



Artificial urinary sphincter erosion and infection: a contemporary review of perioperative considerations and management

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Abstract: Surgical treatment options have long been a part of the treatment armamentarium in the field of male stress urinary incontinence (SUI) and will continue to play an important role moving forward given the dramatic improvement they can have on a patient's quality of life and urinary tract function and control. The artificial urinary sphincter (AUS) is widely considered the gold standard treatment option for male SUI given its breadth of effectiveness in mild, moderate, and severe cases of SUI. As with any surgery, there are potential perioperative risks and complications that all patients must be aware of when weighing the pros and cons of different treatment options. Two of the most dreaded complications of AUS surgery are urethral cuff erosion and device infection, both necessitating a subsequent surgery for device explant. The goal of this clinical practice review article is to examine and discuss the perioperative factors and management of these complications. Effectively treating these complications is of utmost importance, not just to address the acute clinical problem for patient health and safety, but also to provide the patient with the best chance of pursuing AUS replacement surgery in the future, given that the vast majority of these patients will develop recurrent bothersome SUI after the eroded and/or infected device is removed. By reviewing pertinent patient factors, preoperative and postoperative considerations, device-specific characteristics, surgical techniques, and patient counseling, this article serves as a thorough and practical clinical review guide for practicing urologists who perform male incontinence surgery.

Keywords: Artificial urinary sphincter (AUS); infection; erosion

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Introduction

The artificial urinary sphincter (AUS) is considered the gold standard treatment option for male stress urinary incontinence (SUI) as it is an effective option for the complete spectrum of symptom severity. A majority of men who have undergone AUS surgery achieve satisfactory continence levels and tangible improvements in quality of life, which has led to the device's success and popularity (1).

As with any surgery, there are potential complications and risks involved. Two of the most dreaded complications for AUS surgery, in particular, include device infection and urethral erosion (*Figure 1*), both of which require device removal. Infection typically occurs in the setting of urethral erosion and is rare if erosion is not present. Long-term outcomes for the AUS show that the median age of the male patient undergoing AUS surgery is 71 years with a 31.2% rate of secondary surgery due to infection, erosion, device

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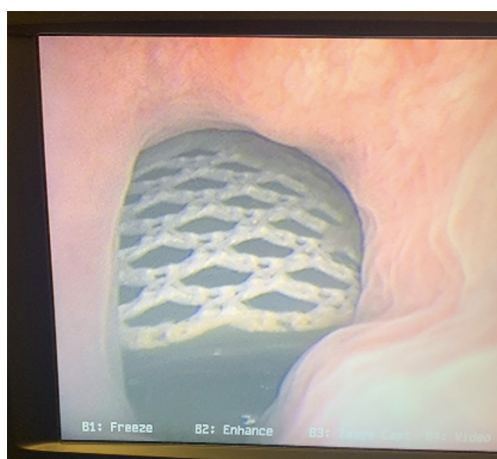


Figure 1 Cystoscopic evidence of artificial urinary sphincter cuff erosion.

malfunction, urethral atrophy, or pump malpositioning (2). Thus, one of the main goals for a prosthetic surgeon is to strike the balance of achieving satisfactory continence levels for each patient while also limiting surgical complications that may require device removal or revision.

Published data on AUS surgery show infection rates between 0.46–7% and cuff erosion rates between 3.8–10% (1,3). Certain patient factors, perioperative management decisions, device-specific characteristics, and surgical techniques have been shown to impact device longevity and complication rates. In this clinical practice review, we aim to educate the practicing urologist by expanding upon those important perioperative factors and the management of AUS infection and erosion.

Methods

A thorough literature review was conducted using the PubMed database. With a focus on contemporary practices and trends, the database search was mainly focused to studies within the previous 15-year period, 2008–2023, however there are a minority of included references that fall outside of this date range that we felt important to include. Specific search terms included, but were not limited to, “artificial urinary sphincter”, “AUS”, “infection”, and “erosion”. The search was limited to studies in the English language. Given that our target population was in adult males, we excluded studies on the pediatric or adult female populations.

