

# DAILY NEWS



SATURDAY | MAY 14, 2022

## DON'T MISS

7:30-8:30 a.m.  
Great Hall A  
How I Do It: Common Urologic Procedures

7:30-9:30 a.m.  
Room 207  
2022 Localized Prostate Cancer

7:30-9:30 a.m.  
Room 204  
New AUA BPH Guidelines: How to Best Diagnose and How to Most Effectively and Safely Treat

7:30 a.m.-5:15 p.m.  
Room 271  
Urologic Care for the Advanced Practice Provider

10 a.m.-noon  
Room 207  
3D Printing, Augmented Reality, and Virtual Reality: Why, How, What to Incorporate into Daily Practice

1:30-3:30 p.m.  
Room 204  
Diversity Equity and Inclusion in Urology, What Do We Need to Know?

2-4 p.m.  
Room 344  
The Great Debate

## LEAD THE CHANGE TO INCREASE DIVERSITY IN UROLOGIC ONCOLOGY



As recently as 1990, there were only a handful of women urologists who specialized in oncology. In 2022, there are now 91 female members in the Society of Urologic Oncology (SUO). The AUA has a strong focus on diversity and inclusion, and progress is ongoing. However, more work needs to be done to increase the number female urologic oncology specialists.

“Increasing the number of women in the specialty will help our specialty and other specialties,” said Eila Skinner, MD, the Thomas A. Stamey Research Professor of Urology at Stanford University School of Medicine in California.

In Friday’s session, “Women in Urologic Oncology: Past, Present and Future,” Dr. Skinner led a panel of recognized female leaders in urologic oncology who discussed how women in the specialty got to where they are today and how to

build for the future.

Cheryl Lee, MD, professor and chair of the department of urology at The Ohio State University in Columbus, began by highlighting trailblazers, including Elisabeth Pickett, MD, the first female urologic oncologist, who laid the groundwork for the specialty in 1954.

“The few women in urologic oncology in the beginning were supported by many men through mentorships and sponsorships. Yet, we lacked the critical mass to be able to expand the number of women in the field,” Dr. Lee said. She noted that of the 444,660 patients with genitourinary cancer, which represents 23% of all cases in all sites, 11%, or 49,700, are women. “To better mirror our patient population, the SUO, which has 1,048 members across all member categories, needs a minimum of 115 women members,” Dr. Lee said.

Driving the expansion of

“The few women in urologic oncology in the beginning were supported by many men through mentorships and sponsorships. Yet, we lacked the critical mass to be able to expand the number of women in the field.”

Cheryl Lee, MD

women in urologic oncology will promote surgical excellence, advance academic pursuits, build camaraderie and advocate for issues, funding and research related to female patients with urologic cancer. But how does the specialty get there?

Sarah Psutka, MD, MS, associate professor in the department of urology at the University of Washington in Seattle, presented a plan for increasing women in urologic oncology that’s centered on Women in Urologic Oncology (WUO) within the SUO. The WUO can provide the infrastructure to continue building diversity and equity within the SUO, she said. Core principles of the WUO include representation, mentorship, advocacy, allyship and sponsorship of women in urologic oncology while advancing the objectives of the SUO.

“Equity adds value and builds community,” Dr. Psutka said. When underrepresented groups are welcomed, everyone wins.

Kristen Scarpato, MD, MPH, associate professor in the department of urology at Vanderbilt University Medical Center in Nashville, Tennessee,

addressed the lack of gender diversity in the urologic oncology workforce. “About 11% of practicing urologists are female and only 4% have an oncology focus,” Dr. Scarpato said. “The pipeline of applicants for urologic oncology is impacted by what the workforce looks like.”

People want to share community with their coworkers and want to work with people who look like them, Dr. Scarpato said. Building awareness, being a good mentor, celebrating workforce diversity and fostering a supportive environment can help fortify the applicant interest.

“We know outcomes in medicine are better when we have a diverse workforce,” she said.

Overall, though, “the future looks bright,” said Sima Porten, MD, associate professor in the department of urology at University of California San Francisco. To build a career as a woman in urologic oncology, Dr. Porten recommended building a network of women and men who can guide and support you. She advocated taking risks, talking to people you may not know, being an ally and an advocate for diversity, and leading the change. ●

