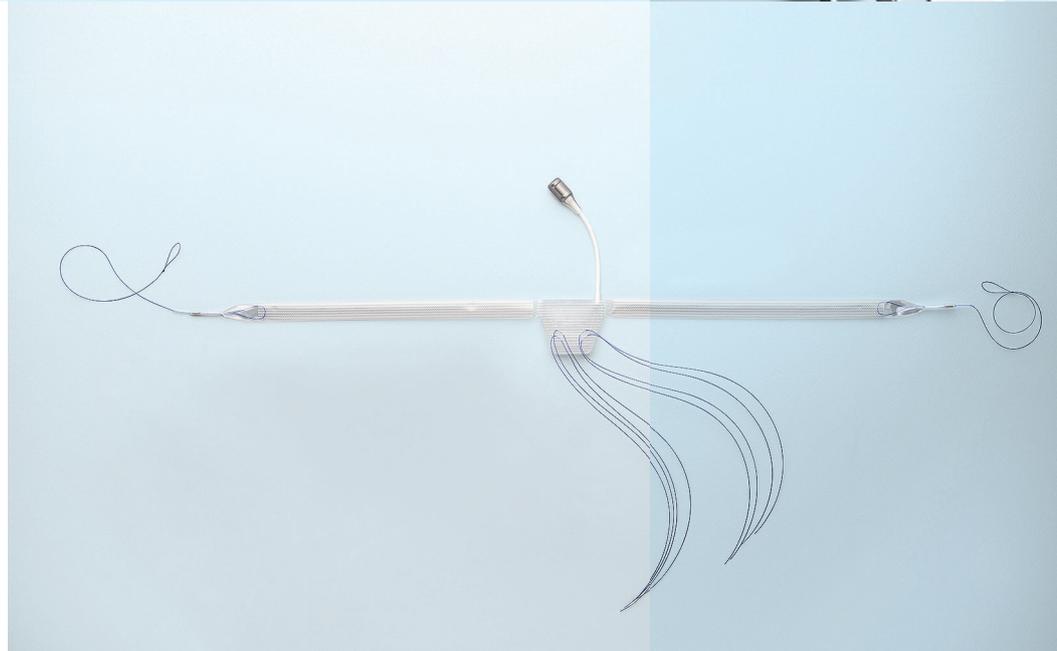


ATOMS

ATOMS Tunneller

TOA Tunneller

Scrotal Port



Solutions for **Urology**

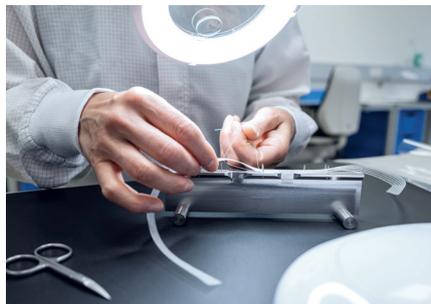
As a leading-edge technology company, A.M.I. Agency for Medical Innovations GmbH develops and manufactures high-quality medical products for surgeons and hospitals around the world. Through innovative surgical techniques in the fields of Coloproctology, Urology and Urogynecology, our products offer less pain and discomfort as well as higher safety for patients.

To assure the highest standards, our team collaborates with internationally recognized experts and surgeons. In this way, we will continue significant progress in innovative surgery.

Innovative solutions

for improved quality of life.





Precision from Austria

Made in Europe.



Solutions for Urology

**Treatment of Male
Urinary Incontinence**
ATOMS System

4

Our company

- Is the leading manufacturer of medical technology with headquarters in Austria.
- Over 20 years of experience in the fields of Coloproctology, Urology and Urogynecology
- High quality manufacturing in Europe
- Subsidiaries in Germany, France and USA
- Worldwide distribution network
- Development and manufacturing partner for medical technology companies with core competencies in precision mechanics, as well as plastics and silicone processing

Our vision

- Development of innovative products for pain-reducing, minimally invasive surgical methods
- Meeting the highest quality requirements of surgeons and patients
- Creating and implementing innovative ideas through close cooperation with experts, surgeons, technicians and scientists
- Our professional sales team continuously engages in constructive exchanges and consultations with our users
- A constant commitment to optimizing all processes related to development, production and service

Treatment of Male Urinary Incontinence

ATOMS

The ATOMS (Adjustable TransObturator Male System) is a long-term, single-use adjustable implant. This hydraulic sphincter-cushion system supports urinary sphincter function in incontinent adult males.

