TAI can help.

TAI has been used for children since the 1980's. Following the development of the required equipment in the last 10 years, it has now become part of routine bowel management for children with ongoing problems.

We know many people, both children and adults, whose everyday lives have been improved using the therapy. With TAI to help gain control over the bowel situation, children have more time to do the things they want to do. With this comes increased confidence, and you as a parent or caregiver save a lot of worries, effort and time.

We have gathered information from healthcare professionals, scientific experts, parents and users. We hope to increase your knowledge and motivation to start using TAI together with your child!

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# TAKE CONTROL AND SAVE TIME WITH TAI

Living with bowel problems can be difficult, and it affects not only the child but also routines and the life of the whole family.

Many caregivers with a child suffering from bowel dysfunction, struggle for far too long with dietary and stool (poop) changing medication, such as laxatives or stool softeners, without satisfactory results. But there is a better solution available.

TAI is a successful therapy for many children living with bowel dysfunction. TAI restores a healthy bowel routine, and helps your child to regain control of when and where to go to the toilet. With that, the inconvenience of accidents eventually disappears, and both you and your child can start living your life without constantly thinking about the bowel and toilet needs. In short, when the bowel works, life works.

However, TAI may feel strange or intimidating in the beginning, and it may take some time to get it right. As the stomach and bowel is a complicated system, it needs time to adjust to new routines. But it will be worth it in the long run.

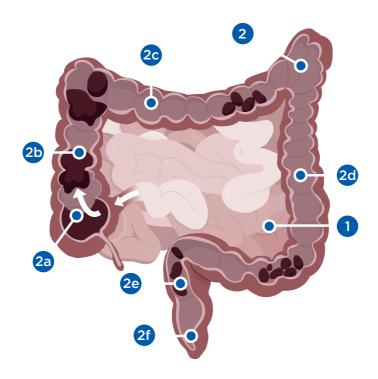




## THE DIGESTIVE TRACT

After food has been digested in the stomach, it passes into the small intestine. The main function of the small intestine is to absorb nutrition. The colon absorbs salts and water and converts the remains to poop.

The time it takes for the poop to move along through the colon can vary from hours to days. Poop is stored in the rectum, until a signal is sent to the brain that it is time to go. That is when we feel a need to go to the toilet.



- 1 Small intestine
- 2 Large intestine
- 2a Cecum
- 2b Ascending colon

- 2c Transverse colon
- 2d Descending colon
- 2e Rectum
- 2f Anal canal



# WHAT HAPPENS IN THE BODY WHEN THE BOWEL DOESN'T WORK?

Bowel dysfunction is a condition that can have many different causes. A child can have a bowel dysfunction as a result of birth anomaly such as spina bifida or anorectal malformation, it can be developed as a result of injury or illness, like a spinal cord injury or most commonly, there is no underlying reason for bowel dysfunction at all.

Bowel dysfunction often results in constipation, bowel leakage and/ or pooping problems. It is not uncommon to suffer from these disorders all at the same time.

Constipation is very common if you have bowel dysfunction.

Constipation is characterized by infrequent and irregular bowel movements, resulting in hard, dry poop, which is difficult to pass.

Bowel leakage is another common problem for children with bowel dysfunction. It causes involuntary release of poop.



# WHAT HAPPENS WITH LIFE WHEN THE BOWEL DOESN'T WORK?

Living with bowel dysfunction can be difficult. Children with bowel dysfunction may experience pain, bloating, loss of appetite and also soiling many times a day. This often results in emotional upset, embarrassment and social insecurity.

Many families spend a considerable amount of time trying to manage these problems. The time it takes to eat, go to the toilet or trying to go to the toilet, wash clothes after leaks and/or change diapers, care for chafed and sore bottoms, has a considerable impact on everyday life. Realistically, this limits play time and the child's possibility to participate in social activities.

Many caregivers devote a lot of time trying to find the right treatment for their child. Every new failed attempt can be emotionally draining and lead to a feeling of hopelessness. On top of this, there may be siblings that also crave and deserve attention.

## TRANSANAL IRRIGATION: THIS IS HOW IT WORKS

Transanal irrigation, also knowned as bowel irrigation is a technique for effectively emptying the bowel. It promotes evacuation of poop from the rectum and lower part of the colon by passing water into the bowel.