## INSIDE |

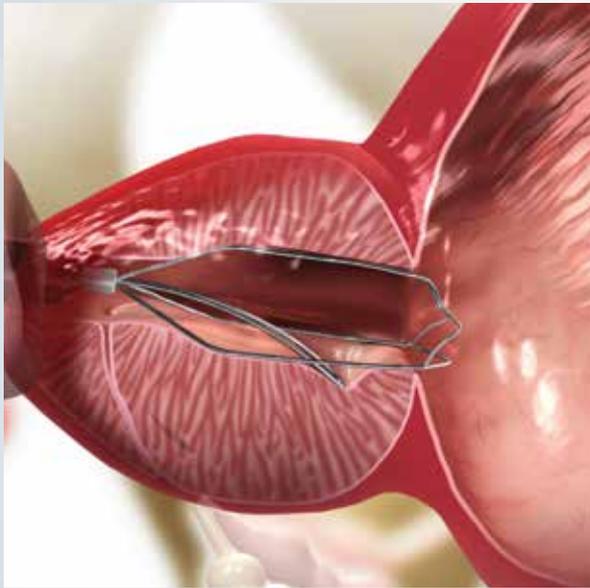
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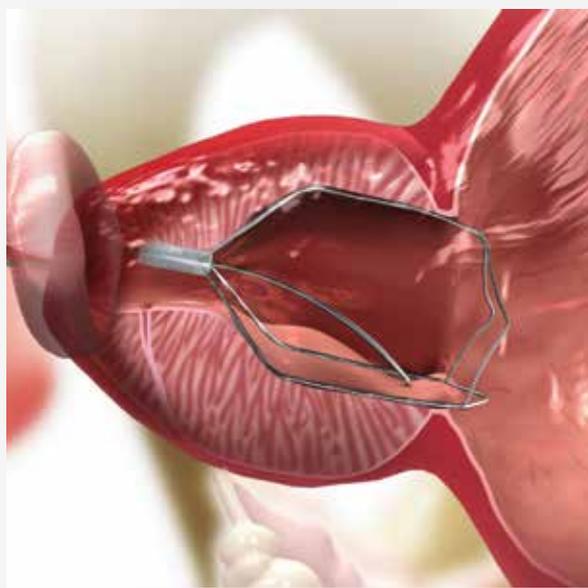
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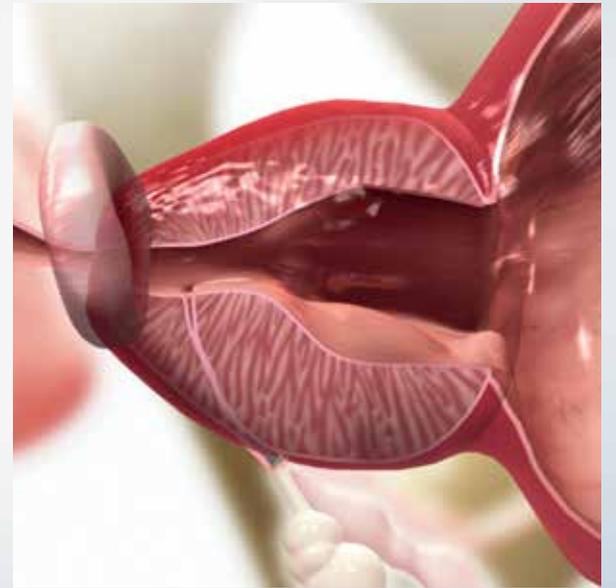
## How the iTind™ Procedure Works



**1** Implantation of the iTind device



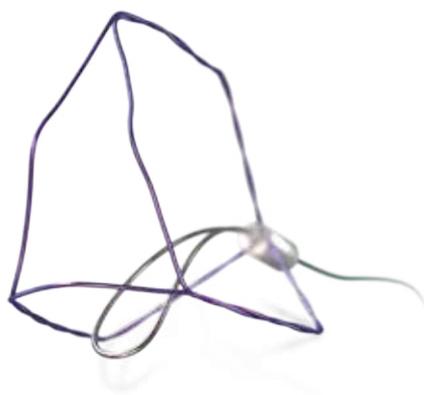
**2** Treatment Period (5 to 7 days)



**3** Removal of the iTind device

### Reshaping BPH Treatment

- The iTind procedure involves a temporarily implanted nitinol device that reshapes the prostatic urethra and bladder neck to deliver significant and long-lasting relief of BPH symptoms, all without heating prostatic tissue or a permanent implant.<sup>1,2</sup> The iTind device can be placed in an outpatient or office setting using either a slim rigid or flexible cystoscope.
- Through continuous ischemic pressure and subsequent tissue necrosis, the iTind device struts slowly expand to reshape the prostatic urethra and bladder neck to better allow urine flow, while preserving erectile and ejaculatory function.<sup>1,2</sup>
- Post-op catheterization is rare, and patients are able to return home during the 5-7 day treatment, at the end of which the device is completely removed.<sup>1</sup>



Before

After



Scan for more information

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Implantation of the iTind device may cause urinary urgency, pelvic discomfort, dysuria or hematuria. In rare cases, iTind may cause urinary tract infection or acute urinary retention.

1. Amparore et al., 2021; 2. Chughtai et al., 2020

# THE FUTURE OF EFFECTIVE CARE IS MULTIDISCIPLINARY

The multidisciplinary team approach, evolving to become the standard of care for managing patients in urologic oncology, served as a hot topic during Friday morning's plenary. Moderated by Leonard Gomella, MD, FACS, and featuring panelists Neal D. Shore, MD, FACS, and Michael Cookson, MD, MMHC, "What Is the Optimal Multidisciplinary Team in 2022: Drafting for the Future" looked at why the team concept has gained popularity and how it can continue to improve.

Dr. Gomella said advances in all areas of urologic oncology in every aspect of the disease, especially prostate, bladder and kidney cancer, have made it preferable for patients with multidisciplinary therapies.

"This can all be facilitated by a strong multidisciplinary care team," he said. "What we need is specific expertise in surgery, radiation oncology, medical oncology, nuclear medicine, genetic testing and molecular

medicine."

As defined by the panel, the multidisciplinary team approach can be delivered three ways:

A multidisciplinary clinical team featuring real-time interaction with the patient, family and specialists where providers go to the patient to provide one common treatment.

A care pathway where providers agree to a predefined treatment map that every team member follows.

Or a tumor board where patients are presented to a group and the findings are transmitted back to the provider

Dr. Gomella said decision making from multidisciplinary treatment plans for high-risk disease often requires input from multiple specialists in consideration for clinical trials, which leads to more effective care. In addition, he said, it has become clear that treatment regret by patients is limited if they have had the opportunity to talk to a series of specialists before making a final decision.



