

# Urology Update

## New Cover Image

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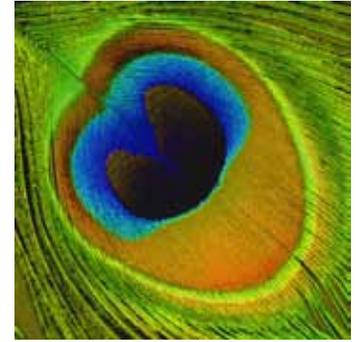
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**MESSAGE FROM MARK A. HABER, M.D., F.A.C.S**

AT GEORGIA UROLOGY, we are one of the largest practices focusing on our specialty in both the Southeast and the United States. There are advantages to such size and scale. One of them is that it allows us to stay on top of and offer our patients the latest in medical technology.

In this issue of *Urology Update*, Dr. Ronald Anglade discusses new technologies for treating Benign Prostatic Hyperplasia (BPH), including the UroLift System and Rezum system.

Among cutting-edge technologies in surgery is the use of robotic machines. Dr. Scott Miller, medical director of the advanced laparoscopic and robotic surgery program at Northside Hospital, provides insights for readers in his article about how best to choose a robotic surgeon.

In terms of kidney stones and technology, Dr. Edan Shapiro describes the use of Extracorporeal Shock Wave Lithotripsy in his article. Also in this issue, Dr. Charles Kaplan provides some advice for men who suffer from erectile dysfunction “when the little blue pill fails,” and Dr. Jerry Yuan describes treatments for vasectomy and vasectomy reversal and their respective success rates.

In pediatrics, Dr. Andrew Kirsch explains the condition of undescended testicles and how we treat it. In my article, I wrote about treatments for overactive bladder for both men and women.

We hope you find this magazine informative. It is our pleasure to share information. As always, we invite your feedback as well.

A special thank you to our physicians, staff members, and partners whose efforts made this fourth edition of *Urology Update* possible.

Thank you.

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The information contained in this publication is not intended to replace a physician’s professional consultation and assessment. Please consult your physician on matters related to your personal health.

# Georgia Urology First in the Southeast to Introduce Innovative Technology to Treat Enlarged Prostate

By Ronald Anglade, M.D.

**Benign Prostatic Hyperplasia (BPH)** is a very common condition in which the prostate enlarges as men get older. More than 70 percent of men in their 60s have symptoms of BPH, which affects more than 500 million men worldwide.<sup>1</sup> While BPH is a benign (non-cancerous) condition, it can cause loss of productivity and sleep, depression, and decreased quality of life.

It is common for men with BPH to experience symptoms such as:

- A frequent need to urinate both day and night
- Weak or slow urinary stream
- A sense of not being able to empty the bladder completely
- Difficulty or delay in starting urination
- Urgent feeling of needing to urinate
- A urinary stream that stops and starts

Many men who experience mild symptoms may choose to do nothing, or “watchfully wait.” However, the prostate gland does continue to grow over time, so seeking treatment with a urologist is recommended — an idea that men who suffer from the condition have to come to terms with.

## BPH Treatment Options

Treatment options for BPH range from medications to surgery, with minimally invasive options in between. It is important to consult with your physician to know which option is best for you.

### Medications

Your doctor might prescribe medications to manage your symptoms. These medications include alpha blockers and alpha reductase inhibitors. Alpha blockers relax the muscles around the neck of your bladder, making it easier to urinate, while alpha reductase inhibitors act to shrink the prostate.

While medications can be helpful in relieving symptoms for some men, patients must continue taking them long-term to keep their symptoms in check.

Some patients might suffer side effects, which include dizziness, headaches, and sexual dysfunction. Some patients might not get adequate relief of their symptoms. More than 17 percent of men on medication for BPH discontinue treatment early for reasons such as dissatisfaction with side effects or failure to get adequate symptom relief.<sup>2</sup>

## Transurethral Resection of the Prostate (TURP)

Transurethral Resection of the Prostate (TURP) is the most common surgical procedure to treat BPH. During this procedure, patients undergo general anesthesia, and prostate tissue is removed. TURP is often considered the “gold standard” for long-term results.

After prostate tissue has been removed, the body needs time to heal. The remaining prostate tissue might actually swell and become inflamed before the desired shrinking effect occurs. Patients might suffer an uncomfortable recovery period that includes short-term problems such as bleeding, infection, erectile dysfunction, and urinary incontinence.

Patients who undergo a TURP procedure must have a catheter attached to a urine bag inserted into their bladder for several days after the procedure. Symptom relief might not occur immediately, but once relief does come, it lasts for a long time in many patients. As with any medical procedure, patients can suffer from long-term side effects. These include dry orgasm (retrograde ejaculation), erectile dysfunction, and incontinence (leaking of urine).

## Laser Resection of the Prostate

TURP may be performed with a laser in procedures called photoselective vaporization of the prostate (PVP) or holmium laser enucleation (HoLEP). Laser therapy lessens the bleeding risks of traditional TURP. However, since prostate tissue is still removed, there can be tissue swelling and an uncomfortable healing time. Typically, a patient who undergoes one of these procedures has to have a catheter inserted into the bladder.

## Thermotherapies

Thermotherapies are minimally invasive treatments where heat energy such as microwave or radiofrequency is applied to destroy prostate tissue. Less invasive than TURP, these treatments are generally safe, can be performed under local anesthesia, and provide moderate symptom relief for some patients.

Applying high heat to the prostate can cause tissue swelling and uncomfortable urinary symptoms during the healing period. Symptom relief does not occur immediately and patients often need to have a catheter that is attached to a urine bag inserted into their bladder during the recovery period.



### The UroLift System

In 2013, the U.S. Food and Drug Administration cleared the UroLift System, a minimally invasive procedure, to treat an enlarged prostate. UroLift is a simple procedure that does not require any cutting, heating, or removal of prostate tissue.

The UroLift procedure is performed by a urologist and can be done in an office setting or in the hospital on an outpatient basis. The urologist uses the UroLift device to lift and move the enlarged prostate tissue out of the way so it no longer blocks the urethra (the passageway that urine flows through). Tiny implants are placed to hold the tissue in place, like tiebacks on a window curtain. The UroLift device is removed, leaving an unobstructed urethra for urine to flow normally again.

Georgia Urology was the first group in Georgia to offer the UroLift System. The practice has performed more procedures than anyone else in the Southeast.

### What Are the Benefits of the UroLift System?

The UroLift System procedure is a safe and simple treatment option that offers rapid symptom relief for men suffering from BPH. While other options tend to require the use of a catheter post-procedure, UroLift does not. It also preserves sexual function and does not involve cutting, heating, or removal of prostate tissue. Clinical studies have shown that the procedure provides a similar level of symptom relief, with fewer side effects.<sup>4</sup>

### Side Effects of the UroLift System

Compared to other BPH surgeries, UroLift has minimal side effects.<sup>3</sup> The most common adverse events reported include blood in the urine (hematuria), pain or burning upon urination (dysuria), a sudden, compelling urge to urinate known as micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.

### The Rezum System

At Georgia Urology, some of our physicians also use a new minimally invasive procedure known as Rezum, which can be performed in a clinic or on an outpatient basis. The physician uses a hand-held device that applies radiofrequency energy to a few drops of water to create vapor. Through a transurethral needle, the water vapor, also known as steam, is injected into the prostate tissue that has blocked the flow of urine. The water vapor kills the extra prostate tissue. Over time, the body absorbs the treated tissue through the natural healing process.

The procedure can provide noticeable improvement within two weeks and does not require general anesthesia. It also preserves sexual and urinary functions.