Discussion

Perioperative antimicrobial stewardship

Per the American Urological Association (AUA) Best Practice Statement on Urologic Procedures and Antimicrobial Prophylaxis [2019], urine should be tested preoperatively in the form of a urine microscopy and/or urine culture to help guide antimicrobial agent selection (4). The majority of urologists will treat positive cultures preoperatively in an attempt to sterilize the urine prior to surgery. However, Kavoussi *et al.* conducted a large retrospective study (713 urologic prosthetic cases) showing no difference in infection rates in prosthetic implantation with or without preoperative urine cultures. In fact, their infection rate of 2% in AUS patients without preoperative cultures was found to be consistent with other published infection rates (5). This area remains a topic of debate among prosthetic urologists for both penile implant surgery and SUI surgery (6).

The Best Practice Statement also highlights that the perioperative antimicrobial choice for prosthetic surgery should include coverage for gram negative rods and *Staphylococcus aureus* for up to 24 hours or less and mentions that there are increasing reports of anaerobic and fungal organisms (4). To evaluate antibiotic prophylaxis practice patterns, Sun *et al.* reviewed the trends of antimicrobial prophylaxis during AUS surgery. They found that there was an increased odds of guideline-adherent regimens of 7.7% per year from 2000 to 2020 with the most common regimen being vancomycin and gentamicin (7). Although they showed an associated decreased risk of surgical complications of any kind, there was not a significant association with infection risk specifically. The authors conclude that further level 1 studies should be obtained to examine the benefit of these proposed antimicrobial regimens. The AUA statement also highlights the use of chlorhexidine and alcohol over betadine for non-mucosal surfaces for skin preparation (4). This was supported by Yeung *et al.*'s randomized controlled trial showing that chlorhexidine-alcohol was superior to povidone-iodine in eradicating skin flora prior to prosthetic implantation without any increased risk of skin irritation (8).

Postoperative antibiotics after AUS implantation is a debated topic among prosthetic surgeons with some prescribing no additional coverage while others prescribe a week or more of antibiotic therapy (6). Dropkin *et al.*

performed a retrospective study examining the routine use of postoperative antibiotic use after AUS implantation and found that it provided no significant change in rates of explant due to device infection or cuff erosion (9). Adamsky *et al.* also conducted a nationwide MarketScan study that included over 14,000 men undergoing urologic prosthetic implantation. They did not find a significant difference in device explant rates based on postoperative antibiotic coverage; additionally, there was no advantage based on class of antibiotic used (10). Despite the evidence, many urologists continue to prescribe routine postoperative antibiotic coverage due to the fear of the consequences of device infection (6,11).

The use of antibiotic coating

In 2008, the antibiotic coating InhibiZone[®] (rifampin and minocycline) was introduced into the market for AUS implantation with the goal of decreasing infection rates, and thus, reducing the risk of device explant. The added cost of the coating was an average of \$1,300. In the first published retrospective series examining its clinical efficacy, de Cógáin and Elliott found an infection rate of 5% in the antibiotic coated population versus 6% in the uncoated population, which was not a statistically significant difference. They concluded that the added cost was not of benefit to the patient (12). A similar study was conducted in 2017 across multiple institutions as part of the Debates on Male Incontinence (DOMINO) project. Within the total of 305 patients, the authors did not find a significant difference in infection or explant rates in those devices that contained the coating (13). Even though the clinical utility of preventing device infection is questionable, many urologists continue to use the InhibiZone[®] coating in AUS surgery. It should also be noted that the coating comes standard on AUS devices made by Boston Scientific Corp. (Marlborough, MA, USA) and surgeons would need to specifically request to use a non-coated implant, which certainly has an effect on its widespread use.

Microbial cultures

Kavoussi *et al.* looked to determine whether there is a correlation between the bacteriology of preoperative urine cultures and postoperative device infections (14). They examined patients undergoing AUS and/or penile prosthesis implantation between 2007 and 2015 and found that there was no increased risk of device infection in patients

with untreated asymptomatic preoperative urine cultures. Additionally, they found that when a device was explanted for infection, there was a 93% discordance between the organism present at the time of device explant and the preoperative urine culture results.

With regard to cultures obtained from explanted devices, there have been multiple studies that looked at the specific speciated organism. It is known that foreign objects within the body harbor biofilm formation and that the study of biofilm can help guide treatment and prevention of infection (15). In a single institutional study, Magera and Elliott found that *Staphylococcus aureus* was the most common organism found in infected implants, followed by *Staphylococcus epidermidis*, followed by Methicillin-resistant *S. aureus* and *S. epidermidis* (16). Ziegelmann *et al.* also found similar results with Staphylococcus species being the most common in patients undergoing AUS revision surgery for non-infectious and non-erosion etiologies (17). Similarly, Leong *et al.* showed that coagulase-negative staphylococci was the most commonly identified bacteria during revision surgery for a non-infectious cause (18).

