AMS Acticon ™ Neosphincter

Package Insert

TABLE OF CONTENTS

CAUTION: Federal Law restricts this device to sale by or on the order of a physician trained in use of the device.

NOTE: Refer to the Operating Room Manual for further information on the Acticon Neosphincter and its implantation.

Brief Device Description

The Acticon Neosphincter is an implantable, fluid-filled, solid silicone elastomer device used to treat severe fecal incontinence. Severe fecal incontinence is defined as the involuntary loss of liquid or solid stool more than once a week. The Acticon Neosphincter may be implanted in either women or men and consists of three interconnected components: an occlusive cuff, a pressure-regulating balloon and a control pump with a septum. The three components are connected with kink-resistant tubing. The Acticon Neosphincter simulates normal anal sphincter function by allowing the anal canal to open at the control of the patient. The occlusive cuff is implanted around a segment of the anal canal. The device maintains continence in the patient by using the pressure of the fluid-filled cuff to occlude the anal canal. To evacuate the bowel, the patient squeezes and releases the pump mechanism, located in the labium or scrotum, several times to move fluid from the cuff to the pressure-regulating balloon implanted in the prevesical space. This movement of fluid empties and collapses the cuff, resulting in the release of the compressive force around the anal canal. Residual pressure within the balloon allows fluid to flow back into the cuff, automatically refilling the cuff within a few minutes. The pressure-regulating balloon maintains pressure in the occlusive cuff. This device contains solid silicone elastomer.

Indications for Use

The Acticon Neosphincter is an implantable device used to treat severe fecal incontinence in males and females eighteen years and older who have failed, or are not candidates for, less invasive forms of restorative therapy.

Contraindications

1. This device is contraindicated in patients whom the physician determines to be poor candidates for surgical procedures and/or anesthesia due to physical or mental conditions.

2. This device is contraindicated in patients with fecal incontinence complicated by an irreversibly obstructed proximal segment of bowel.

3. This device is contraindicated in patients with an active infection.

Warnings

1. Patients with diabetes, spinal cord injuries, musculoskeletal abnormalities, pre-existing stomas, or open sores in the region of the surgery have an increased risk of infection associated with a prosthesis. Patients who are immunocompromised or immunosupressed may also be at a higher risk for infection associated with a prosthesis. Appropriate measures should be taken to reduce the likelihood of infection.

   Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis. Infection followed by explantation of the device may result in scarring which may make subsequent reimplantation more difficult.

2. Erosion may be caused by infection, pressure on the tissue, improper cuff sizing, improper balloon selection, tissue damage, and component misplacement. The cuff may erode around the anal canal or through the perineal skin. The control pump may erode through the scrotal or labial skin. The pressure-regulating balloon can erode into the bladder. Failure to evaluate and promptly treat the erosion may result in a substantial worsening of the condition leading to infection and/or loss of tissue.

3. This device contains solid silicone elastomers. This device does not contain silicone gel. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.

4. Surgical, physical, psychological, or mechanical complications, if they occur, may necessitate revision or removal of the prosthesis. Removal of the device without timely reimplantation of a new device may complicate subsequent reimplantation. The timing of reimplantation should be determined by the treating physician based on the patient's medical condition and history.

Precautions

Patient Related Precautions

1. Patient selection requires thorough preoperative consultation and evaluation by the physician.

2. Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation of an Acticon Neosphincter. Although the prosthesis is designed to restore bowel control, some patients continue to have a degree of incontinence after this procedure.

3. Patients may experience pain when the device is activated in the postoperative period and during periods of initial use. Cases of chronic pain associated with device have been reported. Pain with a severity or duration beyond that which is expected may require medical or surgical intervention. Patients should be counseled on expected postoperative pain including severity and duration.

4. Tissue fibrosis or previous surgery in the area of the implant may preclude implantation of an occlusive cuff at the anal canal.

5. Acute bowel disorders, e.g. diarrhea or constipation, can interfere with proper functioning of the device and may require the use of external pads or manipulations to assist defecation.

6. Any progressively degenerative disease, e.g. multiple sclerosis, may limit the future usefulness of the implanted prosthesis as a treatment of the patient's fecal incontinence.

