

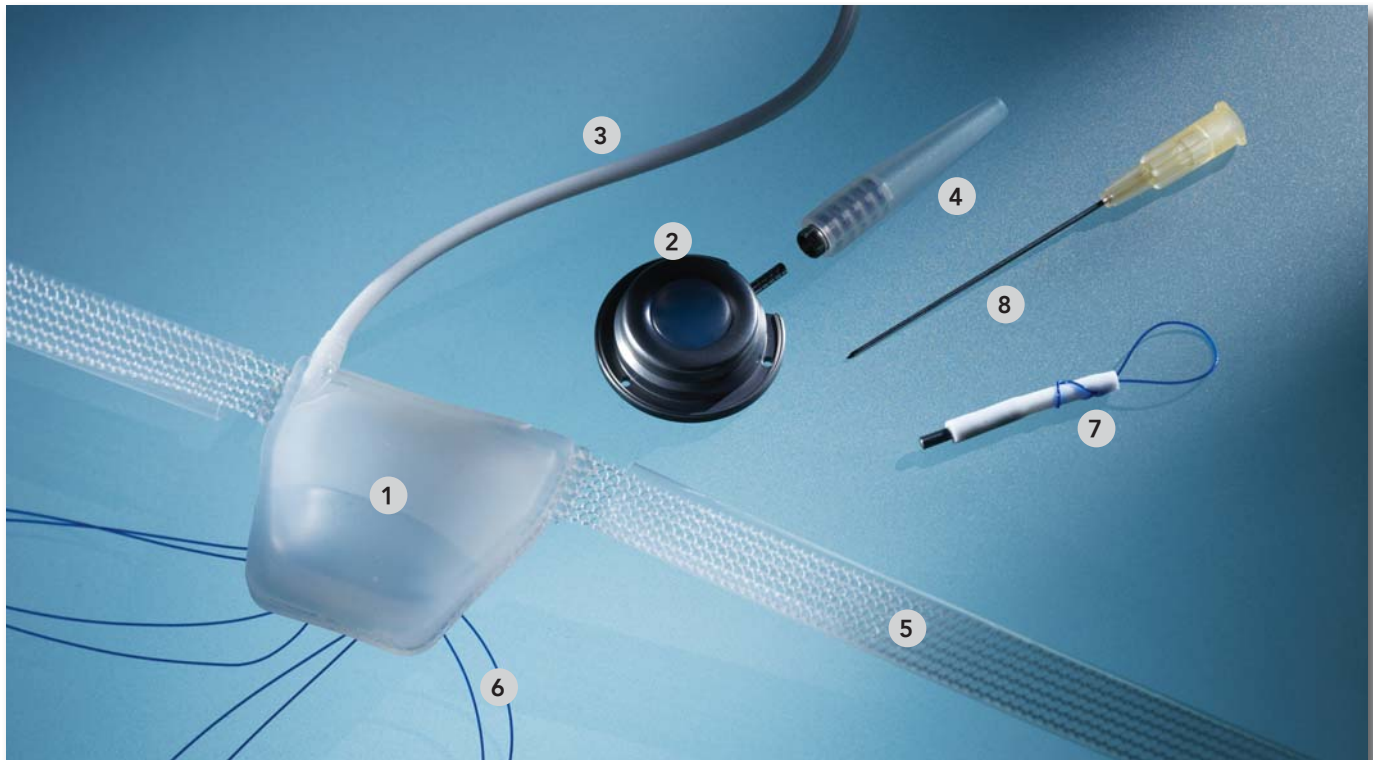
> **Hydraulic system substitutes urinary sphincter function in incontinent males**

- 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. It is particularly effective for severe cases, 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 Port

3 Catheter

4 Catheter protection sleeve

5 Mesh fixation arms

6 Attachment sutures

7 Coupling piece for catheter placement

8 Port needle

The suburethral substitute sphincter cushion

- is located in the middle of the mesh fixation tape 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. There is no point of maximum compression on the urethra and the risk of urethral erosion is significantly reduced.

4-point fixation

- The integrated mesh arms are drawn back around 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.

The flexibility...

- Effective treatment for mild to severe stress urinary incontinence.

