

Wellspect®
A REAL DIFFERENCE

IN CONTROL AFTER RECTAL SURGERY



Navina™

Low Anterior Resection Syndrome – LARS – is a constellation of symptoms or problems you experience in varying degrees after rectal surgery. Rectal function will never be exactly like it was before, but most people will get a decent or acceptable function. This leaflet provides suggestions for ways to manage symptoms you may experience following your surgical treatment. Talk to your healthcare provider about your symptoms. There is help available.

This leaflet also contains information on transanal irrigation (TAI) with Navina Systems. TAI has been proven to be an effective treatment option for those who experience LARS. We hope you will find this leaflet helpful!

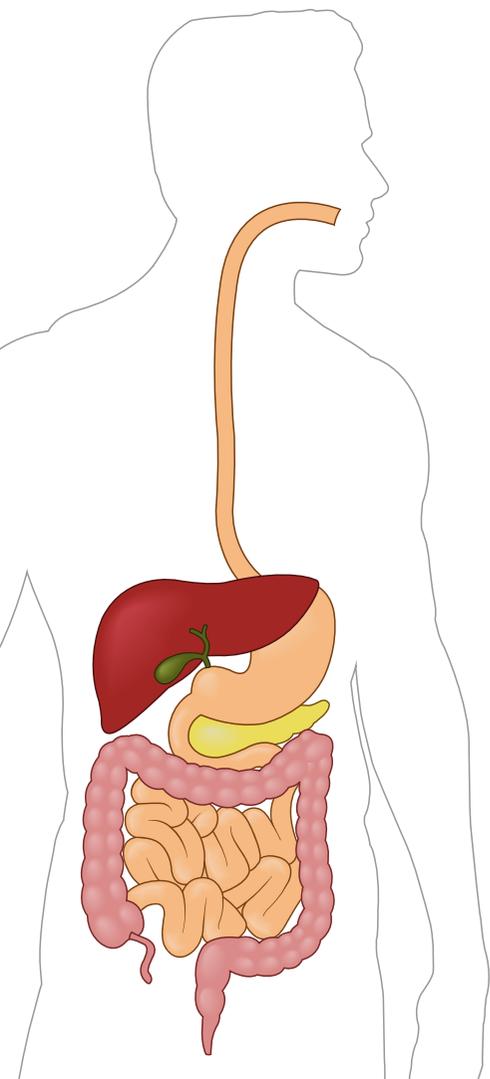
We would like to thank specialist nurses Sara Strandberg and Mari Dahlberg, as well as Associate Professor Louis Banka Johnson (Pelvic Center, Surgery SUH Malmö, Sweden) for their collaboration in the production of this leaflet.