For that reason, he said, the multidisciplinary approach is getting to be quite popular.

"The GU multi-team approach has improved care for patients, and this has been documented in the literature in terms of improved outcomes, better adherence to NCCN guidelines, a broadening of treatment options, an increase in accrual to clinical trials and, most importantly for our patients, less regret regarding treatment decisions," Dr. Gomella said.

The panelists agreed that effective multidisciplinary

teams include some or all of the following:

- A core team featuring a navigator/coordinator and members from
  - urology/urological oncology
  - medical oncology
  - radiation oncology
- Optional members such as a
  - radiologist
  - pathologist
  - nuclear medicine specialist
  - genetic counselor
  - physician assistant or nurse practitioner
  - clinical trials coordinator
  - social worker

- nutrition specialist
- psychologist

Dr. Gomella said it is common for patients and their families to express feeling more comfortable talking to a physician assistant or nurse practitioner, which is an important consideration when it comes to making sure everyone understands the various outcome scenarios.

"(Multidisciplinary teams) offer a high patient satisfaction and retention rate, which is fueled in no small part by the decrease in patient regret," he said. ●

## NEW TREATMENT OPTIONS FOR PATIENTS WITH REFRACTORY NMIBC



Tracy Downs, MD, FACS

these patients due to an increasing array of treatment options.

Dr. Downs moderated Friday's plenary, "Survivor Debate: Non-Muscle Invasive Bladder Cancer Refractory to BCG: Cystectomy, Systemic Immunotherapy, Intravesical Chemotherapy," which highlighted these treatment advancements, beginning with a key step in the process: defining when an NMIBC patient is BCG unresponsive. "The data show it is an important definition to rely upon for how to move forward with these complex patients," Dr. Downs said.

Determining the BCG responsiveness status of a patient with high-risk NMIBC relies on 2018 FDA Framework/Guidance, defined as:

- Persistent or recurrent bladder carcinoma in situ (CIS) ± Ta or T1 within 12 months of completion of adequate BCG—"5+2"
- Persistent or recurrent high-grade Ta or T1 within six months of completion of adequate BCG—no change
- T1HG at first evaluation after single induction BCG—at least five of six induction doses—no change

Defining BCG unresponsiveness is important for treatment planning. BCG-unresponsive

patients are more likely to require radical cystectomy. Those opting for second-line therapies are less likely to remain disease free. BCG-unresponsive also indicates inferior high-grade recurrence-free survival and cystectomy-free survival, Dr. Downs said.

Other guiding principles for managing BCG unresponsiveness in the NMIBC patient include the quality of transurethral resection of a bladder tumor in NMIBC treatment, the importance of prostatic urethra sampling and ureteral/upper tract monitoring.

Case studies were presented involving patients with persistent CIS to assess whether the extent of the disease was adequately evaluated, with expert commentary from Seth P. Lerner, MD, professor of urology and the Beth and Dave Swalm Chair in Urologic Oncology at Baylor College of Medicine in Houston, Texas, and James M. McKiernan, MD, the John K. Lattimer Professor of Urology and chair of the Department of Urology of the College of Physicians and Surgeons and urologist-in-chief at New York-Presbyterian/Columbia.

In high-risk patients with persistent or recurrent disease within one year following treatment with two induction cycles of BCG or BCG

maintenance, Dr. Downs noted that AUA Guidelines 2020 recommend that clinicians offer radical cystectomy.

Still, new treatment options for are available; others are expected to be ready for routine use in the near future. For patients with intermediate or high-risk NMIBC, 2020 AUA/SUO NMIBC Guidelines recommend that within 12 months of adequate BCG therapy for patients unwilling or unfit for radical cystectomy, a clinician may recommend clinical trial or offer alternative intravesical therapy, such as valrubicin, gemcitabine, docetaxel or combination chemotherapy. A clinician may also offer systemic immunotherapy with pembrolizumab to a patient with CIS within 12 months of completing adequate BCG therapy.

Moreover, systemic immunotherapy is FDA approved and guideline endorsed with emerging intravesical immunotherapy data. Intravesical combination chemotherapies are now guideline endorsed with promising multiagent trial data. Combination trials of intravesical and systemic therapies are also ongoing.

"After 21 years without an FDA approval, the menu of options is exciting," Dr. Downs said. ●

### Applications for AUA Diversity & Inclusion Chair

The AUA is currently seeking a highly qualified member to fill the position of Diversity & Inclusion Chair beginning August 2022.

A job description with information about qualifications and time commitments will be posted online at [AUNet.org/D&IChair](https://www.aunet.org/D&IChair).

Applications will be accepted May 23 through June 16, 2022.



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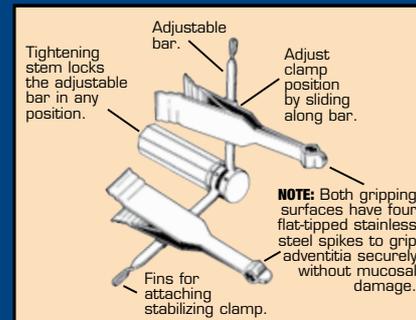
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Industry Clinical Update  
(ICU) Theaters

Friday, May 13 to Sunday, May 15

## ICU THEATERS SHOWCASE NEW DEVELOPMENTS IN UROLOGY

**M**ore time than usual has passed since urological professionals were last able to gather for an AUA Annual Meeting, but that doesn't mean advancements in the field of urology have slowed. This year's Industry Clinical Update (ICU) Theaters—which premiere non-continuing medical education (CME) programming that showcases new products, services and research findings—will feature more programs than ever before. For the first time ever, the AUA will have two theaters running for three days of the meeting, with the expansion to two theaters because of high demand.