Another important facet of device infection is the actual colony count of bacteria. In a study on clinically uninfected genitourinary prostheses undergoing reoperation for reasons other than infection, Licht *et al.* obtained cultures from 65 penile implants and 22 AUS devices. They found that low colony counts of *S. epidermidis* were isolated from 40% of penile implants and 36% of AUS devices. Only 3 of these devices went on to become infected and all showed a much higher colony count of another organism (19). The authors posit that the incidence of infection attributed to *S. epidermidis* may be overstated.

Risk factors to consider during preoperative counseling

The preoperative patient counseling is vital to establish proper expectations for AUS outcomes and education on potential risks and complications, especially for those that are considered higher risk. “Fragile” urethras, defined as those with previous radiotherapy, prior failed AUS, or previous urethroplasty surgery, have been found to have a higher risk of failure due to device malfunction, cuff erosion, or device infection (20–27). Additionally, older age (greater than 80 years), diabetic patients, need for anticoagulation, history of stroke or coronary artery disease, and those with a history of smoking were also found to have a statistically significant increased risk of AUS complication, including the need for device removal (25,28–30).

Hypogonadic men should also be counseled on the increased risk for explant as low testosterone has been found to be an independent risk factor for cuff erosion (31,32). It is also important to note that in a retrospective study of 113 patients who underwent AUS implantation, there was a 45% incidence of patients who were found to have a low serum testosterone (<280 ng/dL) prior to surgery (33). This shows that nearly half of the patients undergoing AUS placement are already at an increased risk of urethral erosion. This may be partially due to an increased number of patients requiring androgen deprivation therapy (ADT) for the treatment of prostate cancer, although ADT has not been shown to have a statistically significant increased risk of AUS explant (34). Further studies are needed in this area to determine the impact of hypogonadism in this setting and the potential benefit of testosterone replacement therapy.

The patient with concomitant male SUI and erectile dysfunction who wishes to undergo tandem placement of inflatable penile prosthesis (IPP) and AUS should also be thoroughly counseled on this approach. The synchronous implantation may provide a decreased cost to the patient as well as one less surgery under general anesthesia. Yet, the literature is divided in terms of outcomes. Segal *et al.* retrospectively studied 55 patients who underwent combined AUS and IPP placement. Compared to patients who underwent a single insertion of IPP or AUS, there was no increased rate of infection or erosion (35). This contrasts with Sundaram *et al.*'s retrospective study of 366 AUS operations. The authors showed a significantly higher rate of erosion in the AUS/IPP group (11.6%) compared to the AUS only group (4.3%) (36). Thus, these patients should be educated that the results are mixed, and surgeon preference likely plays a strong role in this decision.

Surgical considerations

Prosthetic surgeons have described and innovated various surgical approaches in attempts to decrease the risk of urethral erosion, especially in revision cases where placing a smaller cuff at the same site is not feasible and/or there are limited new cuff locations along the bulbar urethra. The transcorporal approach has traditionally been used in high-risk settings. Redmond *et al.* showed that the transcorporal approach has a lower revision and erosion rate compared to standard cuff placement in patients with a "fragile" urethra, as defined previously (37). Similarly, a multi-institutional study in France studied 464 patients who underwent AUS

implantation in the setting of a fragile urethra. They found that in the subset of patients who had a previous AUS explant, the transcorporal approach tended to bring longer explant free survival compared to the traditional bulbar approach, although this difference did not reach statistical significance (38). However, Kurtzman *et al.*'s 2023 study showed that in high-risk patients, the transcorporal cuff was associated with an increased risk of explant for infection/erosion across all patients and specifically in radiated patients (39). The multi-institutional study by Moser *et al.* showed a similar increased risk of complications with transcorporal cuff placement in radiated patients (40). Yet, this is difficult to discern as these radiated patients are already at a higher risk of complication. Mann *et al.*'s study showed that radiation was an independent risk factor for earlier time to erosion (20). The utility and role of the transcorporal approach continues to be debated among prosthetic urologists. A modification of the transcorporal approach is the Gullwing Technique. This is highlighted by the use of bilateral corporal grafting to cover the lateral and ventral surfaces of the urethra to theoretically help reduce the likelihood of urethral erosion, although no long-term studies have been published on this (41,42).

