# DAILY NEWS



FRIDAY | MAY 13, 2022

### **DON'T MISS**

### 7:30-7:50 a.m. Great Hall A

Second Opinion Cases: Focal Therapy for Prostate Cancer: Should It Replace Standard of Care?

### 7:30-9:30 a.m. Room 211

Advancing Gender Equity in Urology: Allyship for Men and Advocacy for Women

### 8:05-8:25 a.m. Great Hall A

Panel Discussion: Women in Urologic Oncology: Past Present and Future

### 1-2 p.m.

Great Hall A
Semi-Live Surgeries/Surgical
Techniques: Oncology

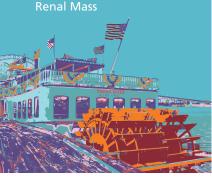
### 1-3 p.m. Room 345

Editorial Workshop: Gettin Published and Beyond

### 2-2:15 p.m. Great Hall A

AUA Guidelines: Localized Prostate Cancer

### 2:45-3 p.m. Great Hall A AUA Guidelines Update





# **WELCOME TO AUA2022**

he 2022
AUA Annual
Meeting will
be like no
other. Whether you
are physically in New
Orleans or learning
online from home,
AUA2022 has been
developed in a way that
combines the best of
both worlds to deliver

innovative, evidence-based, quality education for urologists and urological health care professionals in formats that accommodate both in-person and virtual learning.

"We have a very dynamic program for the meeting this year," said John Denstedt, MD, FRCSC, FACS, FCAHS, secretary of the AUA and professor of urology at Western University in London, Canada. "We will present cutting-edge material with a focus on new technology and other hot topics



Dr. John Denstedt, AUA Secretary

in the diagnosis and treatment of urological disorders."

More than a hundred hours of science and education will be offered at AUA2022, covering the full spectrum of urology. The meeting will include a robust offering of learning and

engagement, including abstracts, keynotes, surgical videos and space to connect with sponsors, exhibitors and educators from around the globe.

Programming highlights include:

- Plenary sessions featuring today's leaders in urology and popular sessions like Crossfire Debates, Semi-Live Surgeries/ Surgical Techniques, Second-Opinion Cases, When Disaster Strikes and How I Do It.
- New clinical guidelines.

and treatment of urological disorders."

John Denstedt, MD

We will present cutting-edge material with a focus

on new technology and other hot topics in the diagnosis

John Denstedt, MD, FRCSC, FACS, FCAHS

- More than 85 instructional courses
- Poster, podium and video sessions.
- Confederación Americana de Urología (CAU) program.
- Special programming that includes the Young Urologists and Residents Forums.
- New Bladder Cancer Forum.
- Industry programming that highlights the latest technologies and advances, including the new Emerging Corners and Robotics Theatre programs.

In addition to participating in the live event, all attendees will have access to on-demand recordings through August 31, 2022.

Dr. Denstedt said that although he is excited about this year's programming, he's even more excited to be able to attend the event in person.

"It's been two years, and we think a lot of people, both domestically and internationally, are excited about getting back to an in-person meeting," he said. "We have all seen some benefits from virtual meetings but miss the networking that is facilitated by in-person meetings—the human-to-human interactions and casual discussions that can occur in both scientific and social settings."

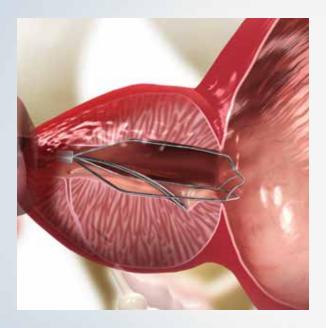
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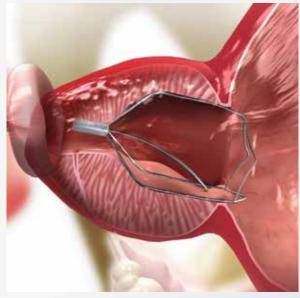
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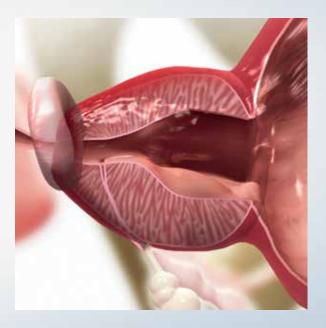




# How the iTind™ Procedure Works







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

### **VISIT OLYMPUS BOOTH 537**

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

# UPDATED GUIDELINES IMPROVE MANAGEMENT OF RENAL MASSES

UA guidelines for the evaluation, management and follow-up of localized renal cancer have been updated for the first time since 2017. The new guidelines are based on critical evaluations of the literature through January 2021.