7. Adequate manual dexterity, strength, and motivation are required for proper use of the device.

8. Trauma or injury to the pelvic, perineal or abdominal areas, such as impact injuries associated with sports, can result in damage to the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction

including replacement of the prosthesis. The physician should advise patients of these possibilities and warn them to avoid trauma to these areas.

9. If a radiopaque solution is used instead of sterile isotonic saline to fill the device, ensure the patient is not allergic to the radiopaque solution.

10. Receptive anal intercourse may damage the occlusive cuff and is not recommended for patients implanted with this prosthesis.

11. Vaginal delivery of children may interfere with future proper functioning of the occlusive cuff. Patients should be made aware of the need to discuss the presence of the Acticon device with their doctors should they become pregnant. A cesarean delivery may be recommended in order to avoid damage to the device.

12. No safety or effectiveness data exists for patients with a history of inflammatory bowel disease or pelvic radiation. The potential for increased risk of erosion in these patients is unknown.

Surgery Related Precautions

1. Improper cuff sizing, improper balloon selection or other causes, such as surgical trauma, poor tissue viability, and concomitant medical procedures, may result in tissue erosion, migration of components, or continued incontinence.

2. Component migration can occur if the cuff is sized improperly, if the pump or balloon is not positioned correctly, or if the tubing lengths are incorrect. Migration can result in pain, complications, device malfunction and surgical revision.

3. Unsuccessful outcomes may result from improper surgical technique, anatomical misplacement of components, improper sizing and/or filling of components.

4. Although reinforced tubing has been designed to be more resistant to tubing kinks, tubing kinks may still result from tailoring the connecting tubing to an improper length during the implant procedure.

Device Related Precautions

1. This device is subject to wear and eventual failure over time. It is not possible to predict how long the implanted prosthesis will function in a particular patient. The device should not be considered a lifetime implant.

2. If the deactivation valve is closed when the cuff is inflated, fluid cannot transfer from the cuff to the balloon and sustained fecal obstruction may arise as a result:

    a. In the event of large pressures within the bowel, automatic pressure relief that normally occurs with the device would be prevented. Cycling the device can relieve the fecal obstruction.
    b. Cycling the device may be difficult if deactivation occurs when the pump bulb is deflated. If unable to cycle the prosthesis, squeezing the sides adjacent to the deactivation button will allow fluid to fill the pump bulb and then the pump can be cycled normally.
    c. Release of the deactivation valve may require greater pressure than that used to cycle the device.

3. Use caution when passing any instrument through the anal canal. For certain procedures, e.g. anal ultrasound or colonoscopy, first deflate the cuff then deactivate the device prior to passing any instrument through the anal canal.

4. System pressure changes may occur over time. This may result in changes in continence status. To increase system pressure, fluid may be added to the device through the septum port.

Adverse Events

No deaths, life-threatening conditions or unanticipated adverse events were reported in the clinical study that was conducted by AMS to support the safety and effectiveness of the Acticon Neosphincter. The most frequently reported device-related adverse events were pain/discomfort, infection, and erosion.

Three hundred ninety-five (395) device-related or potentially device-related events occurred in 102 patients during the study. The majority (318) of the device-related adverse events were mild or moderate. Surgical interventions were required for 142 events, including 81 revisions in 56 patients. More than one type of intervention may have been used for each event and patients may have had multiple events treated with the same intervention.

Table 1 lists the frequency and types of device-related adverse events reported from the clinical study and the methods of intervention used to treat the adverse events.

Table 1: Methods of Intervention for Acticon Neosphincter Study Adverse Events(n=115)

