NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of Artificial anal sphincter

Introduction
This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Date prepared
This overview was prepared by ASERNIP-S in November 2002.

Procedure name
Artificial anal sphincter
Synonyms: artificial bowel sphincter
Acronyms: AAS

Specialty society
Association of Coloproctology of Great Britain and Ireland

Executive summary
A high morbidity rate occurs with implantation of the artificial anal sphincter, with infection and/or erosion being the most common. Where implantation is successful, patients can expect varying degrees of continence to liquid and flatus. Explantation rates are high, with rates in the presented studies ranging from 17% (under 2 years follow-up)[1] to 44% (4 years follow-up).[2] This includes an explant rate of 30% (1 year follow-up), from a large multicentre study[3] (112 patients).

Indication(s)
The causes of faecal incontinence are diverse. Existing treatment options include medical therapy, bio feedback techniques and surgery in selective patients. Existing surgical treatment includes sphincter repair, sacral nerve stimulation, encirclement procedures, muscle transposition (dynamic graciloplasty). Some patients may require a colostomy if other techniques fail. The claimed advantage of an artificial anal sphincter is for a small number of patients with end-stage faecal incontinence who cannot accept a colostomy.

Summary of procedure
A fluid filled cuff is placed around the anal canal, mimicking the natural function of the sphincter muscle. When the fluid is displaced from the cuff, via a patient controlled pump, defaecation can take place.

Originally the American Medical Systems (AMS) urinary sphincter, AMS800® was adapted for use as an artificial bowel sphincter. The Acticon Neosphincter™ artificial bowel sphincter (American Medical Systems, Minneapolis, Minnesota, USA) has now been developed. The artificial anal sphincter has three components: an inflatable cuff (the sphincter), a pressure regulating balloon and a control pump.

The bowel is prepared by the administration of an enema or whole gut irrigation. The cuff is inserted around the upper anal canal and tubing from the cuff is channelled along the perineum and connected to a control pump placed subcutaneously in the scrotum or labia. The control pump is then connected by tubing to a pressure-regulating balloon that has been implanted in the abdominal wall. The balloon holds approximately 40ml of radio-opaque solution and the control pump regulates the transfer of fluid from the balloon to the cuff so that when the cuff is filled with fluid, continence is achieved. By pressing the pump several times, fluid is displaced from the cuff back to the balloon, allowing defaecation. Once defaecation is complete, the fluid slowly returns to the cuff and continence is again achieved. The cuff is not activated until 8 weeks postoperatively, to allow sufficient healing.

Literature review

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until November 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports (2002), relevant online journals and the Internet were also searched in November 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on Artificial Anal Sphincter in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. Foreign language papers were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base, and that could be translated in the time available.

Studies were rejected for reporting no clinical outcomes, being review articles, or involving techniques other than treatment of faecal incontinence by implantation of an artificial anal sphincter. In the case of duplicate publications, the latest, most complete study was included. Studies were selected for extraction of data firstly if they were comparative, then case series were rated as to number of patients, breadth of study population (therefore multicentre studies were rated most highly) and length of follow-up. One non-randomised comparative study was excluded as the article was in Spanish and there was no English abstract available to indicate inclusion. Included studies are highlighted in bold in the reference list. Studies for which data were not tabulated are listed in the annex following the reference list.

List of studies found
Total number of studies: 26

- Randomised controlled trials – 0
- Systematic reviews – 0 (The Australian Medical Services Advisory Committee (MSAC) report on "Placement of Artificial Bowel Sphincters in the Management of Faecal Incontinence" should be available mid-2003).
- Non-randomised comparative studies – 1 (excluded as the article was in Spanish and no English abstract was available).
- Case series – 22 (of which 5 are presented in this overview)
- Case reports – 3

RCTs in progress
None located.

