AUA2022 New Orleans
May 13-16, 2022 | Ernest N. Morial Convention Center | New Orleans, Louisiana

DAILY NEWS

SUNDAY | MAY 15, 2022

DON'T MISS

7-11:30 a.m.
Room 262
Residents Forum

7:30-9:30 a.m.
Room 204
Complications of Robotic Urological Surgery: Prevention, Recognition and Management

8:45-9:05 a.m.
Great Hall A
John Duckett Memorial Lecture: Lifelong Learning, What's in It for Me?

10-10:20 a.m.
Great Hall A
Panel Discussion: The Impact of the Internet on Sexual Medicine

10:30-11:45 a.m.
Room 228
Surgical Technology & Simulation: Training & Skills Assessment

1-2 p.m.
S&T Hall, Booth 1521
Residents Bowl: Finals

1-3 p.m.
Room 344
Research Forum: Early Career Investigators Showcase

PATIENT ENGAGEMENT DRIVES IMPROVED HEALTH CARE DELIVERY AND RESEARCH

The practice of urology takes teamwork, with patients being valued members of the team. Still, patients often aren't included in clinical discussions, treatment recommendations, research prioritization, or research design and conduct.

"It's equivalent to developing a consumer product without factoring consumer needs into product development and marketing," said Angela Smith, MD, director of urologic oncology at the UNC Lineberger Comprehensive Cancer Center in Chapel Hill, North Carolina, during Saturday's Journal of Urology® Lecture 2022: "Engaging Patients: A Challenge to Our Care Delivery and Research Priorities."

If you neglect consumer needs and feedback, the product isn't apt to be a success. Medicine is similar. "We've been leaving the patient out for decades," Dr. Smith said. "It's no wonder over half of our clinical trials fail, due to issues such as lack of recruitment."

Patient engagement combines interventions designed to increase patient activation—their knowledge, skills and willingness to manage their own health care—to promote positive patient behavior, such as obtaining preventive care or exercising regularly. Patient engagement is one strategy to achieve the triple aim of improved health outcomes, better patient care and lower costs.

"Engaging patients is a challenge to our care delivery and research priorities, but it's worthy of our time because it can lead to better outcomes and can reduce costs," Dr. Smith said. "When patients are engaged in their own health care, they're likely to use fewer services."

How can you intentionally engage patients in your practice or institution? Dr. Smith offered these recommendations:

- Direct care: When providing patients with information about a diagnosis, ask them about their treatment plan preferences. With an engaged patient model, "treatment decisions are made based on medical evidence and your clinical judgment, but also on patients' preferences," Dr. Smith said.
- Organizational design and governance: Survey patients about their care experiences. Hospitals can involve patients as advisors or advisory council members. "Patients can co-lead hospital safety and quality improvement committees," Dr. Smith said.
- Policy making: A public agency can conduct focus groups with patients to ask opinions about a health care issue. Use patients' recommendations about research priorities to make funding decisions for allocating resources to health programs. "Have an actual patient on your committees that create policies," Dr. Smith said.

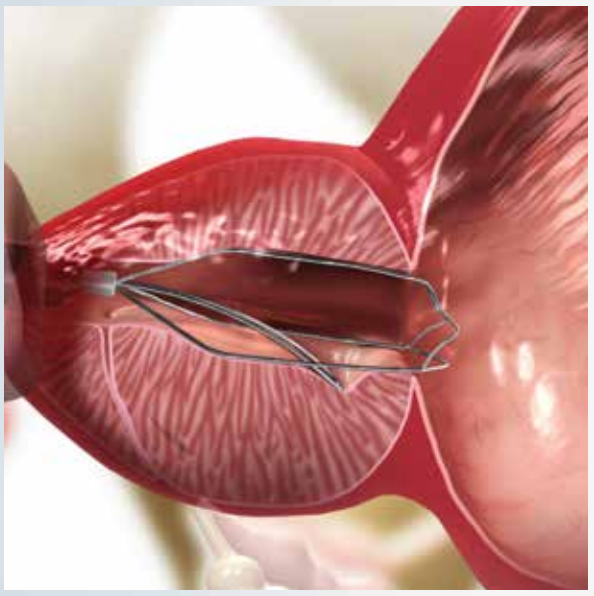
Intentional patient engagement also plays an important part in clinical research. "For urologists at the forefront of innovation, having studies that include the patient's voice helps channel which intervention to create and practice," Dr. Smith said.