TAI is carried out by instillation of water into the rectum via a rectal catheter. When the catheter is removed water and poop come out. TAI is a method free from drugs or chemical use of any sort.

Regular irrigation of the bowel, effectively empties the colon and rectum so that it stays empty until the next irrigation. This not only prevents accidents, it also gives control over time and place of pooping. Insertion of water creates a mass movement from the ascending colon which helps push out any poop and therefore prevents constipation. Other significant advantages with TAI are reduction of time and energy spent on bowel management, which is positive for both children, caregivers and other family members. Older children and teenagers can often learn to perform the procedure themselves, giving them more independence and self-confidence.

#### No more bowel accidents

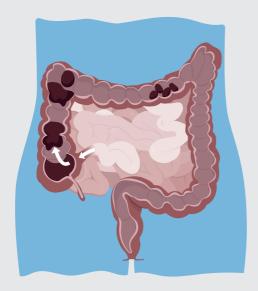
When the training period is over and your child's bowel has adapted to TAI, they should have achieved a bowel routine, avoiding both constipation and accidents. The aim of TAI is to restore a regular and well-functioning bowel allowing your child and you to live a life that is not limited by bowel issues.

Reduced risk of accidents creates confidence, saves time and allows more time for a social life, both for the child and family. A more predictable bowel emptying routine can also make caregivers feel more confident about their child being away from home, e.g. in school or with friends.

#### Time for play

Once your child has learned the procedure and his/her body has adapted to it, the irrigation should only take between 15 and 60 minutes. TAI is usually performed either daily, every other day or twice a week depending on your child's needs.

## TAI allows your child to focus on the more fun things in life

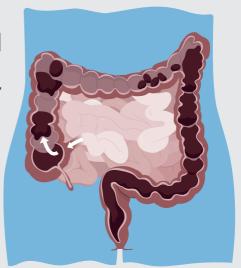


### Life with TAI

TAI empties a larger part of your bowel<sup>1</sup>, this may allow your child longer periods between toilet breaks.

### Life without TAI

For many children, under treated bowel problems means constipation, incontinence, many toilet breaks and a feeling of insecurity / lack of confidence.



<sup>&</sup>lt;sup>1</sup> Christensen et al. Dis Colon Rectum 2003;46:68-74

## MOTIVATION AND EXPECTATION

TAI is a good long-term solution that does not require invasive surgery or drug therapy. But TAI is not a quick fix. It is important to have realistic expectations of what TAI can do for your child and how long it may take to achieve satisfactory results. An initial commitment of up to 4-12 weeks is necessary in order to stabilize the bowel, to find your child's optimal treatment parameters and to develop a good individualized bowel management routine.

As your child's caregiver you are the most important person for your child's success with TAI. Motivation, patience, long-term commitment and a structured everyday life will help your child succeed.

It is important for all involved to know what it takes to succeed and have talked it through before you begin. Be prepared mentally and also prepare your child if possible. Talk to your child about the therapy and the Navina™ System and that it may take time and effort during the training period.

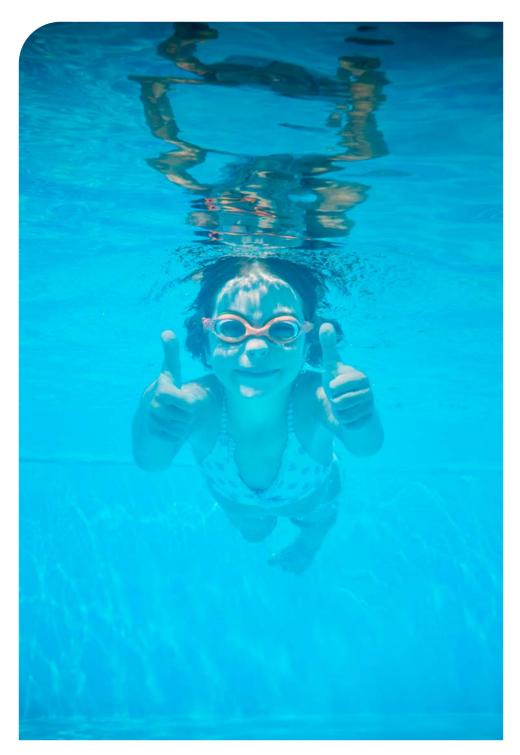
Setting up a goal is something that often works well, for both caregivers and children, especially for coaching the child to continue even if he or she is initially unhappy using irrigation. For instance, a goal can be to become free from diapers when starting school, to be able to wear normal underwear like their friends, or to be

able to engage in new activities, such as swimming. But all children have different needs. For children, it can also work better to set short-term goals along the way.