#### References

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# Vasectomies and Vasectomy Reversals: What to Know

By Jerry Yuan, M.D.



**Getting a vasectomy**, once a permanent and non-reversible decision, is now a potentially more flexible birth control option for men who might one day wish to father children naturally, thanks to improvements in reversal techniques. Even men who had the procedure performed years ago now have options for possibly reversing their vasectomies.

Do keep in mind sperm banking is readily available and is an option you should discuss with your partner prior to proceeding with a vasectomy.

Understanding how vasectomies work and the techniques used in the performing and reversing them will help you make the right decision for your situation.

## How Do Vasectomies Work?

A doctor may use one of two mostly similar methods to perform a vasectomy. One method requires the doctor to make one or two incisions in your scrotal sac. The doctor then blocks the tubes, vas deferens, that carry sperm (which is created in your testicles) to the prostate to allow for the sperm to be part of the ejaculate. This will prevent the sperm from entering a female and causing pregnancy. The other method your doctor may use is a minimally traumatic entry via a puncture, rather than an incision, to reach the

tubes. The incisional procedure takes about 20 minutes and leaves one or two small scars, while the puncture method takes even less time and heals quicker.

A typical vasectomy is performed in the office or a designated surgical facility under local anesthesia (you're awake during the procedure) or light sedation such as oral valium. You might get a general anesthesia (you go to sleep) if you prefer or as deemed necessary by your doctor. With a local anesthesia, you might feel some minimal discomfort during the short procedure, not unlike that of a dentist's visit.

After a vasectomy, you might feel some pain and discomfort for a day or two, but should be able to return to work shortly after that. Your doctor will prescribe a pain medication. Ice is another initial option to ease the pain. Most folks do well with over the counter pain relief medications such as Tylenol & Aleve.

You should be able to begin having sex again within a week, although your vasectomy will take about three to six months to be determined to be successful, so you'll need to use birth control during that time period.

## What Happens After I Have a Vasectomy?

After a vasectomy, you'll still have an ejaculate during sex, complete

with the same seminal fluid but minus the sperm. The sperm that's blocked from leaving your testicles is harmlessly absorbed by the genital track upstream to the vasectomy. You and your partner shouldn't notice any difference in your performance. Your erection or stamina shouldn't decrease and you'll produce the similar volume of ejaculate, your testosterone levels won't change, and you will not have a decrease in penile sensitivity or pleasure. The only end result of vasectomy is the physical transport of sperm toward the prostate and ejaculation; none of the other male sexual functions are impacted.

In addition, your testicles will continue to create sperm, which you can harvest for an in-vitro fertilization, if desired. You can also try a vasectomy reversal if you'd like to father children in the future.

### Effectiveness of Vasectomies

Vasectomies are a highly reliable and effective means of male birth control. Short term or early failure rate is about 0.5 to 1 percent in the first few months. After the initial period of three to six months and once verified to be successful, vasectomies should remain nearly 100 percent effective (1 in 2,000 late failure). Immediately after a vasectomy is performed, sperm still resides in the tubes that were blocked. To be safe, you'll need to use other birth control methods during sex for about 90 days. You'll provide your doctor with a semen sample after this initial waiting period to make sure your seminal fluid is sperm-free.

About 20 percent of men will need more than three months before their semen is clear of sperm, according to the National Institutes of Health. Here's how the NIH compares birth control effectiveness rates:

- Vasectomy: 10-20 couples out of every 10,000 get pregnant
- Birth control pills: 500 couples out of every 10,000 get pregnant
- Condoms: 1,400 couples out of every 10,000 get pregnant

### What Are the Risks?

The main risks of a vasectomy are not specific to this type of surgery. Rather, the risks are the same ones you have with any other surgery, such as a post-operative infection or other complications. In rare cases, there could be long-term pain or sensitivity necessitating additional treatment or procedures. About 1 in 250 men experience some desire or performance issues, but these stem from psychological issues, not the physical surgery. According to Planned Parenthood's FAQ page on vasectomies, "There is no physical cause for sexual dysfunction associated with vasectomy."

### Can Vasectomies Be Reversed?

Vasectomies can be reversed with the chance of any reversal procedure working — depending on several factors. Those include the time interval when the original vasectomy was performed, the procedure used to perform the vasectomy, whether or not your body developed antibodies to work against the sperm, and the skill of the surgeon. A consultation with a doctor who specializes in vasectomy reversals will help you determine the likelihood your vasectomy can be successfully reversed.

Unlike a vasectomy, a reversal operation needs to be done under general anesthesia; the microscopic precision required simply can not be achieved or maintained under local anesthesia.

The reversal procedure required may be a straight-forward reversing of the vasectomy, where the two ends of the vas (vas to vas) are reconnected if the intraoperative findings are favorable; success rate may be as high as 90 percent for those who meet the most optimal criteria. Other men, especially those whose vasectomies were performed 10 years ago or more, may not qualify for this vas to vas procedure. The standard procedure may not suffice due to blockage upstream, which calls for a more tedious procedure called vas to epididymis. This procedure is technically challenging and can only be attempted by those with proper microsurgical training. Vas to epididymis typically results in a lower chance of success. Even if either procedure is successful, pregnancy rates will still vary based on a couple related factors, one of which is the fertility status of the partner. Determination of the surgical outcome may take up to six to 12 months as sperm count progressively improves in quantity and quality.



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# What You Should Know About Undescended Testicles

By Andrew J. Kirsch, M.D., F.A.A.P., F.A.C.S.

*The condition of cryptorchidism, more commonly known as undescended testicles, affects about one in every 25 full-term infants. Cryptorchidism is a condition at birth in which one or both testicles remain in the upper scrotum, groin, or abdomen and have not been positioned properly in the scrotum.*

## Why It Matters

The testicles are strategically located in the scrotum, which maintains a lower temperature than the rest of the body. Once young boys have their testicles in the proper place, it can reduce the risk of problems that can arise later, including infertility and testicular cancer.

In fact, it's estimated that a male with an undescended testicle is between four and 10 times more likely to develop testicular cancer than a male whose testicles are in their normal position. The variance depends on how high up the testicle is located.

The good news is that an undescended testicle usually corrects itself

in more than half of the cases by six months' of age. However, after this time, descent of the testicles is unlikely and current guidelines recommend that a child who continues to experience this condition should be examined by a pediatric urologist. The situation becomes even more critical in the older child, when, if the testicles are still undescended, the risk of testicular damage exists.

## The 'Retractile' Testicle

Some children who were born with normal, descended testicles will later find that a testicle appears to be missing. What could be the cause? Sometimes, due to a muscle reflex, a testicle moves back and forth between the groin and the scrotum. This is not an undescended testicle but what is known as a "retractile testicle," and it is easily diagnosed by a physician who can manipulate the testicle into the scrotum where it should remain during a physical exam. Most cases resolve by age 7. However, in about 10 percent of cases, a testicle might move into the groin, or "ascend," and become undescended. In that case, surgery is needed.



## What Causes an Undescended Testicle?

The cause of undescended testicles is unknown, but it may be related to genetics or even to environmental factors that affect the hormones or nerve activity related to testicular development. It is believed that pregnant mothers who smoke, use alcohol, or who are exposed to second-hand smoke or certain pesticides may be more likely to give birth to a child with an undescended testicle.

## Diagnosis

Sometimes an undescended testicle can be felt as a small bump in the groin, but for a more accurate diagnosis in testicles that cannot be felt, laparoscopy (a minimally invasive procedure during which a small camera is inserted into the abdomen with the child under general anesthesia), is effective — not only to find the undescended testicle but, in some cases, to bring it down to the scrotum (a procedure called as “orchidopexy”). At times, laparoscopy will reveal that there is no testicle present. It also might reveal only a small amount of non-functioning testicle tissue, which can then be removed. The use of imaging studies, such as ultrasound, is not recommended to identify undescended testicles.

