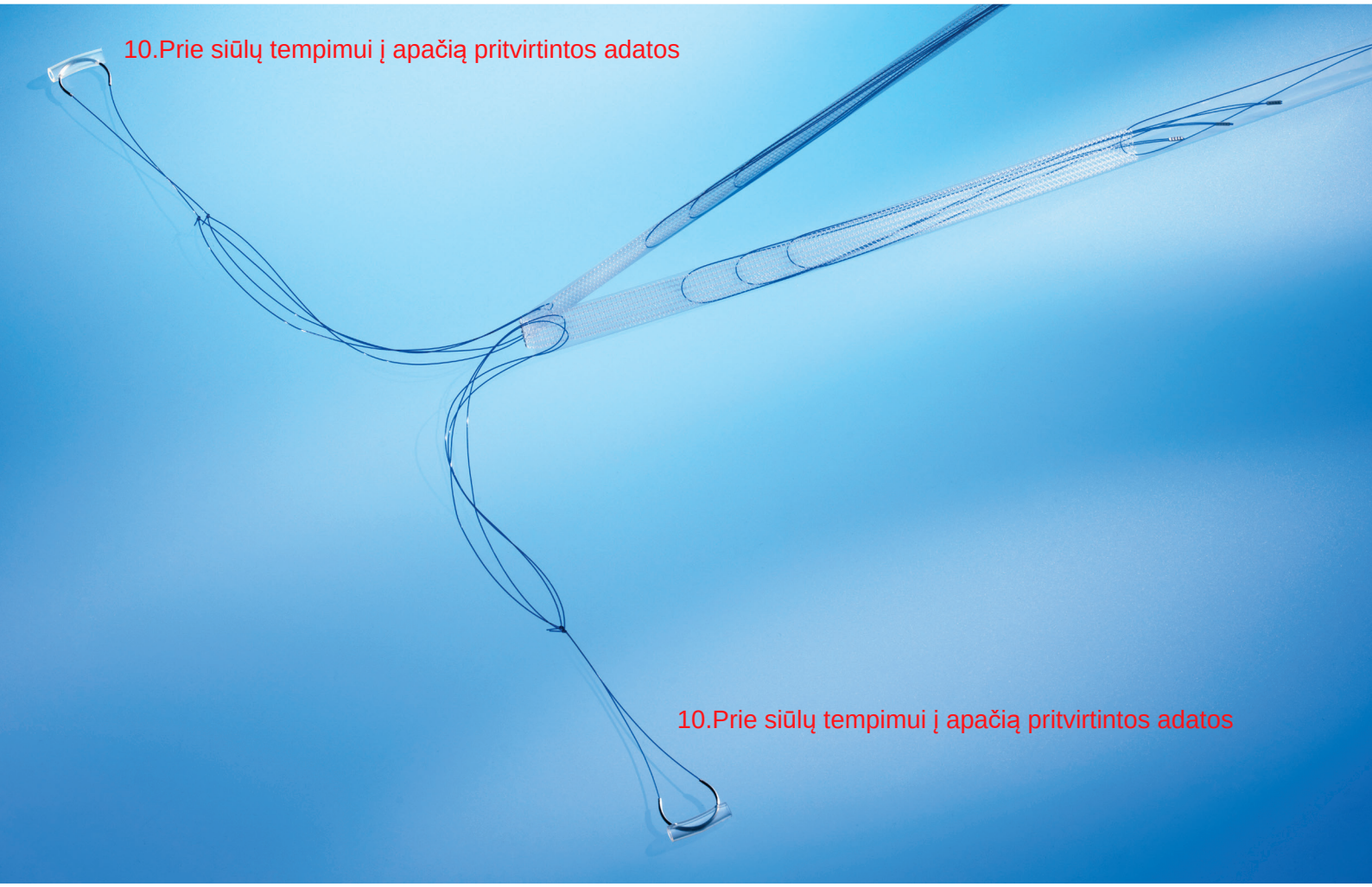
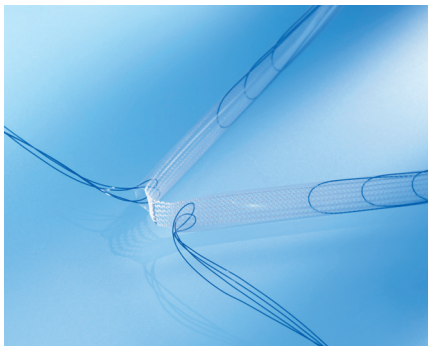
A.M.I.® TVA TOA Slings



7.1 Reguliuojamas moterų šlapimo nelaikymo raištis



Customised treatment for female SUI

- Soft, but firm macroporous sling
- With integrated sutures for two-way tension adjustment up to five days after implantation
- Counteract difficult cases of persisting incontinence or urinary retention post-operatively with no reintervention!