“These lunch-and-learn sessions play a very important role in our learning experience,” said Ashley E. Ross, MD, PhD, associate professor of urology at Northwestern University Feinberg School of Medicine in Chicago. “When you go to a plenary or a late-breaking abstracts session, you are seeing very new knowledge. These ICU Theater non-CME sessions focus on products and

procedures that are available right now. Often, what you learn in the plenary may change your practice next year—if it gets approved. What you learn in the ICU Theaters can change your practice next week.”

The AUA is featuring 14 sessions across two ICU Theaters in New Orleans. ICU Theater I is in Booth #1043 in the Science & Technology Hall. ICU Theater II is in Great Hall B, next to the plenary. Both theaters are open Friday through Sunday, and all sessions are 60 minutes and include a meal.

“Unlike a scientific session that is designated as CME, where you may not get to discuss implementation into practice and the practicalities of using a product or a procedure, the ICU Theater format lends itself to that kind of real-world discussion. You have an opportunity to discuss real applications back and forth with the audience. Whether you are a presenter or in the audience, the ICU Theater is a very different experience than a traditional platform presentation,”



said Sanoj Punnen, MD, MAS, associate professor in the Desai Sethi Urology Institute at the University of Miami and Sylvester Comprehensive Cancer Center in Florida.

ICU Theater sessions are generally industry sponsored and typically discuss specific products and procedures, all rigorously reviewed through industry compliance. Where CME sessions tend to focus on basic, translational and clinical research, the ICU Theater focus is implementation.

“These presentations are very well reviewed under very strict guidelines,” said Jeffrey Frankel,

MD, urologist and medical director at Seattle Urology Research Center. “ICU Theater is an opportunity to see what is going on in the real world with a product that is FDA-approved and available.

“The most valuable commodity most of us have is time,” Dr. Ross said, “so being able to double-dip a learning opportunity and a meal can be a real advantage. I would urge attendees to peruse the ICU Theater schedule just as carefully as the plenaries and other CME sessions. Combining both can be a much more efficient use of the limited learning time we all have in New Orleans.” ●

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1. Roehrborn, J Urol 2013

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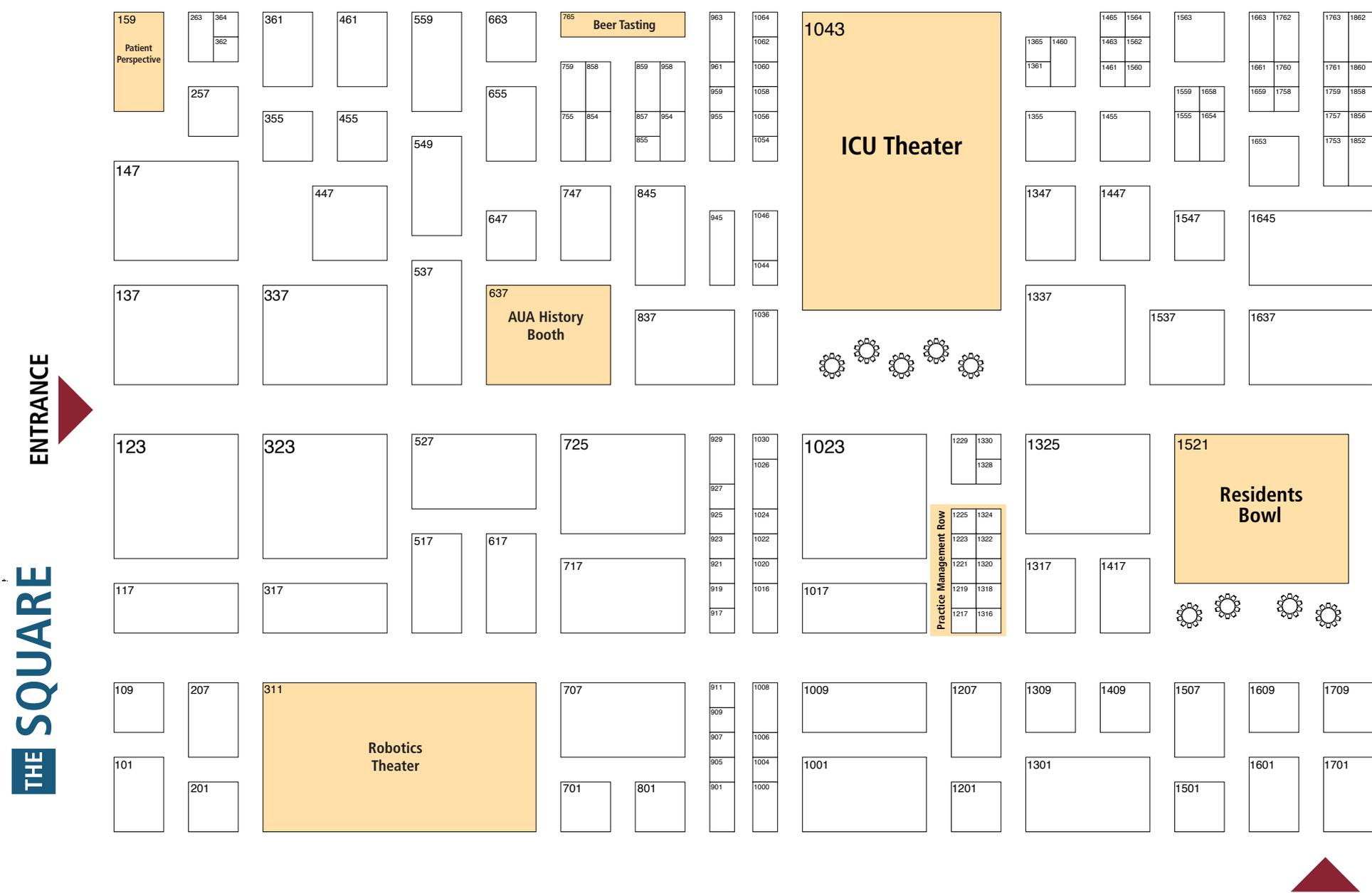
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# EXHIBIT FLOOR MAP



