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## Artificial urinary sphincter – new devices in male urinary incontinence treatment

### Nowe konstrukcje zwieraczy hydraulicznych wykorzystywane w leczeniu nietrzymania moczu u mężczyzn

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#### Conflict of interest

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None

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#### Summary

The incidence of male stress urinary incontinence (UI) ranges from 4.81 to 32.17% and usually increases with age. UI can be a consequence of surgical treatment of benign prostatic hyperplasia (BPH) and/or prostate cancer (PCa). The American Medical System type 800 (AMS800) has been the most common and, until recently, the only artificial urinary sphincter (AUS) available for UI surgical treatment. Due to differences in UI grades and a considerable number of complications as well as costs associated with AUS implantation, several new devices for UI treatment have been introduced in the recent years. These devices offer novel technological solutions, which in theory should provide at least similar functional outcomes and lower complications associated with the classical AMS sphincter. The study provides a review of new devices for male stress UI treatment.

#### Streszczenie

Częstość występowania nietrzymania moczu (ang. *urinary incontinence* – UI) wśród mężczyzn wynosi od 4,81 do 32,17% i wzrasta wraz z wiekiem. UI może być następstwem leczenia chirurgicznego mężczyzn dotkniętych łagodnym rozrostem gruczołu krokowego (ang. *benign prostatic hyperplasia* – BPH) i/lub rakiem gruczołu krokowego (ang. *prostate cancer* – PCa). Najczęściej stosowanym i do niedawna jedynym sposobem leczenia nietrzymania moczu u mężczyzn była implantacja sztucznego zwieracza cewki moczowej (ang. *artificial urinary sphincter* – AUS) typu AMS 800 (American Medical System). Ze względu na różnice w stopniu nasilenia nietrzymania moczu, niemałą liczbę powikłań oraz koszty związane ze wszczepieniem AUS, w ostatnich latach powstało szereg nowych urządzeń dedykowanych chorym dotkniętym UI. Konstrukcje te posiadają nowe rozwiązania technologiczne, które powinny zapewnić co najmniej podobne wyniki czynnościowe i doprowadzić do zmniejszenia liczby powikłań towarzyszących wszczepieniu AUS. W opracowaniu przedstawiono przegląd nowych urządzeń stosowanych w leczeniu mężczyzn chorych na wysiłkowe nietrzymanie moczu.

#### INTRODUCTION

Male urinary incontinence (UI) is a rare condition. Depending on the characteristics of patients, the incidence of male stress urinary incontinence ranges from 4.81 to 32.17% (1) and usually increases with age (2, 3).

UI can be a consequence of surgical treatment of benign prostatic hyperplasia (BPH). In patients treated with transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP) or open

enucleation of adenoma (OEA), a low-grade urinary incontinence or total urinary incontinence develop in 2.2 and 1%, 1.8 and 0.1% as well as 1.9 and 0.5% of cases, respectively (4).

Patients treated with radical prostatectomy (RP) due to prostate cancer (PCa) develop UI more frequently. The incidence of UI after RP, irrespective of the technique adopted (open, laparoscopic or robotic), is similar and ranges from 1 to 40%, but discrepancies

between subsequent series result from differences in defining UI and the length of the follow-up (5-7).

If a PCa patient undergoes external beam radiotherapy (EBRT) or brachytherapy (BT), UI occurs in 0-18.8% and 0-13% of patients, respectively (8-11).

Irrespective of the UI cause, 6-9% of cases are managed surgically (12-15).

Artificial urinary sphincter (AUS) implantation is the basic treatment method. Until recently, the only device used in such cases was American Medical System type 800 (AMS800). It was introduced to common practice in 1983 and has been used ever since in a nearly identical form (16). AMS800 guarantees full continence and/or quality of life improvement in 79% (61-100%) of patients. In long-term follow-up, effects are permanent. The re-intervention rate resulting from AUS infection or urethral erosion ranges from 3.3 to 27.8% (17).

Due to differences in UI grades and a considerable number of complications as well as costs associated with AUS implantation, several new devices for UI treatment have been introduced in the recent years.

### SUBURETHRAL SLINGS

High efficacy of suburethral slings in female UI made this technique also used in male patients. They create a subcystic barrier that improves continence and guarantees efficient micturition. These implants can be divided into two basic types: non-adjustable and adjustable tapes with adjustable pressure on the urethra.

#### SUBURETHRAL NON-ADJUSTABLE SLINGS

The first tape of this type, which currently is no longer used, is the InVance tape.