Adverse Event Type	Number and (%) of Patients[1]	Number of Events[2]	Methods of Intervention[3]			
			None Required	Medication	Surgery	Other[4]
Pain/Discomfort	37 (32.2)	44	15	15	8	14
Infection	36 (31.3)	41	0	16	33	3
Erosion	24 (20.9)	28	0	3	27	2
Recurring fecal incontinence	22 (19.1)	29	2	3	13	11
Constipation	22 (19.1)	33	2	26	2	7
Impaction	21 (18.3)	27	2	7	3	17
Surgical injury	15 (13.0)	15	2	0	11	1
Wound problems	12 (10.4)	13	7	2	1	3
Mechanical malfunction	12 (10.4)	15	1	0	13	1
Wound separation	10 (8.7)	10	4	4	1	2
Difficult evacuation	10 (8.7)	13	1	5	1	8
Rectal bleeding	9 (7.8)	9	5	1	2	1
Edema	9 (7.8)	10	3	3	4	2
Erythema	9 (7.8)	10	3	6	1	2
Fever	7 (6.1)	7	0	6	1	0
Anorectal condition	7 (6.1)	8	1	0	1	6
Device migration	7 (6.1)	9	1	0	7	0
Device Fit	6 (5.2)	6	2	1	3	1
Device Function	6 (5.2)	7	0	0	0	7
Wound drainage	6 (5.2)	7	1	2	1	3
Gastrointestinal condition	5 (4.3)	6	1	1	2	2
Diarrhea	5 (4.3)	7	2	1	0	4
Ecchymosis	4 (3.5)	4	3	0	0	1
Malposition	4 (3.5)	4	1	0	3	0
Device operation difficulty	3 (2.6)	3	0	0	0	3
Other [5]	27 (23.5)	20	7	3	1	9
Totals		**395**	**67**	**106**	**142**	**117**

[1]Patients may have had more than one type of event. [2]Patients may have had more than one event of the same type.
[3]There may have been more than one type of intervention for each event, and patients may have multiple events that are treated with the same intervention.
[4]Other interventions reported included: fluid added to pump via septum (15), enema (14), deactivation of device (13), patient education (11), and hospitalization (9). There were 18 reports of an unspecified "other" intervention.
[5]Other adverse events included abscess (2), difficult device activation (2), hematoma (2), intraoperative bleeding (2), seroma, urinary tract infection, acute renal failure, ankle pain, chest rash, decreased perianal sensation, hip ulcer, hyperglycemia secondary to infection, mild pancreatitis, night sweats, osteomyelitis, patient dissatisfaction, patient falling, couldn't pump device, device locked, post-stoma takedown paralytic ileus, morphine reaction, respiratory distress, severe acute esophagitis, urinary retention (2), vaginal rash and weakness.

The following risks of implantable anal sphincters or their materials have been reported in the medical literature but did not occur during the prospective study: tubing kink, tubing leak, cuff tab tearing, scrotal adhesion.

Clinical Study

A multi-center, prospective, non-randomized clinical trial was undertaken to evaluate the safety and effectiveness of the device. Each patient served as his or her own control. The primary endpoint assessed changes in patients' continence using Fecal Incontinence Scoring System (FISS) scores at pre-, 6-, and 12-months. Secondary endpoints assessed changes in anorectal manometry, health status, and quality of life factors affected by fecal incontinence. Self-administered questionnaires were used to assess continence, health status, and patient quality of life. Safety data related to adverse events and revision surgery were collected on case report forms. Inclusion criteria for the study included:

- a history of fecal incontinence for at least six-months
- at least one prior non-surgical treatment for incontinence
- age ≥ 18 years, and
- a FISS score of ≥ 88.

Exclusion criteria included:

- Crohn's Disease or Irritable Bowel Syndrome as the only cause of fecal incontinence
- extensive pelvic irradiation or radiation therapy that compromised the anal canal
- active pelvic sepsis
- pregnancy
- fragile or scarred perineum, and
- patients who engage in receptive anal intercourse.

A total of 115 patients were enrolled at 19 sites. One-hundred twelve (112) patients were implanted with the device. Follow-up intervals occurred at activation (n=98), 6-months (n=73), and 12-months (n=69). Three-quarters of the study patients were female and the mean age was 49 (range 18-81) years. Ninety-two patients (80%) were Caucasian. Mean duration of incontinence was 14 (range 1-54) years. Table 2 presents the distribution of patients by etiology.

