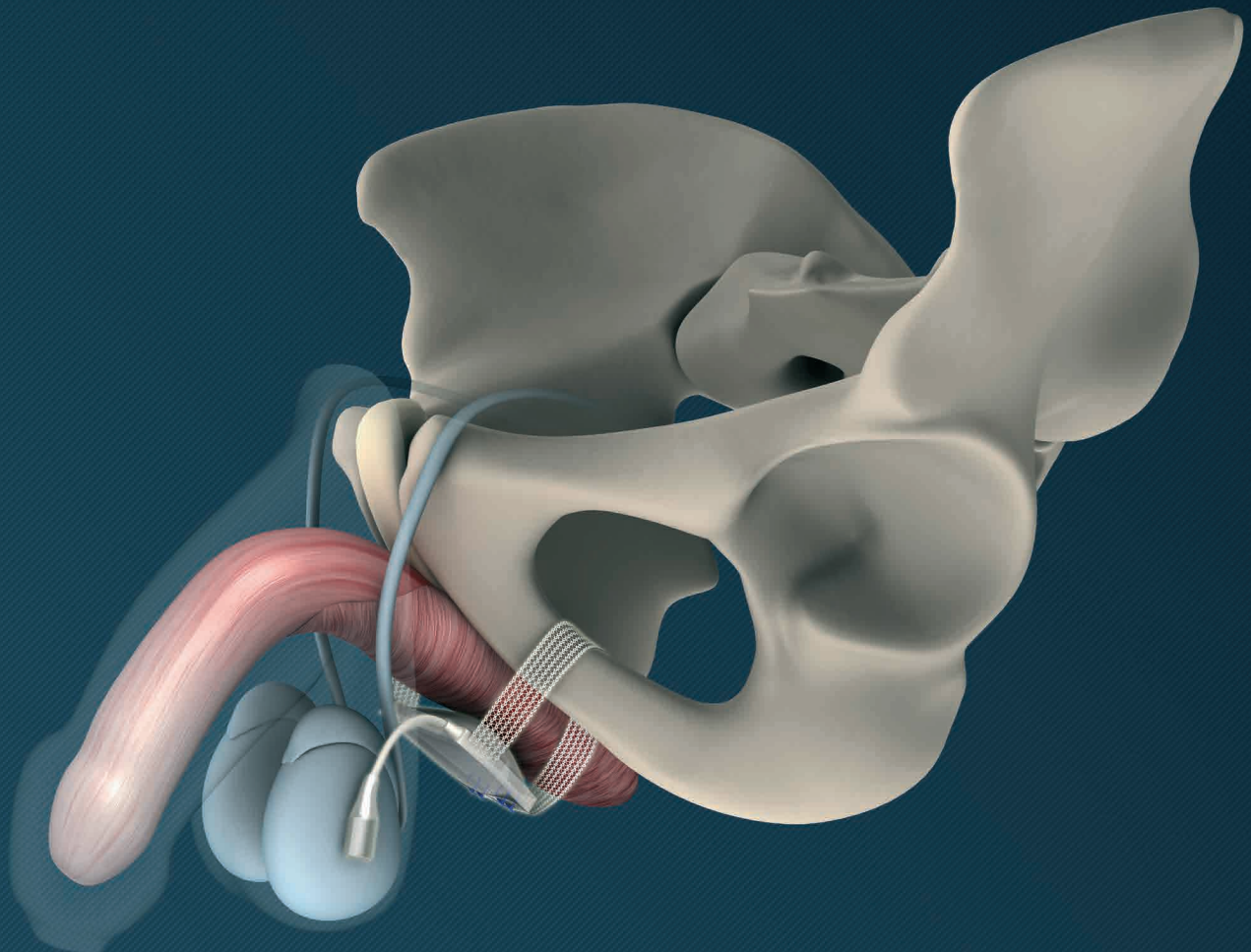


A.M.I.® ATOMS System

ATOMS = Adjustable TransObturator Male System

Product Group Urology | Issue 05/2019



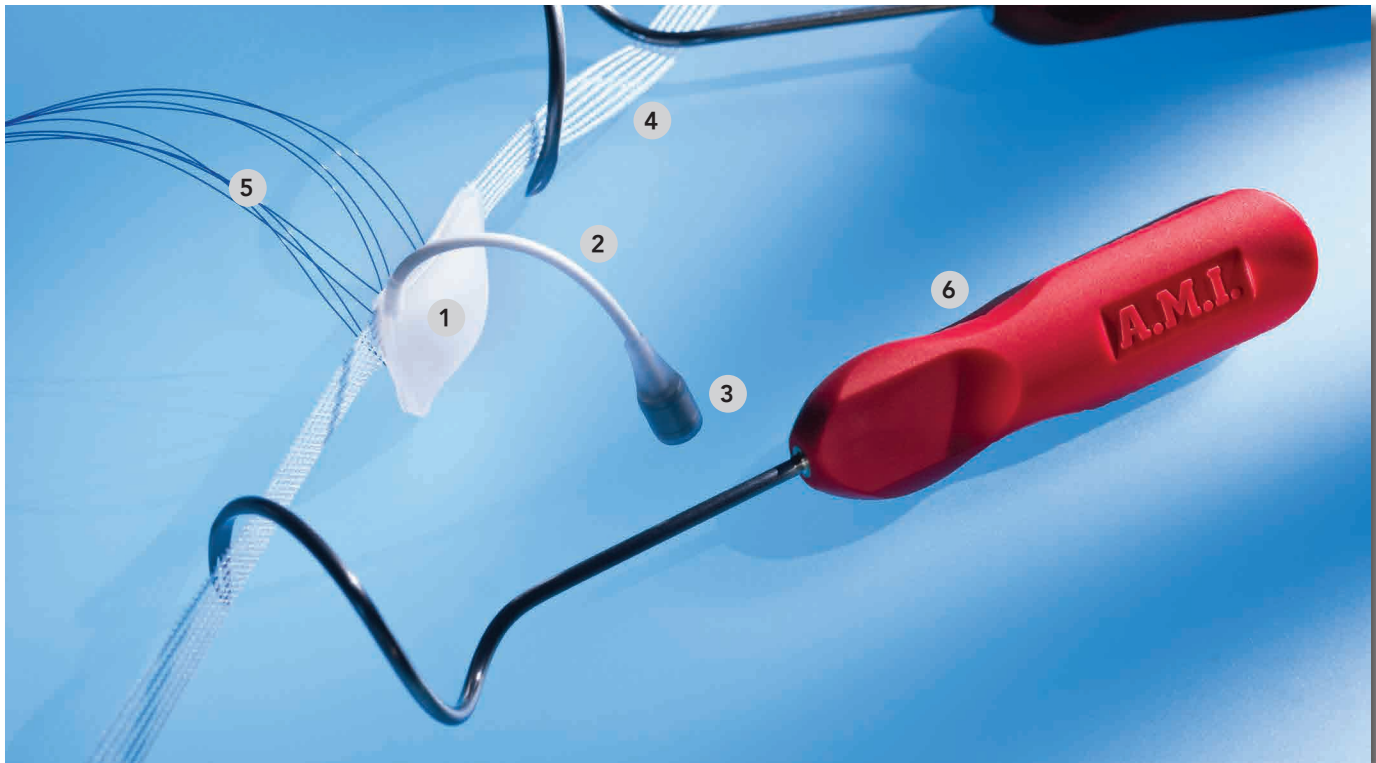
Hydraulic system substitutes urinary sphincter function in incontinent males

- Long-term, adjustable implant
- Hydraulic system with no mechanical parts
- Innovative, anatomical 4-point fixation

The system is suitable for all degrees of urinary incontinence, and can also be used after radiotherapy.

A.M.I.® ATOMS System

The treatment of male stress urinary incontinence still presents a significant challenge, particularly after radical prostatectomy. The A.M.I. ATOMS System combines a minimally-invasive and low-risk method with the option of quick and easy adjustment to the system at any time after the implantation.



1 Suburethral substitute sphincter cushion

2 Catheter

3 Scrotal Port

4 Mesh arms for fixation

5 Fixation sutures

6 Tunneller

The suburethral substitute sphincter cushion

- is the central part of the implant and filled via the port-catheter connection after the operation. Patient-specific adjustment requires no surgical intervention and can be made at any time to counteract either continuing incontinence or urinary retention.
- ensures a gentle, evenly-distributed pressure on the bulbospongiosus muscle to reduce the risk of urethral erosion. There is no specific point of maximum compression on the urethra.

