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Expanding Treatment Options with the Next Generation of Male Sling Technology

Highlights of an expert roundtable discussion on early experiences with a new advancement in the treatment of post-prostatectomy incontinence

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Expanding Treatment Options with the Next Generation of Male Sling Technology

Highlights of an expert roundtable discussion on early experiences with a new advancement in the treatment of post-prostatectomy incontinence

Dr. Webster: When I first heard about the AdVance™ Male Sling (American Medical Systems, Minnetonka, MN, USA), I was pretty skeptical, but I went to watch Dr. Gozzi and Dr. Rehder perform four cases. After the first case, I was impressed this was a smart procedure, and by the time all four were done, I was convinced it is the next generation in male sling technology. I think others who have performed this procedure share my enthusiasm and belief that the AdVance Male Sling is a major step forward in treating male stress urinary incontinence. This technology has the potential to dramatically increase the treatment of patients suffering from mild to moderate SUI who would not be traditional AUS candidates.

Dr. Rehder, please explain the concept and features of this sling and the instrumentation you and Dr. Gozzi developed for performing the procedure.

"The AdVance™ Male Sling is a major step forward in treating male stress urinary incontinence."

DR. GEORGE WEBSTER

Dr. Rehder: AdVance is a retro-urethral sling designed to provide proximal support to the posterior support structures of the urinary sphincter. The underlying rationale for this sling relates to the theory that there is laxity of the posterior sphincter after radical prostatectomy to the extent there might be sphincteric urethral prolapse and to the observation that there is often prolapse of the entire perineum in men with severe incontinence. In addition, we knew that a transobturator sling placed around the proximal bulb beyond or behind the urethral lumen would not totally obstruct the urethra, even when the sling is pulled as tight as possible, because the urethra dips underneath the symphysis pubis. Therefore, our thought was to create a non-compressive, self-anchoring sling sys-

tem to support the center of the pelvic floor and augment or support residual sphincter function.

Dr. Gozzi: We worked with American Medical Systems (AMS) to develop a sling and needle passers specific for the male anatomy. The needle passers are designed to implant the sling with an outside-in transobturator approach. We found that a larger helical needle was needed in males to ensure consistent placement and outcomes. The needle also features a flattened tip to avoid damage to critical structures and the handle is configured to allow maximum torque so that the surgeon can simply twist without having to regrip in order to pass it into the wound. The mesh itself has flaps in the center to provide support and repositioning. Lastly, there are two absorbable tensioning sutures that prevent the mesh from folding over on itself, and the mesh has stiffened edges that afford improved tensile strength and tissue fixation.

PATIENT SELECTION

Dr. Webster: What patients are appropriate candidates for the AdVance Sling?

Dr. Rehder: A man must have residual sphincter function. The best and most consistent results will be achieved in patients who have mild to moderate incontinence, although we've had some experience in patients with more severe incontinence that shows it may be possible to restore continence in those men if part of the sphincter is intact.

Dr. Gozzi: The ideal patient for this procedure is a man with urinary incontinence post-radical prostatectomy without any previous treatments. Radiotherapy, bulking agents, failed stem cell therapy and previous scarring urethral surgery are all compromising factors. You might improve their continence, but our early experience demonstrates that you seldom get them totally dry in the longer term.

Dr. Webster: I use cystoscopy to assess the sphincter and make sure it is free of large sector defects and overt scarring. I also check to see if the patient is able to coapt the sphincter when asked to tighten the buttocks.



Dr. Rehder: The most important test to see whether proximal bulbar relocation is the answer for the patients' incontinence is the "perineal support test". In lithotomy while observing the sphincteric urethra with endoscopy and supporting the perineum with an index finger behind the level of the urethral lumen, coaptation of the urethral lumen should be seen. When you see that you know that supporting the dorsal sphincteric support structures leads to the residual sphincter function to take effect.

Dr. McCammon: Ruling out segmental defects is important in post-prostatectomy patients. However, I've had patients with incontinence after TUR who had a segmental defect between the 5:00 and 7:00 o'clock positions who've done well with the AdvVance sling.

Dr. Knoll: I think the sling can be effective in a TUR patient with a segmental defect between the 3:00 and 9:00 o'clock position, but will probably not be as effective if the defect is located anteriorly, between 9:00 o'clock and 3:00 o'clock. The reason for the difference has to do with the anatomical repositioning achieved with the sling and the fact that it might cause some minor occlusion.