Summary of key efficacy and safety findings
See following tables;

Abbreviations:

AMS	American Medical Systems
CGS	Continence Grading Scale
FIQOL	Fecal Incontinence Quality of Life
FIS	Fecal Incontinence Score
HSQ	Health Status Questionnaire
N/A	not applicable
QOL	Quality of Life
SD	Standard deviation
SE	Standard error

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Case series			
Christiansen et al.[13] 1999, DENMARK 17 patients (11/17 (65%) female) *Follow-up*: median 7 (range 5 –10) years *Selection criteria*: Between 1987 and 1993, patients with indications of anal incontinence from neurologic disorder, anal atresia or failure of previous treatment for anal incontinence underwent implantation.	Explantation 2/17 (12%) postop – due to infection 1/17 (7%) 6 months postop – infection which started as erosion (Explantation rate from infection 3/17 (18%; 95% CI 4% to 43%) 2/17 (12%) within 1 year postop – mechanical malfunction 2/17 (12%) 2 and 3 years postop – due to severe chronic diarrhoea from diabetic enteropathy (1) and severe rectal emptying dysfunction (1) 8/17 (47%) had a functioning AAS ≥ 5 years after implantation Revisional procedures were performed in 5/8 (63%; 95% CI 24% to 91%) Continence score (modified Williams scale) Prior to surgery, all patients were incontinent for solid stool and had an incontinence score of 5. After 5 years or more follow-up, 1/8 (12.5%) were continent to solids, liquids and flatus (score 1), 3/8 (37.5%) were continent to solids and liquids but not flatus (score 2), 3/8 (37.5%) were continent to solids with occasional incontinence to liquids (score 3), 1/8 (12.5%) had occasional episodes of incontinence to liquids (score 1), 0/8 (0%) had frequent episodes of incontinence to solids and liquids (score 5).	*Infection* 3/17 (18%) – resulting in explantation	*Potential for bias*: Small study numbers. 2/17 (12%) patients were lost to follow-up due to death from unrelated causes. *Outcome measures and their validity*: The validity of the modified Williams scale (1 to 5 for full continence to faeces and flatus to frequent episodes of incontinence to solid and liquid stool) was not specifically stated. *Other comments*: 6/17 (35%) implanted with a urinary sphincter (AMS 800, American Medical Systems, Minneapolis, MN, USA), 11/17 (65%) implanted with a modified version of the urinary sphincter (cuff-tab strengthened, wider cuffs, enlarged pressure regulating balloon).

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Devesa et al.[14] 2002, SPAIN 53 patients (35/53 (66%) female) *Follow-up*: 26.5 ± 14 (range 7-55) months *Selection criteria*: not stated. Patients submitted to implantation between 1996 and 2000.	<u>Explantation</u> 10/53 (19%) due to skin or septic complications 2/10 patients underwent reimplantation but were again explanted because of the same complications <u>Revisions</u> 14/23 (60% of patients with complications) underwent one or more revision surgeries <u>Changes of device</u> 3/53 (6%) of patients required changes of the device between 17 and 32 months postop <u>Functional results</u> 26/43 (60%) of patients with the device in action used the pump; in 5/43 (12%) the cuff was always activated as patients could evacuate without difficulty, in 12/43 (28%) the cuff was nearly always deactivated due to the patients' own decisions. Significant improvement of continence (p=0.000)* 43 (98%) of patients had permanent continence to stool, 29 (66%) to gas, and 17/26 (65%) to liquid. 48% reported some type of soiling, minimal and occasional in 36%, minimal but frequent in 10% and significant in 2%. <u>Manometry results</u> Significant improvement in resting (p=0.000)* and squeeze pressures (p=0.000)* No significant change in rectal sensitivity parameters. <u>Quality of life</u> (25 patients) Significant improvement in all subscales (p=0.000)*	<u>Perioperative events</u> Abnormal bleeding 7/53 (13%) Vaginal perforation 4/53 (7.5%) Rectal perforation without apparent contamination 2/53 (4%) Unnoticed urethral perforation 1/53 (2%) (More than one event occurred in 3/53 (6%) patients) <u>Mortality</u> 0/53 (0%) <u>Early complications</u> (from time of implantation until activation 8 weeks postop) Wound separation 8/53 (15%) Infection 7/53 (13%) {in 4 patients, wound separation was first noticed} Haematoma 7/53 (13%) Fever of unknown origin 1/53 (2%) Urethral fistulas 1/18 male patients (5.5%) Impaction 5/53 (9%) Diarrhoea 4/53 (8%) <u>Late complications</u> Cuff erosion 5/50 (10%) Pump erosion 4/50 (8%) Primary infection 3/50 (6%) {In 2 patients infection and erosion were coincident} Impaction 11/49 (22%) {1 patient still has a diverting stoma} Pain 4/50 (8%) Pump malfunction 1/49 (2%) {1 patient still has a diverting stoma} System leaks 1/50 (2%)	*Potential for bias*: 28/53 (53%) of patients were lost to follow-up; cuff explanted (10), patients from other countries (14), patients who could not attend (3), missing after discharge (1). *Outcome measures and their validity*: The validation of the Jorge and Wexner grading scale (0 to 20 where 0 is normal) was not specifically stated. The validity of Faecal Incontinence Quality of Life Scales was not specifically stated. Anal rectal tests included anal manometry, rectal sensitivity, measurements of pudendal nerve terminal motor latency, electromyography of the external sphincter and endoanal ultrasound. *Other comments*: All patients implanted with the Acticon Neosphincter® (American Medical Systems, Minneapolis, MN, USA). * As stated in text

