



Learning to use your
new prosthesis:

A GUIDE FOR MEN

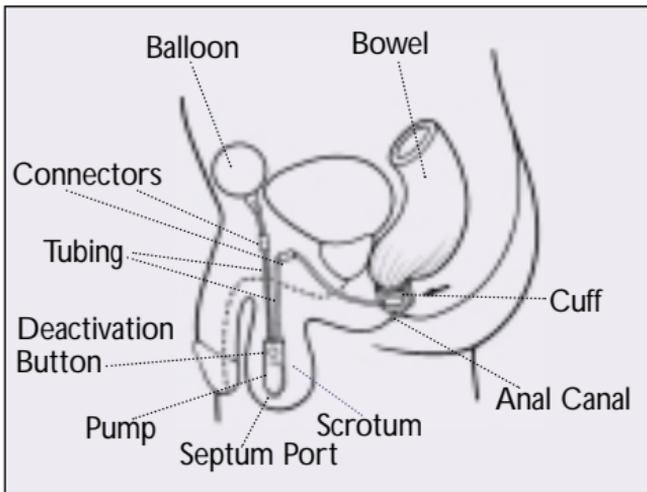




The Acticon™ Neosphincter is a small, fluid-filled prosthesis that is completely implanted within the body. The Acticon prosthesis has been developed to treat severe fecal incontinence (the accidental loss of solid or liquid stool at least weekly). It is designed to mimic the natural process of bowel control and bowel movements.

This brochure will explain how the Acticon prosthesis works within your body to improve bowel control. This brochure is designed to supplement the information you receive from your doctor.

Location of the Device in Your Body



There are several parts to the Acticon prosthesis. This section explains where these parts are implanted in your body.

Cuff: The cuff surrounds the anal canal. (The tube that carries stool out of your body).

Balloon: The balloon is implanted in the abdomen in the space next to the bladder.

Tubing: The components of the device are connected by tubing that allows fluid to move within the device.

Pump: The pump lies in the scrotum. It can be felt through the skin. The lower part of the pump is soft and squeezeable, and the upper part containing the deactivation button is hard.

Deactivation Button: This small button can be felt on the upper, hard part of the pump.

Septum Port: The septum port can be felt at the tip of the lower, soft part of the pump.

How the Device Works

The cuff, which is filled with fluid, gently squeezes the anal canal closed.

To defecate (have a bowel movement), the cuff is opened by squeezing and releasing the lower, soft part of the pump several times. This moves the fluid out of the cuff and into the balloon. Because the empty cuff does not press the anal canal closed, stool can now pass through the anal canal.

After defecating, the fluid automatically flows from the balloon back to the cuff. When the cuff is full, it compresses the anal canal.



When the cuff is closed, the stool cannot pass through the anal canal.



When the pump is squeezed and released, the cuff opens, and the anal canal can empty.



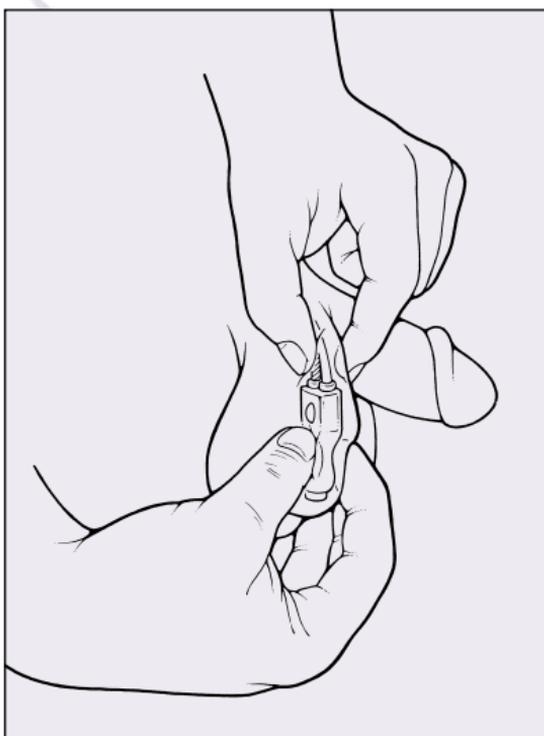
Fluid automatically returns to the cuff, and the cuff again closes around the anal canal.

Using the Prosthesis

To open the cuff to defecate:

- ◆ Feel for the pump in your scrotum.
- ◆ With one hand, gently grasp the tubing above the pump to hold the pump in place.
- ◆ With the other hand, squeeze and release the lower, soft part of the pump several times until it is flat.

When the lower part of the pump is flat, the cuff is open and you should be able to defecate.



Squeeze and release the lower, soft part of the pump several times.

To close the cuff to once again have bowel control:

You do not need to do anything to refill the cuff after you defecate. The fluid will automatically return from the balloon to the cuff after several minutes, and the cuff will recompress the anal canal.

After operating the device a few times, you will know how long it takes for the cuff to refill. *You may need to open the cuff a second time in order to complete defecation.*



The cuff automatically refills.