A.M.I.®

A.M.I.® TVA TOA Slings

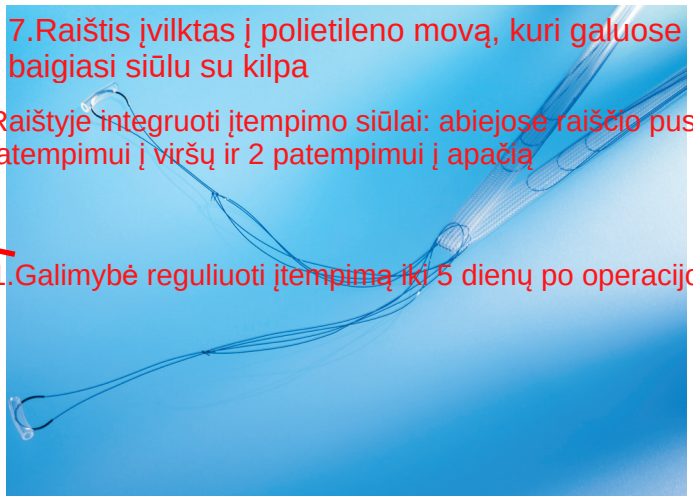
Sling features

3. pagamintas iš minkšto ir elastinio monofilamentinio polipropileno

- Soft, but low-elastic monofilament polypropylene mesh which is firm enough lengthwise to provide the necessary support.
- Large-sized pores that allow seamless tissue integration.
- PE sleeve covering the mesh to facilitate less traumatic placement.

Adjustability - the added extra

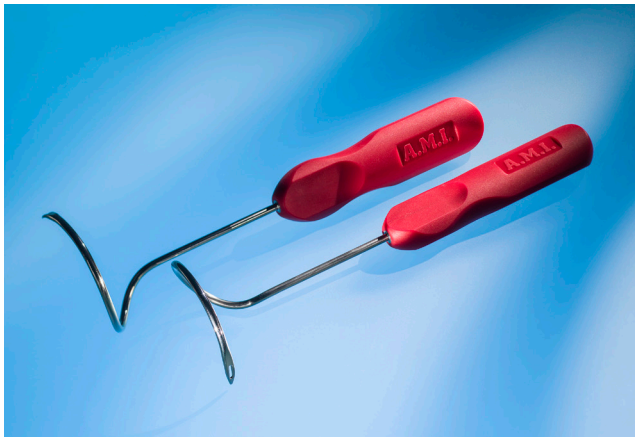
There is a delicate balance between incontinence, continence and obstruction, and calculating the required degree of tension presents a challenge to even the most experienced surgeon. The A.M.I. TOA (Trans Obturator Adjustable) and TVA (Trans Vaginal Adjustable) Slings are equipped with two groups of 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 other 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 (e.g. combined SUI and voiding dysfunction), severe SUI or patients in whom previous suburethal sling implantation has failed.



Tools of the trade

7.2 Transobturatoriniai įvedėjai

A.M.I. offers tunnellers with two different diameter sizes - 4 mm and 3 mm (Slimline). The A.M.I. tunnellers are made of high-grade materials, with ergonomically-designed handles to fit comfortably in the surgeon's hand. The flattened, spatula-shaped, rounded tip design allows smooth tissue and good instrument control during penetration. All tunnellers feature a flattened tip for slightly wider dissection to better accommodate the sling's shape. A.M.I. reusable tunnellers are available for all commonly used tunnelling techniques.



See the difference between the 4 mm and the 3 mm (Slimline) tunnellers!

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

A.M.I.® TVA TOA Slings

Evidence

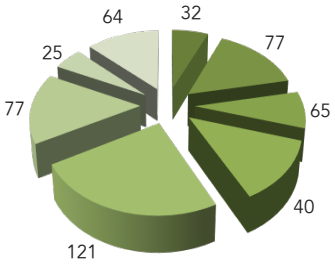
Treatment of stress urinary incontinence (SUI) has been performed since 1997 with TVT slings. 10 years data after implantation of A.M.I. slings show excellent and durable results.

Let the evidence speak for itself! (*)

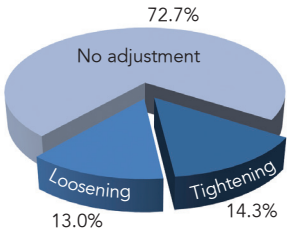
Author / Sling / Year

- Romero et al., TVA, 2017
- Patrelli et al., TOA, 2014
- Lee et al., TOA, 2010
- Youn et al., TOA, 2010
- Costantini et al., TOA, 2009
- Romero et al., TOA, 2009
- Schmid et al., TVA, 2009
- Romero et al., TVA, 2007

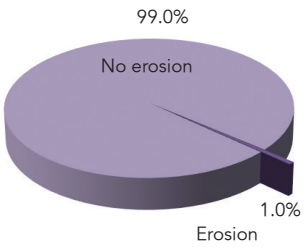
Patients treated



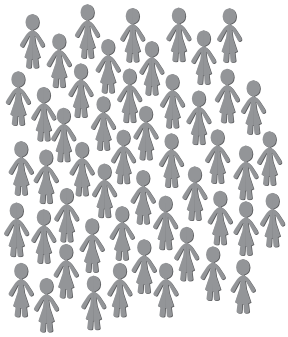
27.3% of patients required adjustment



Low erosion rate



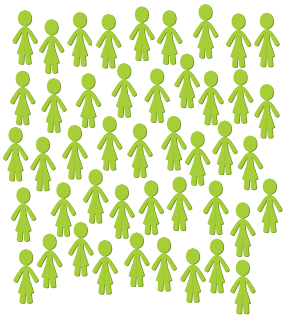
501 patients treated



TVA / TOA

Results

Completely dry	90.4%	Substantial improvement	6.0%	Failed	3.6%



Romero et al., 2017

"Treatment of stress urinary incontinence with the TVA mesh presented a high degree of objective healing and satisfaction at 10 years, with no severe adverse effects."