## Surgery

In most cases, surgery is not recommended for a child who is younger than six months’ of age, but after that period the child should be able to handle anesthesia and the operation itself. During an orchidopexy, the child is placed under general anesthesia. In the overwhelming majority of circumstances, the procedure can be done on an outpatient basis and the child can return to his usual activities within a day or two. Older and more active boys can usually return to full physical activity with two weeks.

During the procedure itself, the surgeon makes an incision about an inch long in the groin and/or scrotum. In most circumstances, the scar from the incision ultimately is barely visible. The surgeon frees the testicle from nearby tissues so that it is allowed to move easily into the scrotum and then he stitches it into place. In some cases, the testicle cannot be freed via an orchidopexy, as it is too high in the abdomen. In these cases, more complex methods are required and, at times, multiple or “staged” surgeries. No parent likes to think of submitting their young child to such a procedure, but orchidopexy boasts a success rate of 98 percent and can prevent further problems.

## A Success Story

The following success story comes from a mother named Richele, who posted the account on the website [berkeleyparentsnetwork.org](http://berkeleyparentsnetwork.org). Richele’s story is reassuring (and informative) for parents who have a son with an undescended testicle.

Our boy was two when we took him for surgery on an undescended testicle... It’s important for parents to know what to expect and to prepare psychologically for the event. It is imperative that parents present a calm reassuring demeanor to the infant/child, and believe me it’s not easy to watch your little one go through this. Your infant must go without anything in his stomach for many hours before the surgery; the time of day for the surgery is important to consider with this in mind. We, for example, chose the first surgery of the day. I was there after he awoke from anesthesia, scooping him up in my arms in his favorite blankie and nursing him. He was fine and is now a happy, healthy almost 5-year-old. If you have questions about the doctor, ask directly about his/her experience with this specific surgery. When I asked our doctor this, he said he had done thousands of these surgeries and had only a handful of very correctable problems.

*Andrew J. Kürsch, MD is Professor and Chief of Pediatric Urology at Emory University School of Medicine, Director of Robotic Surgery at Children’s Healthcare of Atlanta, and partner at Georgia Urology. Georgia Urology is the largest urology practice in Atlanta and the Southeast. Our board certified urologists provide the finest urologic care available and strive for the best outcomes for all of our patients.*

# Kidney Stones

By Edan Y. Shapiro, M.D.

**It’s hard to believe** that something so small could cause such excruciating pain...until you experience a kidney stone making its way through your urinary tract.

Technically known as “urolithiasis” or “urinary calculus,” kidney stones are hard, pebble-like pieces of material formed in the kidneys by high concentrations of certain minerals in urine. They can be smooth or jagged, and can range in size from a grain of sand to (rarely) as big as a golf ball.

Kidney stones are a common affliction. Evidence of them has been found in Egyptian mummies more than 4,000 years old. During the 1800s they were commonly known as “gravel.” Today, they affect nearly 1 in 10 Americans. And, if you’ve ever had one, odds are good you’ll have another one in the future.

Extremely small kidney stones often pass from the kidneys down the ureters into the bladder and out the urethra with little or no pain. But larger stones can get stuck along the way, causing severe pain and sometimes even bleeding. The good news, though, is that they rarely cause permanent damage if treated by a healthcare professional.

## Symptoms and Diagnosis

The symptoms of a kidney stone often appear without warning. They can include pain in the lower back or side, often radiating around to the abdomen. The pain can come and go in waves, and shift to different locations as the stone makes its way down the urinary tract.

Your physician can use lab and/or imaging tests to diagnose kidney stones. A urinalysis can often help determine whether or not a stone is likely to be present, and can also help your doctor to determine exactly what type of stone you may have. Imaging tests, including abdominal x-rays and computed tomography (CT) scans, are used to determine the position and size of stones.

*Continued on page 10*



doctor to determine how you may be able to prevent future occurrences.

Sometimes kidney stones are so large that they cannot be passed, and, in those cases, they become lodged in the kidney or within the ureter on their way out. In these cases, a procedure performed by a urologist is necessary.

There are three main categories of procedures urologists perform to remove kidney stones.

**Extracorporeal Shock Wave Lithotripsy (ESWL)** is the least invasive of these procedures. Typically performed on an outpatient basis, it utilizes high frequency sound waves to break up kidney stones into smaller pieces, which can then pass through your urinary tract.

In **ureteroscopic** procedures, a special thin, lighted telescope is inserted through the urethra into the bladder, and then up the ureters and the kidneys so that the physician can see the stone. During this type of procedure, stones that are found can be broken into smaller pieces and removed. Sometimes a laser is used to break a large stone into smaller pieces.

A **percutaneous nephrolithotomy** is performed when a very large stone is lodged in the kidney. In this procedure, the urologist inserts a nephroscope, another type of lighted scope, directly into the kidney through a small incision in your back in order to locate and remove the kidney stone. Unlike the previous two types of procedure, this one usually requires a brief hospital stay.

#### Afterwards

Once the kidney stone has passed or been removed, your doctor will send pieces of it to a lab to learn more about its composition. You may also be asked to collect your urine for 24 hours in order to determine the levels of minerals it contains.

Based on these analyses, your doctor will be able to give you advice for avoiding more stones from forming in the future.

For **calcium oxalate** stones, the most common type of kidney stone, recommendations typically include making changes in your diet, including reducing sodium, limiting your intake of animal protein, and reducing the amount of foods you eat containing high levels of oxalates (such as spinach, beets, and tea).

The recommendations for avoiding **calcium phosphate** stones are similar, but with no restrictions indicated for oxalates. Those for **uric acid** stones focus on lowering the amount of animal protein in your diet.

And, for all types of kidney stones, you'll be advised to drink plenty of water. Unless you have kidney failure, healthcare professionals recommend that you drink between six and eight eight-ounce glasses each day.

#### Treatments

Depending primarily upon their size and location, your kidney stones can be treated in several ways.

For small stones, your doctor may advise you to do little more than drink lots of fluids – water is best – in order to flush the stone through the ureter and bladder, and finally out of your system. Your doctor might also prescribe a type of medication known as an “alpha blocker” that relaxes the muscles of the ureter, helping you pass your stone more quickly and with less pain.

This process might take a few days. To treat mild pain during this period, the doctor may have you take pain relievers containing ibuprofen, acetaminophen, or naproxen. Stronger medications can be used if your pain is more intense.