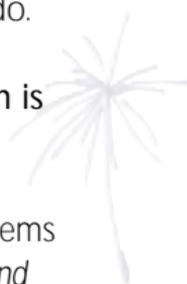


How the Deactivation Button Works

The Acticon prosthesis has a deactivation button so your doctor may “turn off” the device. *The deactivation button is located on the upper, hard part of the pump.* When the device is deactivated, the cuff remains empty. This allows the anal canal to remain open and stool to pass. Your doctor will deactivate the device until you have healed from your surgery, or instruct you to deactivate it at other times. You will not use this button in your normal use of the device; however, if you accidentally deactivate the device by pressing the deactivation button, you need to know what to do.

What happens if the deactivation button is squeezed accidentally?

The device will deactivate and two problems could occur. Fluid will not refill the cuff *and* you will leak stool, or fluid may lock in the cuff *and* you cannot defecate. If either problem occurs, you will notice that the pump feels different to you. You can activate the device to solve these problems.



How to Activate the Device

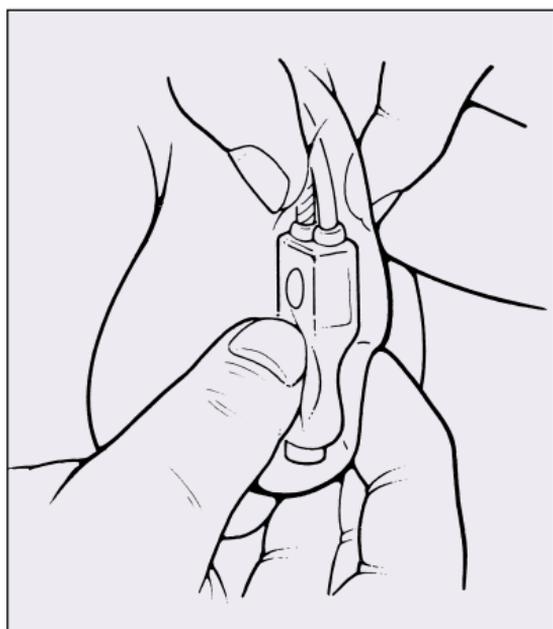
If the lower, soft part of the pump feels harder than usual:

- ◆ With one hand, grasp the tubing above the pump to hold the pump in place.
- ◆ With the other hand, give the lower part of the pump a quick, forceful squeeze.
- ◆ Squeeze and release the pump several times as you normally would.

You may experience pain while activating the device.

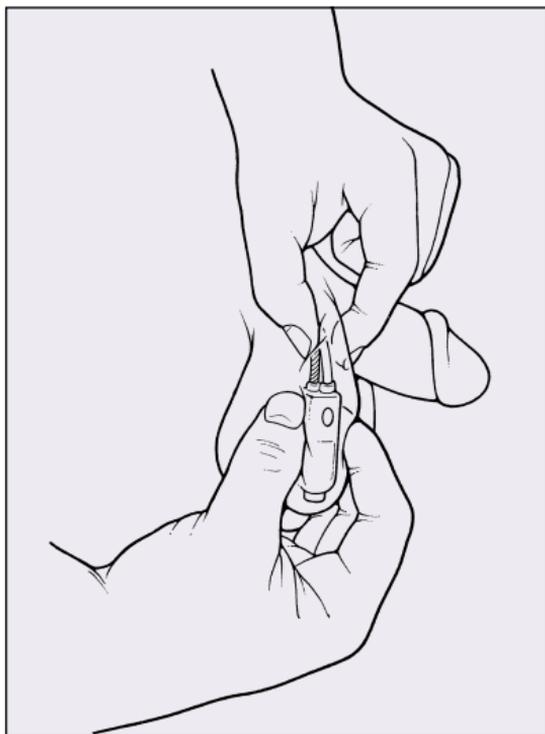


Contact your doctor immediately if these attempts fail.



Give the lower part of the pump a quick, forceful squeeze.

If the lower, soft part of the pump is squeezed flat and doesn't refill as it normally does:



Squeeze the sides of the upper, hard part of the pump, then give a quick, forceful squeeze to the lower part of the pump.

- ◆ With one hand, grasp the tubing above the pump to hold the pump in place.
- ◆ With your other hand, squeeze the *sides of the upper, hard part of the pump*, opposite the button. Use hard, steady pressure.
- ◆ When the lower part of the pump is hard and filled with fluid, give the lower part of the pump a quick, forceful squeeze.

This step may need to be repeated if not successful the first time.

You may experience pain while activating the device.

Contact your doctor immediately if these attempts fail.

Where Can I Get More Information?

This brochure is only part of the information and instructions you will receive from your doctor about the Acticon prosthesis.

During the discussion with your doctor, he or she may also show you a demonstration prosthesis.

Humanitarian Device. Authorized by Federal law for use in the treatment of severe fecal incontinence. The effectiveness of this device for this use has not been demonstrated.



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