Loss of bowel control?

There is a solution.

Officially known as faecal incontinence, the loss of bowel control is a devastating problem for many people worldwide and can affect men and women of all ages. Severe faecal incontinence, the accidental loss of solid or liquid stool at least weekly, is an especially debilitating problem that radically affects everyday life. Yet with the right treatment, sufferers can be freed from the severe restrictions imposed upon them by this affliction. Although it presents a challenging and complicated problem for both patient and physician, it’s important to remember that help is available.

Questions to discuss with your doctor

How much physical strength is needed to operate the system?
The A.M.I. Soft Anal Band System requires a certain degree of manual dexterity and strength to operate the activator and valve.

What are the chances of the system malfunctioning?

How safe are silicone prostheses?
The A.M.I. Soft Anal Band System is made up of just two different materials. One is a pure, medical-grade silicone (rubber) suitable for long-term implants, and the other is pure, medical-grade titanium. This device does not contain any silicone gel or silicone oil. Solid silicone elastomers and titanium have been used for many years as materials for medical implants.

Will my prosthesis ever have to be replaced?
It is not possible to predict how long an implanted prosthesis will work for a particular patient. As with any other biomedical prosthesis, this device is also subject to a certain amount of wear, which may affect its life-span. Such a system should never be assumed to last a lifetime. A malfunction in the system may lead to additional surgery being necessary to replace the implant. Patients should discuss any noticeable changes in the operation of their system with their doctor.

Can I undergo Magnetic Resonance Imaging (MRI) with my prosthesis?
Yes, MRI can be carried out even with the A.M.I. Soft Anal Band System.

Is there a possibility the band will migrate?
Doctors refer to the slow change in position of any part of the system as migration. In this case, migration would generally involve a component moving up towards the surface of the skin. Patients should contact their doctor immediately if any part of the system is visible through the skin, but also in the event that the activator and/or valve cannot be located.

Anal intercourse?
Receptive anal intercourse may damage the band and should be strictly avoided.

Pregnancy and childbirth?
Vaginal delivery of children may interfere with the system’s operation. Discuss vaginal delivery and other options for childbirth with your doctor.

Important note:
This patient guide includes general information on bladder weakness and the corresponding surgical treatment. However, it is by no means a substitute for a consultation and thorough examination by your doctor. Only your doctor can evaluate your personal situation and recommend the treatment and aftercare best suited to your needs, as well as inform you of possible risks.

A.M.I. GmbH
A.M.I. is an Austrian-based manufacturer of innovative medical technology. Our product range includes effective, patient-friendly solutions for various afflictions such as haemorrhoids, incontinence and obesity, all of which can severely affect quality of life. All our products are manufactured according to the highest quality standards, and enable doctors to take even better care of their patients.
An implantable sphincter prosthesis

A.M.I. Soft Anal Band - an implantable sphincter prosthesis

Our anal band is an implantable sphincter prosthesis, or in other words, a surgically-implanted device that simulates the natural function of the anal sphincter muscle to give the patient improved control over bowel movements. It is a small, fluid-filled system with several components, all of which are implanted under the patient’s skin.

How does the system work?

The system consists of five main components:

- A soft, inflatable ring of silicone (Anal Band), which is implanted around the anal canal and can be adjusted in size
- A mechanism called the “activator”
- A valve to open and close the band
- A port, which is used to adjust the amount of liquid in the system and thereby the necessary pressure to close the sphincter
- Tubing, which is radiopaque and connects all the system’s components

The procedure

The operation is carried out under general anaesthetic and takes approximately 1.5 hours. The activator, the valve and the access port can be implanted in the position most comfortable for the patient.

After surgery, the patient is required to stay in hospital for a few days to ensure no complications arise. However, due to the fact that all components lie under the skin and it is not necessary to open the abdominal cavity, the procedure can be considered low-risk with very little blood. Therefore no blood conserves are necessary and immediate post-operative complications are seldom. Furthermore, no nerves of the sphincter muscle are severed and the system can therefore be explanted again at any time with no detriment to the patient.

Function and the procedure

After the procedure

How to allow a bowel movement...

Following the procedure, the patient is asked to wait for six weeks before the band can be filled. During this time, the patient is advised to ensure regular, soft bowel movements, which prevent the wounds - in particular around the sphincter - from being subjected to additional strain. The wounds around the skin pockets in the lower abdomen where the valve and activator lie, should be fully healed beforehand to avoid pain when the system is activated. Once the six weeks have passed, the patient comes back into the hospital and the anal band is filled. Then a sphincter manometry is carried out, and the level of continence is assessed using stress tests.

This filling and subsequent testing ensure the band provides the patient with a closing pressure very close to that of a healthy sphincter muscle.

To allow a bowel movement...

- Feel for the valve under the skin, then gently press down on the valve with one finger to unlock it from the closed position. Opening the valve causes the fluid to move out of the band into the activator’s reservoir, and the activator will start to rise. Keep the valve pressed down for at least 30 seconds to empty the band completely of fluid. Once empty, the band puts no pressure on the anal canal and stool can pass through freely.

Improving Control of Bowel Movements

Designed to mimic the natural function of the anal sphincter muscle, our prosthesis helps patients improve control of their bowel movements.

However, the surgical procedure to implant the A.M.I. Soft Anal Band System is just one aspect of managing faecal incontinence. Eating habits, physical exercise and each patient’s individual attitude can all contribute significantly to the success of the implantation. For most people, physical exercise combined with a sufficient intake of fluids is a highly effective way of regulating bowel activity. For those patients suffering from incontinence as a result of an accident, specially-targeted exercise therapy has a positive effect not only on motoric movements, but also on patients' awareness of their body. This is particularly relevant when considering that patients are required to learn anew the automatic process of emptying their bowel, and must consciously undertake to do so. Last but not least, a good amount of patience is also helpful when learning to handle the situation and the system itself.

- Following the bowel movement, press down gently with your palm on the activator protruding under the skin to return it to its flat position. The fluid flows back into the band, and the band closes gently again around the anal canal. The activator can only be considered closed when it is protruding less and is visibly flatter than in the open position. It is important to see and feel this difference! In case of doubt, simply push the activator a second time to ensure it is securely closed.

Flat activator: System is closed
Protruding activator: System is open, bowel movement is possible

Attitude Exercise Eating habits Anal band

Flax seeds
Avocado
Olive oil
Eating habits

Exercise

- Menu
- Increase fluid intake
- Reduce stress

Attitude

- Increase awareness
- Be patient
- Avoid constipation

- Relaxation
- Stool softeners
- Calm activities

For most people, eating habits, physical activity and each patient's individual attitude can all contribute significantly to the success of the implantation.