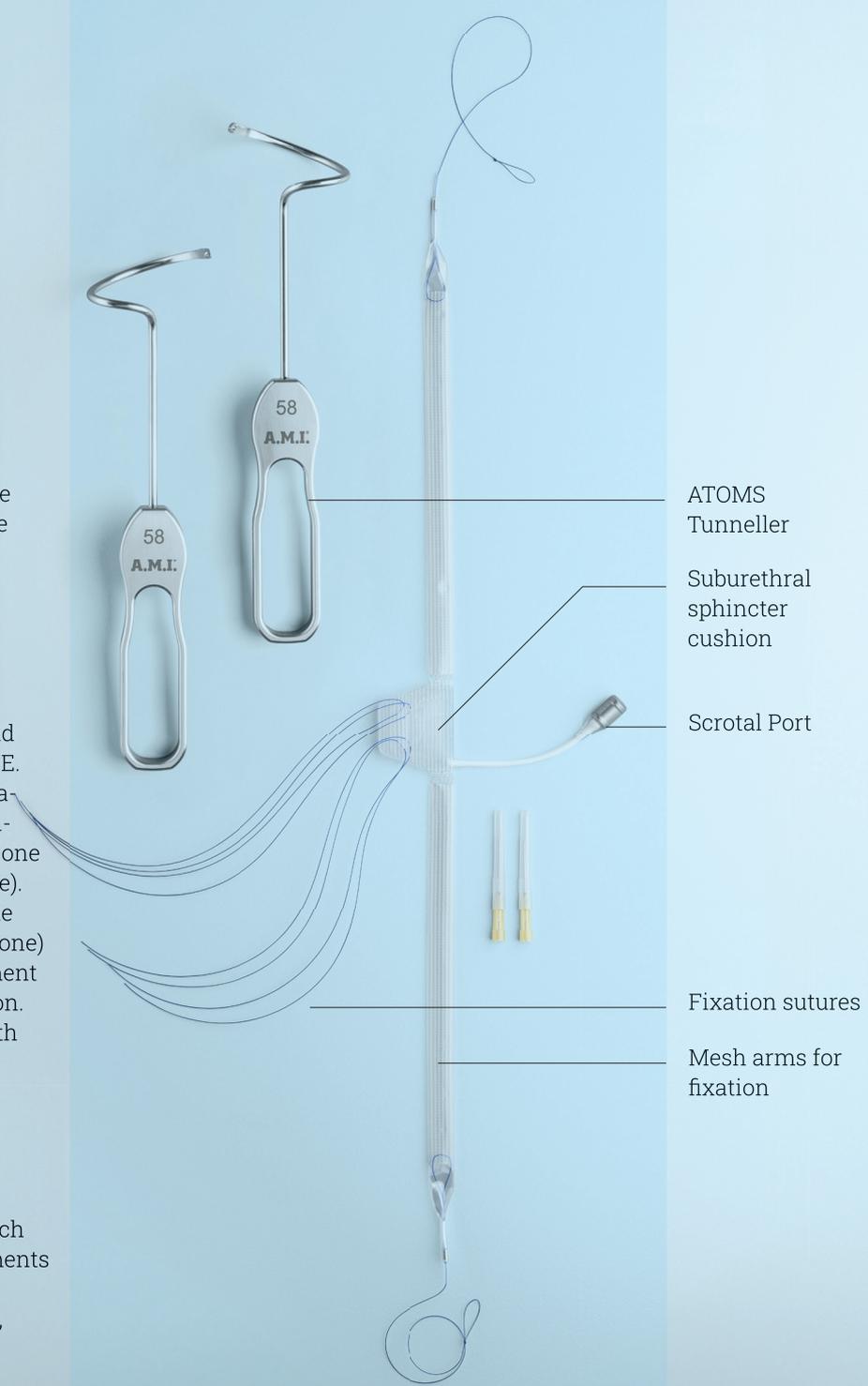
ATOMS is made of biocompatible synthetic material. The protective sleeve for the mesh arms is made of LDPE and the Pull-in aid and protective sleeve for the port is made of PTFE. The permanent implant consists of monofilament (polypropylene) mesh arms with an integrated HCR (high consistency rubber) silicone cushion with fixation sutures (polypropylene). The cushion supports the bulbar urethra. The pre-attached scrotal port (titanium and silicone) provides an intra- or post-operative adjustment by filling (or removing) volume of the cushion. ATOMS is suitable for MRI examinations with magnetic field strengths up to 3 Tesla.