"You can learn patient engagement skills and it doesn't take much effort," she added. Start by routinely asking three questions: Did we engage patients in shared decision making? Do we involve patients when optimizing our clinical operations or developing policy? Are patients involved in guideline development and dissemination? ●

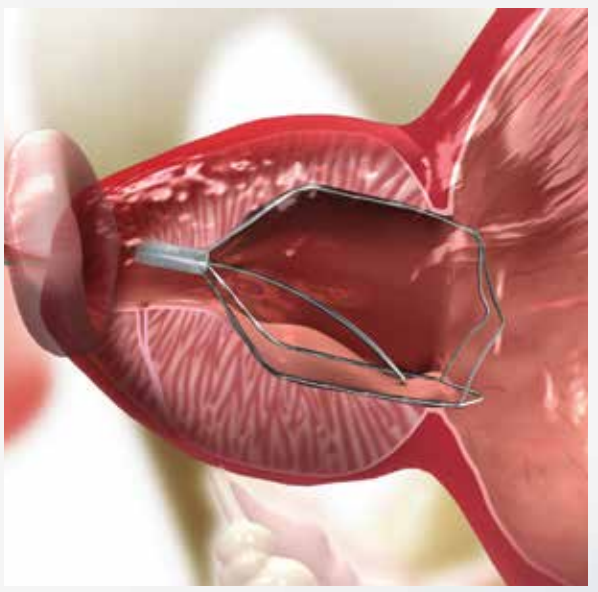
> "Engaging patients is a challenge to our care delivery and research priorities, but it's worthy of our time because it can lead to better outcomes and can reduce costs," Dr. Smith said. "When patients are engaged in their own health care, they're likely to use fewer services."
>
> **Angela Smith, MD**

OLYMPUS

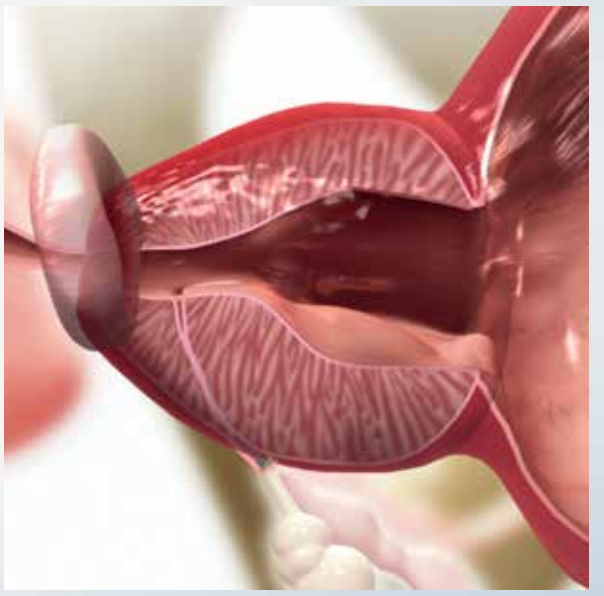
How the iTind™ Procedure Works



1 Implantation of the iTind device



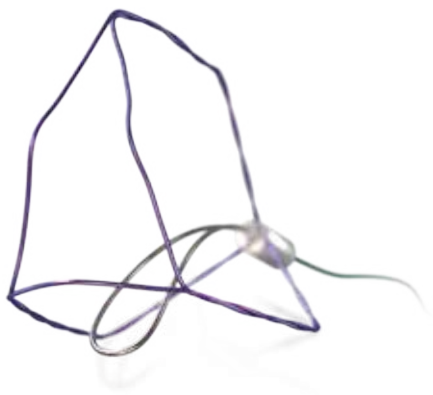
2 Treatment Period (5 to 7 days)



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.[1,2] 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.[1,2]
- 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.[1]



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

 I www.medical.olympusamerica.com I OAIURO0322AD44187

DISASTER RECOVERY

RESCUING LIGHT FROM DARKEST OUTCOMES

Cautionary tales were on display as four surgeons shared the shock and awe behind some truly concerning complications during Saturday morning's plenary session.

Moderated by Randall Meacham, MD, professor and chief of the division of urology at the University of Colorado School of Medicine in Denver, "When Disaster Strikes Again: Preventing and Managing Nightmare Cases in Urology" gave attendees a behind-the-scenes look at a list of worst-case scenarios and some tips on how to avoid those issues in their own practices.

"This morning our colleagues are going into some of the very darkest places they've ever been in hopes that you and I never have to go there ourselves," Meacham said. "These heroes are going to show you some of the most bitter aspects of some truly concerning complications to keep you from experiencing the same bitterness in your own practice."

Tobias S. Kohler, MD, MPH, professor of urology at the Mayo Clinic in Rochester, Minnesota, kicked off the session talking about a 27-year-old type 1 diabetic patient who came to his office with severe erectile dysfunction. The patient had elected to pursue penile implantation in order to have children with his fiancée, but because he'd already had a heart attack and bypass surgery, his case was complex.

