

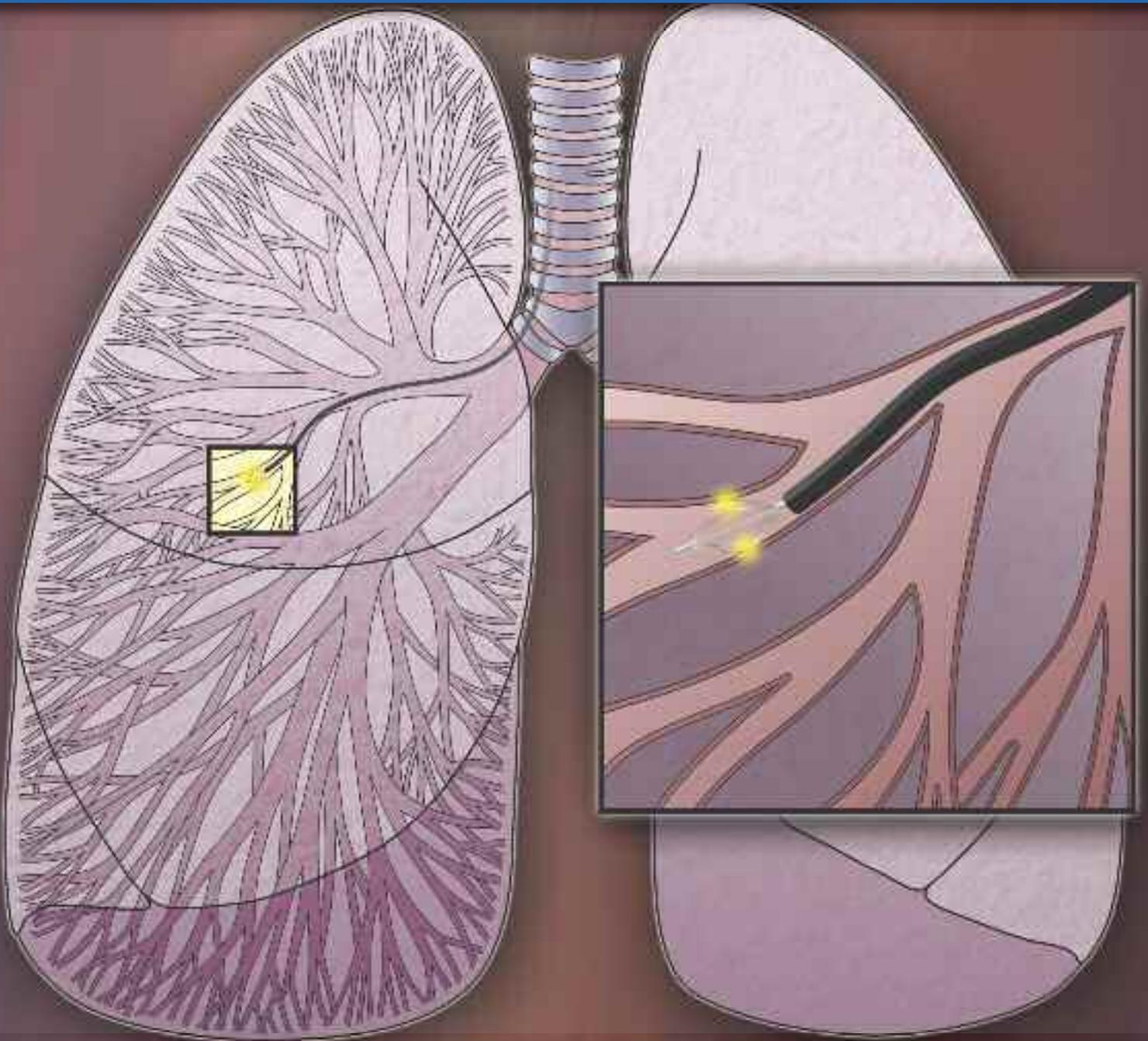


Clinical

UPDATE

Issue 1, 2013

DEBORAH® Heart and Lung Center



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DEBORAH®

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BUSINESS & LEGAL ISSUES FOR HEALTH SYSTEM LEADERSHIP

New Treatment Option for Severe Asthma Patients

Partnering with community pulmonary physicians and allergists – who sit on the front lines of day-to-day asthma management – Deborah Heart and Lung Center’s pulmonary team remains a vital link for those asthma patients who require a more intensive level of medical intervention. For those patients, Deborah is committed to offering the most-advanced medical treatment options, including the newest asthma treatment available – Bronchial Thermoplasty (BT).

