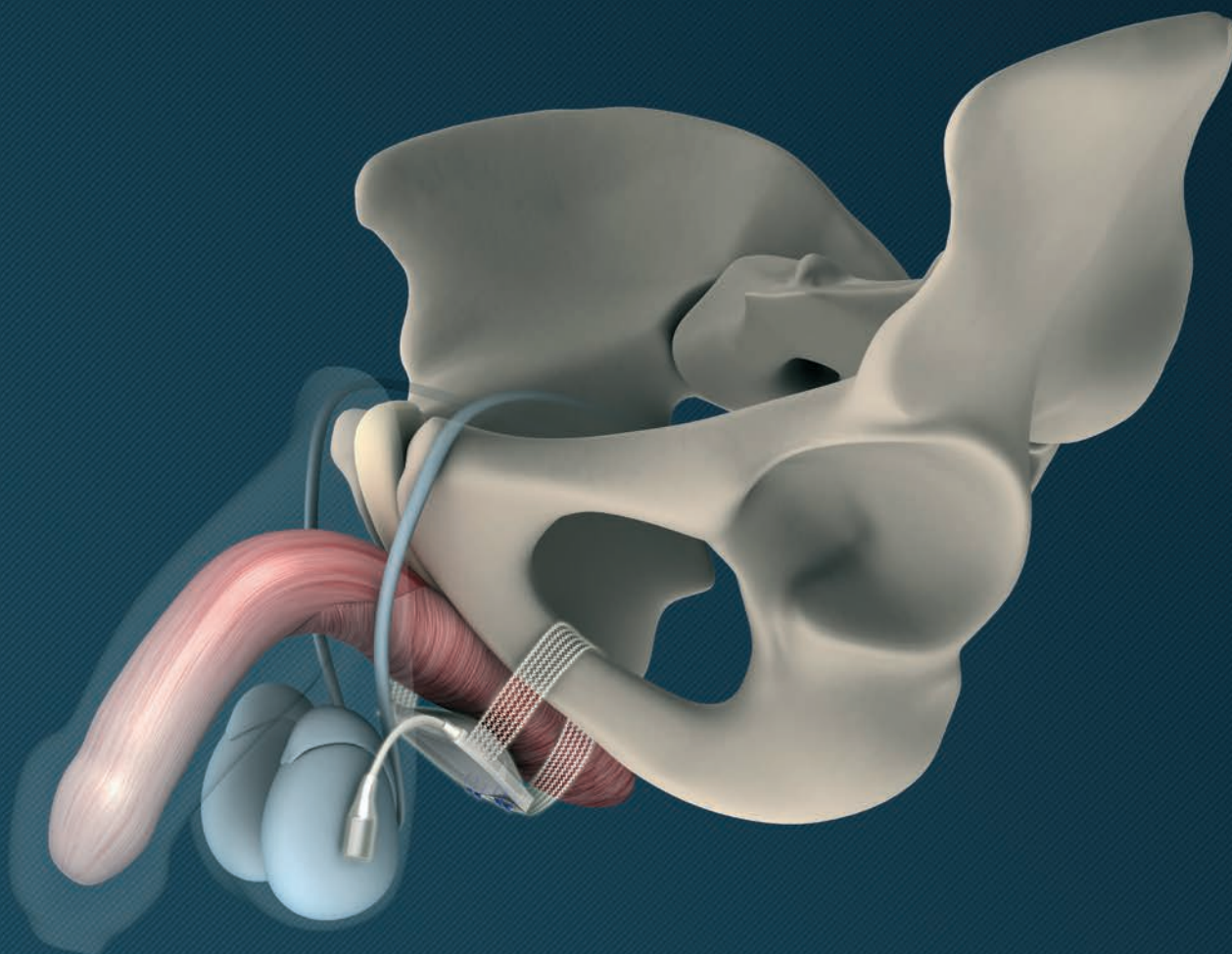


# A.M.I.® ATOMS System

ATOMS = Adjustable TransObturator Male System

Product Group Urology | Issue 11/2016



## 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.

**8 years experience!**

**A.M.I.®**

# 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 fixation