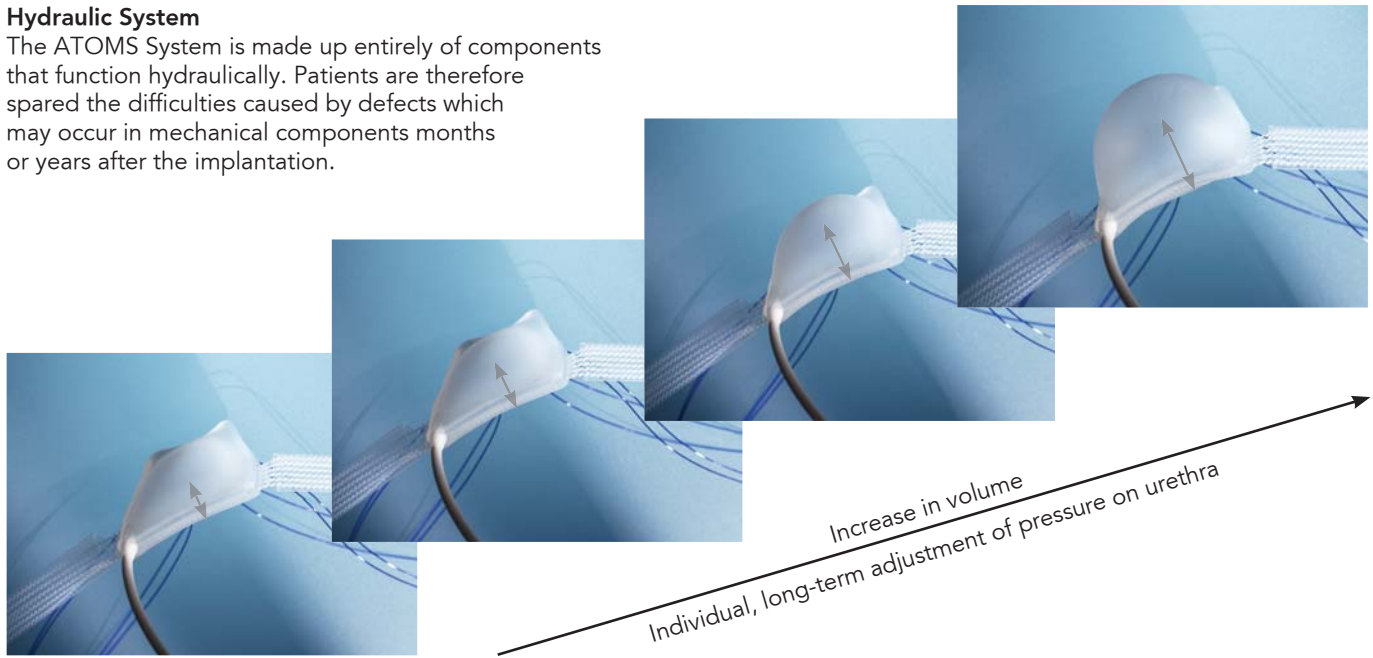
...and the patient friendliness

- 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

The ATOMS System 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.



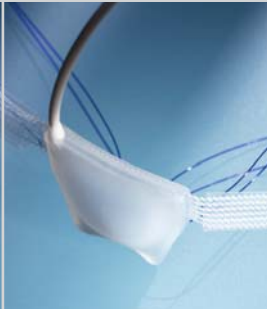




The distal, suburethral placement of the implant underneath the bulbospongiosus muscle allows for use of the system even after radiotherapy. The symmetrical positioning around the urethra is achieved by a 4-point fixation.

The ATOMS implant is secured trans-obturatorically 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.

ATOMS in brief:

- | | |
|-------------------------------------|---|
| - Substitute for sphincter function | Physiological urination with no manual 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 | Not only the operation itself is minimally invasive; adjustment by means of puncture needles also requires no surgery |

A.M.I.® ATOMS System

Order Code	A.M.I. ATOMS Implant	Technical Details
ATS5011 	A.M.I. ATOMS System Multi-part adjustable system to substitute urinary sphincter function in incontinent males	Length of implant: 560 mm Width of tape: 12 mm Dimensions of cushion: 40 x 45 mm Max. filling volume of cushion: 25 ml Materials: Mesh and sutures of polypropylene Catheter and cushion of silicone Adjustment port of titanium 1 single-use system, delivered sterile
TVA5030 	A.M.I. TVA Tunner For placement of the port	Instrument length: 273 mm 1 tunneller, delivered non-sterile, steam autoclavable
TOA5130 	A.M.I. TOA Tunner For transobturatoric 4-point fixation	Instrument length: 245 mm 1 pair of tunnellers (l. and r.) delivered non-sterile, steam autoclavable
ASP 300 	A.M.I. Safe Puncture Port Low Profile Infusion port of titanium with large base-plate, safety edge and tube kink protection	Height 9.8 mm 1 port, delivered sterile
AGB 382 	A.M.I. Port Needle Special needle with lateral hole for safe, non-coring punctures of the port septum	20 G x 50 mm 25 needles / box, delivered sterile

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