A transobturator suburethral non-adjustable AdVance (American Medical Systems) (fig. 1) sling is a monofilament and polypropylene mesh. It is implanted transperineally. The main part of the mesh (the suburethral one) is fitted on the ventral surface of the proximal bulbous urethra, and the tape arms are passed through the obturator foramina. The AdVance system ensures full continence or guarantees considerable improvement in 62-77% of patients in a 3-year follow-up. The implantation technique is relatively simple, which makes the complication rate rather low (18, 19).

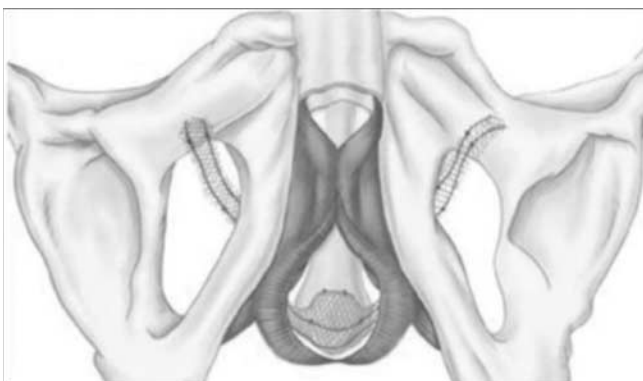


Fig. 1. Suburethral AdVance sling (American Medical Systems)

I-STOP TOMS (CL Medical) (fig. 2) is another non-adjustable suburethral sling. It differs from the previous model in construction and location under the urethra, but the principle underlying its action seems to be similar. Grise et al., in the first study on safety and efficacy of the I-STOP TOMS system, report that 60/69 patients (87%) experienced continence improvement after a year of follow-up. In the investigated group, 41 (59.4%), 14 (20.3%) and 5 (7.3%) patients did not use any pads, used 1 pad or more than 1 pad, respectively. No severe complications were noted. The cavernous bodies were damaged during implantation in 4% of patients. Generally, 91% of patients were satisfied or very satisfied after the procedure (20).

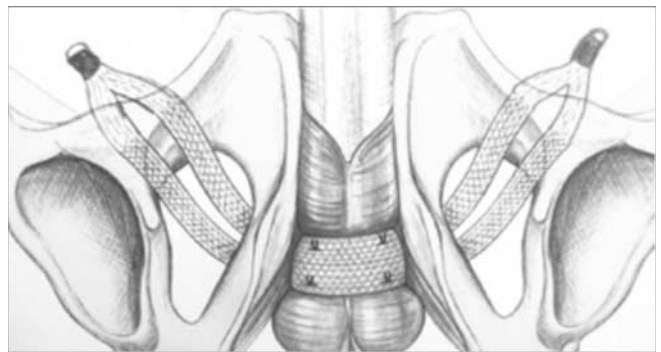


Fig. 2. I-STOP TOMS system (CL Medical)

#### SUBURETHRAL TENSION ADJUSTABLE SLINGS (DEVICES)

In the case of first-generation slings, patients observed gradual deterioration in continence with time. Another problem was hypercontinence in the initial period post-surgery, which occurred in 12-21% of patients (19, 21).

Factors that might be responsible for these phenomena include the lack of a standardized way of adjusting tension during the procedure and post-surgery. The introduction of new-generation devices, characterized by a possibility to regulate pressure on the urethra, was supposed to solve the problem.

#### ARGUS SYSTEM (PROMEDON)

One of the first devices of this type was Argus (fig. 3) in which a silicone pad placed suburethraly could be pulled up postoperatively thanks to arms inserted using the retropubic approach. The blocking mechanism was fixed in the rectus fascia. The Argus sling was implanted in 101 patients. After a median follow-up of 2.2 years, the rate of fully dry patients was 79.2% (80/101). Tape adjustment was necessary in 39 cases (38.6%) approximately 104.3 days after the initial implantation. Twenty-nine patients required sling tightening, which was conducted under regional anaesthesia, whereas 10 patients had it loosened under general anaesthesia. The sling had to be removed in 16 patients (15.8%) due to urethral erosion or infection.