Table 2: Distribution of Patients by Etiology

Etiology of Fecal Incontinence (n=115)	Frequency	Percent (%)
Obstetric Trauma	34	30
Neurological	23	20
Congenital Abnormality	23	20
Anorectal Trauma	21	18
Other[1]	14	12
Total Patients	**115**	**100**

[1] Other etiologies included rectal prolapse (3), idiopathic (3), radiation (1), surgical (3), scleroderma (1), traumatic defecation (1), musculoskeletal (1) and anal canal squamous cell carcinoma (1)

Previous treatments for fecal incontinence were separated into two categories: management and surgical treatment. Management includes less invasive forms of therapy and surgical treatment includes specific anti-incontinence procedures. Several patients had previously experienced more than one type of treatment. Many patients tried and failed not only management but also surgical treatment for incontinence. Table 3 presents the distribution of patients by previous treatments.

Table 3: Distribution of Patients by Previous Treatments

Type of Previous Treatment[1]	Patients[1]	Percent (%)
Management:		
Bowel Management	83	72.2
Biofeedback	25	21.7
Surgical Treatment:		
Sphincteroplasty	38	33.0
Stoma	30	26.1
Rectal Prolapse Repair	12	10.4
Gracilis Muscle Transposition (stimulated)	5	4.3
Gracilis Muscle Transposition (unstimulated)	2	1.7
Postanal Repair	2	1.7
Other[2]	29	25.2

[1] Patients with multiple types of treatments were counted more than once. Percentages were calculated for the number of patients enrolled (n=115). Patients who had more that one procedure of the same type were captured under "Other".

[2] Other includes: Second sphincteroplasty (10), silastic sling (3), repair of imperforate anus (4), revised colostomy (3), repeated rectal prolapse repair (2), repair neosphincter and second gracilis muscle wrap, posterior sagioplasty/vaginal anoplasty, abdominal exploratory/rectopexy and levatorplasty, posterior colporrhaphy/repair perineal body, 4-V advancement flap, neorectum, vaginal and anal reconstruction.

Effectiveness

Fecal Incontinence Scoring System (FISS)

The primary endpoint of the study assessed the effectiveness of the Acticon Neosphincter using the Fecal Incontinence Scoring System (FISS) patient questionnaire. The FISS instrument is a 5-item self-administered questionnaire. Scores range from 0-120 and measure the patient's degree of fecal incontinence. Zero equals fully continent and 120 equals incontinent to liquid or solid stool more than once a day. Table 4 shows the FISS ranges as they relate to the level of fecal incontinence.

Table 4: FISS Scoring System

FISS value	Definition
0	Fully continent
1-30	Incontinent to gas
31-60	Incontinent to seepage
61-72	Incontinent to liquid or solids <monthly
73-84	Incontinent to liquid or solids >monthly
85-96	Incontinent to liquid or solids >weekly
97-108	Incontinent to liquid or solids daily
109-120	Incontinent to liquid or solids >daily

Patients with a FISS score ≥ 88 were eligible for enrollment. A FISS score of 88 or higher means the patient has incontinent episodes one or more times per week. A clinically significant improvement was demonstrated by a reduction in 12-month FISS score as compared to pre-implant FISS score of ≥ 24 points.

At the 6-month follow-up, 67 patients had both a pre-implant FISS score and a 6-month FISS score reported and thus were available for evaluation. The mean FISS scores were 106 at pre-

implant and 50 at 6-months. The mean reduction in FISS score at 6-months was 56 points. Fifty-four (54) of 67 patients lowered their FISS score by 24 or more points. The success rate for the 6-month cohort was 81%.

At the 12-month follow-up, 63 patients had both a pre-implant FISS score and a 12-month FISS score reported and thus were available for evaluation. The mean FISS scores were 105 at pre-implant and 48 at 12-months. The mean reduction in FISS score at 12-months was 57 points. Fifty-four (54) of 63 patients had lowered their FISS score by 24 or more points. The success rate for the 12-month cohort was 86%.

Statistical analysis indicated that the differences between the mean pre-implant FISS scores and the mean scores at 6- and 12-months were both statistically significant ($p<0.0001$).

Intent to Treat Analysis

Of the 115 patients enrolled in the study, 69 (including 6 patients with pre-implant stomas) reported 12-month FISS scores. Of the 46 patients not reporting 12-month FISS scores, three patients were aborted at original implant, six patients had missing data at 12-months, and 3 patients were lost to follow-up. Thirty-four patients were explanted before the 12-month follow-up.