4-point fixation

- the integrated mesh arms are drawn back around the inferior pubic ramus to the middle of the implant to secure the system in place. This eliminates the need for additional fasteners or screws, and ensures a symmetrical 4-point fixation.
- exact fixation of implant in steps of millimeters is possible: reduction of implant fill volume.

The flexibility

- effective treatment for mild to severe stress urinary incontinence.

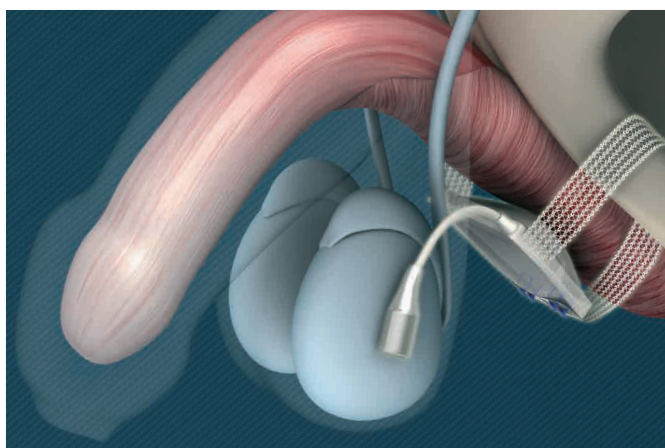
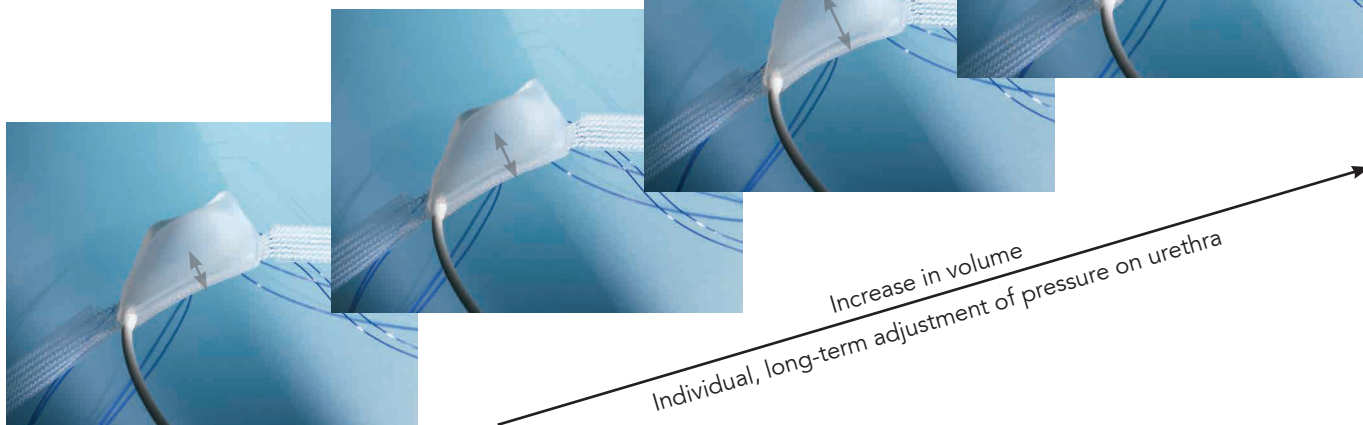
...and the patient friendliness

- patients can urinate freely without having to activate a mechanical component. This means the ATOMS System is also suitable for patients suffering from dementia, or whose cognitive skills may be expected to regress over time. Patients with joint pain (e.g. gout) also benefit from not having to operate the system manually.

A.M.I.® ATOMS System

Hydraulic System

ATOMS is made up entirely of components that function hydraulically. Patients are therefore spared the difficulties caused by defects which may occur in mechanical components months or years after the implantation.



Scrotal Port

The distal, suburethral placement of the implant underneath the bulbospongiosus muscle allows for use of the system even after radiotherapy. The symmetrical positioning below the urethra is achieved by a 4-point fixation. The small, pre-attached scrotal port is palpated with ease by the urologist. Filling the system with saline solution or emptying it is performed with a simple percutaneous needle puncture.

Patient comfort

ATOMS has the advantage that the surgical technique is completely standardized. With today's implantation technique, the already short operating time could be reduced even further. Particularly the integrated scrotal port saves surgical steps, which benefits the patients, the surgeon, the OP staff and lastly the hospital in general.