"By 2020, it became clear that a number of elements in the 2017 guidelines needed to be updated," said Steven A. Campbell, MD, PhD, chair of the AUA Guidelines Panel and professor of surgery at the Cleveland Clinic in Ohio. "Along with updating, the guidelines for following patients with localized kidney cancer after intervention have been merged with guidelines for evaluation and management. We now have just one guideline instead of two."

Dr. Campbell will present an "AUA Guidelines Update" on renal masses during Friday's

AUA Guidelines Update: Renal Mass Friday, May 13 2:45-3 p.m. Great Hall A plenary session, where he will highlight important changes in several areas, starting with expanded indications for genetic counseling.

"Over the past decade, Steven A. our knowledge MD, PhD regarding familial kidney cancer has advanced substantially, and we now recognize that familial etiology is more common than previously appreciated," Dr. Campbell said. "Based on this, the guidelines have been updated to provide a more comprehensive profile for which patients should be considered for genetic counseling."

The revised guidelines also address adjuvant therapy for the first time. The change is a reflection of clinical trials of adjuvant agents showing evidence of potential benefit for some patients.

Advances in imaging also played into the new guidelines. Magnetic resonance imaging (MRI) with contrast can now be used even in patients with



Steven A. Campbell, MD, PhD

severe chronic kidney disease or end-stage renal disease, thanks to the development of secondand third-generation kidney-sparing gadolinium contrast agents.

"This is a real game changer for our daily clinical practice," Dr. Campbell said. "It

was always hard to evaluate patients with severe chronic kidney disease or end-stage renal disease because first-generation MRI contrast agents could lead to nephrogenic systemic fibrosis. Now you can just get an MRI in most patients with very little risk at all."

Indications for renal mass biopsy have been revised in the new guidelines to emphasize a utility-based approach. If biopsy results could change management or help decide between different management options, the procedure may be appropriate. If a biopsy lacks clear clinical utility, the guidelines advise against doing it.

Similarly, recommendations for partial versus radical nephrectomy have been clarified to be more useful. Prior recommendations and current non-AUA recommendations generally advise partial nephrectomy "whenever feasible," Dr. Campbell said.

"We provide more granular recommendations for who actually needs a radical nephrectomy, with the goal of making sure that patients who need a radical get it, while recognizing that radical nephrectomy can be overutilized," he explained.

Indications and rationale for active surveillance have also been clarified to be more specific. Follow-up recommendations for patients on active surveillance are also more detailed than in earlier guidelines.

"These guidelines are specifically designed for the practicing urologist to offer more useful recommendations to help them manage patients in an optimal manner," Dr. Campbell said. "If you see patients with renal masses, this session will be useful in your daily practice for the evaluation, counseling, management and surveillance of this patient population."



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### **EVERY STEP YOU TAKE COUNTS AT AUA2022**



tep up to this year's
Wellness Challenge at
AUA2022. Whether you
are attending in person
or from home, this challenge is an
opportunity to shift your focus to
fitness, being well and maybe even
winning big.

That's the inspiration behind the AUA Wellness Challenge, sponsored by UroGen Pharma, Inc. (booth 837 in the Science and Technology Hall). AUA2022 attendees can start the challenge the first day of the meeting by either downloading the AUA2022 Wellness Challenge app from the Google Play store or the Apple App Store, or stopping by the Heka Health booth (located in The Square). The first thousand attendees who stop by the Heka Health booth will receive a free, AUA-branded fitness tracker to help track their steps as they navigate the convention center.