Fifty-nine (54 non-stoma and 5 stoma) patients had 24-point or greater reductions in FISS scores and were considered successes. Six patients with a pre-existing stoma completed follow-up and had 12-month FISS scores available. To be included in the intent to treat analysis, these 6 patients were assigned a pre-implant FISS score of 106, the average for the 101 non-stoma patients with pre-implant FISS scores. Using this assumption, 5 of these 6 stoma patients had a successful outcome at 12 months.

By an intent to treat analysis which accounts for all enrolled patients, the clinical success rate based on 12-month FISS scores was 51.3% (59 of 115).

Subgroup Analysis of Effectiveness

Two way repeated measures analysis of variance (ANOVA) was performed for subgroups gender, age, etiology, and country on the primary effectiveness endpoint (FISS). The results using Two-way Repeated Measures ANOVA indicated no significant difference for the subgroups, except for gender.

The analysis for FISS indicated a significant difference for males and females. The statistical difference in FISS for males and females does not appear to have clinical implications due to the observed reduction in FISS at 12- months (male=50, female=58). The reductions are greater than the ≥24-point reduction that defines clinical success in the study protocol. Males demonstrated a 42 point (6-month) and 50 point drop (12-month) in FISS scores. Females demonstrated a 59 point (6-month) and 58 point drop (12-month) in FISS scores.

Anorectal Manometry

Anorectal manometry was used to assess anal sphincter function. Patients were assessed by analyzing the difference in manometric resting pressures between the pre-implant visit and follow-up intervals.

Table 5: Anorectal Manometry Resting Pressures (mmHg)

	Pre-Implant	Activation	6 Month Post Activation	12 Month Post Activation
Mean	26	47	46	45
Minimum	0	8	12	14
Maximum	70	78	80	77
Standard Deviation	15	17	16	16
n	106	73	61	53

Average resting pressures increased from 26 mmHg pre-implant to 45 mmHg at 12-months (n=53). The increase in resting pressures from pre-implant to 12-months was significant ($p<0.0001$). A correlation between higher resting pressures and lower FISS scores was indicated at 12-months (correlation = -0.38; $p=0.0039$).

Health Status Questionnaire (HSQ)

The Health Status Questionnaire, developed by Health Outcomes Institute, is a 39-item self-administered questionnaire assessing the patient's own health perceptions and the impact of health on physical functioning, social functioning, and mental health. The HSQ was developed from the SF-36 and MOS-20 questionnaires. The scale for each domain ranges from 0-100 with 100 representing ideal functioning. The total HSQ score is obtained by adding the score from each of the eight domains.

Table 6: Health Status Questionnaire Results

Scale	Mean Δ pre-implant to 12-mos. (n=48)	p-value
Health Perception	9.16	0.0011
Physical Functioning	16.62	<0.0001
Role Limitations/Physical Health	22.02	0.0019
Role Limitations/Emotional Problems	10.34	0.1232
Social Functioning	18.02	<0.0001
Mental Health	13.17	0.0002
Bodily Pain	6.92	0.1610
Energy/Fatigue	7.13	0.0400
Overall HSQ	97.94	<0.0001

Data was available from 48 patients at 12-months follow-up. HSQ mean scores from pre-implant and 12-months follow-up were analyzed and compared. The change in score was significant if the p-value ≤ 0.05. Table 6 lists the scales, the change in scores, and whether or not a significant change was observed. All scales except the Role Limitations/Emotional Problems and the Bodily Pain scales indicated a significant improvement from pre-implant to the 12-month visit. While these two scales did not show significance, they did indicate a change in the positive direction. Overall, the HSQ results indicated a significant improvement in status from pre-implant to 12-month visit.

Fecal Incontinence Quality of Life

The Fecal Incontinence Quality of Life Questionnaire (FIQOL) is a 39-item, self-administered questionnaire designed to assess the impact of fecal incontinence on a variety of activities and feelings. It is a psychometric evaluation, which objectively measures the physical, psychological,

and social impact that fecal incontinence has on the patient's lifestyle. Pre-implant results of the FIQOL demonstrated the distressing effects of fecal incontinence on study patients. The decreases in FIQOL response percentages indicated that the physical, psychological, and social impacts that fecal incontinence had on the patients' lifestyle were diminished from pre-implant to the 12-month follow-up.