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Lehur et al.[1] 2000, FRANCE, SPAIN, BELGIUM 33 patients (24 patients retained for this study; 17/24 (71%) female) *Follow-up*: median 20 (SD 7, range 6-35) months *Selection criteria*: Consecutive patients undergoing implantation at three European institutions since May 1996.	Mean hospital stay 9 ± 4 days Stoma closure for the three patients with colostomy was performed after a mean 8 weeks from implantation. Activation of the device was successful in 23/24 <u>Explants and Reimplants</u> 8 explants in 7/24 (30%) patients {definitive explants in 4/24 (17%) – cuff rupture (1), "unbuttoning" (1), erosion (2) – rupture patient refused reimplantation, other 3 were reimplanted} 3/24 (12.5%) patients were explanted and successfully reimplanted {temporary failure} 17/24 (71%) successful implantation Activated device at end of follow-up 20/24 (83%) <u>Functional results</u> (in 20 patients with successful implantation) *Continence* (Faecal Incontinence Score (FIS)) The difference between preop. and postop. Status was statistically significant ($p<0.0001$) for 6 and 12 months and end of follow-up period. FIS remained unchanged in 1/20 (5%) {failure} *Defaecation* 7/20 (35%) reported minor difficulties in rectal emptying <u>Manometric results</u> Significant difference between closed cuff pressures and preop. and open cuff pressures ($p<0.00001$) Median closing time of cuff to restore anal pressure 4min 40secs (SD 3min, range 38secs – 10min)	Perineal wound dehiscence 2/24 (8%) (1 had device implanted too close to perineal skin and was reoperated after 2 months to reposition the cuff, 1 had pump repositioned under general anaesthesia on day 3) Leg phlebitis 3 weeks postop 1/24 (4%) Urinary tract infection 5/24 (21%) Two female patients with difficulties in rectal emptying developed or worsened a rectocele.	*Potential for bias*: Reason for initially excluding 9/33 patients not stated. Fecal Incontinence Score (FIS) developed by American Medical Systems (AMS). *Outcome measures and their validity*: The validity of the FIS was not specifically stated. Anal resting pressure and time required for the cuff to close was measured. *Other com*ments: All patients implanted with the Acticon Neosphincter® (American Medical Systems, Minneapolis, MN, USA).