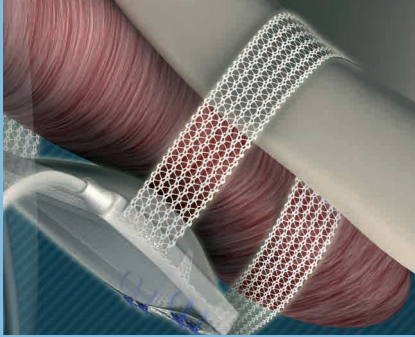
A modified tunnelling is carried out, placing the implant in an "outside-in" method. The careful preparation and exposure of the bulbospongiosus muscle together with an emphasis to avoid entrapping the posterior scrotal nerves are important steps. In most cases, this leads to a quick patient recovery and is associated only with mild post-operative pain. A respectable number of patients will be dry directly after surgery with no need for further adjustment.

Surgical Workshops

To obtain optimal results for your patients as quickly as possible, A.M.I. offers a Surgical Workshop program. At these workshops the surgical techniques are taught, and tips & tricks are passed on by experts to the attending urologists. Patient selection and follow-up are also thoroughly discussed within the group, thereby resulting in an overall excellent training.

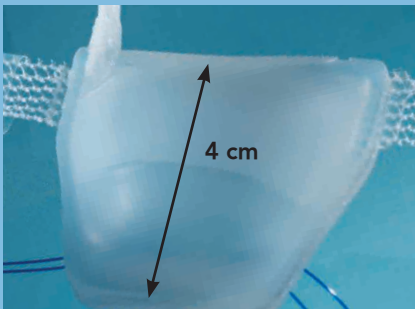
A.M.I.® ATOMS System

Features of ATOMS



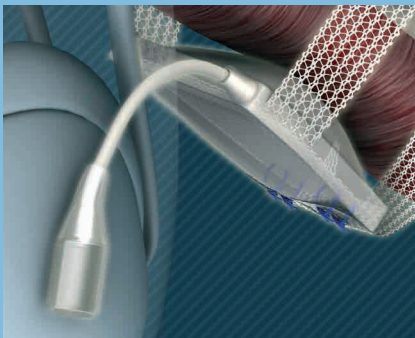
Why a mesh that loops around the inferior pubic ramus? Firmer hold and infection prophylaxis.

The ingenious, patented idea of looping the mesh around the bone as a holding structure is worth mentioning. The integrated mesh will be placed around the inferior pubic ramus, which leads to several advantages: The macroporous mesh integrates well into the tissue. The engraftment leads to an extra firm hold, which is relevant for optimal surgical results. In addition to the firm hold, the macroporous mesh also offers the advantage of reduced foreign body reactions. Tissue ingrowth and revascularization of the surrounding tissue reduce the risk of an infection spreading in the pelvis operatively or post-operatively.



Why a large cushion? Atrophy reduction and erosion prophylaxis.

The effect of the implant is simple: The urologist determines the fill volume of the cushion. A compression of the bulbospongiosus muscle, indirectly of the urethra, increases the urethral resistance. The contraction of the bladder will make a physiological urination possible, but an involuntary loss of urine is reduced or ideally avoided. The size of the cushion determines the pressure on the bulbospongiosus muscle, and the smaller the cushion, the more punctate the pressure is. The soft compression of the large ATOMS cushion allows a low pressure, and a low tissue pressure leads to low atrophy. Limited tissue atrophy means lower risk of erosion. A very limited number of urethral erosions is known to A.M.I. after 10 years of experience with ATOMS, and those few cases were usually associated with a difficult patient situation (e.g. following previous cuff erosion of an artificial urinary sphincter).

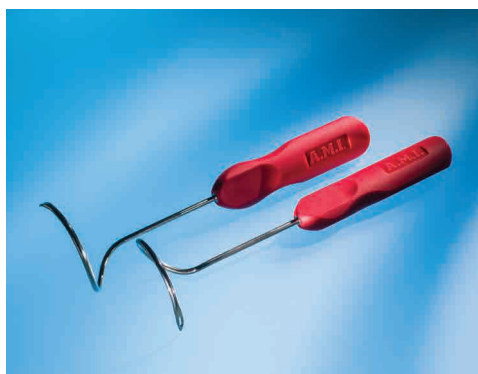


Why does the catheter attach lateral and exit dorsal? Compliant with the anatomy.

