CRT 2018 will feature the latest interventional cardiology technology and trials

Join more than 2,500 interventional and endovascular specialists at CRT 2018 for a comprehensive four-day interventional cardiology conference featuring cutting-edge data in a unique boutique setting. This robust conference will unite more than 200 fellows, experts and 500 faculty from around the world at the Omni Shoreham Hotel in Washington, DC, a few weeks later this year, from Saturday, March 3, to Tuesday, March 6—at the beginning of the cherry blossom season.

“There really is no other meeting that gives you the best content, helps you develop the best skill set to impact your practice and network with everyone,” said CRT Course Chairman Ron Waksman, MD. “You can choose à la carte which tracks and sessions you want to attend and build your agenda based on your personal need for education. It’s all within a close proximity so you don’t have to travel far to find something. Plus, there is something for everyone—whether you’re a physician, a regulator, fellow or industry member.”

The educational agenda includes presentations from 14 meetings and six tracks: Coronary, CRT Valve and Structural Heart, CRT Endovascular, Technology and Innovation, Atherosclerosis and Research and Nurses and Technologists.

Dr. Waksman said CRT 2018 comes on the heels of celebrating 40 years since the first percutaneous coronary intervention (PCI) and 15 years since the first transcatheter aortic valve replacement (TAVR), both technologies that are now reaching their maturity phase. CRT’s agenda will reflect their developments by focusing on more complex PCI cases and extending indications for TAVR, including low-risk patients. CRT will feature a series of late-breaking trials, including the first public presentation of the low-risk TAVR results.

President Barack Obama will keynote CRT 2018

U.S. PRESIDENT BARACK
Obama will reflect on his path to the presidency and his time in office when he takes the stage as CRT 2018’s keynote speaker.

Obama will share his unique perspective as the 44th president on Monday, March 5, at 8:15 p.m., before sitting down with Ron Waksman, MD, CRT 2018 Course Chairman, for a fireside chat to further the conversation about Obama’s life and career.

Born in Hawaii to a mother from Kansas and a father from Kenya, Obama was raised with help from his grandparents, whose generosity of spirit reflected their Midwestern roots.

After working his way through college with the help of scholarships and student loans, Obama moved to Chicago, where he worked with a group of churches to help rebuild communities devastated by the closure of local steel plants. That experience furthered his belief in the power of uniting ordinary people around a politics of purpose, centered in the hard work of citizenship. He found these principles to be powerful tools to bring about positive change.

President Barack Obama
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Structural valves in an ‘avalanche of activity’

Three areas in the interventional cardiology valve world have been experiencing dynamic developments in trials and devices in the past year, according to Ted Feldman, MD, MSCAI, director of the catheterization laboratories at Evanston Hospital in Illinois. The aortic, mitral and tricuspid valves have produced an “avalanche of activity,” with updates expected to be discussed during the Valve and Structural Heart tracks at CRT 2018.

AORTIC VALVE

While transcatheter aortic valve replacement (TAVR) has become established and the procedure in intermediate and high-risk patients has become standard of care, the trial efforts to expand the therapy into lower-risk, asymptomatic and heart failure patients are ongoing.

“At CRT, we can expect to hear a lot of discussion about the impact of these trials,” Dr. Feldman said. “Although the low-risk trials won’t be reported by the time CRT comes in March, we’ll be talking about how they’re going to change practice.”

Low-risk trials include the PARTNER 3 trial, which is measuring the safety and effectiveness of the SAPIEN 3 transcatheter heart valve from Edwards Lifesciences in low-risk patients with aortic stenosis, the Medtronic CoreValve low-risk trial and NOTION (Nordic Aortic Valve Intervention). The low-risk trial efforts are measuring post-interventional morbidity and mortality of TAVR compared to SAVR (surgical aortic valve replacement). Edwards is also enrolling patients in the TAVR-UNLOAD trial to study the impact of TAVR compared to medical therapy in patients with heart failure and moderate aortic stenosis.

Cardiac Dimensions’ CARILLON to treat mitral regurgitation received FDA approval to begin a large randomized U.S. trial in 2016, and the Edwards Cardioband System is enrolling patients in the new U.S. ACTIVE trial to study the safety and effectiveness of system in patients with functional mitral regurgitation.

At CRT 2017, some of the first human cases involving the use of the Edwards PASCAL transcatheter mitral repair spacer were shown. The device is now starting a U.S. early feasibility study, CLASP.

