Deborah®

# Clinical UPDATE

Issue 1, 2016

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## BioMimics Stent
### Imitating the Natural 3D Helical Shape of the Vascular System

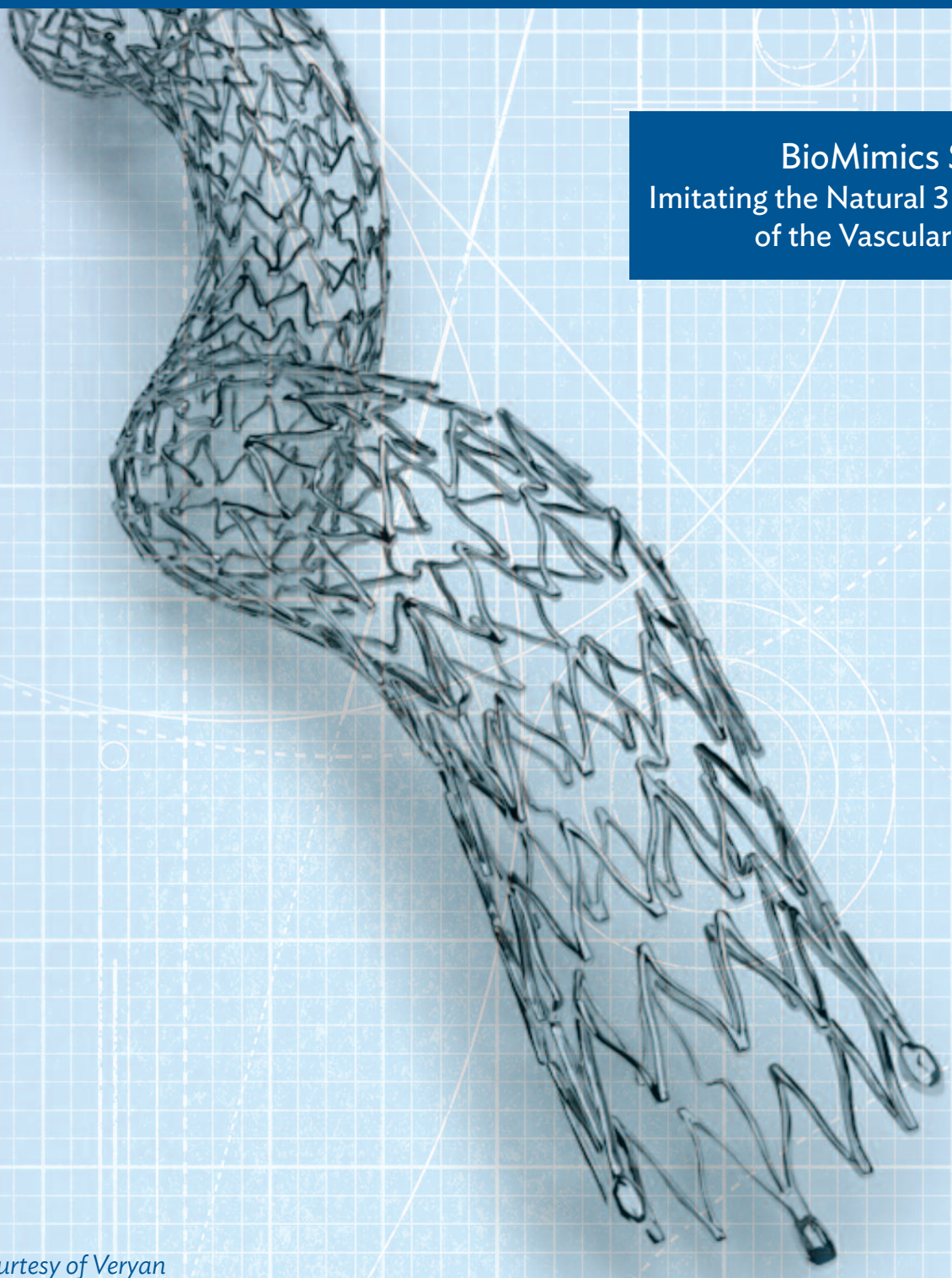


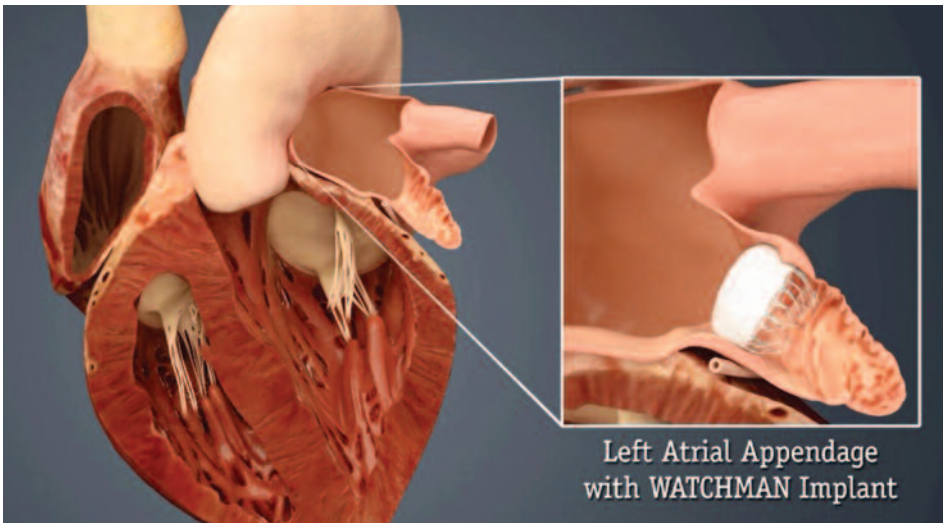
*photo courtesy of Veryan*

# New Treatment Options for Patients with A-Fib

Atrial fibrillation, or A-Fib, is the most common cardiac heart rhythm disorder, affecting more than five million Americans. Twenty percent of all strokes occur as a consequence of A-Fib, with more than 90% of these A-Fib-related strokes due to a thrombus – or clot formation – in an out-pocketing of the left atrium called the left atrial appendage (LAA). These clots can then break off and travel to the brain, blocking blood flow and causing a stroke. These strokes are more often fatal or severely disabling than non-A-Fib strokes.