The catheter outgoing, laterally on top of the cushion, displays straight in the direction of the scrotum. It proceeds without kinks and it touches no other parts of the implant. It proceeds the shortest way on the left side of the scrotum. If necessary, the implant can be adjusted post-operatively by means of a simple percutaneous puncture of the port – even years after the implantation.

A.M.I.® ATOMS System

Features of ATOMS



Tunnellers from A.M.I.: uncompromised quality

The ATOMS implant is secured by a transobturator-approach at four points with the mesh arms. Subcutaneous tunnelling is carried out with helical multi-use tunnellers, which are used to draw the integrated mesh arms through the obturator foramen. The arms are then tied to the pre-positioned attachment sutures, ensuring the implant is anchored firmly in place.



Eco-friendly

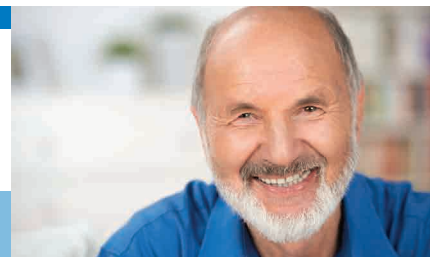
A.M.I. has a clear commitment in protecting the environment and conserving resources. In all areas of business, we take special care to be energy efficient and environmentally friendly, which is reflected in our products. We deliver high-quality multi-use tunnellers which are used when implanting ATOMS. These same tunnellers can also be used for the implantation of female incontinence slings.

By using the multi-use tunnellers, our customers together with A.M.I. act in a responsible manner to help protect the environment.

ATOMS in brief:

- | | |
|-------------------------------------|--|
| - Substitute for sphincter function | Physiological urination with no patient operation |
| - Hydraulic system | No mechanical components |
| - Long term adjustment | System can be adjusted at any time to suit changes occurring over the years in the patient's condition |
| - Minimally invasive | The operation itself is minimally invasive; adjustment requires no surgery |
| - Experience | 10 years experience with ATOMS (7 years published data) |

A.M.I.® ATOMS System



Patient satisfaction

Help your patients win back the quality of life!



"In January 2009 I had surgery for total removal of my prostate. The result of that was severe urinary incontinence with a complete loss of quality of life: sporting, cultural and many other everyday activities were only possible with extreme limitations. I was saved from this seemingly hopeless situation by my urologist, who implanted an ATOMS System for me. With it, I regained my previous quality of life. Now I can do everything that had previously been important to me: cross-country skiing, hiking, playing tennis, travelling, going to the theatre and opera, visiting museums etc. etc. **Life is worth living again.**"

L.R. 72 years old



"In December 2003 I underwent a radical prostatectomy. In January 2005 I received an implant, which constantly caused inflammation. Because of this, I had to have it removed again completely. My last hope was my urologist, who carried out an **ATOMS implantation for me in December 2012 and achieved a small miracle.** Since then my life is worth living again, because I can participate in everyday life with no more problems whatsoever."

F.P. 77 years old



"After undergoing a radical prostatectomy I was incontinent and needed between 15 and 20 pads per day. After 2 years I was still using 5-6 pads per day and a further reduction was simply not possible. **Just under 4 years ago my urologist implanted an ATOMS System for me** and I was completely dry immediately after surgery. This day changed my life. I wouldn't want to be without the ATOMS System anymore, because in my opinion it's the only system on the market that really makes sense."

H.G. 68 years old



"Exactly one year ago I received an ATOMS implant and **it is still working like it did on the first day.** I can do sports and go hiking again, and I feel very comfortable generally."