In addition, the LivaNova Caisson transcatheter mitral valve to treat mitral regurgitation recently successfully completed a case at MedStar Washington Hospital Center. Turn to page 6 to read more about the case.

Dr. Feldman said there are an increasing number of patients with three conditions: mitral annual calcification (MAC), prior surgical bioprosthetic mitral replacements and prior surgical mitral annuloplasty ring repairs. The FDA and Centers for Medicare and Medicaid Services (CMS) have approved mitral valve-in-valve to treat those conditions, while valve-in-ring and valve-for-MAC are under study. Valve-in-valve minimizes the chance for paravalvular leak and left ventricular outflow tract obstruction since there is an existing valve as a landing zone.

The implementation of balloon-expandable TAVR devices into MAC can treat stenosis or regurgitation and remains the most challenging among mitral interventions, since MAC usually precludes any other treatment options.

“MAC doesn’t have a surgical option,” Dr. Feldman said. “And the other two conditions don’t have other good treatment options. Valve-in-valve and valve-in-ring mitral would be a second operation for all of them. Not needing that second operation is a huge advantage to these patients. Many of them, by the time they need a second operation, can’t tolerate it.”

In addition, several additional mitral replacement prostheses for native mitral valve disease are under development and experience is steadily mounting. These programs are making steady progress in terms of human implant experience, so Dr. Feldman expects to discuss those during CRT.

TRICUSPID VALVE

Although the tricuspid field is still in its infancy, experience is steadily growing for tricuspid intervention.

The Trialign device to treat functional tricuspid regurgitation is still investigational, but Mitralign launched a European trial, SCOUT II, to test the system for eventual CE Mark approval.

The MitraClip device (Abbott Vascular) has also been used for tricuspid valve repair, with studies showing it is feasible and safe to treat tricuspid regurgitation and further studies being launched.

LIVE CASES 2018

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<tr>
<th>Location</th>
<th>Institution</th>
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<tr>
<td>Washington, DC</td>
<td>MedStar Washington Hospital Center</td>
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<td>Wynnewood, PA</td>
<td>Lankenau Heart Institute Main Line Health</td>
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<td>Belfast, Ireland</td>
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<td>St. Francis Hospital</td>
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<td>New York, NY</td>
<td>Mount Sinai Medical Center</td>
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<td>Case operators will be women in interventional Cardiology</td>
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CRT 2018 AT-A-GLANCE

**SATURDAY, MARCH 3**
- Morning Symposium
- CRT Valve - Mitral
- CRT Valve - Tricuspid
- BVS Technologies
- Primer and Skills for Endovascular Interventions
- CTS Academy
- ACS & AMI Management
- Atherosclerosis, Imaging & Therapies
- Nurses & Technologists
- Women in Interventional Cardiology Roundtable
- Women and Heart Luncheon
- Keynote: Dovett Quince
- Exhibitor Reception
- Abstract Café
- Evening Symposium: Disparities: Closing the Gap
- Keynote: The Honorable Donna F. Edwards
- Evening Symposium

**SUNDAY, MARCH 4**
- Morning Symposium
- CRT Valve - Mitral
- CRT Valve - Tricuspid
- BVS Technologies
- Primer and Skills for Endovascular Interventions
- CTS Academy
- ACS & AMI Management
- Atherosclerosis, Imaging & Therapies
- Nurses & Technologists
- Women in Interventional Cardiology Roundtable
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- Keynote: Dovett Quince
- Exhibitor Reception
- Abstract Café
- Evening Symposium: Disparities: Closing the Gap
- Keynote: The Honorable Donna F. Edwards
- Evening Symposium

**MONDAY, MARCH 5**
- Morning Symposium
- CRT Valve - Aortic
- DES Bioabsorbable & DCB Technologies
- Masters Transradial Intervention
- CRT Asia-Pacific Meetings
- Essentials of Clinical Research
- CRT Endovascular & CLI
- Complex Coronary Interventions I
- FDA Valve & Structural
- Japan FDA
- Evening Symposium
- Keynote Address given by President Barack Obama

**TUESDAY, MARCH 6**
- Morning Symposium
- Complex Coronary Interventions II
- CRT Stroke and Carotid Intervention
- CRT Valve - Structural Innovations
- Cardiovascular Innovations
- HHS/FDA Town Hall
- VA Interventional Symposium
- FDA Luncheon & Keynote Address
several research trials are underway to test new devices in peripheral artery disease (PAD) for treating patients with either claudication or critical limb ischemia (CLI) as endovascular treatments for these serious conditions continue to gain momentum for their less-invasive nature.