As the caregiver you know your child best.

Sometimes the training period is easier, sometimes harder. As a caregiver, it can be stressful if it's challenging in the beginning. Take one step at the time, and try to remember what a working routine can do for your child's and your family's everyday life in the long-run.

Give it time. It is worth it!





We are all different, and so are our bowels. Therefore, developing a program specifically adapted for your child is key to maintaining compliance and success in TAI.

Comprehensive training is very important when you start. Your healthcare provider should guide you and your child through his/her first session and continue to support you until you feel confident to do it on your own.

Try to be as well-informed and prepared as possible. Get to know your Navina™ System thoroughly before you begin so that you feel as confident as possible before you start to train with your child. This will help you and your child to get a good start.

For some children it may feel scary or uncomfortable to insert the catheter, for others it's not an issue at all. For some children, who have had longstanding constipation, when they first experience the peristalsis (movement of the bowel) with the water pushing the poop out it can be perceived as unpleasant. With reassurance and support these initial fears and concerns soon disappear.

TAI saves time for almost all users, compared to other bowel management strategies such as stool altering medications. However, for the child, the procedure can still be perceived as time consuming. The instillation is fairly quick, but it can take between 10-30 min for the poop to come out. Distracting your child with things they like to do, for example toys, a tablet or a book, is good. You can also let your child be involved in the procedure, such as checking the water volume on the scale of the container.



Letting your child be involved in the TAI routine from the start can be a good way to take away resistance, suspicion and hesitation towards the therapy.

It can also ease acceptance and give your child confidence.

From the start it can be as simple as carrying the system to the bathroom. Helping take pieces out of the bag is a good way to learn the use and name of all the parts. Let your child become comfortable with the system itself – to hold and feel the different parts, perhaps play with it on a teddy or doll.

You can also give them stickers to decorate and make the system their own. Put stickers on the bag, and perhaps mark the water level that you use with a sticker – so that the child knows to what level water should be poured.

When older or ready, the child can be more involved in the procedure, perhaps help filling the water container. Eventually you can let your child hold the catheter while you hold and steer the child's hand and catheter during insertion. Give your child attention for every step learned.

# NAVINA IRRIGATION SYSTEM: THE ONLY IRRIGATION SYSTEM WITH ELECTRONIC OR MANUAL CONTROL

Navina Irrigation System uses the latest technology to help you perform TAI conveniently, safely and consistently with control. For convenience it comes with both a balloon catheter and cone.

The system has been developed in cooperation with users and healthcare professionals to adapt to individual needs and preferences.

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

- Effectively relieves constipation and bowel leakage
- Flexible all parts within the system are fully interchangeable
- Choose between manual and electronic device





#### **Navina Smart app**

Finding optimal treatment parameters can be difficult and take time. The Navina™ Smart app is designed to help personalize therapy faster. The app stores treatment data and allows your child to rate the irrigation. Both you and your child can actively follow the progress over time. The app makes it easy to see which parameters have created the highest ratings. Download for free at appstore or Google play.



#### **Navina Smart**

## Electronic handling with personal settings

Navina Smart is an electronic intuitive and user-friendly control unit. The control has built-in safety for maximum balloon size, water quantity and flow rate. Once the personal settings have been saved, you only need to click start when it is time to irrigate.

The Navina Smart control unit ensures that you get the right balloon size, water speed and volume – every time, regardless of who performs the procedure.

- Precise, safe and controlled sessions
- Irrigation with just the touch of a button



#### **Navina Classic**

## Easy and convenient manual pumping

Navina Classic offers easy pumping, large intuitive controls and color-coded water and air inflation pumps for clear understanding. Navina Classic is the perfect choice when manual irrigation is preferred.