Dr. Jones: I suggest that pad weight, not number of pads used, should also be considered in patient selection and for uniform reporting of outcomes.

Dr. Knoll: I agree, and I think with further experience, we may see some stratification using pad weights that will help us identify good candidates for this procedure. I have not formally analyzed my outcomes, but my impression is that the best candidates for the sling are men with a 1-hour pad weight not exceeding 300 grams. Certainly men with very high pad weights, over 1000 grams, do not benefit from this procedure. However, we are still early on in the experience and this has yet to proven over time.

Dr. Webster: I began selecting patients with very low 24-hour pad weights, less than 100 grams, but have used the sling in a man with a pad weight of 400 grams, and after 1 month, he is totally dry.

TECHNIQUE: NEEDLE PASSAGE

Dr. Webster: Let's discuss the trocars that are used to pass and fix the sling. We've all been using the AMS male trocar, and I have no reservations about its design. However, I've noticed that the angle of attack is critical. Minimal depression or elevation of the hand makes a big difference as to where the tip is aimed. So, accuracy of the transfer will be an important point for learning this procedure. I've also noticed that once the tip has penetrated the obturator fascia, it is only necessary to turn the trocar by about 1-cm to receive the tip onto my finger. If I don't feel the tip instantly, I know it's in the wrong place.

Dr. Rehder: That's absolutely right. The needle was designed to be introduced and kept at a 45-degree angle and turned with a slight twist of the wrist. I agree that if you don't feel the tip immediately after the turn, the trocar should be removed and repassed. I think it helps to visualize the path of the needle by rotating it in space above the wound site once or twice prior to placing it into the stab wound, almost like taking a practice golf swing before hitting the ball. If you keep the 45-degree angle, the passage is extremely safe and easy.

Dr. Jones: I faced a bit of a learning curve initially and I think my problem at first was that my entry site with the needle was not lateral enough. Now I aim for about a 45 degree angle to the adductor longus tendon insertion, roughly about 2 centimeters away from the insertion of the tendon and the needle passage is very easy.

Dr. Rhee: I agree that there will be a learning curve with a segment of surgeons because this group is accustomed to operating via the transobturator approach in females. In males, only a minimal turn is needed once the tip penetrates the obturator membrane. One thing I've observed is the temptation to turn the needle passer too early, and then the tip hits bone. It's important to direct the needle tip straight down through the stab wound, feel the two pops and then simply rotate the passer with the wrist. The surgeon can already feel the bulge of the tissue from the needle tip and

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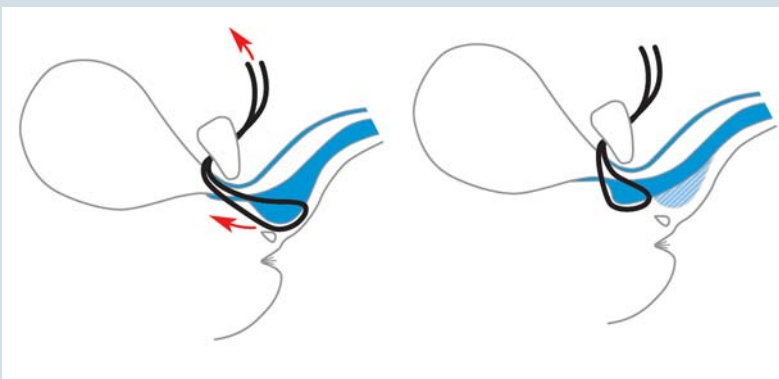
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The AdVance™ Male Sling System repositions the proximal portion of the anterior urethra into the pelvic outlet. Force is applied *parallel* to the lumen, unlike compressive devices that apply force *into* the lumen.

Images courtesy of Peter Rehder, MD.

once the wrist is twisted, the tip comes through right onto the finger of the other hand. It is imperative that the 45 degree angle is maintained.

Dr. McCammon: When teaching the AdVance procedure, I use the analogy of performing a transobturator procedure in a heavier female. Feeling the two pops is important to assure you are in the correct location before making the short turn.