With high risk patients, other innovative techniques have been explored. One described technique includes preserving the dorsolateral fibromuscular tissue that surrounds the bulbar urethra during cuff placement. Cheung *et al.*'s review of this technique in 208 patients had an erosion rate of 2.9% with no patients developing infection (43). Another approach includes the use of a rectus fascial wrap in the setting of prior pelvic radiation. Given the increased risk of erosion, the fascial wrap potentially provides a beneficial vascular supply to the urethral tissue. A prospective analysis of 23 patients undergoing this technique found that 1/23 (4.3%) patients developed urethral erosion postoperatively, while the other 22 patients had achieved either complete or social continence over a median follow-up of 32 months (44). Yet another technique for AUS placement after multiple revisions is the placement of a small intestinal submucosa (SIS) urethral wrap. This provides the urethra with additional tissue and serves as a buffer between the cuff and urethra. Trost and Elliott published a series of 8 patients who underwent the SIS approach. They found that 38% (3/8) of patients were dry, requiring no pads. However, they also reported 38% (3/8) of patients required AUS explant for erosion or infection (45). More robust published data are needed to support the use of these alternative surgical approaches.

The use of the 3.5 cm AUS cuff can also theoretically be used to accommodate patients with a small urethral circumference to optimize continence. However, its clinical use is controversial given the increased risk of complication (6). A multi-institutional study by Brant *et al.* showed that patients who underwent the 3.5 cm cuff placement had a higher device explant rate compared to those who had larger cuffs (21). Other studies have shown that smaller cuff size is a risk factor for urethral erosion and that the 3.5 cm cuff is associated with a higher risk of mechanical failure (46,47). Simhan *et al.* showed that urethral erosion risk is higher in patients that were radiated (21% *vs.* 4%) (48). Yet, there have also been studies that show more positive results of the 3.5 cm cuff. In fact, McKibben *et al.* showed that erosion rates in the 3.5 cm cuff group (10.8%) were similar to those of the 4+ cm cuff group (10.7%) with similar continence rates (49). Additionally, Bergeson *et al.* found that urethral atrophy was a rare cause for revision surgery in the 3.5 cm cuff population (2%) compared to the 4+ cm cuff population (11.6%) (50). The use of a specific cuff size helps optimize continence, but it should also be balanced with the goal of minimizing postoperative complications.

Adequate sizing of the urethral cuff is an important factor to consider in order to optimize urinary continence and minimize the risk of urethral erosion. In fact, the anatomy of the urethra lends itself so that the more proximal segment of the bulbar urethra has a larger circumference from that of the distal bulbar urethra and penile urethra. Thus, more proximal implantation of the cuff leads to a larger cuff size (46,51,52). Rothschild *et al.* examined whether or not there was a difference between intraoperative urethral circumference and cuff size affecting postoperative outcomes. The authors performed a retrospective review of 87 patients who underwent AUS placement and found a median urethral circumference of 38 mm and median difference between urethral circumference and cuff size of 2.5 mm. They found that patients who had a difference of more than 4 mm reported better continence and satisfaction than those with a difference of less than 4 mm. They concluded that selecting the larger of two cuff sizes may be beneficial for continence while also minimizing the risk of erosion (53).

The option of a double cuff (DC) placement has also been used in both the virgin implant and salvage settings. The second cuff is usually placed about 1.5–2 cm distal to the primary cuff (54). In terms of primary implantation, the DC technique can be used, however there is an increased risk of infection, device dislocation, and explantation rates

(30,55). Given these increased risks, there is no indication that the DC should be used in lieu of a single perineal cuff system for primary AUS implantation. The DC technique can also be used in the salvage setting. Maurer *et al.* compared salvage techniques in patients who underwent previous AUS explantation due to erosion or infection. The authors found that there was no statistical difference with regard to infection or erosion in patients who underwent DC implantation when compared to those who instead underwent a transcorporal approach. They did find that there was an overall higher continence rate in the DC approach, however this was not statistically significant (56). Thus, the DC approach may be considered as an option in the setting of secondary, salvage surgery, however surgeons should proceed cautiously.