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NORMAL BOWEL FUNCTION

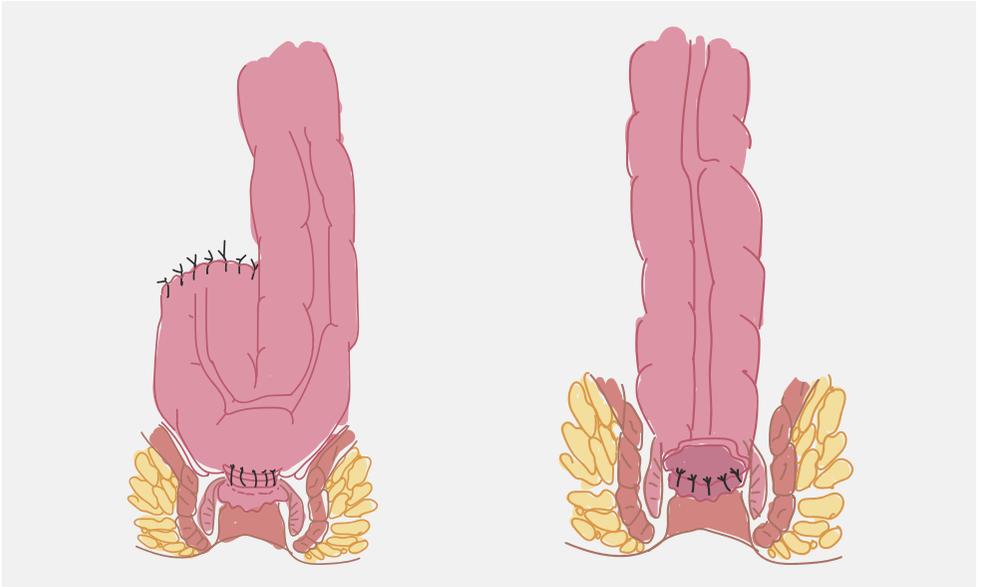


The frequency of bowel movements varies from person to person. It is normal to have a bowel emptying between three times per day to once every three days.

The entire human digestive tract is approximately 29 feet long. Once we have chewed and swallowed food, it is broken down into small particles in the stomach and passes onward through the small bowel, the primary function of which is to absorb nutrients. The contents of the small bowel then pass on to the large bowel. The large bowel receives one to two liters of contents each day, and this material remains in the large bowel for one to three days. A large portion of the bowel content consist of water, residue from food that has not been broken down, salts, and bacteria. Most of the water is absorbed in the large bowel and stool therefore gains a firmer consistency. Stool is transported to the rectum by bowel movements called peristalsis. The rectum functions as a container for stool and once rectum is filled with stool, signals are sent to the brain and we feel the need to empty our bowels. This leads to the relaxation of the anal sphincter and the anus opens. There are two sphincter muscles around the anus, one of which can be controlled voluntarily.

It normally takes one to three days for food to pass through the digestive tract.

LOW ANTERIOR RESECTION SYNDROME (LARS)



In surgery for rectal cancer, all or part of the rectum is removed and the end of the bowel and what is left of rectum/ anus are then connected together.

This junction is called an anastomosis. Depending on the location of the tumor, a high or low resection of the rectum is performed. With a low resection, called low anterior resection, the junction sits further down towards the anus. It is common to have a temporary ostomy (a pouch on the abdomen) called a loop ileostomy to unburden and protect the

anastomosis while healing. The ostomy is removed once the anastomosis has healed, which usually takes about 2-3 months.

The rectum functions as a container for stool, and once this function is removed it may lead to more frequent bowel movements and a sensation of incomplete emptying. Surgery, radiotherapy, and chemotherapy may cause nerve damage, which may lead to impaired rectal sensation and increased

difficulty feeling whether gas or stool is to be passed. It may also be difficult to keep the sphincter closed, leading to a risk of stool or gas leakage.

Radiotherapy may cause inflammatory processes in the bowel, which may lead to chronic changes that make it more difficult for the bowel wall to absorb fluid and hence make the stool looser. This could lead to bowel urgency with a risk of leakage. The radiotherapy and inflammation make the bowel bleed more easily, increase mucous production, and make the bowel wall less elastic.

Chemotherapy often produces acute side effects like nausea, vomiting, and diarrhea. The long-term effects of cytotoxic drugs on

the bowel are not entirely known. Possible damage includes an imbalance in the microflora of the bowel, an effect on bowel movements and damage to the mucosa.