arms

5 Attachment 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.

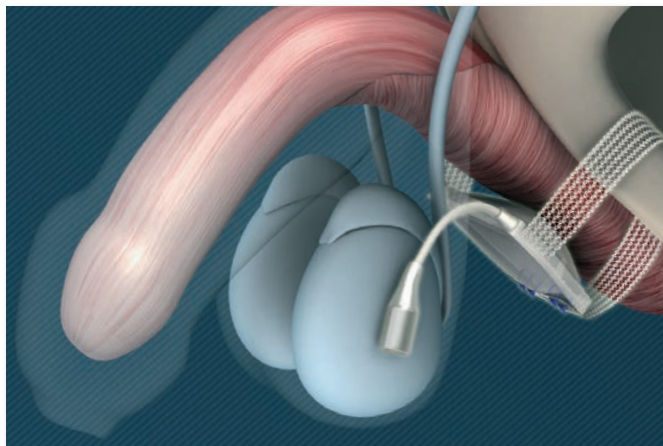
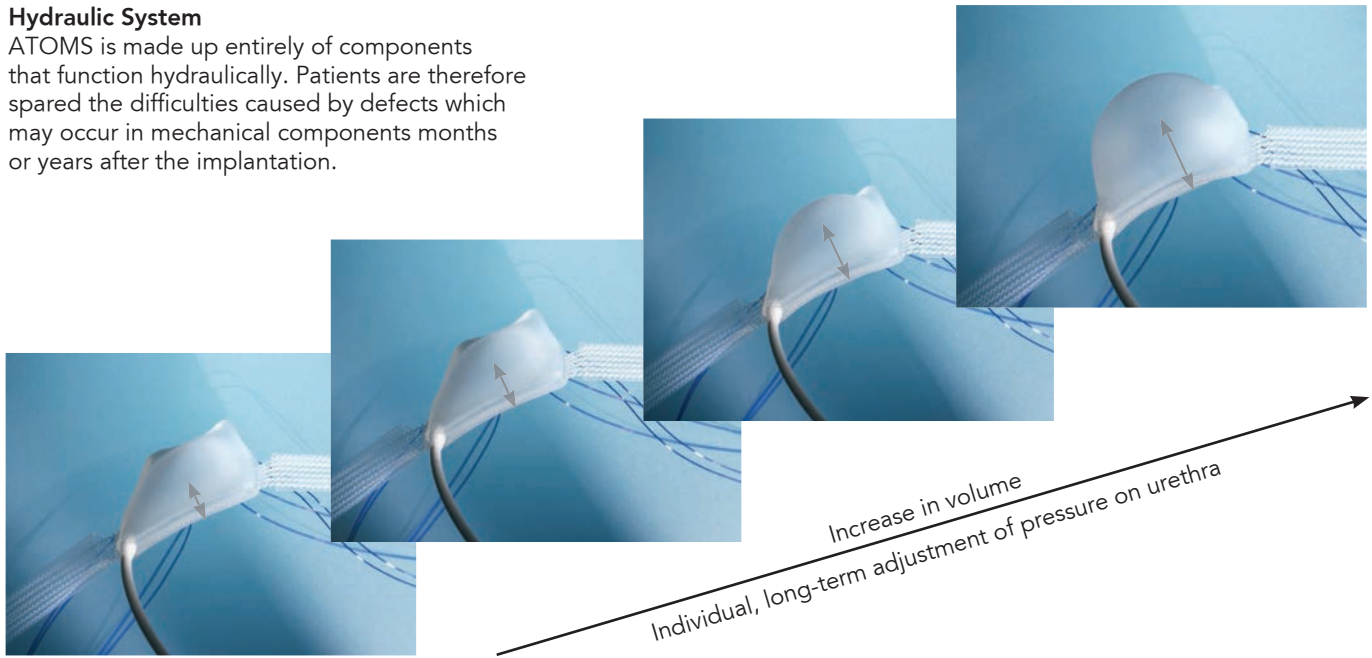
## ...and the patient friendliness

- 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 / painless

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.