From there, just look for 9 QR codes around the convention center to get daily boosts that will help you reach your goal. Each QR code contains clues that will lead you to the next stop. The top steppers at the meeting will be entered into a drawing based on the number of steps taken to win prizes ranging from a free registration to next year's meeting to the top prize of a Peloton bike.

Siena Manoogian, AUA annual meetings coordinator, said the Wellness Challenge launched at last year's meeting. After the pandemic forced a last-minute change away from an in-person event last year, the challenge continued virtually. This year's hybrid event will allow those on site in New Orleans to participate along with those logging in from around the world. That's not the only change this time around.

"What's different from last year is that last year the challenge was based only on walking," Manoogian said. "This year, our app actually tracks all activities. It converts any steps that you walk—so if you go for a run, those steps are different than the steps that you click for just walking all day."

"If you did a mindfulness exercise on the app, you get points for that, too," added Keith Price, AUA senior manager of sponsorships and exhibits. "Or, if you do a yoga session in your room, you can log in and get points. So the challenge has evolved from a standard walking challenge to an overall wellness challenge."

Price said the hybrid nature of the AUA event—and the Wellness Challenge—will be a good opportunity for everyone to be a part of what's going on no matter where they are.

"I think it will be a nice way to have those open conversations and another way to appreciate everyone being back together in person," he said. It will also add an element of inclusivity for those tuning in from home. "I think it's going to be a fun challenge for our international attendees. They won't feel left out if they're back home participating and seeing everything happening on site."

Ultimately, Price said the goal is to promote the overall health and well-being of physicians.

"Urologists were identified as one of the specialties that had the most burnout in a recent study," he said. "So this is a way to bring that to light and encourage them to participate and help with those challenges of burnout."

### Walk and Win!

Prizes will be awarded based on the number of steps you take. A drawing will determine winners in each category.

- GRAND PRIZE Top 10
   Steppers: One winner will receive a Peloton Bike
- PLATINUM 65,000+ Steps: Two winners will receive an Apple Watch
- GOLD 50,000+ Steps:
   Two winners will receive one Complimentary Room Night at an official AUA hotel for AUA2023
- SILVER 35,000+ Steps:
   Two winners will receive a Complimentary AUA2023
   Member Registration
- BRONZE 25,000+ Steps: 10 winners will receive a \$50 Visa Gift Card

AUA Wellness Challenge, Sponsored by UroGen Pharma, Inc. Friday, May 13-Sunday, May 15

### NEW UPDATE TO CLINICALLY LOCALIZED PROSTATE CANCER GUIDELINES

adical prostatectomy and radiation therapy no longer represent the only definitive answers to managing patients with clinically localized prostate cancer. Active surveillance has emerged as the preferred approach for low-risk prostate cancer over the last few years, just one of the changes reflected in recently updated AUA guidelines.

"The field of prostate cancer has changed in important ways in the last five years, and our last guidelines on the management of localized prostate cancer came out in 2017," said James A. Eastham, MD, FACS, professor and chief of urology at the Memorial Sloan Kettering Cancer Center

**AUA Guidelines: Localized Prostate Cancer** Friday, May 13 2-2:15 p.m. Great Hall A

in New York. "This is a timely review and update to reflect new information that has become available since that prior publication."

Recent years have seen increasing use of multiple active surveillance strategies to manage men with lowand intermediate-risk localized prostate cancer, Dr. Eastham continued. For men with higher-risk disease, clinicians are integrating newer forms of radiation therapy and combining radiation with androgen deprivation therapy. There have also been improvements in the understanding of the management of pelvic lymph nodes at surgery and during radiation, as well as a growing use of next-generation imaging modalities.

Dr. Eastham will review the new guidelines, developed in collaboration with ASTRO (the American Society for Radiation

Oncology), during Friday afternoon's plenary session, "AUA Guidelines: Localized Prostate Cancer." The new guidelines are the first update to the comprehensive Clinically Localized Prostate Cancer guidelines published in 2017.