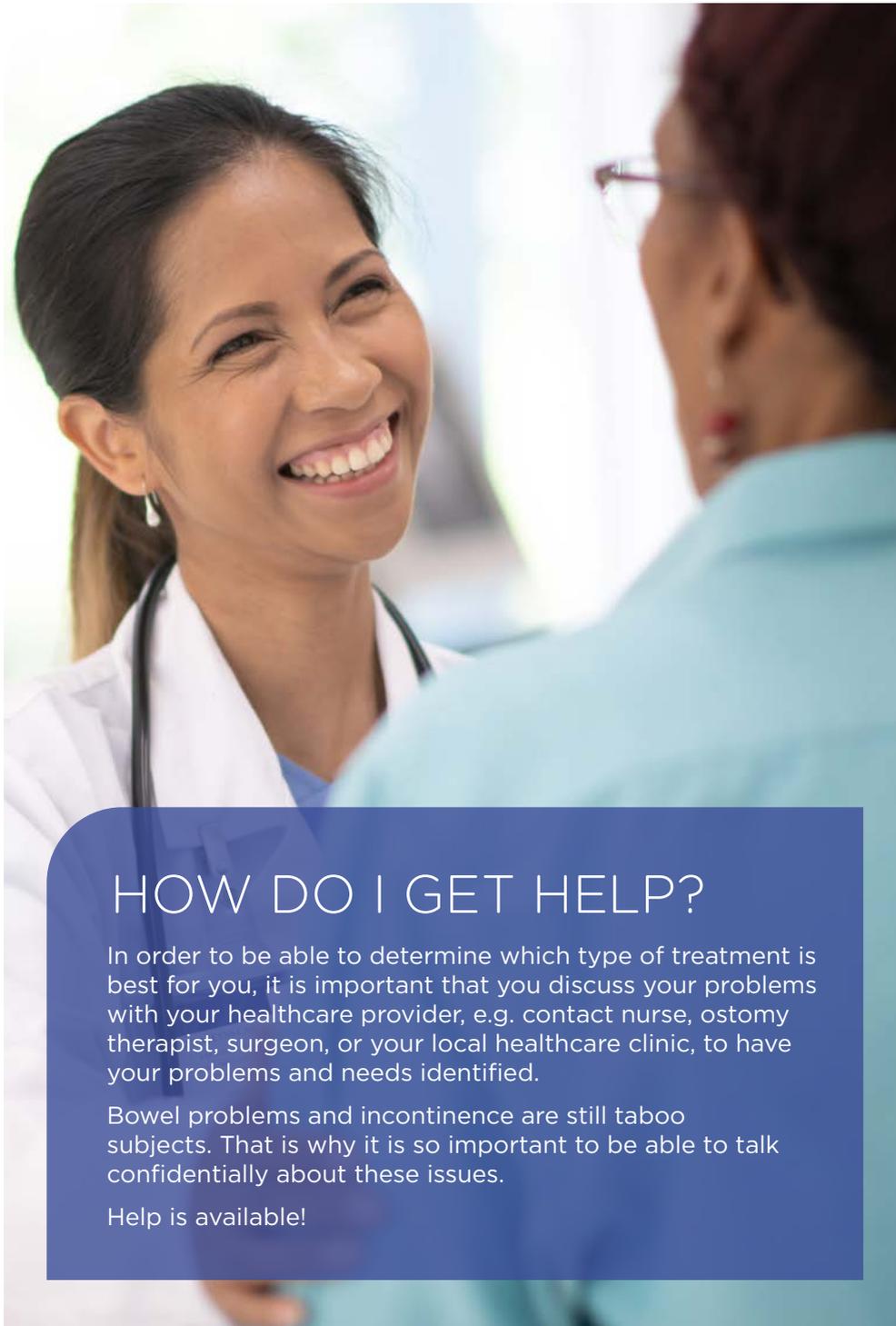
Surgery, radiotherapy, and chemotherapy may each cause side effects individually, and the risk of bowel dysfunction increases if you have had a combination of these. When adding in other factors such as diet, stress, anxiety, and side effects from medication, this may also contribute to even worse bowel function.

This worsened bowel function is called Low Anterior Resection Syndrome (LARS) and is common after rectal surgery.

Symptoms of LARS consist of one or more of the following:

- Involuntary passing of gas
- Frequent bowel urgency
- Defecation urgency
- A feeling of incomplete emptying
- Stool leakage

You may experience secondary complications such as sleep difficulties, pain, sore skin and urinary incontinence as well. Talk to your healthcare provider about your symptoms and what is bothering you most.



HOW DO I GET HELP?