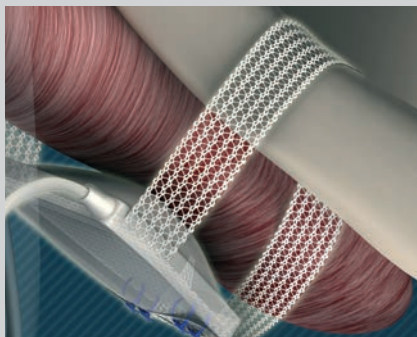
A modified tunnelling is carried out, placing the implant in an "outside-in" method. The careful preparation and exposure of the bulbospongiosus muscle together with an emphasis to avoid entrapping the posterior scrotal nerves are important steps. In most cases, this leads to a quick patient recovery 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

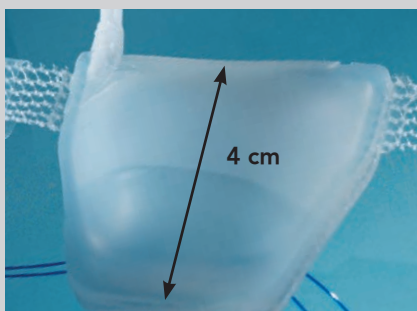
## Features of ATOMS



### Why a mesh that loops around the inferior pubic ramus?

#### Firmer hold and infection prophylaxis.

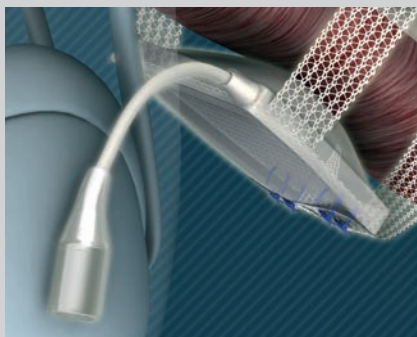
The ingenious, patented idea of looping the mesh around the bone as a holding structure is worth mentioning. The integrated mesh will be placed around the inferior pubic ramus, which leads to several advantages: The macroporous mesh integrates well into the tissue. The engraftment leads to an extra firm 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 big 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, thus 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 big ATOMS cushion allows a low pressure, and a low tissue pressure leads to low atrophy. Limited tissue atrophy means lower risk of erosion. This was the theory in the development less than a decade ago. Today A.M.I. can proudly announce that it looks like the theory worked out well: In fact only a very limited number of urethral erosions is known to A.M.I. after more than 8 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.

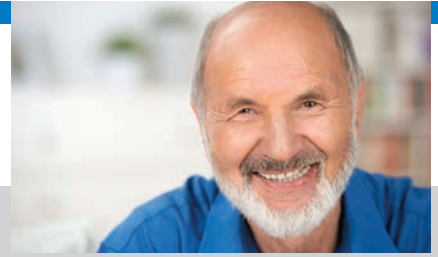
By using the multi-use tunnellers, our customers together with A.M.I. act in a responsible manner to help protect the environment.

### 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                        | More than 8 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

### Initial Experience and Results With a New Adjustable Transobturator Male System for the Treatment of Stress Urinary Incontinence