Among the key components of the new guidelines is a recommendation for active surveillance as the preferred management option for men with low-risk prostate cancer and some men with more favorable intermediate-risk cancer. Prior recommendations included active surveillance as a preferable option, but the new, more definitive recommendation is backed by stronger evidence with longer-term follow-up.

review new data on patient evaluation and follow-up and discuss the potential role of genomic classifiers," Dr. Eastham noted. "Five years ago, we had very little data on

"The new guidelines also

genomic biomarkers. While much research is still needed here, more recent publications are now beginning to show how such tests may be appropriately used to further inform management decisions.

"The new guidelines emphasize shared decision making to a greater extent than the 2017 guidelines," he continued. "In the context of localized prostate cancer, shared decision making means that both patient and physician need up-to-date information regarding the risks posed by the specific cancer as well as the risks posed by various treatment strategies that are being considered."

Some recommendations remain largely unchanged in the new guidelines, Dr. Eastham added. For example, radical prostatectomy and radiation therapy remain the primary



James A. Eastham, MD, FACS

treatment options for men who opt for treatment.

The new guidelines do, however, update the principles of surgery and radiation based on an additional five years of data and treatment experience. The updated recommendations

also reflect the most recent information regarding the occurrence and management of urinary incontinence, erectile dysfunction and other adverse events associated with more invasive treatment choices.

"Prostate cancer is the most common cancer that urologists treat," Dr. Eastham said. "Having the most up-to-date information for the appropriate evaluation and management of this all-too-common cancer is critical for our patients, their outcomes and their quality of life."

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State-of-the-Art Lecture: Single-**Use Ureteroscopes and New Technology: What Is in Store?** Saturday, May 14 1-1:15 p.m. Great Hall A

### **NEXT-GENERATION URETEROSCOPES PROMISE** TO IMPROVE SURGICAL EFFICIENCY, OUTCOMES

he landscape of ureteroscope options is constantly changing. This evolving technology not only offers more precision for urologists, but also better outcomes for patients. Saturday's Plenary: "State-of-the-Art Lecture: Single-Use Ureteroscopes and New Technology: What Is in Store?" will highlight next-generation ureteroscopes and how they may improve your practice and patient care.

One new ureteroscope currently seeking Food and Drug Administration approval uses robotic technology and an intuitive video-game-like joystick that promises better range of motion and more comfortable use compared to the wrist twisting often required with conventional ureteroscopes. "A robotic ureteroscope will be able to make movements we currently can't make with our ureteroscopes," said presenter Ben H. Chew, MD, MSc, who

will feature a video of the technology during this session. Dr. Chew, director of clinical research at the Stone Center at Vancouver General Hospital and associate professor of urology at the University of British Columbia, Vancouver, Canada, will also preview the features and benefits of a ureteroscope with laser automation.

"There's one on the market in Europe now that uses [artificial intelligence] to determine whether you're actually on the stone or not," Dr. Chew said. "If you're not on the stone, the laser won't fire."

This type of laser automation will offer potential safety benefits, and future artificial intelligence advances will aim to automatically set the laser to ideal settings to fragment the stone.

"Urologists are busy and we all don't necessarily have time to ... investigate the best settings. If the robot can figure this out for us, it will make things easier [especially] if the laser can adjust itself as you start lasering the stone," Dr. Chew said.

Second-generation

single-use digital ureteroscopes that offer better resolution, imaging and contrast will also be a focus of Saturday's session. "When you're lasering, you get flashes of light-it's

like looking into the sun-and the contrast of the image can make things very dark. These ureteroscopes will correct that," Dr. Chew said. A single-use ureteroscope

with improved resolution that measures intrarenal pressure was recently approved for use in Canada. It's hypothesized that elevated intrarenal pressure results in more postoperative pain and an increased risk of infection. "But we don't know what a safe pressure is. This ureteroscope will afford us the ability to do more studies.



Ben H. Chew, MD, MSc

We need more information," Dr. Chew said.

Generally, singleuse ureteroscopes offer a number of advantages compared to reusable ureteroscopes, including a 100% deflection and being

clean and ready to go—as long as you have them stocked. Still, are they a smart financial move for your practice? Dr. Chew will offer a cost-analysis of single-use versus reusable ureteroscopes.