In order to be able to determine which type of treatment is best for you, it is important that you discuss your problems with your healthcare provider, e.g. contact nurse, ostomy therapist, surgeon, or your local healthcare clinic, to have your problems and needs identified.

Bowel problems and incontinence are still taboo subjects. That is why it is so important to be able to talk confidentially about these issues.

Help is available!

TREATMENT OPTIONS

There are several treatment options, from simple to more advanced, that can be used either alone or in combination. The treatment must be tailored and adapted to your needs.

Counseling

LARS has a great impact on quality of life. You may feel ashamed to talk about these problems, and also afraid of not having control of your bowel, which lead to limitations in your everyday life. It is important to have the time, space and courage to put your bowel problems into words and discuss with your healthcare provider.

Dietary advice

There is limited research regarding the effect of changes in diet. The effect of diet on the digestive tract varies from person to person and it is therefore difficult to provide standardized dietary advice. One can try to exclude certain foods to see whether discomfort is reduced. Eating frequent small meals and chewing food well can reduce the risk of flatulence and strong bowel movement urgency. Sweets, artificial sweeteners such as Xylitol and Sorbitol, fatty foods and chewing gum can cause increased flatulence and loose stool. Strong spices, coffee and alcohol can increase bowel movements and increase the risk of leakage. Probiotics can have a positive effect on gut flora and may reduce bowel symptoms.

Medication

Bowel-regulating agents stimulate the bowel naturally. They bind fluid, increase the volume of bowel content, normalize the consistency of stool and facilitate emptying. Examples of bowel-regulating agents include psyllium seeds, ispaghula husk and sterculia. Bowel-regulating agents must be taken together with liquids.

Loperamide is a drug that counteracts diarrhea. It causes food to pass more slowly through the digestive tract so that more fluid is absorbed and the stool becomes firmer. Even soft and mushy stools become firmer. Take Loperamide for preventive purposes, e.g. when you know you usually have loose stools. However, it is suggested to start with small doses since the treatment is very individual and the stomach can react quite strongly to the medication.

In case of troublesome gas production, you can try dimethicone. Dimethicone breaks down foam and bubbles, which are mostly caused by swallowed air and which the bowel may find more difficult to deal with after radiotherapy.

Toilet exercises

Concerns about stool leakage can mean that the slightest urge leads to an immediate visit to the toilet. This in turn may stimulate even more frequent urges. You can practice relaxing and resisting the urge reflex. It is fine if you only manage a few seconds in the beginning – it gets easier with time. You should relax and breathe calmly and try to hold it. This can be done on the toilet if it feels too unsafe. If you can hold the stool for a couple of minutes, the urge will subside. Gradually, you can increase the time and distance to the toilet.



Emptying techniques

The bowels are best emptied if you squat. If you are trying to imitate that position, you can sit in the following manner: Knees higher than your hips using a footstool. Lean your body forward and rest your elbows on your knees. Tighten your abdomen and press with the abdominal muscles. You can try holding your hands on your abdomen and force a cough to better understand how the abdominal muscles are used when emptying the bowels. Emptying as thoroughly as possible can be helpful for emptying difficulties, as well as to prevent gas and stool leakage.

Pelvic floor muscle training

By doing pelvic floor muscle training, the muscles of the pelvic floor are strengthened and the muscle strength around the urethra and rectum increases. Pelvic floor muscle training can make it easier to resist bowel movement urgency.

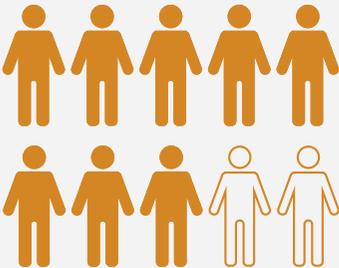
Assistive devices

In case of problems with stool leakage, there are different types of protection. There is special protection for small stool leaks with a carbon filter that effectively removes odors. There are also anal plugs that prevent leakage. A physician should be consulted before an anal plug is used.