## Navina Irrigation System:

## INCLUDED PARTS

#### 1. Water container

- Small and collapsible for discreet storage and transport.
- Sturdy with an integrated scale that maintains its accuracy over time.
- Single compartment design makes it easy to fill and empty.
- Easy to open and close even with reduced hand strength and function.
- Integrated lid (no assembly needed) with pressure valve for increased safety.
- The double scale makes it easy to fill the container with the right amount of water.

#### 2. Tubing\*

- Easy to grip and handle.
- Color-coded and secure connectors to ensure easy and correct assembly.
- Easy to clean.

#### 3. Carrying case

Includes accessories such as grip rings, positioning clip, strap and a lanyard for user convenience.



#### 4. Disposable catheter\*

- Disposable hydrophilic\*\* catheter with rounded tip for maximum comfort, hygiene and safety.
- Flexible balloon design seals the rectum to ensure catheter stays in place and provides a good seal throughout treatment.
- Connector with good grip makes handling easier.
- Balloons tested individually for optimal function and to ensure a good safety margin between maximum inflation and bursting point.



#### 5. Disposable cone

- Disposable hydrophilic\*\* cone made of soft and flexible material designed to fit snugly against the bottom.
- Rounded tip for maximum comfort, hygiene and safety.
- An alternative to the catheter.
- Connector with good grip makes handling easier.



<sup>\*</sup> Catheter, cone, tubing and water container are the same for both Navina Smart and Navina Classic

<sup>\*\*</sup> The hydrophilic surface ensures that the catheter is slippery and comfortable



## GETTING STARTED -CATHETER

To start an irrigation, prepare the system by filling the container with as much lukewarm tap water as you have been instructed to instill (plus some extra for activating the catheter). Activation means that the catheter surface becomes slippery in contact with water. Then connect the tubings between the control unit and water container. More detailed instructions can be found in your Instructions For Use.

After activation, the catheter is inserted into the rectum as far as instructed by your healthcare professional and the balloon is inflated to work as a seal. Inflate either electronically with the Navina Smart control unit; or manually with the Navina Classic control unit. Once the catheter is in place, water can be instilled without leakage.

The size of the balloon and amount of water instilled will be decided and set together with your healthcare professional. Some children will only need 100 ml, while others will be using up to 700 ml. You can observe facial expression and signs of distress closely to determine the individual level.

After water instillation, deflate and remove the catheter and wait for the water and poop to empty into the toilet

#### Instillation - getting started

- 1. Prepare the system
- 2. Activate and insert the rectal catheter as far as instructed by the healthcare professional
- 3. Press To inflate the catheter balloon until the desired balloon size is reached
- 4. Gently pull the catheter slightly down to seal the rectum
- 5. Instill water by pressing •• / •
- 6. Deflate the balloon by pressing (it)



## GETTING STARTED -CONE CATHETER

To start an irrigation, prepare the system by filling the container with as much lukewarm tap water as you have been instructed to instill (plus some extra for activating the cone catheter). Activation means that the cone surface becomes slippery in contact with water. Then connect the tubing between the control unit and water container. More detailed instructions can be found in your Instructions For Use.

After activation, insert the cone into the rectum, as far as you have been instructed by your healthcare professional. Once the cone catheter is in place, water can be instilled.

The amount of water instilled will be decided and set together with your healthcare professional. Monitor the child's face during instillation for signs of distress or discomfort. Stop or pause if it is uncomfortable for the child.

Some leakage may be expected when using a cone, as it may be difficult to get a complete seal. Minor adjustment of the cone's position may help.

After water instillation, remove the cone catheter and wait for the water and poop to empty into the toilet.



#### Instillation - getting started

- 1. Prepare the system
- 2. Activate and insert the tip of the cone
- 3. Instill water by pressing | •• / •





4. Remove the cone



# TRAINING MATERIALS AND ACCESSORIES

Apart from the benefits of Navina Irrigation System, we have developed materials and accessories to facilitate the training period and beyond.



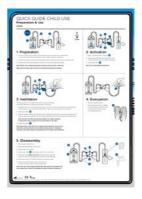
#### **Navina Smart app**

The Navina Smart app can be a useful tool when interacting with your child about the therapy and how it progresses. Read more on page 19.



