

## > The revolution in female sling surgery

- **A**dapt: sling adapts to anatomy
- **A**adjust: post-operative adjustment of sling tension
- **A**meliorate: excellent 10 years results

Triple-**A** sling

## Triple-A sling

### Evidence

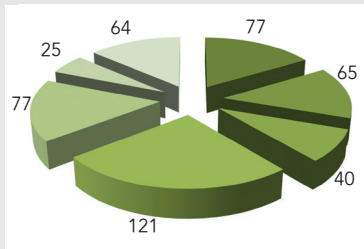
### Ameliorate patient outcome on the long term: excellent 10 years results (\*)

Treatment of stress urinary incontinence (SUI) has been performed since 1997 with TVT slings. 10 years data after implantation of A.M.I. slings show excellent and durable results. Still, innovation doesn't stop. A.M.I. is the first company to bring to the market this new sling concept of sensiTVT. sensiTVT makes sense because it passively adapts sub- and paraurethrally to the patient's anatomy.

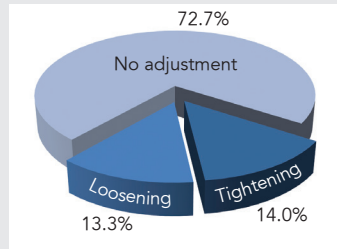
### Let the evidence speak for itself! (\*\*)

#### Author / Sling / Year

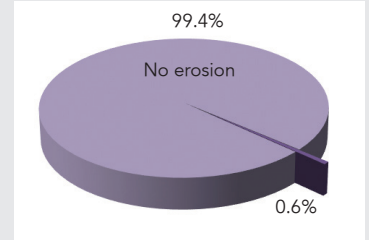
- Patrelli et al., TOA, 2014
- Lee et al., TOA, 2010
- Youn et al., TOA, 2010
- Costantini et al., TOA, 2010
- Romero et al., TOA, 2009
- Schmid et al., TVA, 2009
- Romero et al., TVA, 2007



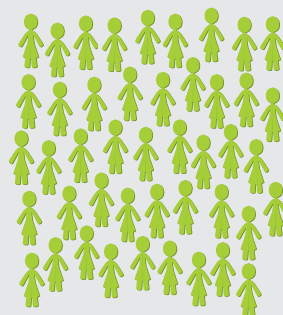
#### 27.3% of patients required adjustment



#### Very low erosion rate: 0.6%



#### 469 patients treated



#### Results

Completely dry	90.4%	Substantial improvement	5.8%	Failed	3.8%
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#### Patrelli et al., 2014



"Our data, similar to a previous study, show a total resolution of SUI of 90.9%, and 92.2% of patients reported complete satisfaction after the procedure. The optimal combination of SUI resolution and patient satisfaction after TOA could be related to the possibility of sling tension modulation in the early postoperative period."

#### Lee et al., 2011



"Our results support the use of TOA as an effective modality for the treatment of SUI in women at risk for persistent postoperative SUI or obstructive symptoms."

#### Schmid et al., 2010



"Detrusor pressure at maximum flow rate (pdet/Qmax) increased significantly as did the maximum urethral closure pressure (MUCP). Patient satisfaction improved significantly."

"Adjustable slings in women with stress urinary incontinence might be indicated in difficult situations after surgical failure."

#### Youn et al., 2010



"These data suggest that better subjective and objective results and residual urine volume can be obtained in the TOA group than those achieved with the traditional non-adjustable mesh and without significant postoperative complications."

#### Costantini et al., 2010



"With this adjustable sling, the obturator route could be an excellent, reliable method of treating patients with urinary incontinence due to MUCP  $\leq 20$  cm H<sub>2</sub>O."

#### Romero et al., 2009



"In conclusion, our results show that persistence of stress incontinence and the development of obstruction after surgery depend largely on the tension applied to the mesh, looser or tighter, during the procedure. They also demonstrate that the transobturator approach (TOA), like the transvaginal procedure (TVA), allows postoperative adjustment of tension thus permitting correction of postoperative incontinence or obstruction. This does not increase surgical complications."

(\*) Data on hand of A.M.I. (\*\*) Data based on internal analysis of seven peer-review published series as described in studies overview chart.