"This was a pretty sick individual," Kohler said. "But he elected to pursue the implant because he wanted children."

Unfortunately, the first procedure didn't work and Kohler removed the device 16 hours after implantation.

"I was up all night worrying about [the patient]," he said. "I really thought the guy's penis might fall off."

The decision to remove the implant was the right one. The patient recovered and came back for a second attempt 13 months later. This time, Kohler said he opted for a smaller catheter, along with other tweaks, but in the end, the result was the same and he was forced to remove the device.

Tobias S. Kohler, MD, MPH

Fortunately, the story resulted in an odd but positive outcome.

"So he ends up back on my schedule and … I open the door to the office and there his wife is holding a newborn baby," Kohler said. "I tried to appear not confused and offered my congratulations. [The patient] says, 'Doc, ever since you removed that second implant, my penis is hard enough for sex.' Turns out there was so much scar tissue from all the damage we'd done, they were able to have a child."

Brian W. Cross, MD, associate professor of urologic oncology at the University of Oklahoma College of Medicine in Oklahoma City; Lindsay Hampson, MD, MAS, assistant professor at the University of California–San Francisco; and Rene Sotelo, MD, professor at the University of Southern California in Los Angeles, followed Kohler presenting cases focusing on (respectively) female organ-sparing cystectomy, suprapubic tube management gone awry, and how to best diagnose and treat superior mesenteric artery syndrome. ●

CROSSFIRE: TO TEST OR NOT TO TEST

Do urologists really need stone analysis and metabolic urine testing? That was the question posed at Saturday afternoon's Crossfire: Controversies in Urology Debate: "Do We Really Need Stone Analysis and Metabolic Urine Testing?"

Moderated by Glenn M. Preminger, MD, professor of urologic surgery at Duke University Hospital in Durham, North Carolina, the Crossfire session teamed "Yea" panelists Justin Friedlander, MD, and Sara Best, MD, against the "Nay" team of Kymora Scotland, MD, PhD, and Ryan Hsi, MD.

Dr. Friedlander, director of endoscopic urologic surgery and the Comprehensive Kidney Stone Center at Albert Einstein Medical Center in Philadelphia, Pennsylvania, came out swinging, saying that yes, stone analysis and metabolic testing are needed for several reasons.

"It helps make the diagnosis; it helps reduce recurrence; it is cost-effective for our recurrent stone formers; and it helps with compliance and management," Dr. Friedlander said. "It is also supported by the AUA guidelines and it gives hope to lifelong disease."

The AUA's current medical management guidelines include the following statements:

- When a stone is available, clinicians should obtain a stone analysis at least once. (Clinical Principle)
- Metabolic testing should consist of one or two 24-hour urine collections obtained on a random diet and analyzed at minimum for total volume, pH, calcium, oxalate, uric acid, citrate, sodium, potassium and creatinine. (Expert Opinion)

Dr. Scotland, assistant professor and endourologist at UCLA in Los Angeles, California, conceded that stone analysis and metabolic testing are guideline-supported items; provide patients with quantifiable targets; help with screening for rarer diseases like cystinuria and primary hypoxia; help noninvasively track patient compliance with fluids and medications; and give hope to patients who have a lifelong disease.

Kymora Scotland, MD

Justin Friedlander, MD

"But let's not forget the actual endpoint here," Dr. Scotland said. "[It] should be stone recurrence. There is no reason to do all of this if there is no effect on stone recurrence.

"It is my position that stone analysis and metabolic testing provide limited utility for most stone formers. [The tests] do not predict recurrence. They do not prevent recurrence, and they may, in fact, increase cost."

In her rebuttal statement, Dr. Best, an associate professor of urology at the University of Wisconsin School of Medicine and Public Health in Madison, said the tests allow for cost-effective precision medicine, improve patient buy-in and maximize patient outcomes.

Dr. Hsi, an associate professor of urology at Vanderbilt University Medical Center in Nashville, Tennessee, countered by positing that the tests are challenging to interpret, uncommonly performed and impractical in certain clinical scenarios. ●

American Urological Association

2022 AUA ANNUAL BUSINESS MEETING

HELD AT AUA2022

Monday, May 16 | 12PM
Rivergate Room, Morial Convention Center

Everyone is invited to attend the AUA's Annual Business Meeting. The agenda includes reports of the President, Secretary, Treasurer, Bylaws Committee and Audit Subcommittee.

Agenda is available at AUAnet.org/ABM

RESIDUAL FRAGMENTS: LEAVE OR CHASE?