Fig. 3. Argus system (Promedon)

### PHORBAS SYSTEM (PROMEDON)

The Phorbas sling (fig. 4) constitutes the development of the Argus system. It combines the idea of a transobturator tape and suburethral pad with pressure on the urethra that can be adjusted by changing the volume of fluid that fills the suburethral element. This manoeuvre is performed in a simple way by puncturing the port placed in the scrotal subcutaneous tissue. The arms and suburethral element are made of silicone, which makes potential explantation easy. Treatment outcomes after using this system have been presented only during a conference. Among 21 patients with moderate to severe UI, the condition subsided in 71.4% of cases (12 patients need no pads, 3 patients use only one pad). On average, patients required the system to be inflated 1.9 times (0-4). Apart from two cases of wound infection, there were no significant complications. None of the devices needed explantation. In a relatively short follow-up (3-18 months, average 5.9 months), urethral erosion or hypercontinence was not observed (22).

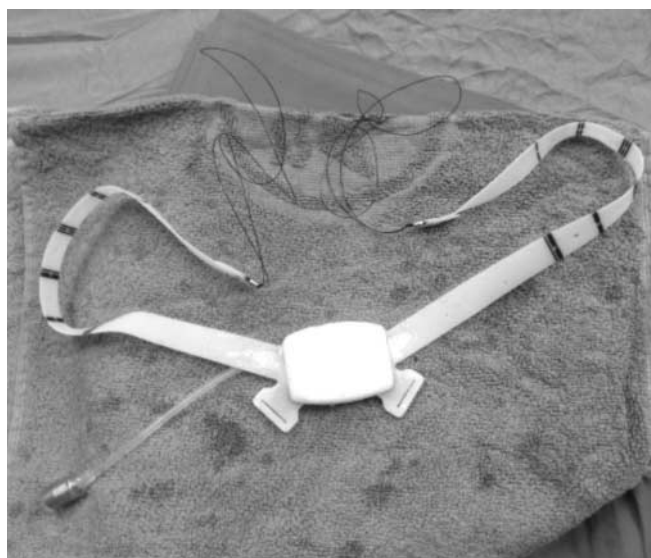


Fig. 4. Suburethral Phorbas system (Promedon)

### ATOMS SYSTEM (AMI)

The ATOMS system (fig. 5) is similar to the device presented above in terms of its construction and general idea of action. The major difference lies in the application of a polypropylene mesh to make the sling arms. The suburethral pad inflation degree is regulated by fluid injected through a titanium port within the scrotal subcutaneous tissue (23).



Fig. 5. ATOMS system (AMI)

In one of the first studies, 99 patients with the ATOMS system implanted were observed for 17.8 months (average). Full continence was observed in 63% and improvement, expressed as using 1-2 pads daily, was seen in 29% of patients. The system required 3.8 (average) corrections of suburethral pad inflation in order to achieve a satisfactory treatment effect. The rate of complications was not significant. The most frequent undesirable effects included oedema of the perineum, scrotum and thighs. There were 4 (4%) cases of infection which, in each case, entailed the removal of the device (24).

### PROACT BALLOON SYSTEM (MEDTRONIC)

The ProAct balloon system consists of two balloons implanted percutaneously in the area of the neck of the urinary bladder. These balloons are connected with a port placed subcutaneously through which they can be filled with fluid, thereby regulating the pressure on the urethra. The device enables full continence to be restored in approximately 65% of patients. The final effect can be achieved after approximately 2.33 fluid adjustments. The risk of complications is not high, and the major adverse effects include urinary retention (1.4%), urethral erosion (8%) and balloon rupture (4.3%). The device needed explantation in about 18% of patients (25).

### PERIURETHRAL CONSTRICTOR (SILIMED)

This device is intended for treatment of urinary incontinence caused by deterioration of sphincteric function in children. It was designed in 1996 by Dr Fabio Vi-

lar (fig. 6). It consists of a rounded cuff connected with a tube and a silicone port. The cuff is placed around the neck of the urinary bladder or bulbous urethra. After 4-6 weeks post-implantation, the device is activated by filling it with fluid. This makes it exert constant pressure on the urethra, thereby efficiently improving continence and post-void residual urine volume (26). In a study by Simone et al., the efficacy of managing mild UI in a group of 43 patients after RP was 86%. Complications developed in 6 (14%) cases: 1 haematoma, 1 erosion, 2 infections and 2 device failures (27).