"One downside to single-use ureteroscopes is the environmental cost. From a user standpoint, it always feels bad to throw something in the trash after every case," Dr. Chew said. From a financial perspective, however, Dr. Chew will offer a "magic number," a caseload threshold that determines when single-use ureteroscopes become more costeffective, based on the literature.

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I. Roehrborn, I Urol 2013

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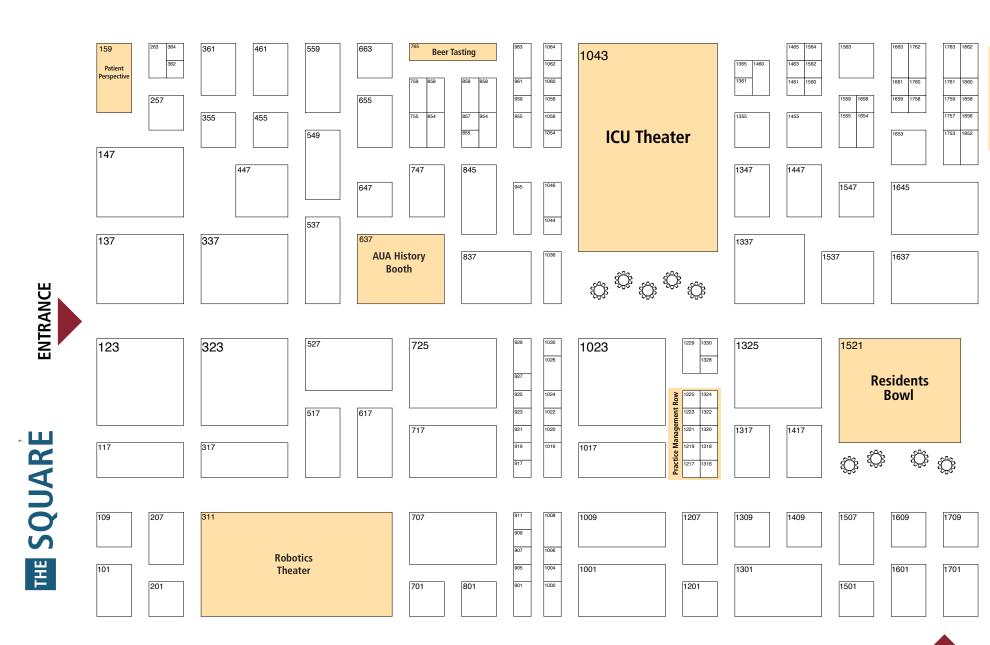


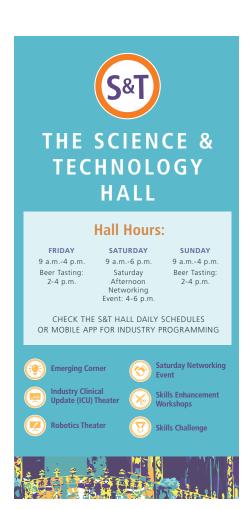


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## EXHIBIT FLOOR MAP





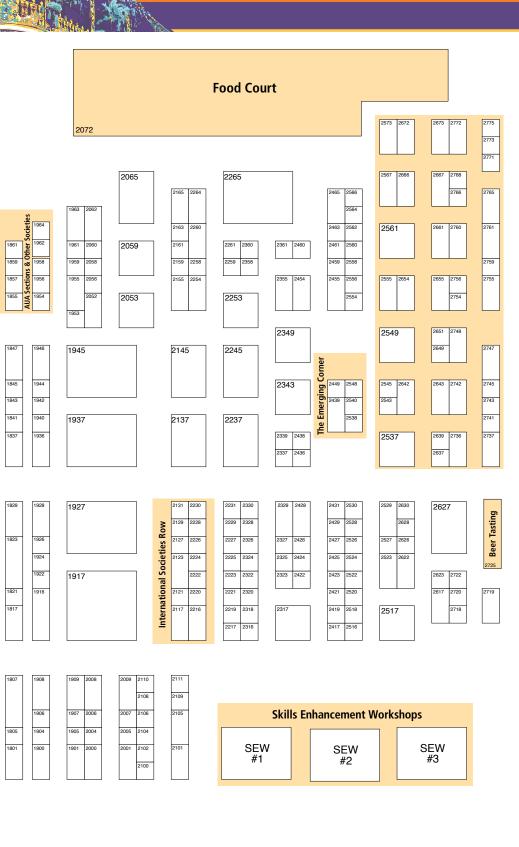
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## SOCIAL MEDIA PLAYS ROLE IN EARLY-CAREER UROLOGY