Transanal irrigation

Transanal irrigation (TAI) is a method of effectively emptying the bowel by introducing lukewarm water into the rectum, through a rectal catheter or cone. If a low volume of water is used it can help to get the last stool out and rinse clean the lowest part of the bowel. If a higher volume of water is used the peristaltic movements of the bowels can be stimulated, which helps to empty a larger part of the bowel from stool and hence reduce the number of bowel movements and the risk of stool leakage. TAI can be used daily, or less frequently. TAI is treatment prescribed by a healthcare professional. For more details, see next page

Studies show that treatment with TAI reduces the symptoms of LARS in 8 of 10 patients.



Peripheral tibial nerve stimulation (PTNS) and sacral nerve stimulation (SNS)

This method involves affecting the nerve traffic to the nerves that control the bladder, bowels and pelvic floor. Mild electrical impulses are administered via the tibial nerve that runs along the inside of the leg, from the foot up to the nerves in the sacrum and pelvic floor. These nerves are part of the system that controls the bowels and bladder. This interaction is important to be able to resist bowel movement urgency and can lead to improved bowel emptying.

SNS is a more advanced form of neuromodulation, in which a device is inserted and provides continuous stimulation.

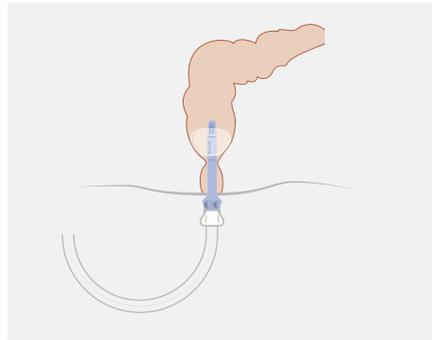
Ostomy

In the event of persistent, major problems, an ostomy may be an option to achieve a better quality of life.

WHAT IS TAI?

Transanal irrigation is a technique for effectively emptying the bowel. High volume TAI promotes evacuation of stool from the lower part of the bowel by passing water into the bowel.

Regular irrigation of the bowel with at least 250 mls of water (high volume TAI), empties a part of the bowel so effectively that it stays empty until the next irrigation. This not only prevents stool leakage, it also gives control over time and place of defecation. Other significant advantages with TAI are reduction of time and energy spent on bowel management, and the fact that it can promote independence from caregivers.



No more bowel accidents

When the training period is over and your bowel has adapted to TAI, the aim will often be to irrigate every other day. The aim of TAI is to restore a regular and well functioning bowel, allowing you to lead a normal life.

Advantages of TAI

- Reduced risk of leakage
- Greater control over when/where
- Empties the bowels effectively
- Saves time and energy

Motivation and Expectation

TAI may feel strange or intimidating in the beginning, and it may take some time to get it right. As your stomach and digestive tract is a complicated system, it needs time to adjust to new routines. But it will be worth it in the long run. Motivation and patience are essential. Be prepared and give yourself time to change habits, both mentally and physically, while the bowel adapts to your new routines. You also need time to find your optimal treating parameters i.e amount and speed of water and size of the balloon.

It is important to have realistic expectations of what TAI can do for you

and how long it may take to achieve satisfactory results. A commitment of up to 4-12 weeks is necessary in order to stabilize the bowel and to develop a good individualized defecation routine.

Give it time. It is worth it!

Training is the key

Education and personalization are key to maintain compliance and success in TAI, and comprehensive training is very important when you start. Ideally, your healthcare provider should guide you through your first session.



NAVINA SECURING INDEPENDENCE

Navina™ Systems is an innovative and user friendly system for TAI that allows you to be more spontaneous in your everyday life.

Navina™ Systems is a complete system for TAI that let you choose between a manual or electronic control unit and a rectal catheter or a rectal cone. Navina Systems makes bowel management easier.



