1 Product

Name	REF	Risk Class		Type of Product
		93/42/EEC	Rule	
ATOMS	ATS5041	IIb	8	medical device
Scrotal Port for ATOMS	ATS5051	IIb	8	spare part
Tubing Connector	ATS5061	IIb	8	spare part
Tubing Plug	ATS5031	IIb	8	medical device

2 Intended Use

The ATOMS is used for the treatment of intrinsic insufficiency after surgical treatment of the sphincter, pelvic surgery or transurethral injury of the urethral sphincter mechanism.

3 Clinical Applications

Male stress urinary incontinence after prostatectomy.

4 Product Description

ATS5041 / ATOMS
The ATOMS consists of a transobturatoric sling, with an integrated balloon, located in the centre of the sling, and a port, that is attached to the balloon with a catheter.

ATS5051 / Scrotal Port for ATOMS
The port used with the ATOMS is available as spare part.

ATS5061 / Tubing Connector
The Tubing Connector (commonly provided together with the spare port) is used to connect the catheter attached to the balloon with the catheter attached to the port.

ATS5031 / Tubing Plug
The plug is a spare part. It is used to close the catheter attached to the balloon, while the catheter is separated from the port, until a new port is implanted.

5 / Functional Principle

The balloon exposes 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.

Positioning of the transobturatoric sling has to assure the balloon is placed at the m. bulbospongiousus. The sling arms are feed through the transobtorator holes and fixed to the balloons backside. The sling is a self-anchoring device. The attached port is positioned in the scrotum.

Via the port, the balloons' filling volume and thereby the compression to the m. bulbospongiosus is adjustable. Filling volume is adjusted by the surgeon and depends on the patients' needs.

6 Technical Detail

6.1 Dimensions

6.1.1 sling

filling volume	max. 25 ml
length of implantable part	560 mm
width of implantable part	12 mm
dimensions of empty balloon	40 x 45 mm
total length including pulling threads	1290 mm
dimensions of threads	USP 0
length of catheter	85 mm
inner diameter of catheter	1,1 mm
outer diameter of catheter	3 mm

6.1.2 port

length	30 mm
diameter	11 mm
diameter of septum	7 mm
thickness of septum	5 mm
height of port chamber (inside)	4,5 mm

6.1.3 Tubing Connector

Length	10 mm
outer diameter	3,5 mm
inner diameter	2,7 mm

6.1.4 Tubing Plug

Length	8 mm
diameter	4 mm

6.2 Materials

6.2.1 Sling

Sling (Mesh ATOMS)	Polypropylene
Catheter	Silicon MED14-4765
Balloon	Silicon MED-4735
Protection sleeves	LDPE
Sutures	Polypropylene
Clamping pieces	Steinless steel DIN 1.4301 (AISI 304)
End of protection tube	PTFE
Silicone adhesive	Silicon MED-1511

6.2.2 Port

Port sleeve	Titan Ti6Al4V ELI
Cover	Silicon MED-4830
Septum	Silicon MED-4750
adhesive	Silicon MED-1137

6.2.3 Tubing Connector

Tubing Connector	Titan Ti6Al4V ELI

6.2.4 Tubing Plug

Plug	Titan Ti6Al4V ELI

6.2.5 General Material Related Data

- Implanted materials are compatible for MRI use with magnetic field strengths up to 3 Tesla.
- The materials used do not contain latex as intentional additive or ingredient.

6.3 Delivery Status

Sterile → method of sterilisation	Ethyleneoxide (EO)
Shelf life	5 years

6.4 GMDN (Global Medical Device Nomenclature)

35280 / Prosthesis, internal, urethral, sphincter

7 Features

- Self-anchoring implant – no need for additional fixation elements.
- Evenly distribution of compression over the complete expanse of the balloon.
  The wider the area of compression, the lesser the needed compression. The lesser the compression, the lower the risk for tissue atrophy. The lower the risk for atrophy, the lower the risk for ureteral erosion.
- Adjustable compression without surgical intervention.
- Effective independently from patients' metal or physical abilities.
- Macroporous mesh structures support integration into the surrounding tissue and prevent from post-operative infection.
- Designed to feature the patients' natural anatomy.
  The catheter, attached to the balloon, leaves the balloon at lateral and runs dorsal directly towards the scrotum.
- Allows for minimal invasive implantation and adjustment, even years after implantation.

Created by

R&D Project Engineer: Philipp Egle

23.06.2014

Date, Signature

Approved by

Regulatory Affairs: Stefanie Hoellger

23.06.2014

Date, Signature