Dr. Rehder: In developing the needle, we tested passage using different prototypes while blindfolded. We wanted to make sure the procedure would be safe if the needle was kept at a 45 degree angle and the tip delivered by rotation. If the angle of attack is incorrect so that your hand is in the 6 o'clock position in front of the obturator fossa, you could hit a corporal body. If it is being passed in the obturator fascia behind the bone, it might hit the urethra or the back portion of the symphysis pubis. So, it is important not to rotate the handle once the needle tip is placed deep into the obturator fossa.

Dr. Gozzi: Again, a good way to visualize this is to perform a "practice swing" with the needle outside of the body prior to inserting it into the stab wound. Surgeons should rotate the needle in space above the body to see the path that the helical needle will take inside of the body and how the tip will meet their index finger.

Dr. Webster: Agreed! In my first case the handle was probably at 3 o'clock or 4 o'clock rather than at 45 degrees, and so the tip of the trocar was aimed towards the vascular ischiorectal fossa and gluteal area. However, if surgeons are careful about having a 45 degree entry, making a 1 cm rotational excursion, and feeling the tip instantly, the passage is very safe.

TECHNIQUE: DISSECTION

Dr. Webster: Let's discuss the dissection. How extensive does it need to be to get the sling in the correct location? My concern is that if the dissection does not go far enough behind the bulb, when the sling is put in and tensioned, it may compress the urethra rather than elevate it, and then we may see problems, including erosion.

Dr. Gozzi: Initially we thought it was not necessary to take the central tendon off, but then most surgeons will stop the dissection prematurely and the sling will just indent the spongiosum instead of relocating the most proximal part of the bulb.

The idea is to mobilize the bulb enough to allow about 2 to 4 cm of proximal relocation. In the mild to moderate cases, it may not be necessary to take the tendon off completely as long as the bulb is mobile, but in the more moderate cases it needs to be taken off.

Dr. Webster: What I'm doing is getting just around the corner. I mobilize

the bulbus spongiosus from the underlying bulb and advance just to the point where it's starting its ascent. Is it safe to do any less?

Dr. Rehder: We found in our pilot study that if we did not take off the perineal body or the central tendon, the sling was still far away from the urethra lumen. However, it wasn't providing the intended proximal relocation.

Dr. Webster: Has anybody done a less extensive dissection and still had success?

Dr. McCammon: I have done it both ways. It appears that by taking the tendon down we have more mobility and consequently better probability of achieving continence. I feel it is important to take the tendon down in patients with moderate to severe incontinence whereas it may not be necessary in milder cases.

Dr. Knoll: When teaching the procedure, I think that it's helpful to show that when you pull the urethra up to 12 o'clock with a forceps, you can feel how fibrous the tendon is with your finger. Then, if you stay in the midline, you can safely continue the dissection to release the tendon and get adequate mobilization of the bulb without having to go all the way around.

TECHNIQUE: TENSIONING

Dr. Webster: Let's discuss tensioning. I've been pulling the sling very tight but always with some trepidation that the man may not void. Dr. Rehder and Dr. Gozzi, what are your tensioning points?

Dr. Rehder: We measured the tension to be about 5 kilograms (11 lbs), which is the same tension used to close abdominal fascia. With a finger on the proximal bulb after the tendon has been taken off, you want to have 2- to 4-cm of proximal movement of the bulb, and then you don't need a dramatic amount of tension on the mesh. The amount of movement can be measured with a sterile ruler.

Dr. Gozzi: It's very difficult to quantify how hard to pull. However, there is no danger of pulling too hard

because once the sleeves are off, the sling relaxes into position and the force on the bulb in this retro-urethral position is very minimal. With the AdVance sling, the force is applied parallel to the urethra, not into it as with compressive slings.

Dr. Knoll: I take my index finger and displace the urethra proximally as far as it will go. Then I pull on the wings of the mesh of the AdVance sling and stop when I meet resistance. When I remove my finger, I'll see that it doesn't displace distally, and then I'm set.

Dr. Jones: I measure the proximal movement of the urethra. My results are consistent when I get around 3 cm of urethral elevation.

Dr. Rhee: The AdVance sling repositions the urethrovesical anastomosis, as a retro-urethral sling and the anatomy of the V-shaped inferior rami limits us to a safe tension. With the InVance sling, tensioning is a concern because of the rare potential of causing long-term retention. I don't think that problem is theoretically relevant to the AdVance sling.