CRT 2018 will act as a hub of information for updates of these ongoing and completed trials as the information becomes available, said William A. Gray, MD, FACC, FSCAI, president of the Lankenau Heart Institute System and the national principle investigator for several of these clinical trials.

“We’ll likely have a couple of live cases from various trials,” Dr. Gray said. “We’re intending to do a Shockwave Lithoplasty® balloon case, and there may be others. Participants will likely see some of this new technology displayed along with new updates on the trials during this year’s meeting.”

The Endovascular track at CRT 2018 will include workshops on innovative technology pulmonary embolism therapies, drug-coated balloons and drug-eluting stents, endovascular aneurysm repair workshops, and current and future approaches to conquering in-stent restenosis.

Clinical Trials to Inform Topics

**SUPERFICIAL FEMORAL ARTERY (SFA) TRIALS**

- Although the Shockwave Medical Lithoplasty® Technology balloon has been cleared for SFA use in the U.S., it’s currently undergoing a trial comparing drug-coated balloon treatment in calcified lesions randomized to receive either Shockwave Lithoplasty® or regular balloon angioplasty in patients with PAD. The trial, DISRUPT PAD III, is the first trial that has specifically called out severely calcified lesions in the SFA as inclusion criteria, Dr. Gray said, noting the Shockwave is one of the most novel balloons on the market.
- Dr. Gray also noted that results of the LIBERTY 360 trial will soon provide revealing real-world data on lower-extremity disease to be discussed at this year’s meeting. As an “all comers” study sponsored by Cardiovascular Systems, Inc., LIBERTY 360 included any endovascular device FDA-approved for treatment of PAD in patients with a variety of clinical characteristics. The trial separated participants into two distinct categories: claudication and CLI, the latter being further stratified into Rutherford 4-5, and Rutherford 6.
- One-year results from LIBERTY 360 were presented at the Amputation Prevention Symposium in August 2013, are often difficult to recruit because of the population and some of the restrictions on entry criteria, Dr. Gray said.

  - “It’s an important population in need of directed solution, so we’re hopeful that Bard can finish their trial in relatively short order and we can have a positive outcome for below the knee,” Dr. Gray said, noting this will likely be a topic of discussion in the DCB session this year.

**CAROTID STENTING TRIALS**

- Carotid stenting is making a mini-comeback in terms of technology development, Dr. Gray said. The Gore SCAFFOLD Clinical Study for Carotid Stenting trial completed earlier this year and reported its 30-day results at the April Charring Cross meeting in London. The results showed an extremely low rate of stroke at 30 days in per-proctocol analysis.

  - “This stent is unique and the first of its kind in the U.S.,” Dr. Gray said. “It’s a 500-micron pore PEPTF mesh-covered, open-cell stent which is intended to reduce plaque protrusion and therefore prevent both early and potentially late events after carotid stenting.”

- There are two other trials using mesh-covered stents. After showing promising results in Europe, the CGuard™ stent from InspireMD and RoadSaver® carotid artery stent system from Terumo are being tested in pivotal U.S. trials.

  - “In my mind, when these stents become available and assuming good one-year data, they’ll be the de facto standard for carotid stenting due to both the theoretical advantage of mesh covering plaque preventing protrusion—which has been amply demonstrated on both IVUS and ICE evaluations—paired with outstanding 30-day safety data.”

- Lastly, CREST 2, (Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial), albeit slow in its enrollment, aims to answer the question whether treatment with angioplasty or endarterectomy is as good or better than treatment with modern medical therapy for patients with asymptomatic severe carotid stenosis.

  - “It’s an exciting time in the endovascular world,” Dr. Gray said, “and the care options for our patients have never been better.”

**ILiac TRIALS**

- The FDA approved the Gore® VIABAHN® VBX Balloon Expandable Endoprosthesis stent in January, making it the only balloon-expandable stent graft with an indication for the iliac artery. Dr. Gray predicts more application of the stent moving forward, since its already making its way into the branch and fenestrated EVAR systems.
Former U.S. Congresswoman’s personal life experiences will shape keynote

The Honorable Donna F. Edwards knows firsthand the importance of having access to health care. After experiencing unusual fatigue and exhaustion in her normally energetic and active lifestyle, she was diagnosed with multiple sclerosis in 2016. Now, she not only works to close the disparity gap in health care from a politician’s perspective, but also uses her experience as a patient to strengthen her advocacy efforts. Edwards will deliver the “Disparities & Closing the Gap” keynote address during Sunday’s evening symposium, speaking to her experiences and advocacy to close the disparity gap in health care.