Amy Krambeck, MD

Are clinically insignificant stone fragments (CIRFs) of less than or equal to 4 mm in the urinary system following an intervention, such as extracorporeal shock wave lithotripsy, ureteroscopy or percutaneous nephrolithotomy, truly clinically insignificant?

"Meta-analysis data indicate that about one-third of patients with residual fragments had a stone-related event requiring reintervention," said Amy Krambeck, MD, professor of urology and chief of the division of endourology/stone disease at Northwestern University in Chicago.

In Saturday's panel discussion, "Residual Fragments After Stone Surgery: Leave or Chase?," Dr. Krambeck cited the literature to build a strong argument for removing residual fragments, including evidence that residual fragments of greater than 2 mm after percutaneous nephrolithotomy are associated with the need for more surgery, infectious complications, renal insufficiency and a poorer quality of life.

"The pain score in patients with small nonobstructing renal stone improved when they were stone-free," Dr. Krambeck said.

Cost is another negative. Treating unplanned residual fragments costs roughly $100 more than the fixed cost of a planned completion surgery for residual fragments. Overall, "residual fragments are associated with increased stone events and the need for treatment, infectious events, decreased quality of life and increased health care costs," she added.

Providing the counterargument for leaving CIRFs alone, Thomas Tailly, MD, PhD, a urologist-endourologist at the University Hospital of Ghent, Belgium, argued that the very definitions of "stone-free" and CIRF are themselves up for debate.

"What size residual fragment is acceptable to leave? What size residual fragment is insignificant? There's a lack of consensus," Dr. Tailly said. Heterogeneity in data causes difficulties in defining residual fragments and their outcome during follow-up. "It's difficult to compare fragments head to head," he said.

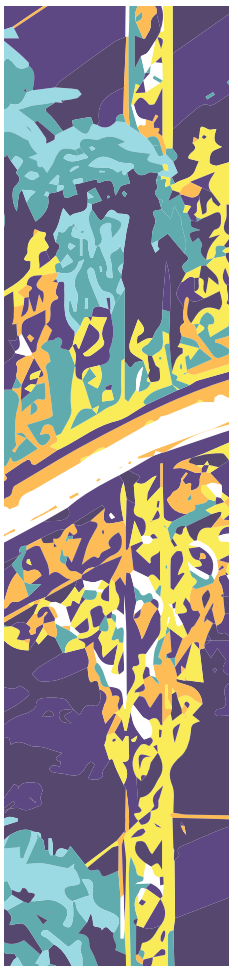
Moreover, Dr. Tailly argued that chasing residual stones of less than 4 mm is not cost-effective because residual fragments of this size are not likely to require reintervention.

What about quality of life for patients who don't undergo residual fragment treatment? Dr. Tailly cited Wisconsin Quality of Life Index questionnaire data from 313 patients, 36.6% of whom had a median 7 mm stone after undergoing stone treatment. "Patients were less happy if they were treated for a residual fragment," Dr. Tailly said.

Dr. Tailly argued that because most residual fragments of less than 4 mm won't need treatment, the routine treatment of residual fragments is more costly than observation.

"Quality of life is worse in patients who are treated for residual fragments, and adequate metabolic evaluation and preventive measures may reduce recurrence," he said.

Whatever course you decide to take, to treat a CIRF or not, "It's important to engage the patient in the decision," said moderator Daron Smith, MD.



ModMed
Urology

It's about time to find your flow

LOOKING FOR INNOVATIVE SOLUTIONS THAT ADDRESS PRODUCTIVITY, WORKFLOWS, PATIENT SATISFACTION AND STAFF RETENTION?

Stop by BOOTH #1609 to see the #1 urology-specific EHR and PM system* that also includes Patient Engagement, Analytics and more.

"To say that I absolutely love this program is an understatement."

— SIJO J. PAREKATTIL, MD, MEDICAL DIRECTOR, AVANT CONCIERGE UROLOGY

Plus, enter our raffle to win a new Apple Watch 7 Series by signing up for a demo at BOOTH #1609!

modmed.com/urology

ModMed
MODERNIZING MEDICINE

NEW APPROACHES CAN IMPROVE KIDNEY TRANSPLANT NUMBERS WORLDWIDE

The demand for kidney transplants far exceeds the supply of organs. A wait-listed kidney recipient can expect to wait five to seven years in North America and even longer in other parts of the world. New approaches to increasing the number of matched kidney donor-recipient pairs can increase transplantation rates and help patients get the lifesaving kidneys they need.

"Just in North America we have more than 100,000 patients on the kidney transplant wait-list," said Alp Sener, MD, PhD, FRCSC, chair and chief of urology at Schulich School of Medicine & Dentistry, Western University, in London, Canada. "If you extrapolate this to the rest of the world, the numbers can be staggering. Anything we can do to increase the number of potential donors will have a significant impact on the quality of life and lifespan of patients living with kidney disease."