You may also be asked to urinate through a strainer to catch any stones that you pass. The results of a lab analysis will provide information on the composition of the stone, enabling your

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**Areas of Interest and Expertise:**

- › General Urology
- › Women's Health
- › Urologic Cancers
- › Kidney Stones



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**Areas of Interest and Expertise:**

- › Pediatric Urology
- › Pediatric Stone Disease
- › Congenital Genitourinary Diseases



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- › Men's Health
- › Prosthetic Urology
- › Male Fertility
- › Vasectomy Reversal



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**Areas of Interest and Expertise:**

- › General Urology
- › Women's Health
- › Laparoscopic and Robotic Surgery
- › Kidney Stones
- › Urologic Cancers



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**Areas of Interest and Expertise:**

- › General Urology
- › Kidney Stones



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**Areas of Interest and Expertise:**

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- › Kidney Stones
- › Men's Health
- › Overactive Bladder



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- › Pediatric Urology
- › Congenital hydronephrosis
- › Hypospadias



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**Areas of Interest and Expertise:**

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- › Childhood Renal Stones
- › Pediatric Laparoscopy and Robotic Surgery
- › Vesicoureteral Reflux
- › Hypospadias



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- › Women's Health
- › Kidney Stones
- › Men's Health
- › Vasectomy



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**Areas of Interest and Expertise:**

- › Men's Health
- › Kidney Stones
- › Overactive Bladder
- › Urologic Cancers
- › Urinary Incontinence





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- > Women's Health
- > Men's Health
- > Vasectomy (No Needle, No Scalpel)
- > Urologic Cancers
- > Kidney Stones



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- > InterStim Therapy
  - > Interstitial Cystitis
  - > Women's Health
  - > Men's Health



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- > Urologic Cancers
- > Robotic and Laparoscopic Surgery
- > Kidney Stones



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  - > Urologic Cancer
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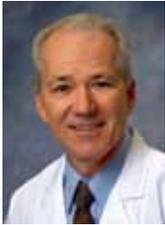
- > Women's Health
- > Men's Health
- > Robotic and Laparoscopic Surgery
- > Urologic Cancers



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**Areas of Interest and Expertise:**

- > Men's Health
- > Kidney Stones
- > Urologic Cancers



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- > General Urology



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- Areas of Interest and Expertise:**
- > Urologic Oncology
  - > Laparoscopic and Robotic Surgery
  - > Kidney Stones
  - > Vasectomy



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- > Urologic Cancers
- > Single Incision Laparoscopic Surgery (Kidney)
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  - > Vesicoureteral Reflux
  - > Hypospadias
  - > Penile Reconstruction
  - > Cryptorchidism



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- Areas of Interest and Expertise:**
- > General Urology
  - > Kidney Stones



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- › Robotic and Laparoscopic Surgery



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  - › Men's Health
  - › Erectile Dysfunction
  - › Kidney Stones
  - › Overactive Bladder



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- › Men's Health
  - › Laparoscopic and Robotic Surgery
  - › Pelvic Prolapse
  - › Erectile Dysfunction
  - › Prosthetic Urology



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  - › Men's Health
  - › Male Fertility
  - › Kidney Stones
  - › Vasectomy Reversal



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  - › Kidney Stones
  - › Women's Health
  - › Overactive Bladder
  - › Men's Health



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  - › Overactive Bladder
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  - › Interstitial Cystitis
  - › Kidney Stones



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- Areas of Interest and Expertise:**
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  - › Reconstructive Surgery
  - › Congenital Genitourinary Problems
  - › Pediatric Stone Disease



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- Areas of Interest and Expertise:**
- › Male Fertility
  - › Urologic Cancers
  - › Men's Health
  - › Kidney Stones
  - › Vasectomy Reversal

# Prevent Urologic Cancers From Affecting You and Your Family

By Barry M. Zisholtz, M.D., F.A.C.S

**Urologists** treat many different types of cancers. The most common cancer we see is prostate cancer. However, our patients also present with bladder, kidney, penile, and testicular cancer and occasionally some other very rare types of cancers.

There are lots of studies and recommendations on how to decrease the risks of acquiring various types of cancer. Interestingly enough, there are a few constants and proven risk factors that can decrease the risk of developing cancer, but unfortunately, there is no way to absolutely prevent the disease if there is a genetic component.

In addition, over the years certain things that were thought to cause cancer might end up being helpful and vice versa. Studies continue to be performed to better identify various risk factors.

It is important to realize that all cancers are not the same, and there are frequently genetic components to different types of cancer.

## Bladder Cancer

Bladder cancer also can be partially attributed to exposure to various chemicals and paint products.

Suffice it to say, that smoking is a significant risk factor for bladder and kidney cancer and many other non-urologic cancers. Clearly, there are other risks, some known and some not known but cigarettes contain known carcinogens that can help cause cancer.

## Kidney Cancer

Kidney cancer is at times related to a genetic predisposition but frequently can be attributed to smoking and other risk factors that are unknown at this time.

## Prostate Cancer

Prostate cancer has been at times attributed to a high-fat diet. Approximately 15 to 20% of prostate cancer can be related to genetic predisposition.

## Penile/Scrotal Cancer

Penile and scrotal cancer are related to various chemical exposures as well as the exposure to human papilloma virus which is a sexually-transmitted disease (HPV).

In this country cancer of the penis is quite rare likely related to the



frequency of circumcision, but in other countries, cancer of the penis is much more common when routine circumcision is not performed.

Also, the prevention of STDs with the use of condoms can decrease the risk of penile cancer.

## General Tips

As we said earlier, the research continues and sometimes what is shown to be beneficial today is shown to be detrimental in the future.

What seems to be very humbling, is that our genes play a tremendous role.

- Environmental exposure is also very important and how much of an individual's disease is related to their individual genetics is not known.
- We all know people that have very bad habits, such as smoking and being overweight but live long lives without developing cancer, and the opposite is also true.
- In terms of coffee intake, artificial sweeteners, the use of aspirin, and the use of antioxidants, none of these are 100% proven to cause or prevent cancer.

So as health-conscious individuals, the best we can do is lead a healthy lifestyle, avoid smoking, exercise regularly, and eat a healthy diet rich in fruits and vegetables. If there is a genetic and family history, go for frequent examinations so that early detection can hopefully save your life.



# Erectile Dysfunction: When the Little Blue Pill Fails

By Charles Kaplan, M.D.

**An estimated 10 percent** of adult males will experience long-term erectile dysfunction, or ED, at some point in their lives. Generally, a failure to achieve an erection less than 20 percent of the time does not constitute a condition that needs to be treated. But for those who have an ongoing issue with getting or maintaining an erection and who also might experience reduced sexual desire, medical attention may be beneficial.

One of the most popular treatments for erectile dysfunction is the drug that goes by the commercial name Viagra (Sildenafil), also known colloquially as “the little blue pill.” Similar oral medications include Cialis (Tadalafil), Levitra (Vardenafil), and Stendra (Avanafil).

A common misunderstanding is that oral medications cause stimulation and erection. All they really do is heighten the signal that causes the release of nitric oxide from the penile nerves. Stimulation is still needed, but the medication removes the roadblock.

However, pills can have side effects, including headache, flushing, stomach upset, and nasal congestion — not the stuff of a great romantic encounter. It also has been reported that pills for ED do not work for about one-third of the men who use them, and that the drugs lose their effectiveness and stop working after a few years.

Fortunately, options in addition to medication exist. So what can you do when the little blue pill fails?

## Underlying Physical Issues

First, look at your overall health. Do you smoke, overdrink, or have diabetes? In most cases, erectile dysfunction can be linked to a physical issue. Common factors associated with erectile dysfunction (besides those noted above) include high cholesterol, heart disease, substance abuse, and injuries to the pelvic area—to name just a few. “Before pursuing ED treatments,” recommends the AARP website, “bear in mind that improving heart health by losing weight, eating a healthier diet, exercising more, and quitting smoking typically enhances erectile performance as well as one’s overall health.”

## Underlying Psychological Issues

In the film *Sleeper*, actor/director Woody Allen called the brain “my second favorite organ.” All kidding aside, he might have had his priorities reversed, because the brain is really the main star in sexual performance (or lack thereof). The fact is that erectile dysfunction can be caused (or made worse) by stress, anxiety, depression, or by other matters related to cognitive health. “The brain plays a key role in triggering the series of physical events that cause an erection, starting with feelings of sexual excitement,” according to a post on the Mayo Clinic website. Counseling can help address those issues, and it can also help a couple learn to deal with the problem constructively and as a team.