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Ortiz et al.[2] 2002, SPAIN 22 patients (17/22 (77%) female) *Follow-up*: 28 (range 6-48) months *Selection criteria*: Patients with severe faecal incontinence that underwent artificial bowel sphincter implantation between Nov 1996 and Jan 2000. Patients had been incontinent for 18 (range 2-39) years due to neuropathy, anal atresia, perineal trauma, direct sphincter disruption from operative trauma, obstetric injury and Steinert's myotonic dystrophy.	<u>Explantation</u> 8/22 (36%) 2/22 (9%) due to infection (postop.) 2/22 (9%) due to perineal pain (12 and 15 months post-op) 4/22 (18%) due to erosion (4, 6, 6 and 46 months postop.) Cumulative probability of explantation was 44% at 48 months. <u>Reimplantation</u> Two reimplantations (1 had perineal infection in early postop. period, 1 had unbuttoning) Therefore, by the end of the study, 24 devices had been implanted in 22 patients and definitive explantation was necessary on 9 occasions in 7 patients. <u>Functional outcome</u> (measured in 15 patients with a functioning implant) Total continence 4/15 (27%) {18% of total patients} Total continence for formed stool 14/15 (93%) {64% of total patients} 1/15 (7%) experienced rare episodes of incontinence Several patients had problems related to continence of liquid stool and flatus, 4 had to wear pads, and 2 considered that these events altered their lifestyle. Continence scores improved before implantation to after operation ($p<0.001$) Resting anal pressure (in patients with a functioning implant) increased from before operation to when the cuff was inflated ($p<0.01$)	<u>Postop. Complications</u> 9/22 (41%) had complications in the postop. period Perineal and abdominal haematoma 4/22 (18%) Perineal wound dehiscence 3/22 (14%) {These 7 patients treated successfully with conservative measures} Perineal infection 2/22 (9%) {resulting in explantation} <u>Complications at follow-up</u> 10/22 (45%) of patients developed 11 complications Refilling of cuff required (1) Migration of pump requiring reoperation (1) Perineal pain (3) {2 explanted} Unbuttoning of cuff at 10 and 12 months (1) {2 reoperations required 1. to rebutton 2. to explant and reimplant a new device} Cutaneous erosion and exteriorisation of tube or cuffs (5) {1 patient required reoperation, 4 patients explanted} Number of surgical reoperations carried out due to complications was significantly higher at follow-up than in the immediate postop. period (relative risk 0.19 (95% CI 0.05-0.78);$p<0.005$)	*Potential for bias*: Small study numbers. *Outcome measures and their validity*: The validity of the Cleveland Clinic Florida 20-point incontinence scoring system was not stated. Other outcomes were measured by anorectal manometry, pudendal nerve terminal motor latency measurement and transanal ultrasonography. *Other com*ments: All patients implanted with the Acticon Neosphincter® (American Medical Systems, Minneapolis, MN, USA).