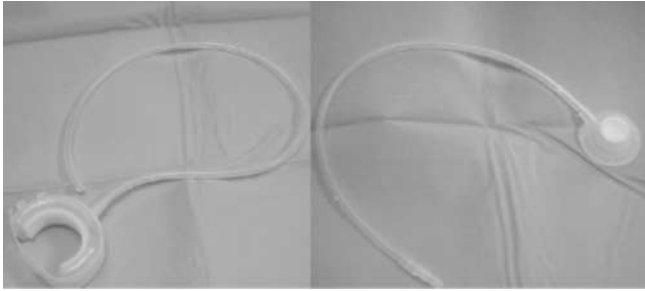


Fig. 6. Periurethral constrictor (Silimed)

Introni et al. implanted periurethral constrictors in 66 patients with severe UI (defined as using 3 or more pads daily) and obtained full continence restoration in 49 (79%) cases and partial improvement, defined as decreased number of pads, in the subsequent 9 (13.6%) cases (28). Complications developed in 7 patients (11%), including 2 cases of infection and 2 cases of urethral erosion. Four (6%) devices were removed. In another study by Lim et al., these devices were removed in over 41% of cases. Among patients who needed no explantation, continence improved in 30% of cases (29). These discrepant results indicate that further investigations concerning the efficacy of this device are needed.

## NEW SPHINCTERIC DEVICES

### ZSI 375 (ZEPHYR Surgical Implants)

ZSI 375 ZEPHYR (fig. 7) is an artificial sphincter that consists of two parts connected with each other by an 11 cm silicone tube: a round silicone cuff fitted around the bulbous urethra and an element containing a pressure control mechanism and a trigger mechanism that opens the cuff, inserted subcutaneously within the scrotum. The sphincter is filled with 4.5 ml of fluid, which is the first element that adjusts pressure in the system. The amount of fluid can be increased or decreased depending on the need by injecting it through the port placed in the part of the sphincter responsible for pressure control. The most important element guaranteeing that appropriate pressure is retained is a spring that exerts pressure upon the fluid. After implantation, the system is deactivated. Six weeks post-surgery, the sphincter is activated by pressing an activation button. The pressure on the urethra ranges from 60 to 100 cm H<sub>2</sub>O, but initially it oscillates from 60 to 70 cm H<sub>2</sub>O. Injection of 1 ml of fluid increases pres-

sure in the system by approximately 10 cm H<sub>2</sub>O. The analysis of data of 36 patients with the ZSI 375 Zephyr system implanted indicated that 75% of patients were fully continent (used 0-1 pads). The follow-up period was 15.4 months (average). The artificial sphincter was removed in 4 (11.1%) patients due to urethral erosion or infection (30). In another work, satisfactory continence was obtained in 32/34 (94.2%) patients, but additional fluid had to be injected to the system in order to increase pressure in 60% of cases. The explantation rate was 2/34 (5.8%) (31).



Fig. 7. ZSI 375 (ZEPHYR Surgical Implants)

### Flowsecure (Sphinx Medical)

The Flowsecure system (fig. 8), designed in 2006 by Professors MD Craggs and AR Mundy, is a precursor of a new type of sphincters, called “dynamic”. It is a fully hydraulic sphincter and the principle of its action is similar to AMS800. The difference lies in an additional balloon, which increases pressure in situations when abdominal pressure rises. This way, the cuff shuts down guaranteeing increased continence during static exercise, sneezing, coughing etc. Moreover, a pump placed subcutaneously within the scrotum, which when pressed deflates the cuff, is fitted with a port enabling injection of fluid to the system, thus increasing pressure. The individual elements of the Flowsecure system are connected with each other, which eliminates the necessity to join them during the procedure. Before implantation, the sphincter is filled with 30 ml of 0.9% NaCl solution and emptied from residual air. Subsequently, after bulbourethral cuff placement, the fluid volume is lowered by 5-7 ml, which deactivates the system. Activation occurs 6 weeks after the procedure. It consists in injection of the same volume of 0.9% saline through the port located in the control pump. The patient opens the cuff by pressing the pump once or twice. If the degree of continence is not satisfactory, the pressure in the system can be increased by injection of saline through the port. It is not recommended to

inject a volume greater than 2 ml at a time. After each such procedure, the degree of continence and post-void residual urine volume should be re-assessed. Directly after activation, pressure exerted by the cuff on the urethra ranges from 40 to 50 cm H<sub>2</sub>O, which makes Flowsecure a low-pressure sphincter. In theory, this is to lower the rate of late urethral erosion caused by persistent ischaemia of the region permanently compressed by the cuff. However, this thesis requires confirmation in studies with a long follow-up. Rodriguez et al. investigated 100 patients with the Flowsecure system implanted. Satisfactory continence, expressed as the usage of 0-1 pad, was achieved in 89 (89%) patients. On average, the patients required three readjustments of the fluid volume for a satisfactory effect. In the follow-up period, the sphincter was removed in 28 (28%) patients. This explantation was caused by early infection in 8% of cases, late infection secondary to fluid injection in 5% of patients, pump rupture during this procedure in 9% of cases and mechanical sphincter damage in 6% of patients. There were no cases of urethral erosion. Based on this experience, the sphincter underwent several modifications and is currently available in a new, slightly changed form.



