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Heart Endovascular & Rhythm of Texas Begins First Commercial, FDA-Cleared, In-Patient Use of DABRA™ to Treat Peripheral Artery Disease

Groundbreaking DABRA System Now Treating Texas Patients Preventing Diabetic Amputations

SAN ANTONIO--(BUSINESS WIRE)-- Today, the Heart Endovascular & Rhythm of Texas announced its latest collaboration with [Ra Medical Systems](#), makers of cardiovascular and dermatology catheters and excimer lasers, to use its groundbreaking DABRA™ System for the treatment of Peripheral Artery Disease (PAD) in order to combat the growing rise of diabetic amputations in San Antonio.

According to the City of San Antonio Metropolitan Health District, 14.2% of Bexar County adults have been diagnosed with (type 1 or type 2) diabetes, which is higher than the state and national average. People with diabetes have a high risk of serious health conditions such as diabetic amputations. In San Antonio, there has been a dramatic rise in the number of diabetic amputations.

The Rhythm Endovascular & Heart Institute of Texas is the first outpatient facility in Texas to commercially work with [Ra Medical Systems](#) to cross and treat arterial blockages via femoral artery access. It is also the first in the country to perform a procedure independent of the clinical trials for FDA clearance. This follows the California Heart & Vascular Clinic in El Centro, Calif., which participated in a FDA clinical study and treated the first post-FDA clearance patient, associated with the study, in early June.

With treating arterial blockages, according to Dr. Charles Bailey, interventional cardiologist of Heart Endovascular & Rhythm of Texas, "There are very few devices that are available today that are effective for opening CTOs (chronic total occlusions). If you can't get those vessels open, the only alternative is surgical, and unfortunately with surgical procedures, it runs the risk of infection," said Bailey. "This laser and catheter is unlike any other device because of its design. The fact that you can open up a vessel that's been closed for a long time and not have to place a stent in it and not have to operate on a patient, is phenomenal," he added.

The device is a catheter and excimer laser system for the treatment of complex and diffuse arterial blockages in the lower vessels. The single-use catheter produces a lumen while minimizing trauma to the vasculature. It is a full catheter tip forward cutter, without the "dead-space" of fiber optic bundle catheters. The DABRA laser photochemically ablates arterial blockages, reducing calcium, thrombus and atheroma, minimizing downstream debris. The

portable laser weighs about 100 pounds. DABRA is covered by most private insurance carriers and Medicare.

“Patients who have had the procedure have matched DABRA’s clinical study results, highlighting the efficacy and safety of this treatment to date, with zero adverse events,” said Dean Irwin, CEO, Ra Medical Systems. “We are thrilled to bring the DABRA system to patients and doctors in San Antonio in the treatment of Peripheral Artery Disease. With shorter procedure times, better patient outcomes and the procedure being less expensive, it’s a win-win-win for patients and their doctors and the healthcare system.”

Rhythm Endovascular & Heart Institute of Texas cath lab is working with [Ra Medical Systems](#) to be part of the next phase of clinical trials for coronary CTOs.

DABRA (Destruction of Arteriosclerotic Blockages by Laser Radiation Ablation) changes the paradigm of vascular treatments clinically and economically, continuing Ra Medical Systems’ decade-long successful track record of delivering better, safer, faster and less-expensive solutions to treat complex and chronic medical conditions. Compared to other treatments for arterial blockages, Ra Medical Systems’ DABRA has shorter procedure times, better patient outcomes and is less expensive. Combined with its safety profile and versatility, these DABRA advantages may reduce the costs that are associated with treating Peripheral Artery Disease and ultimately lead to greater patient access to, and success with, interventional procedures.

According to the Centers for Disease Control and Prevention (CDC), approximately 8.5 million people in the United States have PAD, including 12-20% of individuals older than age 60 and people of Hispanic origin may have similar to slightly higher rates of PAD compared to non-Hispanic whites. Risk factors for PAD include smoking, high blood pressure, atherosclerosis, diabetes, and high cholesterol.

Peripheral Artery Disease is [the leading cause of limb amputations. More than 200 million people worldwide](#), including [approximately 8.5 million Americans, suffer from Peripheral Artery Disease](#), a life-threatening condition in which the arteries that carry blood from the heart to the legs and arms narrow and become blocked. [In the U.S. and Europe, Peripheral Artery Disease is responsible for approximately 240,000 amputations every year. Nearly one-quarter of these patients die within 30 days and almost half within a year of their limb amputation.](#)

About Ra Medical Systems

Ra Medical Systems was founded in 2002 to commercialize excimer lasers and catheters for the treatment of dermatologic and cardiovascular diseases. Its flagship product, Pharos, launched in 2004 and revolutionized the dermatology world with its technology and affordable business model for greater patient access to treatment. Today, Ra Medical Systems continues to make history as it commercializes the DABRA System.

About Heart Endovascular And Rhythm of Texas (HEART)

Heart PA is a group of interventional cardiologists and a vascular surgeon who all specialize in treating patients with PAD. Their goal for every PAD patient is to avoid surgery or amputation if possible. Heart PA is located at 1202 E. Sonterra Blvd., Bldg 6 Ste 604, San

Antonio TX 78258. Heart PA's phone number is 210-844-2393. www.heartdoc.care

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