**Purpose:** We report on our initial experience in terms of efficacy and safety with a new, self-anchoring adjustable transobturator male system (A.M.I.® ATOMS System) for the treatment of male stress urinary incontinence after prostate surgery. **Materials and Methods:** In this prospective, nonrandomized single center study conducted between March and December 2009, patients with stress urinary incontinence secondary to prostatic surgery were treated with the ATOMS device. Urethroscopy, filling and voiding cystometry were performed pre-operatively for all patients. In addition, incontinence symptoms were assessed, and a physical examination, 24-hour pad test and 24-hour pad count were performed before and after surgery. **Results:** A total of 38 patients were included in the study (36 after radical prostatectomy, 2 after benign prostatic hyperplasia surgery). No intraoperative complications occurred. Mean number of adjustments during followup was 3.97 (range 0 to 9). At a mean followup of 16.9 months (range 13 to 21) the overall success rate was 84.2%. Of the successful cases 60.5% were considered dry (0 to 1 pad and less than 15 ml/24-hour pad test) and 23.7% improved (more than 1 pad per 24 hours but more than 50% decrease in pad use and less than 100 ml per 24-hour pad test). In 15.8% of the patients the treatment was considered to have failed (more than 2 pads daily and greater than 100 ml on 24-hour pad test). **Conclusions:** The treatment of male stress urinary incontinence with the ATOMS is safe and effective. It is an excellent first or second line treatment for mild to moderate male stress urinary incontinence, even after external irradiation. The option of longterm, minimally invasive adjustment to respond to patient needs is a significant advantage of this new implant.

J. Seweryn - J Urol 2012; 187: 956

### After radiotherapy

## Evidence

### Treatment of stress urinary incontinence after radical prostatectomy. Adjustable transobturator male system – results of a multicenter prospective observational study

**Background:** The adjustable transobturator male system (ATOMS<sup>®</sup>) is a new method for the treatment of male stress urinary incontinence. This article presents the results of a prospective multicenter observational study with this system. **Patients and methods:** Between March 2009 and March 2011 a total of 124 patients with persistent stress urinary incontinence after radical prostatectomy received the ATOMS system. Postoperative adjustments via the implanted port chamber were performed after 6 weeks and thereafter when necessary. Post-operative evaluation consisted of medical history, micturition protocol, 24-h pad tests, 24-h pad counts and sonography. **Results:** The mean age of the patients was 71.2±5.5 years (range 58-85 years). Previous incontinence surgery had been carried out in 36.3% of patients while 34.5% of patients had a previous history of radiation treatment. The mean operation time was 48.3±11.2 min (range 36-116 min) and the mean hospital stay was 3.8±1.2 days (range 2-6 days). No intraoperative urethral or bladder injuries occurred. After removal of the transurethral catheter on the first postoperative day, temporary urinary retention occurred in 3 patients who were conservatively treated. Transient perineal/scrotal pain or dysesthesia was observed in 75 patients (60.5%) and resolved after 3-4 weeks of non-opioid analgesics. There were no perineal infections; however, infections at the port site occurred in 3 patients (2.4%) leading to explanation of the system in all cases. The average number of adjustments to achieve the desired result was 4.3±1.8 (range 2-7). After a mean follow-up of 19.1±2.2 months (range 12-36 months), there was a significant reduction in the mean number of pads/24 h from 8.8 to 1.8 (p<0.001). The overall success rate was 93.8% with 61.6% of the patients being dry and 32.2% of the patients showing improvement. **Conclusions:** The results of the study demonstrate the safety and efficacy to date of the ATOMS system for treatment of stress urinary incontinence after radical prostatectomy.

M.R. Hoda - Der Urologe A July 2012; pp. 1-9

#### Success rate 93.8%

### Early results of a European multicentre experience with a new self-anchoring adjustable transobturator system for treatment of stress urinary incontinence in men