TECHNIQUE: TACKING SUTURES

Dr. Webster: What about tacking the wings of the mesh? I may be an outlier, but I wonder if the pexing or tacking sutures are really necessary. What do others think?

Dr. Stone: I pex the broad portion distally and I just fold it underneath proximally. I can't say whether pexing makes any difference because I've never tried it without, but it seems to support the sling and keep it from distorting.

Dr. Knoll: I pex it proximally in the middle near the membranous urethra before putting tension on the wings and it seems to lay the graft so I know where to pex it distally. Then I do the tensioning and pex it in the midline distally in the corpus spongiosum. I don't think pexing the wings affects the success of the procedure, but I think it helps the sling lay nicer and makes it easier to obliterate the empty space.

Dr. Rhee: I feel the pexing sutures do make a difference in allowing you to

Good candidates for AdVance™

- Mild to moderate incontinence
 - 1-5 ppd
 - < 200 g 1 hour pad weight
- Post RP or TURP
- Residual sphincter function

get as much proximal relocation as possible. My surgical pearl is to place the proximal (deepest) suture in first when the sling is loose because that avoids having to struggle to tie the suture proximally deep in the wound. Then I simply suture the distal stitch.

Dr. McCammon: I think that placing the tacking sutures more distally enables greater mobilization into the pelvis, and that may be helpful for patients with more moderate to severe incontinence.

Dr. Rehder: First we did no tacking, then we tacked just the distal portion, and then we started tacking both the proximal and the distal portions, especially in cases where the bulb had been taken off completely and in men with more moderate plus incontinence, thereby placing the sling more distally on the bulb.

I agree that tacking may not be necessary in the very mild cases. However, it is needed to keep the sling from slipping proximally too much in men

who have atrophic tissues secondary to radiation therapy or old age.

ANESTHESIA AND CATHETERIZATION

Dr. Webster: I've been doing all of my cases with spinal anesthesia. What are others using?

Dr. McCammon: I have used spinal and general without any problems.

Dr. Rhee: I have as well.

Dr. Webster: What are you doing in terms of postoperative catheterization?

I've been doing this as an outpatient procedure and some men are sent home so quickly that perhaps they have been unable to void at discharge because the anesthesia has not worn off yet. Therefore, I've been teaching my patients to do self-catheterization.

Dr. McCammon: I keep the patients in the hospital overnight with a catheter and remove it early the next morning. I've had three patients who couldn't void by that time, but by 48 hours they were all fine.

Dr. Rhee: We do these cases on a Friday, leave in a catheter, and have the patients return on Monday morning to do a trial void in the nurse's clinic. We've not had anybody in retention, but it may depend on the baseline sphincteric function.

The AdVance™ Male Sling System implanted

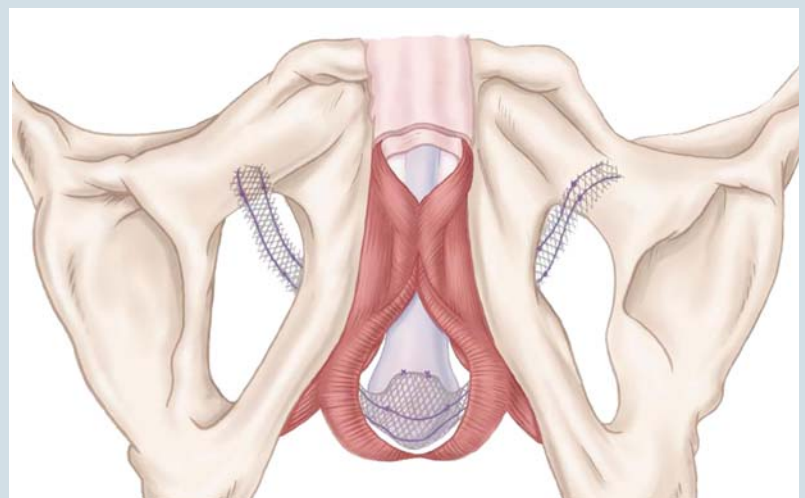


Image courtesy of AMS.

Dr. Jones: We perform these as an outpatient procedure. The patients return two days post-op for catheter removal.