arly career urologists are no doubt skilled in social media. They can post and tweet with the best of them. But understanding social media's true impact on the career of a young urologist is not without challenges.

Discussing the pros and cons of social media is the focus of Saturday's Young Urologists Forum, co-chaired by Sammy Elsamra, MD, associate professor at Rutgers Robert Wood Johnson Medical School in New Brunswick, New Jersey, and chair of the AUA's Young Urologists Committee, and Jay Simhan, MD, associate professor of urology at the Fox Chase Cancer Center in Philadelphia, Pennsylvania. Despite a young urologist's social media savvy, according to Dr. Elsamra, there's still plenty learn.

Young Urologists Forum Saturday, May 14 10 a.m.-12 p.m. Room 278

"Can social media help

your professional reputation? It can help some in your local community as well as with peers and in research," Dr. Elsamra said, "but there are other considerations, too."

Dr. Elsamra believes that your practice's positive social media presence can result in referrals within your community and sometimes even further. Although many people associate urology with older patients, younger patients, who have grown up with social media, have urology needs, including postpartum women and children, he said.

However, there are pitfalls to the use of social media in your urology practice, too. Dr. Simhan reminds urologists to consider whether their posts are offensive, for example. Even the mention of circumcision, he said, can turn patients away. As young urologists craft social media posts, they should remember to keep their sense of humor in check as well as their opinions, even clinical opinions that seem harmless.

"If you come out with a

statement about a treatment or plan of care for patients, it may not fit all patients and may be contrary to other urologists' opinions," Dr. Simhan said.

As far as the different social media platforms that are available, Dr. Elsamra said Facebook often is the best forum for promoting your practice in your local community, while Twitter is effective for sharing information about research and networking with colleagues. Although Dr. Elsamra admits he is not an "Instagram super user," he said it may provide a balance between Facebook and Twitter.

Regardless of the platform, Drs. Elsamra and Simhan advise young urologists to develop a social media plan that includes what they'll post, with what frequency and the person or persons at their practice who will be responsible for the task.

Featured panelists adding to the discussion on social media during the forum include:



Sammy Elsamra, MD



Jay Simhan, MD

Stacy Loeb, MD, PhD, MsC, a professor of urology at New York University Grossman School of Medicine in New York, "Global Perspective, Promise and Pitfalls of Social Media."

Rena D. Malik, MD, assistant professor of urology at the University of Maryland School of Medicine in Baltimore, "Choosing a Platform (Instagram, YouTube, TikTok)—What Platform Is a Right Fit?"

Aditya Bagrodia, MD, assistant professor of urology at UT Southwestern School of Medicine in Dallas, "Nuts & Bolts of Podcasts, Defining Success with Social Media, Passion Project." Justin Dubin, MD, andrology fellow at Northwestern University Feinberg School of Medicine in Chicago, "Why You Should Use Social Media, Experience with Twitter, Passion Project to Avoid Burnout."

"Our four speakers have figured out a way to have a significant social media presence and can give examples to young urologists on how to do it to enhance their professional armamentarium," Dr. Elsamra said.

The Young Urologists Forum is designed to inspire and motivate early career professionals and help them in their common struggles as young urologists. Additionally, the forum will present the Young Urologists of the Year Award and close with the sponsor symposium, "Complications and Recurrence after Focal Therapy for Prostate Cancer." The symposium, sponsored by FUJIFILM, will be led by Andre Luis de Castro Abreu, MD, assistant professor of clinical urology at Keck Medicine, University of Southern California in Los Angeles.