Edwards was the first African American woman elected to represent Maryland in the U.S. Congress. She served five terms after being elected in a special election in June 2008. Edwards is currently a senior fellow at the Brennan Center for Justice. A graduate of Thomas Stone High School in Charles County, Maryland, she earned a Bachelor of Arts degree from Wake Forest University, where she was one of only six black women in the class of 1980, and now serves as a trustee. After college, Edwards began her career at the United Nations Development Program. In addition to her service at the UN, Edwards worked for the Lockheed Corporation in 1989 from the University of New Hampshire School of Law.

In her distinguished career, Edwards worked as an attorney in private practice, clerked for a District of Columbia Superior Court Judge and worked as a public interest lawyer. As a nonprofit executive, Edwards co-founded and led the National Network to End Domestic Violence, spearheading the effort to pass the Violence Against Women Act in 1994.

In Congress, she served on the Committee on Transportation and Infrastructure, Committee on Standards and Official Conduct, the Tom Lantos Human Rights Commission and the Committee on Science, Space and Technology, serving as the lead Democrat on the Subcommittee on Space. In her last term, Congresswoman Edwards was a member of the Democratic leadership team as co-chair of the House Democrat’s Steering and Policy Committee.

Biggest Loser trainer to keynote 10th annual Women & Heart Luncheon

The 10th Annual Women & Heart Luncheon will feature veteran health and fitness expert Dolvett Quince as the keynote speaker.

As one of the trainers on The Biggest Loser, Quince has dedicated himself to “helping people change their lives, one rep at a time.” Believing in the importance of reshaping mentally to transform physically is central to Quince’s fitness philosophy, which he will discuss in his keynote, “Reshape Your Mind, Body, and Future.” On Sunday, March 4, from 12 p.m. to 2 p.m. as part of the Nurses and Technologists track.

Since his humble beginnings as one of four siblings in foster care, Quince has never forgotten where he came from. It’s what keeps him motivated, paying it forward to his clients both mentally and physically.

During his early years as a trainer at the YMCA, he noticed that by helping his clients shape their bodies, he also was improving their self-esteem, creating an overall desire for better health. He still uses that philosophy today on The Biggest Loser and at his Body Sculptor Fitness Studio in Atlanta. Quince joined The Biggest Loser in 2011 and led his team and contestants to the win in his first two seasons. The show’s 14th season tackled childhood obesity and focused on helping teenagers lose weight and get healthy—a mission Quince is extremely passionate about and speaks on often.

In June 2012, Quince also participated in NBC’s celebrity competition series, Stars Earn Stripes, produced by Mark Burnett and Dick Wolf. And in November 2013, Quince released his first book, The 3-1-2-1 Diet. In his signature style, he helps readers reshape themselves mentally to transform themselves physically.

His business attracts such celebrity clients as Angela Bassett, former Baltimore Ravens tight end Daniel Wilcox, actor Michael Jai White and many more. Additionally, worldwide pop sensation Justin Bieber hired Quince to train him on his latest tour. Quince also developed the renowned Me and My Chair workout DVD, a low-impact, high-intensity 30-minute workout system that helps users tone up and slim down while using only a household chair.
Caisson’s TMVR system proves successful at MedStar Hospital

The days of open-heart surgery for treating patients with moderate to severe mitral regurgitation may soon be gone with the advent of LivaNova’s investigational Caisson valve.

A team of doctors, including CRT 2018 Course Chairman Ron Waksman, MD, recently successfully completed a transcatheter mitral valve replacement (TMVR) procedure at MedStar Washington Hospital Center using the Caisson valve. This was the first Caisson case performed at MedStar, but the 14th successful case overall for the medical device company, which is working its way toward performing the procedure in 20 patients for its ongoing PRELUDE early feasibility study. In conjunction with PRELUDE, Caisson is conducting the INTERLUDE trial, designed at getting the CE Mark in Europe. That will be a precursor for the forthcoming ENSEMBLE pivotal trial in an effort to receive FDA approval.