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Wong et al.[3] 2002, USA, CANADA, FRANCE 115 patients (86/115 (75%) female) *Follow-up*: activation (8 weeks), 6 and 12 months *Selection criteria*: Multicentre cohort study. Original recruitment goal was to recruit 100 patients, a total of 115 patients were enrolled after screening and were implanted between Feb 1997 and Jan 2001.	*Efficacy based on 112 patients* 112/115 were implanted, 3 were never implanted (6 procedures were aborted due to tissue perforation during dissection (4) {3/4 went on to be implanted at a later date} 1/4 was removed from the study, the fifth aborted patient also had a failed dynamic graciloplasty and the cuff was not long enough to encircle the anal canal – removed from the study, the sixth aborted procedure occurred in a patient who was found to have a megarectum intraoperatively – removed from the study) *Operating time* 124 (range 37-210) mins *Average length of hospital stay* Canada 7 (range 4-14) days US 5 (range 1-15) days Europe 26 (range 11-59) days Fecal Incontinence Score *Results for patients who did not have a stoma preimplant* Statistically significant improvement from preimplantation to 6 months follow-up ($p<0.0001$) and preimplantation to 12 months follow-up ($p<0.0001$). At 6 months follow-up 50/63 (79%) has a "successful outcome" defined as a reduction of 24 points on the FIS or more. At 12 months follow-up 47/55 (85%) had a successful outcome. | | Patient number | mean FIS score | FIS range | mean reduction | |---|---|---|---|---| | preimplant | 101* | 106 | 71-120 | N/A | | 6 months | 63 | 105 | 71-120 | 54 | | 12 months | 55 | 105 | 71-120 | 57 | *14/112 patients had preexisting stomas *Results for patients (14) who had a stoma preimplant* 6/14 had completed the 12 month FIS. 6/14 were subsequently explanted (mostly due to infection). 1/14 was lost to follow-up, 1/14 had not completed the 12 month questionnaire. 12 month follow-up FIS were available for six patients and given that these patients had no preimplant scores comparisons could not be made at follow-up, but an assumption was made that the nonstoma preimplantation mean was 106, the stoma	*Safety based on 115 patients* 443 adverse event reported (59 not device related) – 384 device-related complications occurred in 99 (86%) patients 0 (0%) life threatening or unanticipated adverse events occurred. Summary of adverse events | Complication | # of patients[I] | # of complications[II] | No intervention[III] | Medication[IV] | Surgery[III] | Other interventions[III,IV] | |---|---|---|---|---|---|---| | Pain | 37 | 44 | 15 | 14 | 9 | 13 | | Infection | 38 | 43 | 0 | 15 | 35 | 3 | | Impaction | 21 | 27 | 2 | 7 | 3 | 17 | | Constipation | 20 | 31 | 2 | 25 | 1 | 7 | | Erosion | 24 | 28 | 0 | 2 | 27 | 1 | | Faecal incontinence | 21 | 28 | 2 | 3 | 13 | 16 | | Surgical injury | 15 | 15 | 2 | 0 | 11 | 1 | | Wound problems | 11 | 12 | 7 | 2 | 0 | 3 | | Difficult evacuation | 10 | 13 | 1 | 5 | 1 | 8 | | Wound separation | 10 | 10 | 4 | 4 | 1 | 1 | | Rectal bleeding | 9 | 9 | 5 | 1 | 2 | 1 | | Erythema | 8 | 9 | 3 | 5 | 1 | 2 | | Device function | 7 | 9 | 0 | 0 | 0 | 10 | | Edema | 7 | 8 | 2 | 1 | 4 | 1 | | Anorectal condition | 7 | 8 | 1 | 0 | 1 | 6 | | Fever | 7 | 7 | 0 | 6 | 1 | 0 | | Device migration | 7 | 9 | 1 | 0 | 7 | 0 | | Malfunction | 7 | 9 | 0 | 0 | 8 | 1 | | Wound drainage | 6 | 7 | 1 | 2 | 1 | 3 | | Device fit | 6 | 6 | 2 | 1 | 3 | 2 | | Diarrhoea | 5 | 7 | 2 | 1 | 0 | 3 | | Gastrointestinal condition | 5 | 6 | 1 | 1 | 2 | 2 |	*Potential for bias*: Industry support was given by the manufactures of the Acticon Neosphincter® (American Medical Systems, Minneapolis, MN, USA). FIS developed by American Medical Systems. 2/112 (2%) were lost to follow-up at 6 months, 3/112 (3%) were lost to follow-up at 12 months. *Outcome measures and their validity*: The validity of the Fecal Incontinence Scoring System (FIS) Questionnaire and Fecal Incontinence Quality of Life (FIQOL) Questionnaire was not specifically stated. The Health Status Questionnaire (HSQ) was validated. The FIS was specifically designed for the study. Other measurements included anorectal manometry, endoanal ultrasonography and pudendal nerve terminal motor latency testing. *Other com*ments: All patients implanted with the Acticon Neosphincter® (American Medical Systems, Minneapolis, MN, USA).

Continued over…

patients would also have a preimplantation score of at least 106 as their incontinence was severe enough to warrant a colostomy. 5/14 (35%) had a successful outcome which if added to the nonstoma patients, an overall clinical success of 52/61 (85%) of patients.

Intention to treat

33 patients were explanted leaving 79 implanted patients remaining at 12 month follow-up. 3 were lost to follow up (76) of which 55 nonstoma and 6 stoma patients were available for 12 month follow-up –18 patients were excluded from the final analysis resulting in a total patient denominator of 97. On an intent to treat basis, clinical success was 51/97 (53%) counting 36 patients that were not implanted or who were explanted as failures.