J.K. 73 years old

Evidence

Patient satisfaction with adjustable transobturator male system in the Iberian multicenter study

Backgrounds: Patient-reported outcome measurements are important for urinary incontinence. We analyze self-assessed patient satisfaction and define the clinical profile of patient with highest satisfaction with the adjustable transobturator male system (ATOMS). **Methods:** Patient perception of results was evaluated in a series of 181 patients after ATOMS adjustment. Baseline incontinence severity was defined in pads-per-day (PPD) as mild (2), moderate (3–5) or severe (≥ 6), and dryness as use of none or one security PPD. Post-operative pain at discharge was evaluated by 0–10 visual analogue scale and complications by Clavien–Dindo classification. Multivariate analysis was performed to anticipate "very much better" than baseline perception on patient global impression of improvement and a predictive nomogram was developed. **Results:** Dryness was achieved in 80.7% (94.9% mild, 80.8% moderate and 65.8% severe groups). Mean pad-test and padcount decrease with respect to baseline was 458 ± 330 ml and 3.2 ± 1.9 PPD, respectively (both $p < .0001$). Complications presented in 25 (13.8%). The proportion of patients that self-declared satisfied with the procedure was 87.1%; 90.6% perceived their situation "better" and 48.1% "very much better" than before. Multivariate analysis revealed best perception is defined by dryness after adjustment ($p < .0001$), baseline severity of incontinence ($p = .007$), low post-operative pain at discharge ($p = .0018$) and lack of complications ($p = .007$). **Conclusions:** Self-assessed satisfaction with ATOMS is very high. Factors that predict best perception of improvement include dryness, baseline SUI severity, presence of complications and pain level during admission. Radiotherapy and device generation were not independent predictors. A nomogram to predict patients that are completely satisfied with ATOMS after adjustment is proposed.

J.C. Angulo - World Journal of Urology 2019;1-9.; DOI: 10.1007 s00345-019-02639-4

Dry rate: 80.7%

Evidence

Effectiveness of Adjustable Transobturator Male System (ATOMS) to Treat Male Stress Incontinence: A Systematic Review and Meta-Analysis

Introduction: Adjustable transobturator male system (ATOMS) is a surgical device developed to treat male stress urinary incontinence (SUI) after prostate surgery. The objective was to assess the effectiveness of the ATOMS device to treat male SUI as described in the literature. **Methods:** Two independent reviewers identified studies eligible for a systematic review and meta-analysis of various sources written in English, German and Spanish, using the databases PubMed, EMBASE and Web of Science. We excluded studies on female incontinence. We employed the DerSimonian and Laird method for defining heterogeneity, calculating the grouped standard mean deviation (SMD). The primary objective of this review is the assessment of clinical efficacy based on the achievement of dryness after device adjustment defined as use of no pad or one safety pad per day (PPD). The secondary objective was focused on analysing improvement of incontinence with the device. Magnitude of effect was calculated by analysing decrease in pad count (PPD) and/or in 24-h pad test. Number and severity of complications according to Clavien–Dindo classification were also reviewed. **Results:** The pooled data of 1393 patients from 20 studies (13 retrospective and 7 prospective) showed that treatment with ATOMS resulted in a mean 67% dryness rate and 90% improvement after adjustment. Mean total number of system fillings per patient was 2.4. Mean pad count and 24-h pad test decrease were - 4.14 PPD and - 443 cc, respectively. There is significant heterogeneity of the sample analysed, mainly based on variable baseline severity of incontinence, proportion of patients treated with irradiation and different generation devices. Proportion of irradiated patients affected dryness rate ($p = 0.0014$), together with baseline severity of incontinence ($p = 0.0035$) and different generation device used ($p < 0.0001$). Standardized mean follow-up was 20.9 months, with complications occurring in 16.4% (major complications 3.0%) and explantations in 5.75%. No randomized study has been developed so far to compare ATOMS to other devices for treating male SUI. **Conclusion:** Despite the evidence being exclusively based on descriptive studies and limited follow-up, ATOMS has proven to be a safe alternative to treat different degrees of male SUI after prostate surgery. Better results are evidenced for patients with less than 6 PPD before implantation, non-irradiated patients and use of third-generation device with silicone-covered pre-attached scrotal port.