Table7: Fecal Incontinence Quality of Life

Characteristic	Pre-implant (n=113)	12-months (n=67)
Feel I have no control over bowels	89%	9%
Worry about bowel accidents*	86%	22%
Alter activities to be near bathroom	81%	33%
Worry about being embarrassed*	80%	25%
Bowel accidents always on mind*	78%	25%
Use pads	77%	39%
Worry about others smelling stool on me*	76%	19%
Locate bathrooms when someplace new	76%	34%
My life is more difficult	70%	15%
Avoid wearing light colored clothing	69%	24%
Cannot do the things I want to do*	68%	16%
Feel ashamed*	66%	18%
Plan schedule around bowels	65%	21%

Table 7 lists patient responses to statements about fecal incontinence and its effects. The percentages indicate responses of either "Most of the time" or "Strongly agree". For example, when asked to respond to the statement *Due to accidental bowel leakage, I feel I have no control over my bowels*, 89% of patients responded "Most of the time" before implant whereas 9% responded "Most of the time" at 12-months. The response choices were "None", "A little", "Some", or "Most of the time". Patients responded "Strongly agree" to statements marked with an asterisk (*). Response choices were "Strongly disagree", "Somewhat disagree", "Somewhat agree", and "Strongly agree".

Revision Surgery

Revisions were reported in the clinical trial. Revision surgery included repositioning, removing and/or replacing one or more device components. The 395 device-related adverse events in the study resulted in 81 device revisions. The 81 revisions occurred in 56 out of 112 implanted patients. The patient revision rate for the study was 50.0%. No long-term adverse sequelae were reported in association with revision surgery in the clinical trial.

Table 8: Device Revisions from Acticon Neosphincter Clinical Study

Reasons for revision [1]	Number of Events[2]	Number of Patients	% of patients (n=112)
Infection	30	28	25.0
Erosion	27	24	21.4
Malfunction	13	11	9.8
Recurring Incontinence	11	10	8.9
Migration	7	6	5.4
Pain	6	6	5.4
Patient Dissatisfaction	4	4	3.6
Malposition	3	3	2.7
Other[3]	13	13	11.6
Total:	81	56	50.0

[1] More than one reason may exist for each revision e.g., infection and erosion.

[2] Patients may have multiple occurrences of the same event type.

[3] Other reasons for revision included replacing previously removed cuff (2), incision open (1), two stage device removal (2), cuff opened (3), cellulitis/erosion of the peritoneal skin (1), improperly sized cuff (1), constipation (2) and ano-urethral communication (1)

The most common indications for revision surgery were infection (28 patients) and erosion (24 patients). Overlap of infection and erosion occurred in 13 cases. Cuff erosions occurred in 22 patients (rectum 12, perineum 10). Pump erosions occurred in four (4) patients and one (1) patient had a tubing erosion. Some patients experienced more than one type of erosion. The third most frequent cause for revision was device malfunction. The revision rate for malfunctions was 9.8%. Fourteen patients (14) had two revisions, one patient had three revisions, and three patients had four revisions.

Ten patients who underwent one or more revision surgeries prior to the 12-month visit had functional devices at 12 months. Six of these patients were considered as clinical successes at 12 months. Two additional patients were stoma patients who would be considered as clinical successes if assigned the average pre-implant FISS score of 106.

Device Explants
Device explants represent a subset of the 81 revisions listed in Table 8. The reasons for device explant are listed in Table 9. At the 12-month follow-up, 34 patients (30% of implanted patients) experienced 38 explants. The mean time from implant to explant was 4.2 months (0.3 – 14.2).

Table 9: Device Explants from Acticon Neosphincter Clinical Study

Reasons for explant	Number of Events[1]
Infection	12
Infection and erosion	12
Erosion	11
Recurring Incontinence and pain	2
Ano-urethral communication	1
Total Explants	**38**

[1]Patients may have multiple occurrences of the same event type.