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### **INDICATION**

JATENZO® (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 byportension and recovalisate whether the henefits of IATENZO outweigh its risks in patient
- 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 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
- 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
- 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
- whether to use or to continue to use JALENZO. JALENZO 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. psychiatric adverse events.

  JATENZO is not indicated for use in women.

- 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. cause is evaluated.
- Androgens, including JATENZO, may promote retention of sodium and water. Edema, with or without

- Aniorogenis, including JALENZO, may promote retention or 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
- discontinuation of testosterone therapy. Morntor the lipid profile periodically, particularly and 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.
- · Dépressión 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.

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

- 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 nations with cardiac range or hope tightings.
- 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

### **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, including BOXED WARNING on increases in blood pressure



# **VOICES&VIEWS**

JOIN THE CONVERSATION ON TWITTER. AND INSTAGRAM #AUA2022 🍑 👩



### @VUMCurology

Vanderbilt Urology

We all try to follow, but often hard to keep up with @urogeek and @UroCancerMD! Looking forward to **#AUA22 @AmerUrological** 

#### Patient Perspectives, All new at AUA2022!

Elevate your awareness of patient voices and shared decision making at AUA2022 with the new Patient Perspectives program. On Friday, May 13 from 1-3 p.m., selected abstracts will be presented by ten patients on topics such as the experience of prostate cancer patients, trans and nonbinray patient perspectives, and diagnostic uncertainty in benign renal masses and more!

The Patient Perspectives abstracts will be presented in **S&T Hall Booth #159**. The new program will be presented live on Friday, May 13 from 1-3 p.m., then play continuously from Saturday, May 14 - Sunday, May 15. This new program is supported by Pfizer.

### **Learn More**

### @gottsled

Debra Gottsleben

Excited to see this announcement about the Patient Perspectives Program at #AUA22 hmm wonder who'll be speaking about diagnostic uncertainty in small/benign renal masses? Hope to see my urologist friends at 1:50 in S&T Hall Booth #159!

### PRODUCT SPOTLIGHT





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Quantib booth 1944



forward to about AUA2022?

I am truly looking forward to seeing and interacting with friends and colleagues, attending the educational sessions and

experiencing the vibrant New Orleans environment. Best of all, with the hybrid format, I no longer have to race back and forth between sessions. I can just catch on video what I missed later that day or after the meeting.

> Jay D. Raman, MD, FACS Penn State Health Milton S. Hershey **Medical Center**

AUAU 2022 is called a "national meeting" because it is truly After two years of virtual interactions, the chance to actually meet my friends,

colleagues, mentors, former residents, fellows and more is what has me counting the days. I can't wait to learn something new from so many people I respect in our field and feel that energy of connections restored with those we've missed for too long.

Aseem R. Shukla, MD Perelman School of Medicine, University of Pennsylvania Philadelphia, Pennsylvania



While I always enjoy the science presented at the AUA and learn a great deal, this year I am most looking forward to just getting together

and seeing people in person. After two years of social distancing and Zoom meetings, it will be great to sit in the same room together and speak face to face as opposed to face and computer screen!

> David F. Penson, MD, MPH, MMHC Vanderbilt University Medical Center



of urology—all in person!

forward to learning about cutting-edge research in urology, networking with colleagues from around the world and making new friends who share a love

> Angela M. Smith, MD, MS University of North Carolina Chapel Hill, North Carolina





#### 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

- <u>Cardiovascular Risk</u>: Administer nitrates concomitantly only in life-threatening situations under close medical supervision.
- Potential for Drug Interactions when taking ENTADEI: 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 <u>Treatment for BPH</u>: 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 <u>Females</u>: 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.
- <u>Sudden Hearing Loss</u>: Stop use and seek prompt medical attention.

### ADVERSE REACTIONS

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

Most common adverse reactions (≥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 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

### DRUG INTERACTIONS

<u>CYP3A4 inducers</u>: 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.

\*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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