C. Esquinas et al. - *Advances in Therapy* 2018;/10.1007/s12325-018-0852-4

1393 patients - 20 studies

An overview of the ATOMS generations: port types, functionality and risk factors

Background: We report the multicentre comparison of the different port types of the adjustable transobturator male incontinence system (ATOMS, A.M.I., Austria). **Methods:** Between 10/09 and 10/16, 383 patients received an ATOMS. Of these, 63% received the inguinal port (IP, 2009-2013), 23% the intraoperative manually connectable scrotal port (SP, 2013-2015), and 14% the pre-connected fully silicone covered scrotal port (SSP, 2014-2016). During the follow-up period, continence parameters, pain and quality of life ratings and postoperative port-associated complications were evaluated and compared. Statistical analysis was performed with GraphPad Prism 7[®], $p < 0.05$ considered as significant. **Results:** Regarding preoperative parameters (BMI, ASA score, previous radiotherapy/incontinence surgery, and preoperative 24-h pad count/24-h pad test), no significant differences were found. Regarding perioperative parameters, the mean operative time was significantly shorter for the SP and SSP (IP vs. SP $p < 0.0001$, IP vs. SSP $p = 0.0048$, SP vs. SSP $p = 0.697$). Comparison of the postoperative 24-h pad count, 24-h pad test and uroflowmetry data revealed no significant differences. However, the postoperative ICIQ-SF score was significantly better for the SSP ($p = 0.0232$) than the SP. A significant difference was also observed in postoperative port-associated complications. According to the Clavien-Dindo classification, we identified one grade I and 29 grade IIIb complications for the IP, 1 grade I and 6 grade IIIb complications for the SP, but only 2 grade IIIb complications for the SSP (IP vs. SP $p = 0.0231$, IP vs. SSP $p = 0.0189$ and SP vs. SSP $p = 0.0453$). **Conclusion:** The SSP shows fewer complications while retaining comparable efficacy.

S. Mühlstädt - *World Journal of Urology* 2018, 10.1007/s00345-018-2548-4

Success rate: 82.5%





Adjustable Transobturator Male System after Failed Surgical Devices for Male Stress Urinary Incontinence: A Feasibility Study

Objectives: Feasibility study to evaluate the efficacy and safety of Adjustable Transobturator Male System (ATOMS) after failed surgical devices for male stress urinary incontinence (SUI). **Materials and Methods:** Thirty patients were implanted with ATOMS after they were implanted with surgical device/s previously. SUI severity was evaluated as dryness (0–1 pad/day), mild (2 pads/day), moderate (3–5 pads/day), or severe (≥ 6 pads/day). Change in pad-test and padcount after adjustment, operative parameters, patient satisfaction, and number and grade of complications were investigated. **Results:** Previous failed treatment methods were artificial urinary sphincter (AUS; $n = 19$), Advance ($n = 10$), and Virtue ($n = 1$). Six cases had multiple previous treatments. Preoperative SUI was mild 6 (20%), moderate 11 (36.7%), and severe 13 (43.3%). Median pad-test decreased from 435 mL baseline to 10 mL after adjustment and padcount from 4 to 0. Dry-rate was 76.7 and 83.3% declared satisfied. Postoperative SUI distribution was mild in 3 (10%) and moderate in 4 (13.3%). No patient had urinary retention after catheter removal. Complications presented in 4 (13.3%; 3 grade-I, 1 grade-II). After a median of 24 months follow-up, no system experienced infection or urethral erosion and 1 (3.3%) was removed for inefficacy. **Conclusion:** Based on short-term efficacy and patient satisfaction, ATOMS can be a realistic alternative for male SUI after other failed systems, including AUS. The absence of urethral erosion and limited infective problems makes this alternative attractive for cases with previous failed treatments.

J.C. Angulo - *Urologia Internationalis* 2018;1–9.; DOI: 10.1159/0004893

Dry rate: 76.7%

A.M.I.® ATOMS System

Order Code	Product	Technical Details
ATS5041 	A.M.I. ATOMS System Adjustable system to substitute urinary sphincter function in incontinent males	Width of tape: 12 mm Dimensions of cushion: 40 x 45 mm Materials: Mesh and sutures of polypropylene Catheter and cushion of silicone Adjustment port of silicone and titanium 1 single-use system, delivered sterile
TOA5130 	A.M.I. TOA Tunneller For transobturatoric 4-point fixation	Instrument length: 244 mm Steam autoclavable, delivered non-sterile
ATS5051 	Scrotal Port for ATOMS Silicone-wrapped titanium port with catheter connection (tubing connector) for placement in the scrotum during port revision surgery	Diameter 11 mm 1 port, delivered sterile
SFN 0930 G 	A.M.I. Port Needle Special needle with lateral hole for safe, non-coring punctures of the port septum	20 G x 30 mm 25 needles / box, delivered sterile

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These products comply with the requirements of Medical Device Directive 93/42/EEC and are labelled with the CE mark accordingly.

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 SFN 0930 G

CE **TOA5130**



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