In some cases, physical and psychological issues combine. For example, a physical condition (such as diabetes) that contributes to erectile dysfunction might lead to worry about performance — an anxiety that can make erectile dysfunction even worse.



Whether the cause is physical, psychological, or both, have a physician evaluate your situation and your medical history so that you can begin the path to a more satisfying sex life.

### Other Treatments

Oral medications make up just one approach to treating erectile dysfunction. Others include:

- The vacuum erection device (also known as the penis pump). This cylinder-shaped tube fits over the penis and draws blood (via air suction) into the penis. After removing the pump, the user puts an elastic band around the base of the penis to keep the blood where it belongs and hence maintain the erection. The disadvantage: It's a killer to spontaneity.
- Injections and suppositories, like the vacuum erection device, injections increase blood flow to the penis, but without having to use a pump. Suppositories do the same, minus the needle. The disadvantage of injections and suppositories is that many who have tried these methods report a burning sensation. As Dr. Drogo Montague, quoted on the AARP website, puts it: "A man will get an erection but be too uncomfortable to use it." And although a suppository is as small as a grain of rice and is painless to insert, the biggest discomfort may be the cost — up to \$30 per suppository. Another downer: It's reported that less than half of those men who use it have success.

### Surgery

Surgical implants are not recommended as a first option, but they have a high degree of success. With this treatment, inflatable pumps (activated on demand) or semi-rigid rods are inserted on both sides of the penis. The pump prosthesis is reliable, and most work for as long as 15 years. The disadvantage: There is a small risk of complication, such as infection.

In the end, there are a variety of treatments for erectile dysfunction, but your best shot is to understand the underlying cause. This can be a "which came first, the chicken or the egg" conundrum, especially when it comes to psychological issues. In other words, "Am I overanxious because I have erectile dysfunction or do I have erectile dysfunction because I am overanxious?"

With a perceptive physician and a forthright patient, however, the problem of erectile dysfunction can be addressed successfully.

*Georgia Urology is the largest urology practice in Atlanta and the Southeast. Our board-certified urologists provide the finest urologic care available and strive for the best outcomes for all of our patients.*

**Caution:** "Before using any supplement, check with your doctor to make sure it's safe for you — especially if you have chronic health conditions. Some alternative products that claim to work for erectile dysfunction can be dangerous. The Food and Drug Administration (FDA) has issued warnings about several types of 'herbal Viagra' because they contain potentially harmful drugs not listed on the label. The dosages might also be unknown, or they might have been contaminated during formulation." — Mayo Clinic website.

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1. Roehrborn, 2015 Urology Practice, 2-Year L.I.F.T. Study Results;  
2. McVary, 2014 J Sexual Medicine; 3. Shore, 2014 Can J Urology;  
4. Roehrborn, et al., Can J Urol, 2015 Three year results of the prostatic urethral L.I.F.T. Study

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### Important Safety Information for XIAFLEX®

**WARNING: CORPORAL RUPTURE (PENILE FRACTURE) OR OTHER SERIOUS PENILE INJURY IN THE TREATMENT OF PEYRONIE'S DISEASE**

Corporal rupture (penile fracture) was reported as an adverse reaction in 5 of 1044 (0.5%) XIAFLEX®-treated patients in clinical studies. In other XIAFLEX®-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 (3.7%) XIAFLEX®-treated patients.

Signs or symptoms that may reflect serious penile injury should be promptly evaluated to assess for corporal rupture or severe penile hematoma which may require surgical intervention.

Because of the risks of corporal rupture or other serious penile injury, XIAFLEX® is available for the treatment of Peyronie's disease only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX® REMS Program.

- XIAFLEX® is contraindicated in the treatment of Peyronie's plaques that involve the penile urethra due to potential risk to this structure and in patients with a history of hypersensitivity to XIAFLEX® or to collagenase used in any other therapeutic application or application method
- Injection of XIAFLEX® into collagen-containing structures such as the corpora cavernosa of the penis may result in damage to those structures and possible injury such as corporal rupture (penile fracture). Therefore, XIAFLEX® should be injected only into the Peyronie's plaque and care should be taken to avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis



- In the double-blind, placebo-controlled portions of the clinical trials in Peyronie's disease, a greater proportion of XIAFLEX<sup>®</sup>-treated patients (4%) compared to placebo-treated patients (1%) had localized pruritus after up to 4 treatment cycles (involving up to 8 XIAFLEX<sup>®</sup> injection procedures). The incidence of XIAFLEX<sup>®</sup>-associated pruritus was similar after each injection regardless of the number of injections administered
- Because XIAFLEX<sup>®</sup> contains foreign proteins, severe allergic reactions to XIAFLEX<sup>®</sup> can occur. Anaphylaxis was reported in a post-marketing clinical trial in one patient who had previous exposure to XIAFLEX<sup>®</sup> for the treatment of Dupuytren's contracture. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX<sup>®</sup> injections. The safety of more than one treatment course of XIAFLEX<sup>®</sup> is not known
- In the XIAFLEX<sup>®</sup> controlled trials in Peyronie's disease, 65.5% of XIAFLEX<sup>®</sup>-treated patients developed penile hematoma, and 14.5% developed penile ecchymosis. Patients with abnormal coagulation (except for patients taking low-dose aspirin, eg, up to 150 mg per day) were excluded from participating in these studies. Therefore, the efficacy and safety of XIAFLEX<sup>®</sup> in patients receiving anticoagulant medications (other than low-dose aspirin, eg, up to 150 mg per day) within 7 days prior to XIAFLEX<sup>®</sup> administration is not known. In addition, it is recommended to avoid use of XIAFLEX<sup>®</sup> in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin)
- In the XIAFLEX<sup>®</sup> clinical trials for Peyronie's disease, the most frequently reported adverse drug reactions ( $\geq 25\%$ ) and at an incidence greater than placebo included: penile hematoma, penile swelling, and penile pain

Please see Brief Summary of full Prescribing Information, including Boxed Warning, on adjacent pages.

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### Brief Summary of Prescribing Information

For complete information, see the full prescribing information for XIAFLEX.

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Corporal rupture (penile fracture) was reported as an adverse reaction in 5 of 1044 (0.5%) XIAFLEX-treated patients in clinical studies. In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 (3.7%) XIAFLEX-treated patients [see *Warnings and Precautions*].

Signs or symptoms that may reflect serious penile injury should be promptly evaluated to assess for corporal rupture or severe penile hematoma which may require surgical intervention [see *Warnings and Precautions*].

Because of the risks of corporal rupture or other serious penile injury, XIAFLEX is available for the treatment of Peyronie's disease only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the XIAFLEX REMS Program [see *Warnings and Precautions*].

### INDICATIONS AND USAGE

XIAFLEX is indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

### DOSAGE AND ADMINISTRATION

#### Dosing Overview for Peyronie's Disease

XIAFLEX should be administered by a healthcare provider experienced in the treatment of male urological diseases, who has completed required training for use of XIAFLEX in the treatment of Peyronie's disease. XIAFLEX, supplied as lyophilized powder, must be reconstituted with the provided diluent prior to use [see *Dosage and Administration* (2.2)]. The dose of XIAFLEX is 0.58 mg per injection administered into a Peyronie's plaque. If more than one plaque is present, inject into the plaque causing the curvature deformity. A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of two XIAFLEX injection procedures [see *Dosage and Administration* (2.2)] and one penile modeling procedure [see *Dosage and Administration* (2.2)]. The second XIAFLEX injection procedure is performed 1 to 3 days after the first. The penile modeling procedure is performed 1 to 3 days after the second injection of the treatment cycle. The interval between treatment cycles is approximately six weeks. The treatment course therefore, consists of a maximum of 8 injection procedures and 4 modeling procedures. If the curvature deformity is less than 15 degrees after the first, second or third treatment cycle, or if the healthcare provider determines that further treatment is not clinically indicated, then the subsequent treatment cycles should not be administered.