## THE SCIENCE & TECHNOLOGY HALL

**Hall Hours:**

<p><b>SATURDAY</b> 9 a.m.-6 p.m. Saturday Afternoon Networking Event: 4-6 p.m.</p>	<p><b>SUNDAY</b> 9 a.m.-4 p.m. Beer Tasting: 2-4 p.m.</p>
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CHECK THE S&T HALL DAILY SCHEDULES OR MOBILE APP FOR INDUSTRY PROGRAMMING

Emerging Corner

Industry Clinical Update (ICU) Theater

Robotics Theater

Saturday Networking Event

Skills Enhancement Workshops

Skills Challenge

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Exhibitors list as of April 12, 2022



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American Urological Association

# In & Outs

## of Sexual Health

AUA2022 / New Orleans

Did you know that in the late 1800s, injecting extracts of testicles from animals seemed to improve mental and physical capabilities in men?

Learn more about the evolution of sexual medicine at History Booth #637 in the Science and Technology Hall at AUA2022.

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2022  
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US-JEL-00407 03/22

# GROUNDBREAKING ABSTRACTS SPOTLIGHT PATIENT PERSPECTIVES

Everything that urologists and their staff do, every medical exam, test, diagnosis, treatment, procedure and follow-up, depends on patients. Do you know what really matters to the most important stakeholders in your practice?

“Our whole job, our whole existence, is dependent on patients, on caring for patients,” said Phillip M. Pierorazio, MD, chief of urology at Penn Presbyterian Medical Center at the University of Pennsylvania in Philadelphia. “Like most things in health care, the data have lagged behind clinical practice. Giving patients a formal voice is an important part of the care process.”

It’s not that patient perspectives are completely ignored. Instruments such as the AUA Symptom Score have been used to assess benign prostatic hyperplasia



Phillip M. Pierorazio, MD

symptoms and quality of life for decades. But these familiar instruments were designed by clinicians, for clinicians. Patients are more than bystanders—they are key players.

“As clinicians, we have a very specific perspective on the conditions we treat and the experiences of the patients we treat,” said Geolani W. Dy, MD, assistant professor of urology at Oregon Health & Science University in Portland.

“There is a whole world of patient perspectives that are very relevant to the care we are providing that are being inadequately captured through



Geolani W. Dy, MD

traditional research mechanisms. In my field, gender-affirming care, there are a number of power dynamics and historical norms that have potentially harmed patients. This kind of patient-perspective research, conducted by and presented by patients, is an opportunity to deconstruct and reconfigure our understanding and approaches to improve clinical and quality of life outcomes.”

The AUA is putting patient perspectives front and center during “Patient Perspectives Abstracts” from 1-3 p.m. on Friday at Booth #159 in the Science & Technology Hall. This session may be the first by any major medical association devoted solely to patient perspective abstracts researched by and presented by patients to clinicians.

The AUA solicited abstracts from multiple patient groups and received more than 50 submissions. Patient-authors will present a dozen abstracts,

from the role that uncertainty in the diagnosis of renal masses plays in overtreatment as well as in patient anxiety and lack of confidence in medical care post-surgery to the unmet needs of adults with bladder exstrophy, underutilization of pelvic floor physical therapy in treating chronic pelvic floor dysfunction and vulvovaginal conditions, the impact of peer-led support in prostate cancer, the experiences of patients in prostate cancer trials, patient-based education in endometriosis and more.

“The patient view is a fresh, underrepresented perspective,” Dr. Dy said. “These abstracts should inspire clinicians and researchers to think more about the perspectives that they aren’t incorporating. We can better partner with patients and the

broader patient community to improve clinical care and research.”

The session can also answer the often unspoken questions about why patient perspectives are important.

“Just the fact that we are having this session puts the patient perspective on people’s radars and reaffirms that it is important to the AUA, important to clinicians,” Dr. Pierorazio said. “There aren’t many times you get to say, ‘I was there at the first session of this kind.’ Being there, acknowledging that our patients’ voices are important, sends a powerful message as an organization and as a urologist. We are united with our patients, we value their opinions, we value who they are and we want to work with them.” ●

“Just the fact that we are having this session puts the patient perspective on people’s radars and reaffirms that it is important to the AUA, important to clinicians”

Phillip M. Pierorazio, MD

## Patient Perspectives Abstracts

Friday, May 13  
1-3 p.m.  
S&T Hall, Booth #159



# Learn about a new era of patient and physician access to gallium-based PSMA PET imaging.

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Reproductive Urologist

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Sunday, May 15 from 2:30pm – 3:30pm

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### INDICATION

JATENZO<sup>®</sup> (testosterone undecanoate) capsules, CIII, is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

### Limitation of use

Safety and efficacy of JATENZO in males less than 18 years old have not been established.