Dr. Knoll: I do these procedures on an outpatient basis and send the patient home with a Foley catheter that I remove the next morning.

Dr. Stone: I have operated on some patients with a short-acting general anesthetic that I sent home on the same day without a catheter and who have been able to void.

Dr. Rehder: We do our cases in a short general anesthetic, leave a transurethral catheter for 1 to 2 days and before discharge they get a urinating cystourethrogram as part of a study protocol.

Dr. Gozzi: A spinal might be a reason for transient retention if the catheter is removed straight after the procedure.

CONSIDERATIONS FOR SPECIAL PATIENT POPULATIONS

Dr. Webster: Has the surgery been more difficult or required any technique changes in obese males?

Dr. Knoll: In those men, it is necessary

"The AdVance sling does not preclude future placement of an AUS."

DR. GEORGE WEBSTER

to drive the needle in further through the obturator membrane before you penetrate and so that you do not come up superficially above the bone.

Dr. Rehder: When dealing with an obese patient try to "step toward" the patient displacing the tissue keeping the passer needle at 45 degrees, making sure to "lock" into the obturator fossa before turning the needle. The 45 degree angle of the passer needle should be maintained whether dealing with an obese or slender patient.

Dr. Webster: Does anyone have experience in post-radiation patients?

Dr. Gozzi: Post-radiation patients can be improved but the atrophic tissues remain problematic. The dissection should be carried out more carefully and the bulb mobilized completely.

Dr. McCammon: I've operated on three men who had received radiation

therapy. It's important to counsel them about a risk of erosions, but they've done well. One is dry, and the others have gone from four pads a day to one and are very happy.

Dr. Rhee: The AdVance sling is appealing for use in these men because of its mechanism of action — it repositions the urethrovesical anastomosis without relying on passive compression.

Dr. Knoll: I've seen a difference in outcomes based on pad weight. I operated on a few postradiation patients whose pad weight was under 500 grams and they did well, but I also had a few men with higher pad weights, and they did not do well at all.

Dr. Webster: The postradiation patients may be a difficult group and the pad weight and sphincter appearance may help guide our selection. Men with a lower pad weight whose sphincter is not fixed open may not get the same result as a patient who has not had radiation, but they may still benefit with enough improvement that the outcome is acceptable.

Dr. Rehder: Postradiation does not make the operation technically more difficult. The dissection has to be more careful though because of the often very atrophic tissues up to the extent that the bulbospongiosus muscle is virtually absent. Important is the fact that you still want to get proper proximal movement of the proximal urethral bulb.

Dr. Webster: Does prior perineal surgery add any degree of difficulty to this procedure? I've not used the AdVance sling in any patient who had a perineal prostatectomy, but I've done many artificial sphincters in that group, and it seems to me that it is not going to make a difference whether the radical prostatectomy was done through a perineal, robotic, or retropubic approach.

I think there may be a difference if you are trying to salvage continence with an AdVance sling in a patient who has had an AUS because there may be some scarring of the bulb that precludes its rotation and elevation back up into the pelvis. I have a number of AUS patients who had severe erosions that necessitated excision and reanastomotic urethroplasty and are now incontinent again. They would appear



A. The unique features of the AdVance™ sling mesh were designed for repositioning the male urethra.

B. AdVance helical needles, developed for use in the male anatomy, are designed to implant the AdVance sling mesh via an outside-in transobturator approach.

Images courtesy of AMS.

to be a good candidate for an AdVance sling, but I wonder if the system would rotate back and up.

Dr. Rehder: It would seem that if the bulb is fixed to prevent that backward rotation, the AdVance sling might not work. However, if the AUS was placed distal enough so that the proximal bulb is still mobile, it may still be considered an option.

Dr. Knoll: In my experience, the AdVance has not been effective at all in a patient with an eroded sphincter who has significant scarring.

Dr. McCammon: I have placed an AdVance sling in two men who have had previous urethral reconstruction following an eroded AUS. One had an almost 50% improvement but the other had no improvement at all. Therefore, I would agree that you may not get much mobility in these men after urethral reconstruction.

Dr. Rhee: The InVance sling is placed more distally, more distal than an AUS cuff and much more distal than the AdVance sling.