The safety of more than one treatment course of XIAFLEX is not known.

The table below displays an overview of the volume of sterile diluent for reconstitution and the reconstituted XIAFLEX solution to be used in the intralesional injection [see *Dosage and Administration* (2.2)].

#### Volumes Needed for Reconstitution and Administration

Sterile Diluent for Reconstitution	
Volume	0.39 mL
Reconstituted XIAFLEX Solution to be Injected <sup>1</sup>	
Volume	0.25 mL

<sup>1</sup> The reconstituted XIAFLEX solution to be used in the intralesional injection contains 0.58 mg of XIAFLEX. Note: The entire reconstituted XIAFLEX solution contains 0.9 mg of XIAFLEX. Reconstituted XIAFLEX solution remaining in the vial after the injection should be discarded.

#### Reconstitution of the Lyophilized Powder for Peyronie's Disease

- Before use, remove the vial containing the lyophilized powder of XIAFLEX and the vial containing the diluent for reconstitution from the refrigerator and allow the two vials to stand at room temperature for at least 15 minutes and no longer than 60 minutes. Visually inspect the vial containing XIAFLEX. The cake of lyophilized powder should be intact and white in color.
- After removal of the flip-off cap from each vial, using aseptic technique swab the rubber stopper and surrounding surface of the vial containing XIAFLEX and the vial containing the diluent for reconstitution with sterile alcohol (no other antiseptics should be used).
- Use only the supplied diluent for reconstitution. The diluent contains calcium which is required for the activity of XIAFLEX.
- Using a 1 mL syringe with 0.01 mL graduations with a 27-gauge ½-inch needle (not supplied), withdraw a volume of 0.39 mL of the diluent supplied.
- Inject the diluent slowly into the sides of the vial containing the lyophilized powder of XIAFLEX. Do not invert the vial or shake the solution. Slowly swirl the solution to ensure that all of the lyophilized powder has gone into solution.
- The reconstituted XIAFLEX solution can be kept at room temperature (20° to 25°C/68° to 77°F) for up to one hour or refrigerated at 2° to 8°C (36° to 46°F) for up to 4 hours prior to administration. If the reconstituted XIAFLEX solution is refrigerated, allow this solution to return to room temperature for approximately 15 minutes before use.
- Discard the syringe and needle used for reconstitution and the diluent vial.

#### Identification of Treatment Area for Peyronie's Disease

- Prior to each treatment cycle, identify the treatment area as follows:
  - Induce a penile erection. A single intracavernosal injection of 10 or 20 micrograms of alprostadil may be used for this purpose. Apply antiseptic at the site of the injection and allow the skin to dry prior to the intracavernosal injection.
  - Locate the plaque at the point of maximum concavity (or focal point) in the bend of the penis.
  - Mark the point with a surgical marker. This indicates the target area in the plaque for XIAFLEX deposition.

#### Injection Procedure for Peyronie's Disease

- The reconstituted XIAFLEX solution should be clear. Inspect the solution visually for particulate matter and discoloration prior to administration. If the solution contains particulates, is cloudy, or is discolored, do not inject the reconstituted solution.
- Apply antiseptic at the site of the injection and allow the skin to dry.
- Administer suitable local anesthetic, if desired.

- Using a new hubless syringe containing 0.01 mL graduations with a permanently fixed 27-gauge ½-inch needle (not supplied), withdraw a volume of 0.25 mL of reconstituted solution (containing 0.58 mg of XIAFLEX).
- The penis should be in a flaccid state before XIAFLEX is injected. Place the needle tip on the side of the target plaque in alignment with the point of maximal concavity. Orient the needle so that it enters the edge of the plaque and advance the needle into the plaque itself from the side. Do not advance the needle beneath the plaque nor perpendicularly towards the corpora cavernosum.
- Insert and advance the needle transversely through the width of the plaque, towards the opposite side of the plaque without passing completely through it. Proper needle position is tested and confirmed by carefully noting resistance to minimal depression of the syringe plunger.
- With the tip of the needle placed within the plaque, initiate injection, maintaining steady pressure to slowly inject XIAFLEX into the plaque. Withdraw the needle slowly so as to deposit the full dose along the needle track within the plaque. For plaques that are only a few millimeters in width, the distance of withdrawal of the syringe may be very minimal. The goal is always to deposit the full dose entirely within the plaque.
- Upon complete withdrawal of the needle, apply gentle pressure at the injection site. Apply a dressing as necessary.
- Discard the unused portion of the reconstituted solution and diluent after each injection. Do not store, pool, or use any vials containing unused reconstituted solution or diluent.
- The second injection of each treatment cycle should be made approximately 2 to 3 mm apart from the first injection.

#### Penile Modeling Procedure for Peyronie's Disease

Penile modeling helps relieve curvature deformity and straighten the penile shaft. At a follow-up visit 1 to 3 days after the second injection of each treatment cycle, perform a penile modeling procedure (as described below) on the flaccid penis to stretch and elongate the treated plaque:

- Administer suitable local anesthetic, if desired.
- Wearing gloves, grasp the plaque or indurated portion of the flaccid penis about 1 cm proximal and distal to the injection site. Avoid direct pressure on the injection site.
- Using the target plaque as a fulcrum point, use both hands to apply firm, steady pressure to elongate and stretch the plaque. The goal is to gradually create bending opposite to the patient's penile curvature, with stretching to the point of moderate resistance. Hold pressure for 30 seconds then release.
- After a 30 second rest period, repeat the penile modeling technique for a total of 3 modeling attempts at 30 seconds for each attempt.

In addition to the in-office penile modeling procedure, patients should be instructed to self-perform penile modeling activities at home each day for the 6-week period following the investigator penile plaque modeling visit of each treatment cycle as follows:

- During spontaneous erections, gently attempt to straighten the penis without producing pain and hold the penis in a straightened position for 30 seconds.
- The flaccid penis should be gently stretched three times daily. Slow, gentle force should be used without producing pain.

### CONTRAINDICATIONS

XIAFLEX is contraindicated in:

- the treatment of Peyronie's plaques that involve the penile urethra due to potential risk to this structure.
- patients with a history of hypersensitivity to XIAFLEX or to collagenase used in any other therapeutic application or application method [see *Warnings and Precautions*].

### WARNINGS AND PRECAUTIONS

#### Corporal Rupture (Penile Fracture) or Other Serious Injury to the Penis in the Treatment of Peyronie's Disease

Corporal rupture was reported as an adverse reaction after XIAFLEX injections in 5 of 1044 (0.5%) XIAFLEX treated patients in the controlled and uncontrolled clinical trials in Peyronie's disease.

In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture can not be excluded. These patients were managed without surgical intervention, but the long-term consequences are unknown.

Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 patients (3.7%) in the controlled and uncontrolled clinical trials in Peyronie's disease [see *Adverse Reactions*].

Signs or symptoms that may reflect serious injury to the penis should be promptly evaluated in order to assess for corporal rupture or severe penile hematoma, which may require surgical intervention.

Injection of XIAFLEX into collagen-containing structures such as the corpora cavernosa of the penis may result in damage to those structures and possible injury such as corporal rupture (penile fracture). Therefore, XIAFLEX should be injected only into the Peyronie's plaque and care should be taken to avoid injecting into the urethra, nerves, blood vessels, corpora cavernosa or other collagen-containing structures of the penis.