Fig. 8. Flowsecure system (Sphinx Medical)

## The Tape Mechanical Occlusive Device – Aroyo (GT Urological)

Aroyo is a hydraulic, mechanical one-piece sphincter. To date, it has successfully passed all implantation tests in animals and humans, and has been registered for UI treatment in Europe. This is a one-piece device. A cuff of adjustable circumference length is fitted around the bulbous urethra, and a control mechanism of a substantial size is placed in the scrotum. The system is inflated with fluid, and pressure in the system is exerted by a spring system. The target pressure on the urethra ranges from 70 to 80 cm H<sub>2</sub>O (32).

## CONCLUSIONS

The first artificial sphincter, designed in 1973 and modified several times, has been used in an unchanged form since 1983. There is ample evidence supporting the efficacy and safety of AMS800 in UI treatment. In the recent years, several new devices for male UI treatment have appeared on the market. Some of them (suburethral slings) are intended for patients with mild to moderate UI. They are an alternative to an artificial urinary sphincter and ensure satisfactory continence and lower rate of procedure-related complications. New sphincteric devices, such as Flowsecure and Zephyr, are thought to be direct alternatives to AMS800. By eliminating disadvantages of AMS800, these new devices are to provide similarly good outcomes associated with continence and, at the same time, decrease the rate of early and late complications. At present, there are no studies directly comparing these two types of devices. In the case of the new ones, there is a need for studies on larger groups of patients and with longer follow-up periods in order to fully confirm their usefulness in UI treatment.

## BIBLIOGRAPHY

- Shamliyan TA, Wyman JF, Ping R et al.: Male urinary incontinence: prevalence, risk factors, and preventive interventions. *Rev Urol* 2009; 11(3): 145-165.
- Thom D: Variation in estimates of urinary incontinence prevalence in the community: effects of differences in definition, population characteristics, and study type. *J Am Geriatr Soc* 1998 Apr; 46(4): 473-480.
- Koyama W, Koyanagi A, Mihara S et al.: Prevalence and conditions of urinary incontinence among the elderly. *Methods Inf Med* 1998 Jun; 37(2): 151-155.
- McConnell JD, Barry MJ, Bruskewitz RC: Benign prostatic hyperplasia: diagnosis and treatment. Agency for Health Care Policy and Research. *Clin Pract Guidel Quick Ref Guide Clin* 1994 Feb; 8: 1-17.
- Rodriguez E, Skarecky DW, Ahlering TE: Post-robotic prostatectomy urinary continence: characterization of perfect continence versus occasional dribbling in pad-free men. *Urology* 2006; 67: 785-788.
- Krupski TL, Saigal CS, Litwin MS: Variation in continence and potency by definition. *J Urol* 2003; 170: 1291-1294.
- Olsson LE, Salomon L, Nadu A et al.: Prospective patient-reported continence after laparoscopic radical prostatectomy. *Urology* 2001; 58: 570-572.
- Lawton CA, Won M, Pilepich MV et al.: Long-term treatment sequelae following external beam irradiation for adenocarcinoma of the prostate: analysis of RTOG studies 7506 and 7706. *Int J Radiat Oncol Biol Phys* 1991 Sep; 21(4): 935-939.
- Wallner K, Roy J, Zelefsky M et al.: Fluoroscopic visualization of the prostatic urethra to guide transperineal prostate implantation. *Int J Radiat Oncol Biol Phys* 1994 Jul 1; 29(4): 863-867.
- Blasko JC, Ragde H, Luse RW et al.: Should brachytherapy be considered a therapeutic option in localized prostate cancer? *Urol Clin North Am* 1996 Nov; 23(4): 633-650.
- Talcott JA, Clark JA, Stark PC, Mitchell SP: Long-term treatment related complications of brachytherapy for early prostate cancer: a survey of patients previously treated. *J Urol* 2001 Aug; 166(2): 494-499.
- Penson DF, McLerran D, Feng Z et al.: 5-year urinary and sexual outcomes after radical prostatectomy: Results from the prostate cancer outcomes study. *J Urol* 2005; 173: 1701-1705.
- Begg CB, Riedel ER, Bach PB et al.: Variations in morbidity after radical prostatectomy. *N Engl J Med* 2002; 346: 1138-1144.
- Steineck G, Helgesen F, Adolfsson J et al.: Quality of life after radical prostatectomy or watchful waiting. *N Engl J Med* 2002; 347: 790-796.
- Stanford JL, Feng Z, Hamilton AS et al.: Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer: the Prostate Cancer Outcomes Study. *JAMA* 2000; 283: 354-360.
- Szopiński T, Chłosta PL, Borówka A: Wyniki leczenia nietrzymania moczu z użyciem sztucznego zwieracza cewki moczowej. *Post N Med* 2012; 4: 325-334.
- Van der Aa F, Drake MJ, Kasyan GR et al.: Young Academic Urologists Functional Urology Group. The artificial urinary sphincter after a quarter