#### wellspect.com

At wellspect.com you will find information that gives you an introduction to the bowel system, TAI therapy and much more. You will also find user testimonials and interviews, both here and in the Wellspect blog.



## Navina System Quick guides

Short guide that gives you everything you need to know about how to operate Navina Irrigation System.



#### Series for children

Everyone needs to poop, but we can do it in different ways. The purpose of the series is to make the introduction of TAI less dramatic.

A few instructional images are included, which can be used in discussions and interactions together with the child.



#### Personalize your Navina System

The stickers allow your child to decorate the Navina System and make it more personal. Ask your healthcare professional for a sticker sheet.



#### Navina activity book

An activity book for children to make them feel more familiar with the Navina System. It includes steps to learn the different parts of the system, as well as puzzles, color figures and more to make it fun.

#### NAVINA IRRIGATION SYSTEM: Q&A

#### - How far should you insert the catheter?

The catheter needs to be inserted far enough so the balloon sits in the right position in the rectum (bottom). Your nurse will show you exactly how far to put it in.

#### - In which position should you sit?

It is important to sit comfortably on the toilet. Use a potty training seat/seat insert (usually for very little kids) and a step for the feet if necessary. Sitting with the knees slightly higher than the hips is the best position.

#### How much may I inflate the small catheter using Navina Classic on a child?

As each child is different your nurse will advise you, but in general we suggest starting with up to 1 maximum 2 pumps.

#### - How does that work for Navina Smart?

Be guided by your nurse who will advise you what settings to use. We often find that initially children may only tolerate a small balloon volume but as they get used to the procedure they become comfortable with the most effective inflation. For the small catheter, balloon sizes 1-3 should be used.

#### - How much water should be pumped in?

The volume of water depends on the size of the child and their initial tolerance to the irrigation. It is common to start with 10 ml/lb body weight. This shall be decided together with a healthcare professional familiar with TAI in children.

#### - How often will we need to do the procedure?

From the start it is good to irrigate every day and after an initial period of 1–2 weeks,

most users can slow down and irrigate every other day.

#### - How long will it take?

For most children irrigation takes 15-60 min.

#### - Can my child do it on his/her own?

Yes that's the goal. However, children should always be accompanied by an adult caregiver, who performs the procedure, until that caregiver considers the child able to perform the procedure by himself/herself.

#### - What is a normal routine?

The 'normal' routine is whatever fits within your family lifestyle. For most children, with and without bowel dysfunction, the bowel works in a regular manner. It is therefore good to also irrigate regularly – some families find the evening, about 30 mins after their meal to be the most practical.

## - For how long should the child try the procedure before it is effective?

Most families find a routine and pattern that works within the initial "tuning" period (4-12 weeks).

#### - Does it hurt?

Some children express fear and worry about starting TAI. TAI should not hurt but some children may interpret 'normal' peristalsis (movement of the bowel) as discomfort when they first experience the irrigation working. If the water is too cold, it may cause stomach cramps. The water temperature should be lukewarm, approximately 96.8-100.4 °F.

#### I followed the instructions but no poop came out?

Abdominal massage, coughing or movement may encourage the water to come out. It may be due to constipation or dehydration. Irrigating 30 minutes after eating or drinking may help to stimulate the natural activity of the bowel. If the problem persists, contact your nurse.

#### - Is it ok to use tap water?

You should irrigate using clean lukewarm tap water (96.8-100.4 °F.). As a general rule, if you can drink the water it is okay to irrigate with.

#### - Do I have to wash my child afterwards?

Some caregivers find showering in conjunction with irrigation is a good

routine, but it is not necessary, as long as your child stays clean and dry. The child will just need to wipe their bottom as they would after a 'normal' bowel movement (poop) and of course do their normal hand-washing routine.

### - What about diet, can my child eat and drink whatever he or she wants?

Eating a varied diet is good for digestion and bowel health and recommended for everyone.

#### - How does it work in school?

Commonly, this is not a procedure that would be carried out in school, and hence should not influence daily activities.

#### 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 3 years who suffer from bowel leakage, chronic constipation and/or timeconsuming 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

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 % 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).



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.

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