Panel Discussion: Novel Methods to Boost Kidney Transplantation Globally
Monday, May 16
1-1:20 p.m.
Great Hall A

Dr. Sener will moderate the panel discussion "Novel Methods to Boost Kidney Transplantation Globally" on Monday from 1 to 1:20 p.m. Two panelists will discuss new approaches that may help increase the number of living donor kidneys available for transplantation.

Jeffrey Lorne Veale, MD, professor of urology at the University of California, Los Angeles David Geffen School of Medicine, has pioneered the use of a voucher system that effectively lets living donors give a kidney to a recipient today in return for a voucher that can later be redeemed for a future transplant by another person.

"The voucher could allow a parent whose child has a chronic kidney condition that will progress to transplantation at some point in the future to donate a kidney now for a wait-listed recipient," Dr. Sener said. "In return, the parent gets a voucher that guarantees an organ in the future when his or her child has progressed to needing a replacement organ, and the parent is no longer in prime physical condition to donate. That kind of flexibility has opened up transplantation numbers. Dr. Veale will discuss the program and share the data they have collected."

Michael A. Rees, MD, PhD, professor of urology and director of renal transplantation at the University of Toledo Medical Center in Ohio, has taken an international approach to ensuring patients across many countries receive lifesaving organ transplants. "Dr. Rees founded a nonprofit organization that works with transplant centers to find matches for incompatible donor and recipient pairs," said Dr. Sener. "This program has grown internationally and helps countries maximize paired donation programs.


Michael A. Rees, MD, PhD


Alp Sener, MD, PhD, FRCSC


Jeffrey Lorne Veale, MD

"Dr. Rees led the first global kidney exchange transplant in which a paired exchange mechanism was used to overcome the barrier of receiving a kidney transplant by a patient in another country," he said. "Creating chains between donor-recipient pairs in North America and overseas can lead to better surgical outcomes for patients in underserviced countries. In this manner, everyone wins."

Both approaches that will be discussed at the plenary session are highly regarded in the transplant literature in North America, Dr. Sener added, but slightly less so in urology because most of the transplants performed in North America are done by general surgery teams. It is important for urologists to know of the pioneering impact Drs. Rees and Veale are making on the global transplant community.

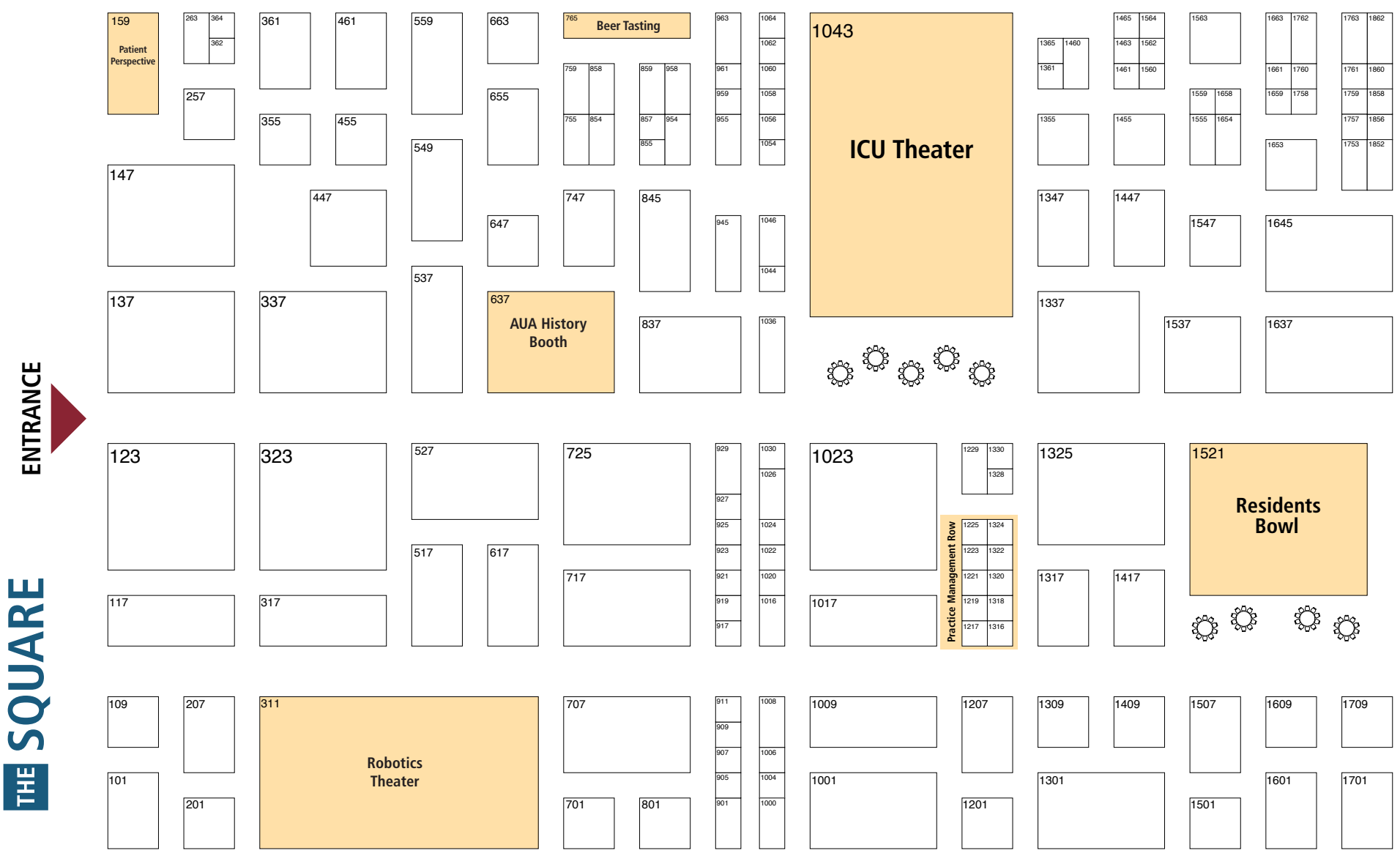
"Something as simple as voucher programs or the creation of international transplant chains can have a tremendous immediate impact on patient care and survival," Dr. Sener said. "At the same time, they can have a multimillion-dollar impact on the total health care system by getting patients off of costly dialysis." ●