In terms of device activation, many urologists keep the AUS deactivated at the time of surgery and proceed with activation at the first postoperative appointment around the 6–8-week mark. This allows time to minimize the theoretical risk of erosion by allowing the pseudocapsule to form while also minimizing the patient discomfort of utilizing the pump in the immediate postoperative period. However, immediate reactivation of the AUS following isolated cuff exchange has not been shown to increase erosion risk (57).

Postoperative urethral manipulation

Urinary retention can occur in the acute postoperative phase given the urethral manipulation that occurs during surgery along with the effects of anesthesia. In fact, patients should be counseled that postoperative retention is a risk factor for cuff erosion (22). However, in general, most urologists abide by the principle that prolonged urinary retention >48 hours should be managed with a suprapubic catheter as urethral catheterization longer than this period can risk erosion (58). Additionally, endoscopic manipulation with an activated AUS can also lead to an increased risk of device infection or erosion (59). Thus, it is vital to ensure device deactivation for any endoscopic urologic procedure.

AUS explant considerations

In the setting of cuff erosion and/or device infection, AUS explant is indicated. Patients may present with a spectrum of symptoms indicating either cuff erosion or infection ranging from minor changes in urinary symptoms to sepsis (60). In fact, Diao *et al.* found that scrotal inflammatory

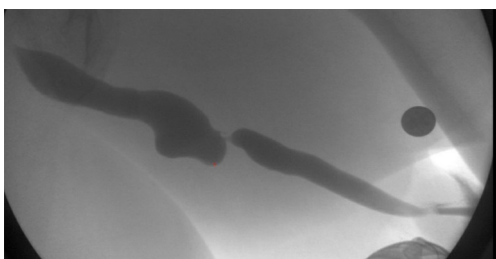


Figure 2 Retrograde urethrogram demonstrating high grade bulbar stricture after artificial urinary sphincter cuff erosion.

symptoms (tenderness, erythema, swelling) are the most common presenting symptoms, although obstructive voiding symptoms and worsening incontinence are also common (61). Urologists should have a low threshold to pursue cystoscopy if these symptoms are present to assess for urethral erosion. Retrograde urethrogram can also be considered as an adjunct study, however, this should not replace the need for direct cystoscopic evaluation.

Explant in the setting of infection requires the removal of all device components, especially when there is gross pus found in the surgical site. However, in the setting of reoperation for cuff erosion without obvious infection or mechanical malfunction, the method of “drain and retain” may be utilized, if necessary. This involves draining the pressure regulating balloon of all fluid at the time of explant, cutting the balloon tubing as high as possible in the surgical field, and allowing the balloon to retract back into the wound out of view. The reason for such a maneuver is to avoid the potentially tedious and dangerous dissection involved with attempting to remove the balloon, especially if it is located deep in the pelvis near critical vascular structures and visceral organs (62,63). In many cases, this alternative maneuver is not necessary, however it can be utilized in the appropriate “damage control” setting.

The timing of explant surgery can vary. In the septic patient with obvious signs of device infection, it may be indicated to urgently explant the AUS to stabilize the patient. Fortunately, this is not a common presentation. In the setting of diagnosed cuff erosion in a stable patient without concerning infectious symptoms, explant is usually carried out on an outpatient basis in the following days. Long delays in management can allow for continued urinary extravasation through the eroded urethral site, leading to a higher risk of infection and development of systemic symptoms. However, one must also consider the morbidity

of surgery in certain populations. Shumaker *et al.* published a case series on the management of cuff erosion with either delayed explant or non-surgical management (observation). These were all asymptomatic men who were found to have urethral erosion. They describe two patients whose devices were simply left deactivated with a known urethral erosion. One of these patients had surgery cancelled due to medical comorbidities including cardiac issues and a recent stroke. Another patient was managed with a suprapubic catheter with no desire for another AUS (64). This highlights the importance of shared decision making and weighing the potential pros and cons of each approach. Timely AUS explant remains the standard of care in this setting, but there may be rare exceptions.