Anorectal Manometry

The difference in resting pressures between preimplant and 12 month postactivation was statistically significant ($p<0.0001$)

Fecal Incontinence Quality of Life (FIQOL)

Use of pads and diapers

Preimplantation – pads 99/113 (58%), diapers 58/113 (51%)
12 months post activation – pads 32/59 (54%), diapers 10/59 (17%)

Daily activity and enjoyment of life

Preimplantation - 90/112 (80%) reported daily activities limited by incontinence most of the time, 96/113 (86%) reported altering their activities most of the time to stay near the bathroom, 101/113 (89%) reported being unable to hold their bowel movement long enough to reach a bathroom, 92/113 (81%) avoided prolonged physical activity, 92/113 (81%) reported enjoying life less due to their incontinence.
6 months post activation – 53/69 (77%) reported marked improvement or resolution of incontinence and therefore experienced little limitation of their daily activities, 48/69 (70%) expressed little fear of going out, fewer patients were embarrassed or ashamed compared to preimplantation, majority of patients reported no feelings of depression.
12 months post activation – 12/59 (20%) reported being unable to hold their bowel movement long enough to reach the bathroom, 17/59 (29%) avoided prolonged physical activity, 41/59 (70%) *rarely* avoided activities such as going out to movies and visiting friends, 18/59 (30%) of patients reported enjoying life less due to their incontinence.

Ecchymosis	4	4	3	0	0	1
Abscess	3	3	0	1	3	2
Device operation	3	3	0	0	0	3
Malposition	3	3	1	0	2	0
Haematoma	2	2	1	0	0	1
Operative bleeding	2	2	0	0	1	2
Seroma	1	1	0	0	0	1
Urinary tract infection	1	1	0	1	0	0
Other	17	20	6	3	1	9
Totals	99	384	64	100	138	120

[I] Patients may have had more than one type of complication
[II] Patients may have had more than one complication of the same type
[III] There may have been more than one type of intervention for each event, and patients may have had multiple events treated with the same intervention
[IV] Other interventions include fluid added to system (15), enemas (13), deactivation of device (12), hospitalisation (8), patient education (9), disimpaction (6), observation (8), wound care (7), catheterisation (2), clear liquids (2), xrays (2), pump manipulation (2), colostomy or revision surgery offered (3), local therapy (3), antibiotics stopped (2), suture (2), total parenteral nutrition (2), fibre (2), cuff sizer removed, flexible sigmoidectomy, unspecified (18).

Health Status Questionnaire (HSQ)
Matched data was available on 44 patients who completed the HSQ preimplantation and 12 months post activation and based on FIS 35/44 (80%) were clinically successful, 4 were failures and 5 did not have 12 month FIS scores.
Statistically significant improvement ($p<0.0001$) of mean total HSQ score was noted between preimplantation and 12 months post activation.

Explantation
41/112 (37%) implanted patients underwent complete device explantation (due to erosion and/or infection)
7/41 (17%) were reimplanted and retained a functional device at the end of follow-up
9/41 (22%) are still awaiting reimplantation.
Definitive explant rate at 12 month follow up was 34/112 (30%)

Device survival
At 12 months follow-up, 75/112 (67%) had functioning devices.
At 12 months 75.99% (SE 0.0427) were free from any surgical revision and 92.91% (SE 0.0378) of patients were free from explant.

Specialist advisor's opinion / advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- The Specialist Advisors considered the main efficacy concern to be the frequent need to remove the implanted artificial sphincters.
- Their main safety concerns were the risk of infection, erosion and evacuation difficulties.
- Appropriate training in surgical technique is required to perform this procedure.
- There is some controversy, as numbers in reports are inconsistent and reports do not relate to all implants and therefore reporting may be subject to bias/inappropriate denominators. There is a need to know the "true" success rates, ie. with the correct denominators of all implants.
- There is currently no specific code for the procedure, but a new code is warranted if the use of artificial anal sphincters continues.