Focal·One®
ROBOTIC FOCAL HIFU

The Leading **Prostate Focal Therapy** Controlled by Urologists

Hands-On Simulations
Booth #117 | FocalOne.com

EXHIBIT FLOOR MAP



EXHIBITOR LISTING

see EXHIBITORS page 10

EXHIBITORS

continued from page 9

Q-R

S

T

U

V

W

X-Y-Z

Exhibitors list as of April 12, 2022

American Urological Association

2022 AWARD WINNERS

RAMON GUITERAS AWARD
Glenn M. Preminger, MD
For outstanding service to the AUA and for pioneering and innovative work in the field of endourology

HUGH HAMPTON YOUNG AWARD
Arthur L. Burnett II, MD, MBA
For groundbreaking advances in male sexual health, as well as advocacy, diversity and humanitarian contributions

GOLD CYSTOSCOPE AWARD
Angela B. Smith, MD, MS
For outstanding leadership and contributions in bladder cancer and outcomes research

MID-CAREER AWARD
Kirsten L. Greene, MD, MS
For inspired institutional leadership, clinical expertise and service in the development of AUA guidelines

LIFETIME ACHIEVEMENT AWARD
Barry A. Kogan, MD
For outstanding leadership and contributions to the practice, science and education of pediatric urology

EUGENE FULLER TRIENNIAL PROSTATE AWARD
Claus G. Roehrborn, MD
For numerous contributions to the scientific study of BPH and its treatment

VICTOR A. POLITANO AWARD
Craig V. Comiter, MD
For a defining career centered on investigation, innovation and education in treating incontinence

WILLIAM P. DIDUSCH ART & HISTORY AWARD
Kevin R. Loughlin, MD, MBA
For demonstrating a passion for medical history and extensive publications on urological history

DISTINGUISHED CONTRIBUTION AWARD
Aria F. Olumi, MD
For outstanding contributions as AUA Research Chair, strengthening the pipeline of surgeon-scientists and researchers

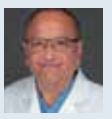
DISTINGUISHED CONTRIBUTION AWARD
Chandru P. Sundaram, MD, MS
For outstanding contributions in endourology and as a member of the AUA Board of Directors

DISTINGUISHED SERVICE AWARD
Toby C. Chai, MD
For exemplary contributions to the science of urology and advocacy for urological research

DISTINGUISHED SERVICE AWARD
Barbara B. Hartford
For innovative and impactful management of AUA finances, especially during the worldwide pandemic

DISTINGUISHED SERVICE AWARD
Janet V. Skorepa
For exemplary service in enriching AUA education, the Annual Meeting and member services

DISTINGUISHED SERVICE AWARD
Martha K. Terris, MD
For outstanding contributions to urological research and to the creation of the SEARCH database