Infection, erosion, or a combination of infection and erosion accounted for 35 of the 38 explants. Out of the 34 patients who had explants, 7 are candidates for reimplant and 27 are permanent explants. The 27 permanent explants exited the study.

Patient Counseling Information

Patients should be counseled in order to have a realistic expectation of the physical, psychological and functional outcome of the implantation. The risks, benefits and potential adverse events of all available treatment options should be discussed with the patient and considered by the physician and patient when choosing a treatment option. Patient information brochures are available from AMS to help the patient understand these issues. The brochures also discuss the device, the implant procedure, how-to-use the device, and results from the clinical study. The patient information brochures should be provided to patients prior to the surgery.

Some patients may become dissatisfied by the presence of the prosthetic device in their body. This issue should be discussed with the patient prior to the surgery. Patient dissatisfaction may lead to device removal. Patients should also be aware that the Acticon Neosphincter is not considered a lifetime implant.

An appropriate patient history, including history of personality disorders, and diagnostic work-up should be a part of the patient decision making process. Discuss with the patient the possibility of an allergic reaction to the materials in the device (See Silicone Information).

Silicone Information

This device is composed of a number of materials, including solid silicone elastomers and a fluorosilicone lubricant. Silicone gel is not a component in the materials of this device. Solid silicone elastomers have been commonly used in a variety of biomedical devices for over 40 years. Silicone fluids have an extensive history of use in medical devices.

Scientific literature has included reports of adverse events and other observations in patients with implantable silicone devices. As reported, these events/observations indicate "allergic-like" symptoms and in other cases a symptom complex associated with immunological disorders. No casual relationship has been established between these events and silicone elastomer or fluorosilicone lubricant.

There are reports of malignant tumor formation in laboratory animals only associated with implants of relatively large size. Many different materials are associated with this effect in animals, silicone elastomers among them. No such effect has been described in humans.

Extensive testing has been conducted on all materials in the AMS Acticon Neosphincter. This testing indicated that no toxicological response was attributable to the materials. However, some of the materials caused minor irritation when implanted in animals.

Silicone elastomer particulate shedding and particulate migrations to regional lymph nodes have been reported in the literature on penile implants. There are no known clinical sequelae to this phenomenon.

Magnetic Resonance Imaging (MRI) Information

Several studies regarding MRI and AMS prostheses have concluded that the presence of an AMS prosthesis will not produce harmful effects during scanning. These studies were conducted by Robert C. Lange, Ph.D., Yale University and Frank G. Shellock, Ph.D., Cedars-Sinai Medical Center, Los Angeles. Dr. Lange produced his study for American Medical Systems and Dr. Shellock produced his studies independently for publication in the *American Journal of Roentgenology* (AJR) and *Radiology*.[1,2,3,4]

In these studies, the metallic components in AMS prostheses were subjected to magnetic field strengths up to 1.5 Tesla and showed no unsafe magnetic interaction. The small stainless steel components in AMS prostheses may distort the uniform magnetic field in the vicinity of the implant, although it is unlikely that these components will interfere with normal MRI. However, the complete compatibility profile of these products within a MRI field has not been established.

Inventory Returns and Product Replacement Information

Before returning any components, whether explanted or unused (sterile or nonsterile), customers must fill out the Return Goods Form located on the last page of the Patient Information Form. Follow **all** of the instructions on the form carefully, and be sure that the components have been thoroughly cleaned before returning them to AMS.

In all cases, obtaining credit or percentage of credit for a returned component is subject to approval under the terms of the AMS Return Goods Policy and the AMS Product Replacement Policy. For complete information regarding these policies, contact the AMS Customer Service Department.

---

[1] Shellock F, *MR Imaging of Metallic Implants and Materials*: A Compilation of the Literature, AJR, October 1988.

[2] Shellock F, *MR Imaging and Biomedical Implants, Materials and Devices: An Updated Review*, Radiology, 1991, Vol 180, pp. 541-550.

[3] Shellock F, MR *Procedures and Biomedical Implants, Materials and Devices*: 1993 Update, Radiology, 1993, Vol. 189, pp. 587-599.

[4] Shellock F, *MR Procedures and Metallic Objects: Update 1997.* Philadelphia, Lippincott-Raven, 1997, pp. 101, 110.