### IMPORTANT SAFETY INFORMATION FOR JATENZO (testosterone undecanoate)

#### WARNING: INCREASES IN BLOOD PRESSURE

- **JATENZO can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.**
- **Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of JATENZO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.**
- **Due to this risk, use JATENZO only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

### CONTRAINDICATIONS

JATENZO is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate, in women who are pregnant, in men with a known hypersensitivity to JATENZO or its ingredients, or in men with hypogonadal conditions that are not associated with structural or genetic etiologies as JATENZO has not been established for these conditions and there is a risk of increased blood pressure with JATENZO that can increase the risk of MACE.

### WARNINGS AND PRECAUTIONS

- JATENZO can increase blood pressure, which can increase the risk of MACE, with greater risk in patients with established cardiovascular disease or risk factors for cardiovascular disease. Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled. Monitor blood pressure approximately 3 weeks after initiating, increasing the dose, and periodically while on JATENZO, and treat any new or exacerbations of hypertension. Re-evaluate benefits and risks of continued treatment with JATENZO in patients who develop cardiovascular risk factors or disease. JATENZO is contraindicated in men with hypogonadal conditions such as "age-related hypogonadism" because the efficacy of JATENZO has not been established for these conditions and the increases in BP can increase the risk of MACE.
- Polycythemia may require a lower dose or discontinuation of JATENZO. Check hematocrit prior to initiation and every 3 months while a patient is on JATENZO and if hematocrit becomes elevated, stop JATENZO until hematocrit decreases to an acceptable level. If hematocrit increases after JATENZO is restarted, stop permanently.
- Some studies, but not all, have reported an increased risk of major adverse cardiovascular events (MACE) in association with use of testosterone replacement therapy in men. Long-term clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use JATENZO. JATENZO can increase blood pressure, which can increase the risk of MACE.
- Monitor patients with benign prostatic hyperplasia (BPH) treated with androgens due to an increased risk for worsening signs and symptoms of BPH. Patients treated with androgens may be at increased risk for prostate cancer and should be evaluated prior to initiating and during treatment with androgens. Monitor prostate-specific antigen (PSA) levels periodically.
- Postmarketing reports of venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone replacement products like JATENZO. Evaluate patients with signs or symptoms consistent with DVT or PE and, if a VTE is suspected, discontinue JATENZO and initiate appropriate workup and

management.

- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If abuse is suspected, check testosterone levels to ensure they are in therapeutic range. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and anabolic androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.
- JATENZO is not indicated for use in women.
- Large doses of androgens can suppress spermatogenesis by feedback inhibition of pituitary FSH. Inform patients of this risk before prescribing JATENZO.
- Prolonged use of high doses of methyltestosterone has been associated with serious hepatic adverse events. JATENZO is not known to cause these adverse events; however, patients should be instructed to report any signs of hepatic dysfunction and JATENZO should be discontinued while the cause is evaluated.
- Androgens, including JATENZO, may promote retention of sodium and water. Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.
- Gynecomastia may develop and persist in patients being treated for hypogonadism.
- The treatment of hypogonadal men with testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.
- Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy. Monitor the lipid profile periodically, particularly after starting testosterone therapy.
- Use JATENZO with caution in cancer patients at risk of hypercalcemia. Monitor serum calcium concentration regularly during treatment with JATENZO in these patients.
- Androgens, including JATENZO, may decrease concentrations of thyroxine-binding globulin, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.
- Depression and suicidal ideation have been reported in patients treated with JATENZO in clinical trials. Advise patients and caregivers to seek medical attention for manifestations of new-onset or worsening depression, suicidal ideation or behavior, anxiety, or other mood changes.

### ADVERSE EVENTS

The most common adverse events of JATENZO (incidence  $\geq 2\%$ ) are headache (5%), increased hematocrit (5%), hypertension (4%), decreased HDL (3%), and nausea (2%).

### DRUG INTERACTIONS

- JATENZO can cause changes in insulin sensitivity or glycemic control. Androgens may decrease blood glucose and may require a decrease in the dose of antidiabetic medications.
- Anticoagulant activity may be affected by androgens. More frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking warfarin, especially at initiation and termination of androgen therapy.
- Use of testosterone and corticosteroids concurrently may increase fluid retention and requires monitoring in patients with cardiac, renal, or hepatic disease.
- Some prescription and nonprescription analgesic cold medications contain drugs known to increase blood pressure and concomitant use of these medications with JATENZO may lead to additional increases in blood pressure.

### USE IN SPECIFIC POPULATIONS

The safety and efficacy of JATENZO in pediatric patients less than 18 years old have not been established. Improper use may result in acceleration of bone age and premature closure of epiphyses.

There have not been sufficient numbers of geriatric patients involved in controlled clinical studies utilizing JATENZO to determine whether efficacy or safety in those over 65 years of age differs from younger subjects. There is insufficient long-term safety data in geriatric patients utilizing JATENZO to assess the potentially increased risk of cardiovascular disease and prostate cancer.

**Please see the full Prescribing Information on [JATENZOPI.com](http://JATENZOPI.com), including BOXED WARNING on increases in blood pressure.**

**clarus**  
THERAPEUTICS

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### QUESTION OF THE DAY

What is one thing you learned today that you will implement into your practice back home?