GOLD-HEADED CANE AWARD
Julio M. Pow-Sang, MD, MBA
For a superlative career dedicated to advancing urologic oncology, resident education and physician development

PRESIDENTIAL CITATION
Patricia M. Banks, MS
For outstanding leadership in advancing AUA programs during the worldwide pandemic

PRESIDENTIAL CITATION
Diane E. Bieri, Esq.
For outstanding service and teamwork in navigating AUA operations during the worldwide pandemic

PRESIDENTIAL CITATION
Christian G. Chaussy, MD
For world-renowned leadership and unsurpassed contributions in shock wave lithotripsy and high-intensity focused ultrasound

PRESIDENTIAL CITATION
Rodney Davis, MD
For dedicated military service and for outstanding contributions to minimally invasive techniques for the treatment of urological malignancies

PRESIDENTIAL CITATION
Inderbir S. Gill, MD, MCh
For scientific innovations in robotic and laparoscopic oncologic surgery

PRESIDENTIAL CITATION
Victor W. Nitti, MD
For outstanding contributions as the AUA Education Chair advancing the Urology Core Curriculum and AUA*University*

Jelmyto®
(mitomycin) for pyelocalyceal solution

INNOVATION & INSPIRATION AWAIT

The experience starts here.

UroGen® Pharma

COMPETITION COMING TO ROBOTIC SURGICAL SYSTEMS

The world of robotic surgery is about to shift. Multiple new robotic surgical platforms have been approved or are in the approval pipeline, all with the promise of potential improvements in performance, cost or both over the current market-dominant leaders.

"Until very recently, for urology, robotic surgery has really meant the da Vinci® Surgical System from Intuitive Surgical," said S. Duke Herrell, MD, FACS, professor of urological surgery and of biomedical and mechanical engineering at Vanderbilt University, and director of robotic surgery for Vanderbilt Medical Center in Nashville. "Intuitive Surgical has had first-mover advantage with massive financial and market success around the world. We are just now finally seeing the first systems to challenge them emerge that have actually reached approval and use in several countries. It's not just laparoscopic robotic systems, there is growth in new types of procedural-specific robotics such as flexible endoscopic robots and rigid endoscopic robots as well."

S. Duke Herrell, MD, FACS

Dr. Herrell will moderate the panel discussion "Laparoscopic Robotic Surgical Systems–Emerging Systems in Urology Use" on Monday from 9:05 to 9:50 a.m. Urologists from Asia, Europe and North America will discuss their personal experiences with new systems in clinical use.

Some of these new systems are very similar to the da Vinci® system in terms of design and underlying mechanisms, whereas others have significant differences, Dr. Herrell said, and all continue to evolve.

What most urologists call surgical robots are truly "telepresence manipulators" that allow a surgeon to control instruments from a remote station that can be across the room or potentially a continent away. The technology underlying the da Vinci® system was originally developed for remote surgery to help military surgeons deliver care in places they could not get to physically.

That same approach, manipulating wristed instruments at a distance guided by 3D camera vision for the surgeon, eased many of the barriers that had delayed the widespread adoption of laparoscopic surgery for complex urological surgeries. Every urologist has seen the impact that the da Vinci® system has had on day-to-day practice, urology training and patient expectations.

As Intuitive Surgical continues to roll out its own innovations, competitors are developing and rolling out their own augmentations to image guidance and other key functions. There is also interest in automating surgical subtasks, which has already been done by orthopedic systems to improve drilling an area of bone for an implant.

"If a human sets up the robot properly and programs it correctly to perform a task that requires an immense amount of accuracy and precision and repetition, a robot can outperform a human—that's why auto manufacturers have incorporated robots," Dr. Herrell said. "What a robot doesn't do well is deal with variation. If we can't program a robotic car to reliably drive down the street in a complex scenario without running things over, we're not ready to put a robot in charge in a complex surgical task."

Even if surgical robots are not likely to replace surgeons in the near future, expect to see more robots in the operating room and interventional suites. Pulmonologists are already using bronchoscopy robots to access lung masses for biopsy that are small and hard to localize with conventional bronchoscopes.

At least two companies are thought to be developing flexible robots that promise improvements on current generations of flexible ureteroscopes, Dr. Herrell noted. Another device manufacturer is developing a rigid endoscopic robot platform, deploying multiple 1-mm arms through a 26Fr scope for enucleation, en-bloc transurethral resection of bladder tumors (TURBT), hysteroscopy and other procedures that can benefit from retraction, precise tissue removal and tissue manipulation.