Dr. Webster: This is an important point because urologists might consider the AdVance sling as a salvage procedure after a late failed AUS. It seems that it might be an option if the AUS was more distal and the bulb maintains its mobility, but otherwise not.

Dr. McCammon: We have placed an AdVance in a failed AUS patient and he has done great. The dissection was easy and the cuff was not damaged nor the capsule entered.

Dr. Webster: It's true that the AdVance sling does not preclude future placement of an AUS. However, will any changes in technique be necessary, such as moving the cuff location more distally or using a transcorporeal approach? And, will the risk of erosion be affected?

Dr. Knoll: I've used the AdVance in a few patients whose pad weight was over 1000 grams with the expectation they would not do well, and I have now gone back and implanted an AUS. I used a transperineal approach, and I found the dissection was not very diffi-

"We're now in an era where patients are coming in with higher expectations for outcomes after their cancer surgery."

DR. EUGENE RHEE

cult because the sling gets so well incorporated with the tissue. However, I placed the cuff a little more distally than I usually would, thinking there might be some compromise of the urethral blood supply and wanting to avoid that to reduce the risk of erosion.

Dr. Jones: I had one patient that was not happy with the outcome after the AdVance sling. I was able to place an AUS utilizing the transverse scrotal approach. The AdVance sling was left in place as I felt no need to remove the device. The dissection was perhaps a little more difficult but that is because I place the cuff quite proximal. I have seen him in follow up and he is doing well, completely dry with no pad use.

Dr. Gozzi: We've had to reposition the sling in two men whose sling came loose because they exercised or lifted heavy items immediately postop. We found the sling was attached to the bulbospongiosus muscle, but we could easily dissect the bulb off it on the inside because it wasn't grown into the bulb. Therefore, I think the sling will not compromise the blood supply, although further experience is needed to know for certain.

Since the sling is very proximal, I don't think it would be necessary to change the position of the AUS. However, a transcorporeal approach might be preferred.

PATIENT SATISFACTION

Dr. Webster: Let's address patient satisfaction. I've operated on ten men and they are among my happiest patients. They knew they were receiving something brand new, and they were ecstatic about their outcomes because they far surpassed their expectations. Furthermore, the procedure is short, done in an outpatient setting, and was associat-

ed with minimal morbidity.

If we can continue to offer those benefits and are avoiding all of the complications associated with an AUS or InVance, the AdVance sling will be a real winner. Only time will tell, but my feeling is also that unlike with other techniques where factors such as relaxation, movement, or resolution of edema may lead to later failures, because this sling is an immovable device, early success will translate into persistent success.

Dr. Stone: Some men are very apprehensive about having an InVance or even an AUS. The AdVance sling procedure is much less invasive, associated with a lack of postoperative pain, and as you say, has been a real winner.

Dr. Rehder: We often do not realize how much patients suffer because of incontinence. Many patients are also still traumatized after having had major cancer surgery. Knowing that there is help available for treating urinary incontinence, that is not a major operative procedure, most of these men welcome this help and are extraordinarily happy with the quick and so far seemingly lasting success of this procedure.

Dr. Rhee: We're now in an era where minimally invasive approaches to radical prostatectomy are here to stay, and patients are coming in with higher expectations for outcomes after their cancer surgery. The one pad a day patient will have assumed he should be completely dry after a laparoscopic or lap assisted robotic prostatectomy. We are already seeing more patients wanting a permanent treatment for their mild or moderate incontinence that doesn't require activation or manipulation and that allows a rapid return to work and daily activities. I've been very impressed with how comfortable men are after the AdVance sling procedure. They have minimal to no pain.

Dr. Jones: Patient satisfaction has been great. The AdVance Male Sling will offer a minimally invasive solution for the patient with mild urinary incontinence post prostatectomy. However, proper patient selection will be important for physicians to be mindful of when utilizing this new procedure. ■



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anything like it.

When the world leader in male continence solutions announces a truly revolutionary technique for restoring bladder control, you better take a look. The new AdVance™ male sling system is a whole new way of looking at incontinence repair. It's a permanent solution for mild to moderate stress urinary incontinence, and a minimally invasive surgery. It's only available from the name you trust most: AMS. Seeing is believing.

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For a complete list of indications, contraindications, warnings and precautions, refer to the product Instructions for Use or contact your AMS representative.