"I'm interested in this Jelmyto (treatment for low-grade upper tract urothelial cancer) used for upper tract transitional. I have a big upper tract practice. I do a lot of oncology, and I'm trying to see if we can potentially get expanded criteria to use for some of my high-grade patients in my practice who have solitary

kidneys, so that's what I wanted to pick their brain about. I'm hoping to try and use that for a few people in my practice."

**Garry Sandhu, MD, BS**  
St. Louis, Missouri



"I'm a researcher, so based on the sessions, it's the findings of our colleagues and collaborative research that's happening in the field and taking those findings and applying them to our field. So far, a lot of it was in the surgical sessions, but I'm going to a lot of sessions later that are going to be in the basic science. I'm hoping that there definitely will be findings that we can take home."

**Christina Sharkey, MA**  
Boston, Massachusetts



"So far I've been to instructional courses that talked about guidelines and evidence-based data, so that's what I'll take back to my own practice and clinic to help my patients that way. I went to a practical urodynamics session. I have a lot of patients who need urodynamics, so now I can use what I learned from the session and apply it so I can better explain to my patients what urodynamics is and explain basically what I'm seeing on the tests."

**Candace Tan, PA-C**  
Chicago, Illinois

# VOICES&VIEWS

JOIN THE CONVERSATION ON TWITTER, AND INSTAGRAM #AUA22  



**Justin Dubin, MD**

@justindubinmd

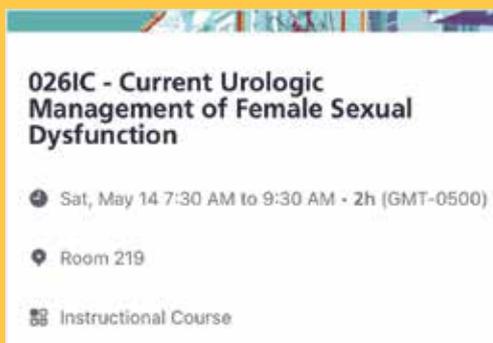
There are some really incredible pins at #AUA22 My personal favorite (and my go-to trivia team name) is Urethra Franklin



**Kevin Chu, MD**

@kevinchumd

Excellent and informative talk as always by @SaveYourSexLife on relation between obstructive sleep apnea and various Men's Health ailments. Working up OSA has never been easier, and patients will reap the benefits. #AUA22 @SMSNA\_ORG



**Rachel S. Rubin, MD**

@drachelrubin

Want to learn about female sexual medicine and how urologists play a huge role? Come find me at #AUA22

The @AmerUrological is a fierce supporter of this topic! Blessed to have them on our team!



**Ranjith Ramasamy**

@ranjithramamd

What an incredible opportunity to mentor @DrDenise\_ as part of the Urology Scientific Mentoring and Research Training (USMART) Academy from @AmerUrological - she is already a force and can't wait to follow her successes #AUA22

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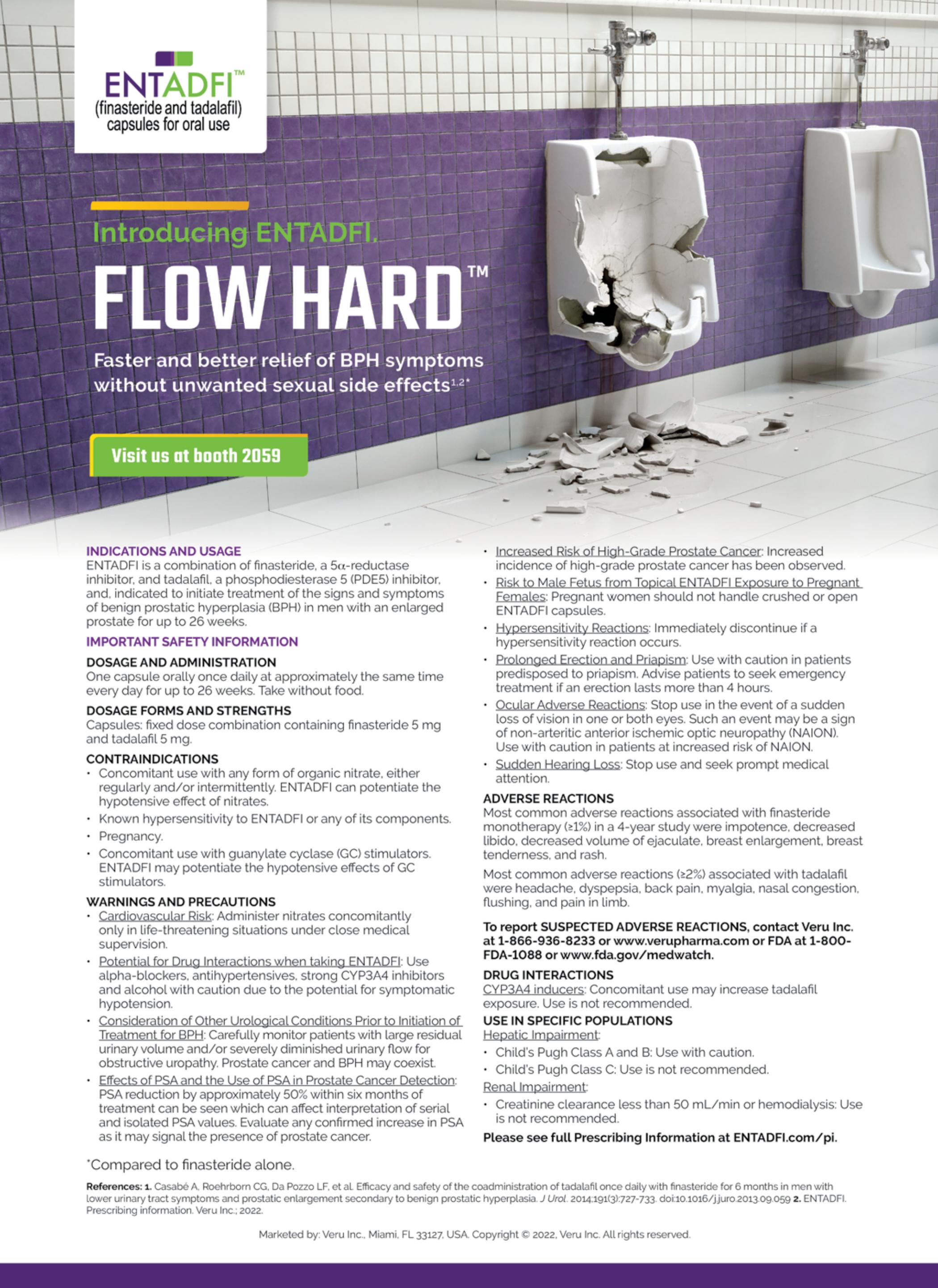
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without unwanted sexual side effects<sup>1,2\*</sup>