+ A.M.I. Tunnellers

A.M.I. Tunnellers are multi-use devices, which are designed to meet the anatomic requirements for implant insertion. A slot at the tip enables the attachment of sling pull sutures, which are used to pull the implant in place.

ATOMS Tunneller and TOA Tunneller

The ATOMS and TOA Tunneller are intended to be used as an instrument to place the mesh arms around in inferior pubic ramus during ATOMS implantation to treat male stress urinary incontinence.





Treatment of Male Urinary Incontinence

ATOMS

The cushion applies compression to the m. bulbospongiosus and thereby to the urethra. This compression reduces involuntary loss of urine while still facilitating a physiological contraction to cause deliberate urination.

The sling is a self-anchoring device and the symmetrical positioning of the cushion below the urethra is achieved by a 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.

The attached port is positioned in the scrotum. Via the port, the filling volume of the cushion and thereby the compression to the bulbospongiosus muscle is adjustable. Filling volume is adjusted using a non-coring port needle by the surgeon and depending on the patient's anatomy and needs.

Features

- Self-anchoring implant – no need for additional fixation elements.
- Functional independency of patient's mental and / or physical abilities (no manual activation/deactivation necessary)
- Efficient improvement of incontinence in male patients with mild, moderate and severe stress-urinary incontinence (after radical prostatectomy/prostate surgery)
- Postoperative adjustment of the implant by a minimal invasive treatment for multiple times to improve efficacy for each patient without increased risk of complications
- Very low risk of intraoperative complications

Benefits [1] - [17]

- Implant postoperatively adjustable for all degrees of incontinence in patients with an existing residual sphincter muscle function
- Improved Quality of Life (QoL) in male patients with stress urinary incontinence (SUI)



Indication of ATOMS

Surgical treatment for male stress urinary incontinence



Animation video



Surgery video

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ATOMS System

Order Code		Product	Included in delivery
ATS5041		<p>ATOMS Adjustable system for treatment of male stress urinary incontinence System contains:</p> <ul style="list-style-type: none"> • implant with soft, adjustable suburethral cushion • integrated, silicone-coated titanium port • non-coring port needles 	<p>Single-use system, delivered sterile</p> <p>For the ATOMS surgery with ATS5041 the following product is needed: 1x TOA5130 TOA Tunneller or 1x ATS5010 ATOMS Tunneller</p>
TOA5130		<p>A.M.I. TOA Tunneller Reusable instrument of stainless steel for outside-in tunnelling. Treatment of male stress urinary incontinence with the A.M.I. ATOMS System</p>	<p>1 pair, helical (left and right), delivered non-sterile steam autoclavable</p>
ATS5010		<p>ATOMS Tunneller Reusable instrument of stainless steel for outside-in tunnelling. Treatment of male stress urinary incontinence with the A.M.I. ATOMS System</p>	<p>1 pair, helical (left and right), delivered non-sterile steam autoclavable</p>
ATS5051		<p>Scrotal Port for ATOMS Scrotal port with catheter, tubing connector and 2 port needles</p>	<p>1 unit, delivered sterile</p>
ATS5061		<p>Tubing Connector Connection piece made from titanium for catheter-to-catheter connection, e.g. for port-revision with ATOMS implant. Includes catheter spare piece of 200 mm</p>	<p>2 units in 1 box, delivered sterile</p>
ATS5031		<p>Tubing Plug Made from titanium For temporary closure of ATOMS catheter</p>	<p>2 units in 1 box, delivered sterile</p>
SFN 0930 G		<p>Port Needle Port needle for adjustment for the ATOMS Scrotal Port Needle Length: 30 mm, 20 G x 30 mm</p>	<p>25 needles / box, delivered sterile</p>



The products contained in this brochure meet the requirements of REGULATION (EU) 2017/745 and are labelled with the CE mark accordingly: AT5010, TOA5130



The products contained in this brochure meet the requirements of the Medical Device Directive 93/42/EEC and are accordingly marked with the CE mark: AT5031, AT5041, AT5051, AT5061

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