**Objective:** To report our experience with a new self-anchoring adjustable transobturator male system (ATOMS<sup>®</sup>; AMI, Austria) for the treatment of stress urinary incontinence (SUI) in men. **Patients and Methods:** A total of 99 men, in a number of centres, were treated for SUI with the new ATOMS<sup>®</sup> device. The device was implanted in all patients using an outside-in technique by passing the obturator foramen and anchoring the device to the inferior pubic ramus. The titanium port was placed s.c. on the left symphysis region. Adjustments were performed via port access. Postoperative evaluation consisted of physical examination, 24-h pad test, and 24 h-pad count. Preoperatively and at 6-month follow-up, patients completed a validated quality-of-life questionnaire. Two-way ANOVA was used to analyse changes over time. Within-group effects for time were tested using post hoc Dunnett's contrasts of baseline values vs subsequent measurements. **Results:** The most common indication was SUI after radical prostatectomy (92.9%). Failure of previous surgeries was present in 34.3% patients and 31.3% patients had undergone secondary radiation. The mean (SD; range) surgery time was 47 (13.8; 29-112) min. Temporary urinary retention occurred in two patients (2%) and transient perineal/scrotal dysaesthesia or pain was reported by 68 patients (68.7%) and resolved after 3-4 weeks of non-opioid analgesics. There were four (4%) cases of wound infection at the site of the titanium port leading to explantation. No urethral or bladder injuries related to the device or erosions occurred. The mean (SD; range) number of adjustments to reach the desired result (dryness, improvement and/or patient satisfaction) was 3.8 (1.3; 1-6). After a mean (SD; range) follow-up time of 17.8 (1.6; 12-33) months, the overall success rate was 92% and the mean pad use decreased from 7.1 to 1.3 pads/24 h (P < 0.001). Overall, 63% were considered dry and 29% were improved. **Conclusion:** Treatment of male SUI with this self-anchored adjustable system is safe and effective.

M.R. Hoda / G. Primus - BJU Int 2013 Feb;111(2):296-303

#### Patient satisfaction 92%





### Five-year experience with the adjustable transobturator male system for the treatment of male stress urinary incontinence: a single-center evaluation

**Background:** We report on our 5-year experience with the adjustable transobturator male system (ATOMS<sup>®</sup>, A.M.I., Feldkirch, Austria). **Methods:** Between 10-2009 and 10-2014, 54 patients received an ATOMS. The mean follow-up of this retrospective observational trial was 27.5 ± 18.4 (2.3-59) months. Within each follow-up, the following were evaluated: micturition protocol, 24-h pad count, uroflowmetry and residual volume. Statistical analysis was performed with Sigma-Plot<sup>®</sup> 11.0, p < 0.05 considered as significant. **Results:** Stress urinary incontinence (SUI) I°, II° and III° was seen in 1 (1.9 %), 16 (29.6 %) and 37 patients (68.5 %), respectively. In summary, 48.1 % of the patients became "dry" (0-"safty pad"/day), while 29.6 % achieved at least an "improvement" of about more than 50 % (1-2 pads/day), which corresponds to an overall success rate of 77.7 %. The mean number of pads/day decreased from 7.7 to 1.6. Regarding the initial degree of SUI, patients with mild or moderate incontinence had a significantly better outcome (p = 0.002, 95 % CI 0.9066 to 2.760). Postoperative complications were scaled according to the Clavien classification, in which we have seen 4 grade I-, 1 grade IIIa- and 9 grade IIIb-complications (overall 25.9 %). The evaluation of quality of life by ICIQ-SF showed a significant improvement (p = 0.0001, 95 % CI -14.56 to -11.75). **Conclusion:** The treatment of male SUI using the ATOMS incontinence system achieved the best results in patients with mild and moderate incontinence. For severe incontinent patients, the system represents an efficient alternative.

S. Mühlstädt - World J Urol 2016 DOI 10.1007/s00345-016-1839-x

#### 5 Year experience

# A.M.I.® ATOMS System

Order Code	Product	Technical Details
<b>ATS5041</b> 	<b>A.M.I. ATOMS System</b> 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
<b>TOA5130</b> 	<b>A.M.I. TOA Tunneller</b> For transobturatoric 4-point fixation	Instrument length: 244 mm  Steam autoclavable, delivered non-sterile
<b>ATS5051</b> 	<b>Scrotal Port for ATOMS</b> 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
<b>AGB 382</b> 	<b>A.M.I. Port Needle</b> Special needle with lateral hole for safe, non-coring punctures of the port septum	20 G x 50 mm  25 needles / box, delivered sterile

International patent filed / pending / granted

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**A.M.I.®**