- of a century: a critical systematic review of its use in male non-neurogenic incontinence. *Eur Urol* 2013 Apr; 63(4): 681-689.
18. Rehder P, Haab F, Comu JN et al.: Treatment of postprostatectomy male urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3-year follow-up. *Eur Urol* 2012; 62(1): 140-145.
  19. Zuckerman JM, Edwards B, Henderson K et al.: Extended outcomes in the treatment of male stress urinary incontinence with a transobturator sling. *Urology* 2014; 83(4): 939-945.
  20. Grise P, Vautherin R, Njinou-Ngninkeu B et al.: HOMme INContinence Study Group. I-STOP TOMS transobturator male sling, a minimally invasive treatment for post-prostatectomy incontinence: Continence improvement and tolerability. *Urology* 2012; 79: 458-463.
  21. Bauer RM, Mayer ME, May F et al.: Complications of the AdVance transobturator male sling in the treatment of male stress urinary incontinence. *Urology* 2010; 75(6): 1494-1498.
  22. Huebner W, Herschorn S, Olmedo T et al.: The phorbas system – a new single incision adjustable male sling. International Continence Society Meeting 2014 Poster no 681.
  23. Bauer W, Karik M, Schramek P: The self-anchoring transobturator male sling to treat stress urinary incontinence in men: a new sling, a surgical approach and anatomical findings in a cadaveric study. *BJU Int* 2005; 95: 1364-1366.
  24. Hoda MR, Primus G, Fischereider K et al.: Early results of a European multicentre experience with a new self-anchoring adjustable transobturator system for treatment of stress urinary incontinence in men. *BJU Int* 2013; 111(2): 296-303.
  25. Rouprêt M, Misraï V, Gosseine PN et al.: Management of stress urinary incontinence following prostate surgery with minimally invasive adjustable continence balloon implants: Functional results from a single center prospective study. *J Urol* 2011; 186: 198-203.
  26. Schiavini JL, Damiao R, de Resende Junior JAD et al.: Treatment of post-prostate surgery urinary incontinence with the periurethral constrictor: a retrospective analysis. *Urology* 2010; 75: 1488-1492.
  27. Simone G, Guaglianone S, Papalia R et al.: Periurethral constrictor (Silimed): a new device for treatment of mild urinary incontinence Following radical prostatectomy. *J Urol* 2009; 181 (suppl. 4): 619.
  28. Introini C, Naselli A, Zaninetta G et al.: Safety and efficacy of periurethral constrictor implantation for the treatment of post-radical prostatectomy incontinence. *Urology* 2012 May; 79(5): 1175-1178.
  29. Lima RS, Barros EGC, Souza CA et al.: Periurethral constrictor: late results of the treatment of post prostatectomy urinary incontinence. *International Braz J Urol* 2011; 37(4): 483-487.
  30. Staerman F, G-Llorens C, Leon P et al.: ZSI 375 artificial urinary sphincter for male urinary incontinence: A preliminary study. *BJU Int* 2013; 111: E202-206.
  31. Sandul A, Martins FE, Barros P et al.: The ZSI 375 artificial urinary sphincter: a new device for male urinary incontinence. 7<sup>th</sup> National Congress of Portuguese Association of Neurourology and Urogynecology, Vilamoura, Portugal, November 2010.
  32. Malaeb BS, Elliott SP, Lee J et al.: Novel artificial urinary sphincter in the canine model: the tape mechanical occlusive device. *Urology* 2011; 77(1): 211-216.

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