References

1. **Lehur PA, Roig JV, Duinslaeger M. Artificial anal sphincter: prospective clinical and manometric evaluation. *Diseases of the Colon & Rectum* 2000;43(8):1100-1106.**

2. **Ortiz H, Armendariz P, DeMiguel M, Ruiz MD, Alos R, Roig JV. Complications and functional outcome following artificial anal sphincter implantation. *British Journal of Surgery* 2002;89(7):877-881.**

3. **Wong WD, Congliosi SM, Spencer MP, Corman ML, Tan P, Opelka FG, Burnstein M, Nogueras JJ, Bailey HR, Devesa JM, Fry RD, Cagir B, Birnbaum E, Fleshman JW, Lawrence MA, Buie WD, Heine J, Edelstein PS, Gregorcyk S, Lehur PA, Michot F, Phang PT, Schoetz DJ, Potenti F, Tsai JY. The safety and efficacy of the artificial bowel sphincter for fecal incontinence: results from a multicenter cohort study. *Diseases of the Colon & Rectum 45(9):1139-53,* 2002.**

4. Bytzer P, Talley NJ, Leemon M, Young LJ, Jones MP, Horowitz M. Prevalence of gastrointestinal symptoms associated with diabetes mellitus: a population-based survey of 15,000 adults. *Archives of Internal Medicine* 2001;**161**(16):1989-1996.

5. Drossman DA, Li Z, Andruzzi E, Temple RD, Talley NJ, Thompson WG, Whitehead WE, Janssens J, FunchJensen P, Corazziari E. U.S. householder survey of functional gastrointestinal disorders. Prevalence, sociodemography, and health impact. *Digestive Diseases & Sciences* 1993;**38**(9):1569-1580.

6. Edwards NI, Jones D. The prevalence of faecal incontinence in older people living at home. *Age & Ageing* 2001;**30**(6):503-507.

7. Faltin DL, Sangalli MR, Curtin F, Morabia A, Weil A. Prevalence of anal incontinence and other anorectal symptoms in women. *International Urogynecology Journal* 2001;**12**(2):117-120.

8. Kalantar JS, Howell S, Talley NJ. Prevalence of faecal incontinence and associated risk factors; an underdiagnosed problem in the Australian community? *Medical Journal of Australia* 2002;**176**(2):54-57.

9. Lynch AC, Dobbs BR, Keating J, Frizelle FA. The prevalence of faecal incontinence and constipation in a general New Zealand population; a postal survey. *New Zealand Medical Journal* 2001;**114**(1142):474-477.

10. MacLennan AH, Taylor AW, Wilson DH, Wilson D. The prevalence of pelvic floor disorders and their relationship to gender, age, parity and mode of delivery. *British Journal of Obstetrics & Gynaecology* 2000;**107**(12):1460-1470.

11. Nelson R, Norton N, Cautley E, Furner S. Community-based prevalence of anal incontinence. *JAMA* 1995;**274**(7):559-561.

12. Perry S, Shaw C, McGrother C, Matthews RJ, Assassa RP, Dallosso H, Williams K, Brittain KR, Azam U, Clarke M, Jagger C, Mayne C, Castleden CM, Leicestershire MRC Incontinence Study Team. Prevalence of faecal incontinence in adults aged 40 years or more living in the community. *Gut* 2002;**50**(4):480-484.

13. Christiansen J, Rasmussen OO, LindorffLarsen K. Long-term results of artificial anal sphincter implantation for severe anal incontinence. *Annals of Surgery* 1999;230 (1):45-48.

14. Devesa JM, Rey A, Hervas PL, Halawa KS, aga I, Svidler L, Abraira V, Muriel A. Artificial anal sphincter: Complications and functional results of a large personal series. *Diseases of the Colon & Rectum* 2002;45(9):1154-1163.

ANNEX: Studies that met the inclusion criteria but which were not tabulated.

Altomare DF, Dodi G, La Torre F, Romano G, Melega E, Rinaldi M. Multicentre retrospective analysis of the outcome of artificial anal sphincter implantation for severe faecal incontinence. *British Journal of Surgery* 2001;**88**(11):1481-1486.

Christiansen J, Lorentzen M. Implantation of artificial sphincter for anal incontinence. *Lancet* 1987;**2**(8553):244-245.