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."

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."

Schmid et al., 2009

"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."

Costantini et al., 2009

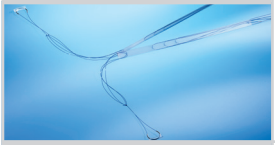
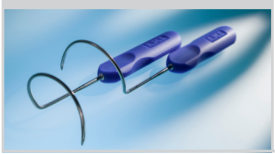
"With this adjustable sling, the obturator route could be an excellent, reliable method of treating patients with urinary incontinence due to MUCP ≤20 cm H_2O."

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 based on internal analysis of eight peer-review published series as described in studies overview chart.

A.M.I.® TVA TOA Slings

Order Code	Product	Technical Details
	4.Tinka naudoti TVA ir TOA procedūroms	
TVA5021 	**A.M.I. TVA Sling** Sling for treatment of SUI, designed for implantation using the transvaginal retropubic approach. Equipped with sutures for post-operative tension adjustment	Polypropylene sling with PE sleeve Total length of sling: 450 mm 5. ilgis 450mm Adjustment sutures (per side): 3 upwards, 2 downwards 1 sling, delivered sterile 1. Sterilus
TOA5121 	**A.M.I. TOA Sling** Sling for treatment of SUI, designed for implantation using the transobturator approach. Equipped with sutures for post-operative tension adjustment	Polypropylene sling with PE sleeve Total length of sling: 450 mm Adjustment sutures (per side): 3 upwards, 2 downwards 1 sling, delivered sterile 12. supakuota po 1 vnt.
TVA5030 	**A.M.I. TVA Tunneller** Reusable instrument for transvaginal retropubic approach	Materials: Stainless steel, silicone Total length: 316 mm Length of handle: 127 mm Diameter: 4 mm 1 instrument, delivered non-sterile, steam autoclavable
TOA5130 	**A.M.I. TOA Tunneller** Reusable instruments (left and right) with a helical shape for transobturatoric approach 1. Daugkartinio naudojimo 3.Išlenkti spiralės forma 4.Kairės ir dešinės 5.Tinkami implantacijai transobturatoriniu būdu iš vidaus į išorę	Materials: Stainless steel, silicone Total Length: 244 mm 6. ilgis 244mm Length of handle: 127 mm Diameter: 4 mm 7. diametras 4mm 2 instruments (l. & r.), delivered non-sterile, steam autoclavable 8.9. Nesterilūs, autoklavuojami 2 vnt.
TOA5140 	**A.M.I. TOA Tunneller Universal** Reusable instruments (left and right) for inside-out transobturatoric approach	Materials: Stainless steel, silicone Total length: 225 mm 6. ilgis 225mm Length of handle: 127 mm Diameter: 4 mm 7. diametras 4mm 2 instruments (l. & r.), delivered non-sterile, steam autoclavable 8.9. Nesterilūs, autoklavuojami 2 vnt.
TVA5040 	**A.M.I. TVA Tunneller Slimline** Reusable instrument for transvaginal retropubic approach	Materials: Stainless steel, silicone Total length: 316 mm Length of handle: 127 mm Diameter: 3 mm 1 instrument, delivered non-sterile, steam autoclavable
TOA5170 	**A.M.I. TOA Tunneller Slimline** Reusable instruments (left and right) with a helical shape for transobturatoric approach	Materials: Stainless steel, silicone Total Length: 244 mm 6. ilgis 244mm Length of handle: 127 mm Diameter: 3 mm 7. diametras 3mm 2 instruments (l. & r.), delivered non-sterile, steam autoclavable 8.9. Nesterilūs, autoklavuojami 2 vnt.
TOA5180 	**A.M.I. TOA Tunneller Universal Slimline** Reusable instruments (left and right) for inside-out transobturatoric approach	Materials: Stainless steel, silicone Total length: 225 mm 6. ilgis 225mm Length of handle: 127 mm Diameter: 3 mm 7. diametras 3mm 2 instruments (l. & r.), delivered non-sterile, steam autoclavable 8.9. Nesterilūs, autoklavuojami 2 vnt.

A.M.I. Headquarters
A.M.I. GmbH
Im Letten 1
6800 Feldkirch . Austria
t +43 5522 90505-0
e info@ami.at
www.ami.healthcare

These products comply with the requirements of Medical Device Directive 93/42/EEC and are labelled with the CE mark accordingly.

CE 0297 TVA5021 TOA5121

CE TVA5030 TOA5130 TOA5140 TVA5040 TOA5170 TOA5180

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