#### XIAFLEX REMS Program

Because of the risks of corporal rupture (penile fracture) or other serious penile injury in the treatment of Peyronie's disease, XIAFLEX is available only through the XIAFLEX REMS Program [see *Warnings and Precautions*].

Required components of the XIAFLEX REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training in the administration of XIAFLEX treatment for Peyronie's disease.
- Healthcare sites must be certified with the program and ensure that XIAFLEX is only dispensed for use by certified prescribers.

Further information is available at [www.XIAFLEXREMS.com](http://www.XIAFLEXREMS.com) or 1-877-313-1235.

#### Hypersensitivity Reactions, including Anaphylaxis

In the double-blind, placebo-controlled portions of the clinical trials in Peyronie's disease (Studies 1 and 2), a greater proportion of XIAFLEX-treated patients (4%) compared to placebo-treated patients (1%) had localized pruritus after up to 4 treatment cycles (involving up to 8 XIAFLEX injection procedures). The incidence of XIAFLEX-associated pruritus was similar after each injection regardless of the number of injections administered.

Because XIAFLEX contains foreign proteins, severe allergic reactions to XIAFLEX can occur. Anaphylaxis was reported in a post-marketing clinical trial (Study 3) in one patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture. Some patients with Dupuytren's contracture developed IgE-anti-drug antibodies in greater proportions and higher titers with successive XIAFLEX injections. Healthcare providers should be prepared to address severe allergic reactions following XIAFLEX injections.

#### Risk of Bleeding in Patients with Abnormal Coagulation

In the XIAFLEX controlled trials in Peyronie's disease (Studies 1 and 2), 65.5% of XIAFLEX-treated patients developed penile hematoma, and 14.5% developed penile ecchymosis (see Adverse Reaction Table).

Patients with abnormal coagulation (except for patients taking low-dose aspirin, e.g., up to 150 mg per day) were excluded from participating in these studies. Therefore, the efficacy and safety of XIAFLEX in patients receiving anticoagulant medications (other than low-dose aspirin, e.g., up to 150 mg per day) within 7 days prior to XIAFLEX administration is not known. In addition, it is recommended to avoid use of XIAFLEX in patients with coagulation disorders, including patients receiving concomitant anticoagulants (except for low-dose aspirin).

#### ADVERSE REACTIONS

The following serious adverse reactions in patients with Peyronie's disease are discussed in greater detail elsewhere in the labeling: Corporal rupture (penile fracture) and severe penile hematoma [see *Warnings and Precautions*]. In other XIAFLEX-treated patients, a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded [see *Warnings and Precautions*].

#### Clinical Studies Experience in Patients with Peyronie's Disease

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. In the controlled and uncontrolled clinical studies of XIAFLEX in Peyronie's disease, 1044 patients received a total of 7466 XIAFLEX injections.

#### Corporal Rupture and Other Serious Penile Injury

Corporal rupture was reported as an adverse reaction after XIAFLEX injections in 5 of 1044 (0.5%) XIAFLEX treated patients. In other XIAFLEX-treated patients (9 of 1044; 0.9%), a combination of penile ecchymoses or hematoma, sudden penile detumescence, and/or a penile "popping" sound or sensation was reported, and in these cases, a diagnosis of corporal rupture cannot be excluded. These patients were managed without surgical intervention, but the long-term consequences are unknown.

Severe penile hematoma was also reported as an adverse reaction in 39 of 1044 patients (3.7%) in the controlled and uncontrolled clinical trials in Peyronie's disease [see *Adverse Reactions*]. The data described below are based on two identical, pooled, randomized, double-blind, placebo-controlled, multi-center trials through Day 365 in patients with Peyronie's disease (Studies 1 and 2). These trials included 832 patients of whom 551 and 281 received XIAFLEX and placebo, respectively. In these trials, patients were given up to 4 treatment cycles of XIAFLEX or placebo. In each cycle, two injections of XIAFLEX or two injections of placebo were administered 1 to 3 days apart. A penile modeling procedure was performed at the study site on patients 1 to 3 days after the second injection of the cycle. The treatment cycle was repeated at approximately 6-week intervals up to three additional times, for a maximum of 8 total injection procedures and 4 total modeling procedures [see *Clinical Studies in the full Prescribing Information*]. The majority of Peyronie's patients experienced at least one adverse reaction (92% XIAFLEX-treated patients, 61% placebo-treated). Most adverse reactions were local events of the penis and groin and the majority of these events were of mild or moderate severity, and most (79%) resolved within 14 days of the injection. The adverse reaction profile was similar after each injection, regardless of the number of injections administered. The most frequently reported adverse drug reactions ( $\geq 25\%$ ) in the XIAFLEX clinical trials in patients with Peyronie's disease were penile hematoma, penile swelling, and penile pain. The table below shows the incidence of adverse reactions that were reported in greater than or equal to 1% of XIAFLEX-treated patients and at a frequency greater than placebo-treated patients after up to 8 injections in the pooled placebo-controlled trials through Day 365.

#### Adverse Reactions Occurring in $\geq 1\%$ of XIAFLEX-Treated Patients with Peyronie's disease and at a Greater Incidence than Placebo After Up to Four Treatment Cycles in Studies 1 and 2 Combined

Adverse Reaction	XIAFLEX N=551	Placebo N=281
All Adverse Reactions	84.2%	36.3%
Penile hematoma <sup>a</sup>	65.5%	19.2%
Penile swelling <sup>b</sup>	55.0%	3.2%
Penile pain <sup>c</sup>	45.4%	9.3%
Penile ecchymoses <sup>d</sup>	14.5%	6.8%
Blood blister	4.5%	0
Penile blister	3.3%	0
Pruritus genital	3.1%	0
Painful erection	2.9%	0
Erectile dysfunction	1.8%	0.4%
Skin discoloration	1.8%	0
Procedural pain	1.6%	0.7%
Injection site vesicles	1.3%	0
Localized edema	1.3%	0
Dyspareunia	1.1%	0
Injection site pruritus	1.1%	0
Nodule	1.1%	0
Suprapubic pain	1.1%	0

<sup>a</sup> Includes: injection site hematoma and penile hematoma were reported with the verbatim term of penile bruising or injection site bruising in 87% of subjects.

<sup>b</sup> Includes: injection site swelling, penile edema, penile swelling, local swelling, scrotal swelling, and injection site edema.

<sup>c</sup> Includes: injection site pain, penile pain, and injection site discomfort.

<sup>d</sup> Includes: contusion, ecchymoses, penile hemorrhage, and injection site hemorrhage.

Severe penile hematoma or severe injection site hematoma were reported in 33/551 (6.0%) of XIAFLEX-treated patients and 0/281 (0%) of placebo-treated patients, in Studies 1 and 2 combined.

#### Reports of penile "popping" sounds or sensations

A popping noise or popping sensation in the penis, sometimes described as "snapping" or "cracking", and sometimes accompanied by detumescence, hematoma and/or pain, were reported in 73/551 (13.2%) XIAFLEX-treated patients and 1/281 (0.3%) placebo-treated patients.

There were no clinically meaningful differences in the incidence of adverse events following treatment with XIAFLEX based on the severity of baseline erectile dysfunction or concomitant phosphodiesterase type 5 (PDE5) inhibitor use. XIAFLEX was not associated with shortening of penile length in clinical trials in the treatment of Peyronie's disease.