"Robotics has already changed the landscape and the practice of urology in dramatic ways," Dr. Herrell said. "This session will explore the current state and competition that is emerging in the laparoscopic robot world, the kinds of robots that are already in use and hints of what is coming in other areas of urology." ●

Laparoscopic Robotic Surgical Systems–Emerging Systems in Urology Use
Monday, May 16
9:05-9:50 a.m.
Great Hall A

JATENZO®
(testosterone undecanoate)
Capsules

Booth
1507

WE PUT THE T IN ORAL SOFTGELS. LITERALLY.

This is individualized testosterone replacement therapy in a form that fits him.

Join us in The JATENZONE (Booth 1507) to learn all about JATENZO.

ICU Theater: An Individualized Approach to Oral Testosterone Replacement Therapy
Parviz K. Kavoussi, MD, FACS
Reproductive Urologist
Austin Fertility & Reproductive Medicine | Westlake IVF | Austin, Texas

Sunday, May 15 from 2:30pm – 3:30pm

Scan the QR code or visit JATENZOHCP.com to learn more.

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 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 ≥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, including BOXED WARNING on increases in blood pressure.

clarus THERAPEUTICS

QUESTION OF THE DAY

What is the best thing about being back at AUA2022?

"It's the sheer amount of education and resources just concentrated in one place. In a way, I think our AUA website kind of has that with AUA University. As a resident, I use that frequently with the core curriculum and all that stuff, but to have it in person with everything at your fingertips is something I don't think we get very often and we certainly haven't had for the past two or three years of the pandemic."

Kiran Sury, MD
Philadelphia, Pennsylvania

"The best part for me, at least, is to be back in person and to have those handshake connections and really get to see some people you haven't seen for a few years."

Ryan Nasseri, MD
San Diego, California

"It's to get to see all of the new technologies emerging. I'm very interested in minimally invasive surgery and I know a lot of that originated from urology and that's why I'm here."

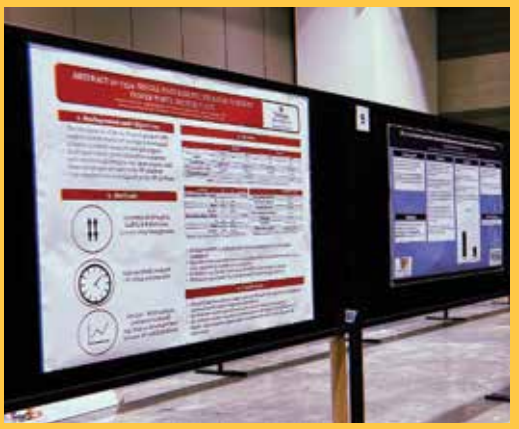
Aya Bsatee, DO
Oak Park, Illinois

VOICES&VIEWS

JOIN THE CONVERSATION ON TWITTER, AND INSTAGRAM **#AUA22**

Muhieddine Labban
@mdlabban
The 2022 **#AQuilon** team and alumni dinner at **#AUA22 #NOLA**
Our strength lies in our #Diversity and 🌎 representation

Ranjith Ramasamy
@ranjithramamd
Social media superstars **@justindubinmd @RenaMalikMD @LoebStacy @AdityaBagrodia** informing the audience how to and not to navigate these various platforms. Such a relevant and important talk. **#AUA22 #UroSoMe**



Daaniya Jamal
@DaaniyaJ
It is so humbling to be surrounded by innovations and improvements in clinical guidelines, noninvasive and invasive surgical procedures, equipment, and diagnostic parameters in both male and female urologic medicine **@AmerUrological #AUA22 #MedTwitter**

KATIE MURRAY
@KSMurrayUro
Amazing how many people I'm meeting for the first time in person that we feel like we have already known one another for years! **#UroSoMe #collaborations @SUO_YUO @AmerUrological #AUA22**

Boston Scientific Urology and Pelvic Health
@bsc_urology
Have you stopped by the **#AUA22** "Ins & Outs of Sexual Health" museum exhibit? Great info on the history of innovation in this important field! **#womenshealth #menshealth**

PRODUCT SPOTLIGHT

ENTADFI™
(finasteride and tadalafil)
capsules for oral use

Introducing ENTADFI.

FLOW HARD™

Faster and better relief of BPH symptoms without unwanted sexual side effects[1,2]*

Visit us at booth 2059

INDICATIONS AND USAGE
ENTADFI is a combination of finasteride, a 5α-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 (≥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
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.

*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.

UROVANT® SCIENCES

Makers of GEMTESA® (vibegron) 75 mg tablets

We look forward to connecting with you in person at this year's AUA meeting!

Thank you for the feedback you've provided to help us bring an important treatment option to the market in 2021.

Learn more about Urovant and how to find us at AUA

Urovant.com/AUA