Acticon™ Neospincter - P010020

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Acticon™ Neosphincter
Manufacturer:	American Medical Systems, Inc.
Address:	10700 Bren Road West, Minnetonka, Minnesota 55343
Approval Date:	December 18, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p010020a.pdf

What is it? The Acticon™ Neosphincter is a surgically implanted device used to help patients with fecal incontinence (accidental passage of stool) to control bowel movements. The device consists of three components linked together by kink-resistant tubing: an inflatable cuff, a manual control pump, and a pressure-regulating balloon.

How does it work? The device is intended to mimic the function of the anal sphincter, the muscle that controls the opening and closing of the anus. During a surgical procedure, the inflatable cuff is placed around the anus. When filled with fluid, the cuff applies pressure to the anus and keeps it closed, thereby preventing passage of stool. The cuff is connected by tubing to the control pump, which is placed under the skin of the scrotum in males or labia in females. The pump in turn is connected to the balloon, which is implanted in the abdominal cavity. When a patient wishes to have a bowel movement, the bulb on the control pump is manually squeezed and released several times. This transfers fluid from the cuff to the balloon by way of the tubing, thereby deflating the cuff and allowing stool to pass. Pressure from the balloon slowly forces the fluid back into the cuff over several minutes, again closing off the anus and preventing the accidental passage of stool. For an illustration of the sphincter: http://medlineplus.nlm.nih.gov/medlineplus/ency/imagepage/9629.htm

When is it used ? The device is used in patients over the age of 18 with incontinence of liquid or solid stool on a weekly or more frequent basis. It is intended for those who have failed or are not candidates for more conservative treatment options.

What will it accomplish? The device may help improve fecal incontinence. In a study conducted within

the United States, slightly over 50% of all patients implanted with the device had either a resolution or a significant improvement in incontinence symptoms by one year's time. The most common side effects were pain, infection, and erosion of the device through surrounding tissue. Half of the patients implanted required at least one additional surgical procedure because of adverse events. Thirty percent (30%) required permanent removal of the device within one year because of complications.

When should it not be used? The device should not be used in people who:

- are poor candidates for surgery and/or anesthesia;
- have obstruction of the bowel; or
- have an active infection in the body.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p010020.html

Other:

National Institutes of Health:

- Information on fecal incontinence with picture and description of digestive system: http://medlineplus.nlm.nih.gov/medlineplus/ency/article/003135.htm
- Bowel retraining for fecal incontinence: http://medlineplus.nlm.nih.gov/medlineplus/ency/article/003971.htm

(Updated 2/14/02)