Deborah has been a regional leader in successfully performing BT since the procedure first received FDA approval two years ago.

Bronchial Thermoplasty – delivered by Boston Scientific’s Alair® System—is the first FDA-approved procedural treatment for asthma, designed to help severe persistent asthma sufferers, whose condition is not well controlled with high-dose inhaled corticosteroids and long-acting beta-agonists such as Advair, Symbicort, and Dulera. Not all patients are candidates for this new treatment approach, but for those who do qualify, treatment involves moderate sedation with a minimally-invasive bronchoscopic procedure performed. During three separate outpatient procedure visits which are scheduled approximately three weeks apart, a different area of the lungs is treated. The first procedure treats the airways of the right lower lobe, the second treats the airways of the left lower lobe and the third and final procedure treats the airways in both upper lobes.

During each procedure a bronchoscope is introduced, followed by the Alair® Catheter and Alair® Controller through which Radiofrequency Energy (RF) is activated in a precisely-controlled manner in order to reduce excessive airway smooth muscle (ASM). Reducing the ASM decreases the constricting effect of that muscle, maintaining a larger opening for easier breathing.



This treatment has been shown to significantly reduce the frequency of exacerbations, asthma attacks, and emergency room visits.

The Alair® RF Controller delivers low-power, temperature-controlled RF energy for a maximum of 10 seconds per activation and a single activation delivers RF energy over a distance of 5 mm. After each activation the catheter is then repositioned contiguously and subsequent activations are performed. Following the procedure, if the patient’s heart rate, blood pressure, oxygen levels, and lung function test are normal, they are usually discharged the same day.

Bronchial Thermoplasty, combined with current asthma maintenance medications under a primary pulmonologist or allergist, is expected to provide long-lasting asthma control and improve asthma-related quality of life for patients with severe asthma.

Studies have indicated that BT contributes to a 32% reduction in asthma attacks; an 84% reduction in ER visits for respiratory distress; a 73% reduction in hospitalizations for respiratory symptoms; and a 66% reduction in lost work and school days. (Data supplied by Boston Scientific Corporation.)

“We are excited to be one of the first hospitals in the area to be able to offer this new procedure,” states Deborah’s Pulmonary Chair, Andrew Martin, M.D. “Since rolling out the use of bronchial thermoplasty, we have seen terrific results

in severe persistent asthma sufferers whose day-to-day quality of life has dramatically improved. Severe asthma sufferers can be referred to Deborah by their primary care physician, pulmonologist, or allergist to determine whether they are a candidate for this new procedure.”♥

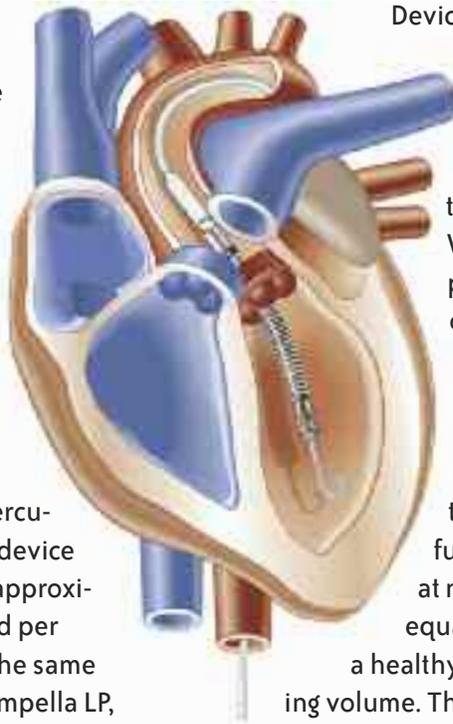
“Since rolling out the use of bronchial thermoplasty, we have seen terrific results in severe persistent asthma sufferers...”

Deborah Introduces Next Generation of Ventricular Assist Devices

Deborah's interventional cardiologists have followed on their successful 2009 debut of the Impella LP 2.5 device, by recently introducing the Impella CP (Cardiac Power). Built on the same foundation as the Impella 2.5, this next-generation left ventricular assist device provides more than a 50 percent increase in pumped blood volume, extending increased support to more critical patients.