#### Immunogenicity

During clinical studies in Dupuytren's contracture and Peyronie's disease, patients were tested at multiple time points for antibodies to the protein components of XIAFLEX (AUX-I and AUX-II). In the Peyronie's disease clinical studies, at 6 weeks after the first treatment cycle of XIAFLEX 0.58 mg, approximately 75% of patients had antibodies against AUX-I and approximately 55% of patients had antibodies against AUX-II. Six weeks after the eighth injection (fourth treatment cycle) of XIAFLEX, >99% of XIAFLEX-treated patients developed high titers of antibodies to both AUX-I and AUX-II. Neutralizing antibodies were assayed for a subset of 70 samples selected to be representative of high and low titer binding antibody responses at week 12 of treatment. For each subject in whom a Week 12 sample was selected, the corresponding Week 6, 18, 24, and 52 samples were assayed if they were also binding antibody positive. Neutralizing antibodies to AUX-I or AUX-II, were detected in 60% and 51.8%, respectively, of patients tested. In patients treated for these two indications, there was no apparent correlation of antibody frequency, antibody titers, or neutralizing status to clinical response or adverse reactions.

Since the protein components in XIAFLEX (AUX-I and AUX-II) have some sequence homology with human matrix metalloproteinases (MMPs), anti-product antibodies could theoretically interfere with human MMPs. In vitro studies showed no evidence of cross-reactivity between anti-drug-antibody positive patient sera and a series of relevant MMPs. In addition, no clinical safety concerns related to the inhibition of endogenous MMPs have been observed.

Immunogenicity assay results are highly dependent on the sensitivity and specificity of the assay used in detection and may be influenced by several factors, including sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to collagenase clostridium histolyticum with the incidence of antibodies to other products may be misleading.

#### DRUG INTERACTIONS

Anticoagulant drugs: XIAFLEX should be used with caution in patients receiving concomitant anticoagulants (except for low-dose aspirin) [see *Warnings and Precautions*].

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

Pregnancy Category B

There are no adequate and well-controlled studies of XIAFLEX in pregnant women. Because animal reproduction studies are not always predictive of human response, XIAFLEX should be used during pregnancy only if clearly needed.

##### Risk Summary

Based on animal data, XIAFLEX is not predicted to increase the risk for major developmental abnormalities in humans.

##### Human Data

Human pharmacokinetic studies showed that XIAFLEX levels were not quantifiable in the systemic circulation following injection into a Dupuytren's cord. Low levels of XIAFLEX were quantifiable in the plasma of evaluable male subjects for up to 30 minutes following administration of XIAFLEX into the penile plaque of subjects with Peyronie's disease [see *Clinical Pharmacology in the full Prescribing Information*]. Almost all patients develop anti-product antibodies (anti-AUX-I and anti-AUX-II) after treatment with XIAFLEX, and the clinical significance of anti-product antibody formation on a developing fetus is not known [see *Adverse Reactions*].

##### Animal Data

Reproduction studies have been performed in rats with intravenous exposures up to approximately 11 times the maximum recommended human dose (MRHD) of XIAFLEX on a mg/m<sup>2</sup> basis, and have revealed no evidence of impaired fertility or harm to the fetus due to collagenase clostridium histolyticum.

##### Nursing Mothers

It is not known whether collagenase clostridium histolyticum is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when XIAFLEX is administered to a nursing woman.

##### Pediatric Use

The safety and effectiveness of XIAFLEX in pediatric patients less than 18 years old have not been established.

##### Geriatric Use

Of the 551 XIAFLEX-treated patients in the double-blind, placebo-controlled, clinical trials in Peyronie's disease (Studies 1 and 2), 100 (18%) were 65 years of age or older and 5 (0.9%) were 75 years of age or older. No overall differences in safety or effectiveness of XIAFLEX were observed between these patients and younger patients.

#### OVERDOSAGE

The effects of overdose of XIAFLEX are unknown. It is possible that multiple simultaneous or excessive doses of XIAFLEX may cause more severe local effects than the recommended doses including serious adverse reactions in the injected area (e.g., tendon ruptures or corporal ruptures dependent on the injection site). Supportive care and symptomatic treatment are recommended in these circumstances.

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Auxilium Pharmaceuticals, Inc.  
Malvern, PA 19355

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**XIAFLEX**<sup>®</sup>  
collagenase clostridium histolyticum

**endo**  
pharmaceuticals  
an endo international company

**It's no fun** when you “have to go” more often than usual. However, people who suffer from such a condition should know they are not alone. At least 33 million other Americans deal with the symptoms, and sometimes inconvenience, of overactive bladder (OAB). It occurs when your bladder releases or outputs urine at the wrong time rather than storing it. That's usually when it “wants to” and not when you want it to.

In addition to the interruptions to your daily life, such as your sleep, finding a bathroom can become priority one when you visit somewhere new. Your symptoms may make you feel different, causing you to avoid social situations or say “no thanks” more often when invited out.

### **Do You Have Overactive Bladder?**

To determine if you have OAB, ask yourself this:

- Do you often have a strong urge to urinate “right now”?
- Do you leak urine following that urge?
- Do you have to urinate eight or more times daily, and do you get up to go to the bathroom at least two times at night?

If so, you may indeed have OAB. It can be caused by a number of factors:

- A urinary tract infection (UTI).
- Nerve damage that causes signals between your bladder and brain to misfire so your bladder “thinks” it should empty even when it's not full.
- Illness such as a stroke or multiple sclerosis.
- By kidney or bladder stones, or by side effects of a medication.

The condition differs in men and women, and increases with age — although it is not a “normal” part of aging. Post-menopausal women and men who have prostate problems are at a higher risk for developing OAB.

### **Causes of Overactive Bladder**

Don't try to guess what's causing your OAB. You can see a specialist, usually a urologist who treats both men and women. Women who prefer to specialize can find a urologist who specializes in the management of the urinary tract system. You'll learn why you have

# What to Know When You ‘Have to Go’

By Mark A. Haber, M.D., F.A.C.S.



it and what treatments can help manage your symptoms. You'll be asked about your urination habits and your medical history. You may be asked to keep a diary of fluid intake, along with a record of how often and how much you urinate.

Your doctor may perform tests including, but not limited to:

- **Urinalysis:** It's obtained from a urine sample to screen for bacteria, blood, or glucose, which could indicate diabetes.
- **Cystoscopy:** A narrow tube with camera and light is inserted through the urethra into the bladder.
- **Urodynamics:** These use a thin tube or ultrasound to determine factors including whether urine remains in your bladder after you have urinated.
- **Uroflowmetry:** A device measures urine quantity and speed of flow.
- **Cystometry:** This diagnostic evaluates bladder pressure and capacity.

### Treatments for Overactive Bladder

Once OAB is diagnosed, your doctor may recommend the following treatments:

- **Lifestyle changes:** Readjust or limit fluid intake and try to avoid drinking alcohol or caffeine.
- **Anticholinergics:** These frequently prescribed medications help control inappropriate bladder contractions that signal an urge to urinate.
- **Botulinum toxin injections:** You may think this drug is only used to "freeze" wrinkles, but it's been shown to improve symptoms as well as anticholinergics do.
- **Behavioral therapy:** Techniques might include education, dietary and lifestyle modification. They also could include bladder training, which can come in the form of electrical stimulation or biofeedback therapy, along with pelvic floor muscle exercises called "Kegels."
- **Neuromodulation:** Your doctor might recommend percutaneous tibial nerve stimulation or implanted sacral nerve stimulation, both relatively recent procedures that modulate bladder reflex pathways to improve bladder control. The first inserts a small needle underneath skin near the ankle that's attached to an electrical stimulation unit. The second is a small, implanted neurotransmitter that stimulates your sacral nerve with mild electrical impulses.
- **Surgery:** For severe cases, when other treatments have not proven effective, surgeries include augmentation, cystoplasty, or urinary diversion.

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