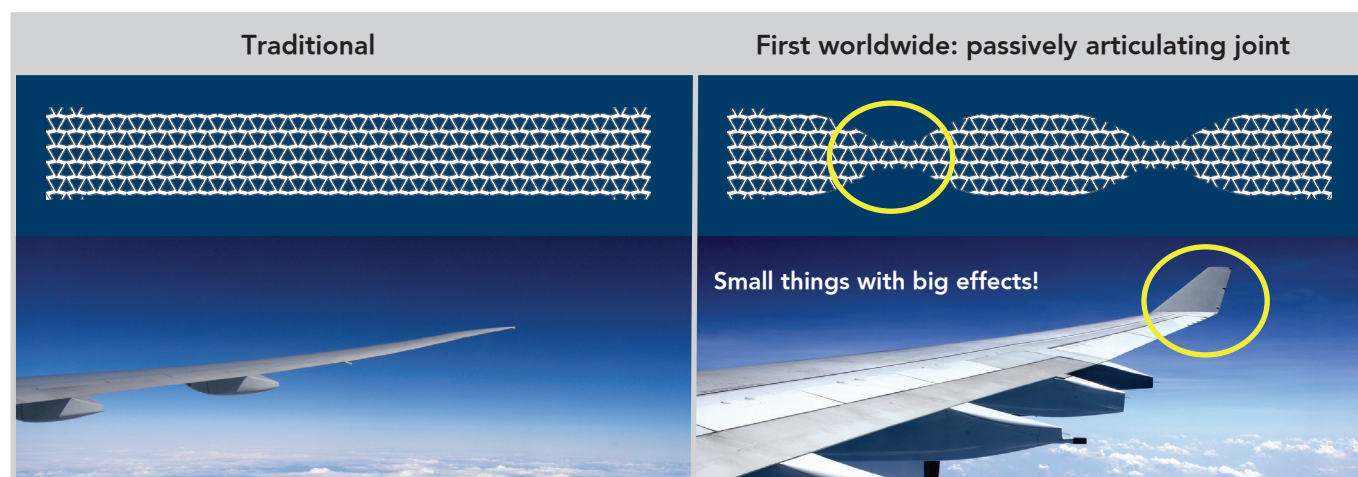
## Triple-A sling

### Sensitivity

### Adapt intra-operatively to patient anatomy

sensiTVT - The latest revolution in treatment of female stress urinary incontinence.

The sensitivity of this sling is second to none. It adapts to the patient's anatomy. The suburethral part of the sling positions smoothly below the urethra, correlating to the surgical preparation. Traditional slings, that are made up of a strip of equally wide material, will have a tendency to transform a part of their tension to the para- and suburethral area. This is where sensiTVT gives that something extra special, passively articulating joints on both sides of the urethra.



This new concept of passively articulating joints deals with two topics that are expected by surgeons (\*) to be improved:

- Vaginal erosion: A mesh that will always be flat will have less tendency to erode vaginally, independent from the tunnelling direction (trans-obturator or retropubic).
- OAB: Long-term issues with OAB should be addressed as well. Tunnellers leave a smaller diameter tunnel in which slings fold. Depending on the direction of the foldings, nerves in the area of the sulcus vaginalis may be compromised, potentially leading to OAB symptoms. sensiTVT has passively articulating joints on each side of the urethra that are in the diameter of the tunnel created during surgery. Therefore, it is expected that sensiTVT may reduce voiding dysfunction.

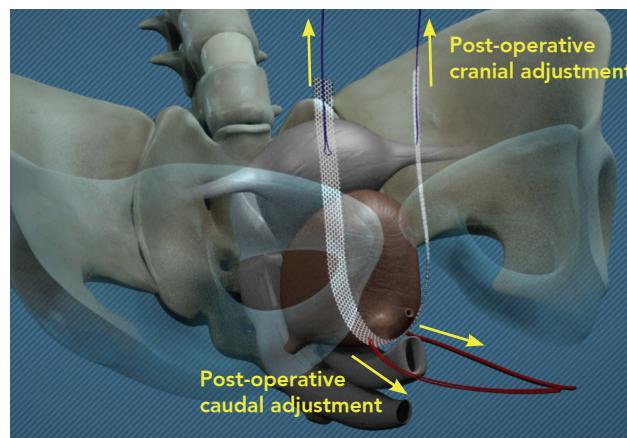
**sensiTVT makes sense!**

## Triple-A sling

### Adjustability

### Adjust sling tension during first post-operative days

There is delicate balance between incontinence, continence and obstruction, and calculating the required degree of tension presents a challenge even to the most experienced surgeons. sensiTVT-A is equipped with two groups of integrated sutures, which are left outside the skin following surgery and enable optimal fine-tuning of tension up to five days post-operatively, with active participation from the patient. One group of sutures can be pulled down to reduce tension if there are signs of urinary retention, while the others can be pulled up to increase tension if incontinence persists. Once the appropriate adjustments have been made, the sutures are removed. The option of post-operative adjustment has been proven particularly effective for high-risk groups, severe SUI or patients in whom previous suburethral sling implantation has failed.







## 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 for the implantation of our slings.

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

## sensiTVT - the latest revolution in treating SUI

Adapt

Adjust

Ameliorate

Order Code	Product	Technical Details
SUI5011	<b>sensiTVT</b> Sling for treatment of female SUI with passively articulating joints and adaptable suburethral graft.	Polypropylene mesh sling with PE sleeve Total length of sling: 450 mm 1 sling, delivered sterile
SUI5021	<b>sensiTVT-A</b> Sling for treatment of female SUI. Equipped with: a) passively articulating joints and adaptable suburethral graft. b) with sutures for post-operative tension adjustment.	Polypropylene mesh sling with PE sleeve Total length of sling: 450 mm Adjustment sutures (per side): 3 upwards, 2 downwards 1 sling, delivered sterile
TVA5030	<b>A.M.I. TVA Tunneller</b> Reusable instrument for transvaginal retropubic approach	Materials: Stainless steel, aluminium Total length: 317 mm Length of handle: 127 mm 1 instrument, delivered non-sterile, steam autoclavable
TOA5130	<b>A.M.I. TOA Tunneller</b> Reusable instruments (left and right) with a helical shape for transobturatoric approach	Materials: Stainless steel, aluminium Total length: 249 mm Length of handle: 127 mm 2 instruments (l. & r.), delivered non-sterile, steam autoclavable
TOA5140	<b>A.M.I. TOA Tunneller Universal</b> Reusable instruments (left and right) with a larger radius for transobturatoric approach	Materials: Stainless steel, aluminium Total length: 227 mm Length of handle: 127 mm 2 instruments (l. & r.), delivered non-sterile, steam autoclavable

International patent filed / pending / granted

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