Patients with A-Fib are therefore frequently put on warfarin (Coumadin) – or one of the newer blood thinners – to prevent clot formation. Warfarin requires frequent blood testing and is not always well tolerated. Additionally, as patients with A-Fib get older, their risk for stroke increases, as well as their risk of bleeding from blood thinners.

Deborah's interventional cardiologists, electrophysiologists, and cardiology teams have combined their expertise on a new implant – WATCHMAN™ – offering a novel approach to managing strokes caused by A-Fib.




For patients with non-valvular atrial fibrillation, the WATCHMAN left atrial appendage (LAA) closure implant provides a non-surgical alternative to long-term warfarin therapy. The implant, delivered via the groin, closes off the LAA, keeping harmful blood clots from leaving the LAA and entering the bloodstream. With the risk of stroke reduced, over time patients are usually able to stop taking oral anticoagulants like warfarin – welcome news for patients who seek a non-drug alternative to manage their stroke risk from A-Fib.

# LUCY Study Focuses on Endovascular Treatment of Abdominal Aortic Aneurysms (AAAs) in Women

The LUCY study "TriVascular Evaluation of Females Who Are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair" examines the potential for improved clinical outcomes associated with using the Ovation Abdominal Aortic Stent Graft platform for endovascular repair of abdominal aortic aneurysms (EVAR) in women, as well as men. The lack of adequate treatment options -- primarily due to more conventional large-bore EVAR systems -- is a persistent issue for female AAA patients. Clinical literature shows that women diagnosed with AAAs experience aortic expansion at a rate that is 40-80% faster than men, which can result in aortic rupture at smaller diameters. Due to their smaller stature, women with AAAs also typically have smaller femoral arteries, resulting in more challenges with vascular access. Often there may also be hostile aortic neck anatomy, resulting in significantly decreased options for on-label EVAR treatment. For more information about trial enrollment, contact Principal Investigator Richard Kovach, MD, at KovachR@Deborah.org.

# Cutting-Edge Research, Next Generation BioMimics 3D® Stent

Deborah's Clinical Research Department is working on cutting-edge research for the next generation of stents. Developed by Veryan and based on biomimicry, the new BioMimics 3D® stent technology involves adapting traditional straight stent designs to a patented three-dimensional helical shape, which more closely mimics the natural geometry of the human vascular system. BioMimics 3D technology is designed to enhance clinical performance by improving flow conditions and biomechanical performance of stented vessels. The advanced, biomimetic design of the BioMimics 3D stent is intended to provide more flexibility -- as well as kink and fracture resistance, in comparison to other laser-cut nitinol tube stents -- making its unique design of particular importance in the hostile environment of the femoropopliteal artery.

**"We are very excited to be working with this revolutionary new stent, which we expect will soon become state of the art," states Vincent Varghese, DO, Attending, Interventional Cardiologist and lead researcher on the study.**

The BioMimics 3D stent has a unique helical curvature to impart natural geometry to the diseased artery, promoting secondary (swirling) flow and elevated hemodynamic shear stress, which has a protective effect on the endothelium. The helical geometry of the BioMimics 3D femoropopliteal stent is also designed to enable coil-spring shortening of the stented segment during knee flexion and thus mitigate the risk of stented segment compression causing localized strains, which in a straight stent may lead to stent fracture and chronic vascular injury.

# Very Unusual Case
## *Successful Late-in-Life PDA Closure*

Deborah recently treated 33- and 45-year-old sisters, both of whom -- through lifetimes of medical missed diagnoses – required closure of a congenital patent ductus arteriosus (PDA). This opening between two major blood vessels leading from the heart is open when a baby is born, and normally closes shortly thereafter.

"It is extremely unusual to not have this diagnosed by the age of three at the latest," states Kintur Sanghvi, MD, Associate Medical Director of the Cath Lab at Deborah. "Because of the missed diagnosis, the disease process had progressed to almost an irreversible high-risk stage and both the sisters had been turned down for any repair by two different University hospitals."

Once at Deborah, both sisters were quickly and correctly evaluated, and two separate minimally invasive procedures repaired their congenital defect.

"It is difficult to comprehend, how not just one -- but two sisters -- could both have been misdiagnosed for so long. I am very glad they came to Deborah!" says Dr. Sanghvi.

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# Clinical *UPDATE*

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## *New Director*

Congratulations to Pedram Kazemian, MD, recently appointed as new Medical Director of Clinical Research.

*Deborah Heart and Lung Center is pleased to share with you our most recent outcomes data. For the entire report go to* ***www.demanddeborah.org/outcomes/.***

*The report includes results produced by our cardiology, electrophysiology and vascular divisions, in addition to cardiac surgery outcomes.*

*We remain appreciative of your ongoing support of Deborah's mission and look forward to providing the highest quality of care for you and your patients in the future.*

*Paul Burns, MD*
*Chair of Surgery, Deborah Heart and Lung Center*

**demanddeborah.org • Call Dr. Burns at 973-632-2123**