The Impella CP is a percutaneous, catheter-based device providing peak flows of approximately four liters of blood per minute, and works with the same console platform as the Impella LP, which delivers 2.5 liters of flow per minute. The device is advanced through a 13 or 14 F sheath inserted

into the femoral artery and provides active heart support with continuous blood flow from the left ventricle into the ascending aorta.



Device manufacturer Abiomed received FDA clearance for its use in September 2012. With Deborah's previous history of Impella use, its interventionalists were well-positioned to easily switch to the more powerful pump, which at maximum flow equals 80 percent of a healthy heart's pumping volume. The increased flow has been extremely beneficial for patients requiring more hemodynamic support.

Jon George, M.D. was Deborah's first interventionalist to use the device. "It allowed me to work with a particularly difficult case, and provided the foundation for a successful procedure."

Kintur Sanghvi, M.D. agrees. "This new Impella enabled us to treat an 81-year old, very high risk for CABG, and also at very high risk for PCI. This was a great success story."

Richard Kovach, M.D., Chair, Interventional Cardiology adds: "This will give us the ability to reach patients who were previously too medically fragile to undergo procedures which could save their lives."♥



*Richard Kovach, M.D.
Chair,
Interventional
Cardiology*

News on Clinical Research

Two exciting new clinical research projects underway at Deborah offer innovative new pathways in cardiac care. For information on these, or other research projects, contact Linda Dewey, at 609-893-1200 ext. 5023.

*EVOLVE II trial to Assess the SYNERGY Stent System for the Treatment of Atherosclerotic Lesion(s) – The Synergy Stent System represents the next generation of drug-eluting stents and utilizes a bioabsorbable polymer

that degrades within four months, leaving behind a bare metal stent, thus reducing the need for prolonged dual-antiplatelet therapy. The Promus Element Plus drug-eluting stent will be used as a control for this study. This study is sponsored by Boston Scientific.

*PROspective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE) – A prospective multicenter imaging study for evaluation of chest pain. Objective is to determine

whether an initial non-invasive anatomic imaging strategy with coronary CT angiography (CTA) will improve clinical outcomes in subjects with symptoms concerning for coronary artery disease relative to an initial functional testing strategy (usual care). This study is sponsored by Duke University Clinical Research Institute in collaboration with the National Heart, Lung and Blood Institute (NHLBI).♥

Clinical UPDATE

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Deborah Heart and Lung Center, Browns Mills, NJ 08015

Joseph P. Chirichella, President and CEO

Lynn B. McGrath, MD, Vice President, Medical Affairs

Edmund T. Karam, MD, FACC, FHRS, Medical Editor

Marketing and Public Relations: Thomas J. Campbell III, Director;

Donna McArdle, Writer/Editor; June Lambert, Coordinator;

Susanna Kanzler, Proofreader

Media Communications Department: Frances Marshall, Layout/Design;

Barbara Minnick, Cover Design; Agnes Marsala, Photography

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Heart Failure Management-- Primary Care or Specialist?

More than two-thirds of heart failure patients are under the care of a primary care physician (PCP). Many PCPs who care for these patients with progressive, intensifying symptoms, question at what point a specialist should be brought in. Raffaele Corbisiero, M.D., Director of Deborah's Electromechanical Therapy Institute, offers some broad guidelines to address this question.

"In general," he says "we recommend that physicians gauge their patient's progress through the American Heart Association and American College of Cardiology (AHA/ACC)'s stages of heart failure – Stages A-D. In Stage A, a patient is symptomless, but at risk. Here a primary care physician

can have tremendous impact on a patient by encouraging them to make lifestyle modifications like quitting smoking and exercising. Medications are helpful at this stage if a patient has hypertension or other early signs of heart disease."

"In Stage B, we have an initial diagnosis of heart failure by a reduced ejection fraction. At this point a cardiology consult would be warranted to decide if any early procedural interventions can prevent further heart damage."

Dr. Corbisiero adds: "In Stage C with more progressive heart failure, patients are receiving an aggressive mix of medications. It is recommended that patients see a heart failure specialist for regular monitoring,

and certainly by Stage D -- advanced heart failure -- the patient should be transitioned into a specialty program of the caliber offered at Deborah. At any point in this progressive disease, however, Deborah's team is available for patient consult."♥

For more information about Deborah's Electromechanical Therapy Institute, please call 1-800-555-1990 or to refer your patient to Dr. Corbisiero, please call 1-800-214-3452.

*Raffaele Corbisiero, M.D.
Director,
Electromechanical
Therapy Institute*