Price said treating mitral regurgitation in moderate to severe-risk patients in a sick patient population who are not good candidates for surgery was a top priority due to the “vicious cycle” the condition can create. “The heart gets bigger and causes more mitral regurgitation, and more mitral regurgitation causes the heart to get bigger, which then causes more mitral regurgitation,” Price said. “We’re starting with a population that really doesn’t have any other alternatives. We are trying to prove this therapy as kind of a new hope for them to live a better life.”

Caisson’s TMVR system proves successful at MedStar Hospital

The Caisson TMVR system has several unique market differentiators including the fact it was designed solely for transspetal delivery (versus others that use a transapical approach then try to convert) and the valve’s shape. “The valve is also unique because it has a ‘D’ shape,” said Brian Price, vice president of marketing for TMVR at Caisson. “If you think about the mitral valve, it is the shape of a ‘D,’ so it is anatomically correct in that regard. A lot of the other solutions are round, which opens them up to a paravalvular leak.”

The Caisson valve also features four sub-annular anchoring feet and a systolic anterior motion (SAM) management feature to help avoid blocking the left ventricular outflow track. Price said the company hopes to share more information about that feature at CRT 2018 along with updates on the data from the PRELUDE trial.

The TMVR’s two-part system is a prominent feature compared to other valves on the market—first, you place the anchor, then the valve, Price said. The valve is made out of porcine pericardium and has an EOA (effective orifice area) of 3, which is greater than surgical mitral valves used today.

Caisson team members retrained the MedStar doctors so everyone was familiar with the procedure. They also used a 3D printed model of the patient’s heart to simulate the case so the doctors knew exactly what movements to use on the delivery system. Three-dimensional printing and CT scans are used to screen and select which patients can receive the implant to make sure the device will fit.

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CRT 2018 Important Deadline Dates

**ABSTRACT SUBMISSIONS:** Nov. 20

**INNOVATIONS SUBMISSIONS:** Dec. 15

**INTERESTING CASE SUBMISSIONS:** Dec. 15

**LATE BREAKING TRIALS SUBMISSIONS:** Dec. 15

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**ABSTRACT CAFÉ & EXHIBITOR RECEPTION**

**Sunday, March 4**

5:30–7 p.m. • Exhibit Hall

CRT 2018 will host an Exhibitor Reception & Abstract Café to both welcome attendees to CRT 2018 and to feature accepted abstracts on Sunday, March 4. This event is a wonderful networking opportunity for abstract authors, attendees, and exhibitors. Complimentary food and beverages will be served.
The focus on structural valves will move more into the mitral and tricuspid this year with a full day dedicated to mitral technologies and trials. You can read about the latest in the interventional cardiology valve world on page 3.

“Meeting the provide will understand all the mitral anatomy and the new tech that’s going to be implemented in the upcoming trials,” Dr. Waksman said.

The four-day endovascular track will focus on acute stroke management and carotid stenting in addition to the latest technologies for chronic limb ischemia. Turn to page 4 for an update on all things endovascular.

New this year, CRT will feature an all-women live case from Mount Sinai Medical Center in New York. Everyone from the interventional cardiologists to the commentators will be female, which reflects CRT’s emphasis on women in interventional cardiology. CRT will host roughly 20 live cases through the meeting. The sites can be found on page 3.

“In addition, we are going to discuss heavily with experts in the field on three important topics related to atherosclerosis,” Dr. Waksman said.

“We’ll have an in-depth discussion on residual thrombotic risk, the FOURIER trail, which was the first pivotal trial to get PCSK9 therapy to a broader population, and what should be the optimal anticoagulation therapy for patients undergoing PCI or postmyocardial infarction."

Dr. Waksman said CRT will again feature three keynote speakers (addressed on pages 1 and 5), and he is looking forward to moving the field of interventional cardiology forward with the best faculty and attendees.

“I’m looking forward to meeting individuals that are coming with a high level of curiosity that like to engage and that are very active and interactive within the meeting,” Dr. Waksman said. “These individuals will benefit from attending CRT 2018 with respect to education, and practical skills backed by research and science, as well as the social and networking opportunities at the meeting.”

Other CRT 2018 highlights include:

- Three FDA symposia
- Masters course on renal denervation
- Meet the Editors of interventional cardiology journals
- Meet the Chief Medical Officers
- Pipeline Structural Technology

For the most up-to-date meeting information, visit CRTmeeting.org.