AUS surgery in the setting of urethral pathology

Traditionally, prosthetic surgeons abort device implantation if a urethral repair is necessary whether it be due to an iatrogenic injury at the time of surgery or a diagnosed urethral stricture. Yi *et al.* retrospectively examined a large database of 1,508 prosthetic cases and found that 7 patients (0.46%) had a synchronous urethroplasty at the time of implantation with 3 patients undergoing repair of a known urethral abnormality and four having a repair due to an intraoperative injury. Six out of seven of the urethroplasties were completed with primary closure and all patients had a suprapubic tube (SPT) placed with all 7 patients being continent at a mean follow-up of 21.5 months with no infections or erosions identified (65). The authors concluded that a synchronous urethroplasty with SPT can be a safe management method without increased risk of infection or erosion. It is important to note that if there is any intraoperative concern regarding the urethral integrity to support an AUS cuff, aborting device placement is the safest approach.

Urethral stricture is a known potential complication in the setting of AUS cuff erosion, with complete cuff erosion having a higher rate of stricture than partial cuff erosion (66) (*Figure 2*). Pelvic radiation has also been found to be a risk factor for urethral stricture after erosion with Krughoff *et al.*'s study showing a 41.1% higher incidence compared to non-radiated patients who develop erosion (67). In an attempt to prevent subsequent stricture development, some have advocated for an “in-situ” urethroplasty at the time of AUS explant rather than allowing the eroded urethra to heal solely over a urethral catheter. It is important to note that erosion usually occurs on the ventral aspect of the

urethra and secondarily on the lateral aspects of the urethra; dorsal erosion is less common (68). In a retrospective study by Rozanski *et al.*, the rate of urethral stricture disease was significantly reduced amongst those who underwent urethroplasty (38%) versus those treated with only a catheter (85%). The urethroplasty group also had a higher rate of undergoing secondary AUS implantation, thereby indicating the efficacy of urethroplasty in AUS explant for erosion if clinically feasible (69). Siegel *et al.* also advocates for *in situ* urethroplasty as it provides a definitive repair and decreases the time to AUS reimplantation (70).

On the other hand, Kuhlencord *et al.* had a study of 24 patients who underwent transurethral and suprapubic catheter insertion for 3 weeks after AUS explant for cuff erosion. To minimize iatrogenic trauma and urethral tissue mobilization, an *in situ* urethroplasty or urethrorrhaphy were not performed at the time of cuff removal. The authors found that at a median follow-up of 18.7 months, 2/24 patients (8.3%) developed a urethral stricture. They concluded that given the relatively low stricture formation, urinary diversion with catheterization alone was safe in the setting of cuff erosion (71).

The Trauma and Urologic Reconstruction Network of Surgeons (TURNS) group studied patients undergoing AUS replacement after urethroplasty for cuff erosion. They demonstrated a 36% rate of AUS revision or removal due to subcuff atrophy or erosion after a median AUS replacement time of 6 months after urethroplasty (72). Although urethroplasty can be successful to manage the erosion-induced urethral stricture, patients must be counseled that subsequent AUS replacement carries an elevated erosion rate. Chertack *et al.* also published a series of 40 patients who underwent *in situ* urethroplasty for cuff erosion. Their data showed a 35% rate (14/40 patients) of permanent urinary diversion with urethral ligation + SPT, SPT alone, or ileal conduit diversion (73).

Secondary AUS implantation

After an AUS has been explanted, there should be a period of urethral rest to allow the previously devitalized tissue to heal. The duration of this period varies among surgeons. Outpatient cystoscopic and/or fluoroscopic urethrogram evaluation should be performed prior to proceeding with AUS replacement surgery to ensure the urethra is healed and patent. Patients must be thoroughly counseled on the higher incidence of overall device failure and specifically urethral erosion in this setting compared to primary

implantation, which can be up to 4 times higher (74-76). There is also an increased risk of superficial surgical site infections, however studies have shown that there may not be a statistically significant increase in device infection with secondary implantation (74,77).

Conclusions

The main goals of male SUI surgery are to provide the patient with satisfactory improvement in urinary continence and quality of life, while limiting device-related risks and complications, such as urethral erosion and device infection. Patient factors, device-specific considerations, and surgical approach decisions are among the many important principles that practicing urologists must consider to help prevent these dreaded complications and properly navigate them when they do occur. Extensive patient counseling is important prior to any AUS surgery, but especially in patients with a history of prior device explant due to urethral erosion and/or device infection.

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