Navina Smart - intelligent and individually-adapted

Navina™ Smart is an electronic system that allows you to adapt your TAI precisely according to your needs – in a safe, consistent, and controlled manner. Navina Smart has built-in safety for maximum balloon size, water quantity and flow rate. After you have tested and saved your personal settings, all you have to do is press a button to get started.

Navina Smart comes with an App like an irrigation diary and can help you during initiation of TAI.





Navina Classic – intuitive and user-friendly

Navina™ Classic is the user-friendly solution with a manual control unit. It has color-coded connectors and intuitive symbols, which makes it easy to use. Navina Classic is the perfect choice for those who prefer manual irrigation and lets you decide time and place to empty your bowel.





The image used is for illustrative purposes and the person in the image is a model.

HOW I GOT IN CONTROL AFTER MY CANCER DIAGNOSIS

Lennart , 59 patient with LARS

"After suffering from rectal cancer, I first had a stoma. When the stoma was removed and the bowel was reconnected, my bowel emptying did not work. The radiation had damaged the nerves to the sphincter, so I became incontinent. From then on, I suffered from bowel leakage.

Not knowing when I needed to visit the toilet took a huge toll on my life. It was difficult to know whether my bowel was completely emptied after

a visit to the toilet. Sometimes I felt I had complete evacuation, only to then realize I hadn't after leaving the toilet. Sometimes I managed to get back in time, sometimes not.

"Bowel issues are not visible on the outside - it's much easier to understand someone's condition if they are wearing a bandage or a plaster."

“Now I can be spontaneous and do whatever I want, whenever I want.”

I've always enjoyed dining with friends, but my bowel problems made me anxious for days before an evening out and prevented me from enjoying the actual event. Bowel issues are not visible on the outside – it's much easier to understand someone's condition if they are wearing a bandage or a plaster, besides – it's not very easy to talk about bowel leakage. Even if it wasn't my fault, nor my choice, I would still feel ashamed about it.

I received medication to inhibit bowel leakage directly after the first operation, and I started with daily bulking medication immediately after the stoma replacement, so it was both gas and a brake at the same time. I stopped using the bulking medication when I no longer could control my bowel, but I have continued with half the dosage of the stopping medication. These tablets work best at night, to make my bowel calm down and allow for a good night's sleep. I was then referred to a dietician.

“Even if it wasn't my fault, nor my choice, I would still feel ashamed about it.”

When the symptoms still did not disappear, I was readmitted to the Center for Cancer Rehabilitation and referred to its' specialist nurses in continence care. They conducted various tests with anal plugs and small enemas, but then I heard of TAI (Transanal Irrigation)

The first time I heard about TAI and Navina Systems was at this Cancer Rehabilitation Center. My first thought: I'm not ready

for it. I was probably a little scared too even if I was used to invasive and uncomfortable examinations.

After a period with up to ten visits to the toilet, day and night, I changed my mind. I was constantly tired, and the lack of sleep made it difficult for me to do my job. I ate as little as possible during the day to manage traveling to and from work without bowel accidents. My contact person at the Cancer Rehabilitation Center showed me more about how the Navina Systems worked and I got to try a new variant with electronic pump. I had the time to think and reflect for a while about Transanal Irrigation; to feel ready and motivated to try it.

“I had the time to think and reflect for a while about Transanal Irrigation; to feel ready and motivated to try it.”

It took me a while to adapt and get used to the settings, but now I use Navina Smart on a daily basis. It's a totally new life to me. After I empty my bowel, I have the feeling that I can do just about anything. The bowel is such a crucial function, and when stomach and bowel work the way they should, life is so much easier and can be enjoyed again.

Now I can be spontaneous and do whatever I want, whenever I want.”

NAVINA SYSTEMS





NavinaTM

References

1. Cura Pales *et al.*, Ann Coloproctol 2019;35(4):160-166
2. Enriquez-Navascues *et al.*, Colorectal Disease, 2019, 22 (303-309)

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 our initiative Advancing Continence Care Together (ACCT), please visit Wellspect.us.

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