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### INDICATIONS AND USAGE

ENTADFI is a combination of finasteride, a 5 $\alpha$ -reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, and, indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks.

### IMPORTANT SAFETY INFORMATION

#### DOSAGE AND ADMINISTRATION

One capsule orally once daily at approximately the same time every day for up to 26 weeks. Take without food.

#### DOSAGE FORMS AND STRENGTHS

Capsules: fixed dose combination containing finasteride 5 mg and tadalafil 5 mg.

#### CONTRAINDICATIONS

- Concomitant use with any form of organic nitrate, either regularly and/or intermittently. ENTADFI can potentiate the hypotensive effect of nitrates.
- Known hypersensitivity to ENTADFI or any of its components.
- Pregnancy.
- Concomitant use with guanylate cyclase (GC) stimulators. ENTADFI may potentiate the hypotensive effects of GC stimulators.

#### WARNINGS AND PRECAUTIONS

- **Cardiovascular Risk:** Administer nitrates concomitantly only in life-threatening situations under close medical supervision.
- **Potential for Drug Interactions when taking ENTADFI:** Use alpha-blockers, antihypertensives, strong CYP3A4 inhibitors and alcohol with caution due to the potential for symptomatic hypotension.
- **Consideration of Other Urological Conditions Prior to Initiation of Treatment for BPH:** Carefully monitor patients with large residual urinary volume and/or severely diminished urinary flow for obstructive uropathy. Prostate cancer and BPH may coexist.
- **Effects of PSA and the Use of PSA in Prostate Cancer Detection:** PSA reduction by approximately 50% within six months of treatment can be seen which can affect interpretation of serial and isolated PSA values. Evaluate any confirmed increase in PSA as it may signal the presence of prostate cancer.

- **Increased Risk of High-Grade Prostate Cancer:** Increased incidence of high-grade prostate cancer has been observed.
- **Risk to Male Fetus from Topical ENTADFI Exposure to Pregnant Females:** Pregnant women should not handle crushed or open ENTADFI capsules.
- **Hypersensitivity Reactions:** Immediately discontinue if a hypersensitivity reaction occurs.
- **Prolonged Erection and Priapism:** Use with caution in patients predisposed to priapism. Advise patients to seek emergency treatment if an erection lasts more than 4 hours.
- **Ocular Adverse Reactions:** Stop use in the event of a sudden loss of vision in one or both eyes. Such an event may be a sign of non-arteritic anterior ischemic optic neuropathy (NAION). Use with caution in patients at increased risk of NAION.
- **Sudden Hearing Loss:** Stop use and seek prompt medical attention.

#### ADVERSE REACTIONS

Most common adverse reactions associated with finasteride monotherapy ( $\geq 1\%$ ) in a 4-year study were impotence, decreased libido, decreased volume of ejaculate, breast enlargement, breast tenderness, and rash.

Most common adverse reactions ( $\geq 2\%$ ) associated with tadalafil were headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, and pain in limb.

To report SUSPECTED ADVERSE REACTIONS, contact Veru Inc. at 1-866-936-8233 or [www.verupharma.com](http://www.verupharma.com) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

#### DRUG INTERACTIONS

**CYP3A4 inducers:** Concomitant use may increase tadalafil exposure. Use is not recommended.

#### USE IN SPECIFIC POPULATIONS

##### Hepatic Impairment:

- Child's Pugh Class A and B: Use with caution.
- Child's Pugh Class C: Use is not recommended.

##### Renal Impairment:

- Creatinine clearance less than 50 mL/min or hemodialysis: Use is not recommended.

Please see full Prescribing Information at [ENTADFI.com/pi](http://ENTADFI.com/pi).

\*Compared to finasteride alone.

**References:** 1. Casabé A, Roehrborn CG, Da Pozzo LF, et al. Efficacy and safety of the coadministration of tadalafil once daily with finasteride for 6 months in men with lower urinary tract symptoms and prostatic enlargement secondary to benign prostatic hyperplasia. *J Urol*. 2014;191(3):727-733. doi:10.1016/j.juro.2013.09.059 2. ENTADFI. Prescribing information. Veru Inc.; 2022.

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## SCIENCES

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