Christiansen J, Lorentzen M. Implantation of artificial sphincter for anal incontinence. Report of five cases. *Diseases of the Colon & Rectum* 1989;**32**(5):432-436.

Christiansen J, Sparso B. Treatment of anal incontinence by an implantable prosthetic anal sphincter. *Annals of Surgery* 1992;**215**(4):383-386.

Denkers D. [Experiences of patients with fecal incontinence with the AMS anal sphincter prosthesis]. [German]. *Krankenpflege Journal* 1998;**36**(10):379-380.

Dodi G, Melega E, Masin A, Infantino A, Cavallari F, Lise M. Artificial bowel sphincter (ABS) for severe faecal incontinence: A clinical and manometric study. *Colorectal Disease* 2000;**2**(4):207-211.

Gelet A, Meunier P, Platet RL, AbdelRahim AF, Friaa S, Lopez JG, Manzan K, Dubernard JM. Treatment of dual urinary and fecal incontinence by implantation of two AMS 800 artificial sphincters. Case report. *European Urology* 1997;**31**(1):115-117.

Grise PH, Sibert L, Bonnet O, Mitrofanoff P, Mottet O, Cussenot O, Lehur A, Buzelin JM. [Intestinal implantation of an artificial sphincter]. [French]. *Acta Urologica Belgica* 1992;**60**(3):99-105.

Hoogerwerf WA, Pasricha PJ. Taking control of fecal incontinence: early results of an artificial sphincter device. *Gastroenterology* 1999;**116**(4):1005-1006.

Lehur PA, Michot F, Denis P, Grise P, Leborgne J, Teniere P, Buzelin JM. Results of artificial sphincter in severe anal incontinence. Report of 14 consecutive implantations. [see comments.]. *Diseases of the Colon & Rectum* 1996;**39**(12):1352-1355.

Lehur PA, Glemain P, Bruley d, V, Buzelin JM, Leborgne J. Outcome of patients with an implanted artificial anal sphincter for severe faecal incontinence. A single institution report. *International Journal of Colorectal Disease* 1998;**13**(2):88-92.

Lehur PA, Zerbib F, Neunlist M, Glemain P, Bruley d, V. Comparison of quality of life and anorectal function after artificial sphincter implantation. *Diseases of the Colon & Rectum* 2002;**45**(4):508-513.

Michot F, Lehur PA, Forestier F. Artificial anal sphincter. *Seminars in Colon & Rectal Surgery* 1997;**8**(2):116-120.

O'Brien PE, Skinner S. Restoring control: the Acticon Neosphincter artificial bowel sphincter in the treatment of anal incontinence. *Diseases of the Colon & Rectum* 2000;**43**(9):1213-1216.

Ortiz H, Yarnoz C, de Miguel M. [Is dynamic graciloplasty or artificial anal sphincter better in the treatment of fecal incontinence? Preliminary study]. [Spanish]. *Revista Espanola de Enfermedades Digestivas* 2001;**93**(2):130-131.

Riedel JG, Festge OA. [A new treatment method in severe fecal incontinence in children]. [German]. *Chirurg* 1999;**70**(8):935-938.

Romano G, La Torre F, Cutini G, Bianco F, Esposito P. Total anorectal reconstruction with an artificial bowel sphincter: Report of five cases with a minimum follow-up of 6 months. *Colorectal Disease* 2002;**4**(5):339-344.

Vaizey CJ, Kamm MA, Gold DM, Bartram CI, Halligan S, Nicholls RJ. Clinical, physiological, and radiological study of a new purpose-designed artificial bowel sphincter. *Lancet* 1998;**352**(9122):105-109.

Vaizey CJ, Kamm MA, Gold DM, Bartram CI, Halligan S, Nicholls RJ. A prospective clinical, physiological and radiological study of a new purpose-designed artificial bowel sphincter. *Gastroenterology* 1998;**114**(4):G3489.

Wong WD, Jensen LL, Bartolo DC, Rothenberger DA. Artificial anal sphincter. *Diseases of the Colon & Rectum* 1996;**39**(12):1345-1351.