



## Biosense Webster Receives FDA Clearance for the CARTO(R) 3 System

### ***State-of-the-Art Navigational Mapping System Offers Unique Combination of Accuracy, Speed and Efficiency***

DIAMOND BAR, Calif., Oct 15, 2009 (BUSINESS WIRE) -- [Biosense Webster](#), Inc., a worldwide leader in the diagnosis and treatment of cardiac arrhythmias, announced today that the [U.S. Food and Drug Administration](#) (FDA) has cleared for marketing the CARTO<sup>(R)</sup> 3 System, the most advanced three-dimensional imaging technology for use by [electrophysiologists](#) in treating cardiac arrhythmias, commonly referred to as irregular heart rhythms.

It is estimated that 20 million people in the United States suffer from some sort of arrhythmia. [Atrial Fibrillation](#), or AFib as it's more commonly known, is the most prevalent cardiac arrhythmia affecting between 2.3 to 5.6 million adults in the United States alone and is the leading cause of stroke among people 65 years and older.

"The CARTO<sup>(R)</sup> 3 System is the world's most sophisticated 3D mapping platform on the market today and builds upon our long-standing commitment to electrophysiologists and their patients," said Shlomi Nachman, Worldwide President, [Biosense Webster](#), Inc.

The CARTO<sup>(R)</sup> 3 System offers three unique features: Advanced Catheter Location (ACL) Technology, Fast Anatomical Mapping (FAM), and a streamlined workflow feature set referred to as CONNECTION OF CHOICE<sup>(TM)</sup>. These three features work in tandem to enhance a physician's ability to treat an array of simple and complex cardiac arrhythmias.

ACL is a hybrid technology that allows for accurate catheter tip and curve visualization without spatial distortion. This helps the electrophysiologist to orient catheters with precision for diagnostic and therapeutic applications. The system can visualize up to five catheters simultaneously with clear distinction of all electrodes.

FAM is a leading-edge technology that quickly and accurately creates high-resolution, CT-like maps as quickly as an EP can move his or her catheter throughout the cardiac chamber. FAM technology also permits detailed visual enhancement of a specific area of interest within the heart.

CONNECTION OF CHOICE<sup>(TM)</sup> is enabled by the brand new CARTO<sup>(R)</sup> System hardware configuration featuring a central connection point for all catheters and equipment while preserving the signal quality of intracardiac electrograms. Catheter connections have been re-designed for "plug-and-play" functionality and automatic catheter recognition. All of these enhancements have been developed to streamline and simplify workflow in the EP lab.

"Procedure time is consistently cited by EPs as the most significant barrier to increased use of ablation therapy to treat cardiac arrhythmias," said Nachman. "All of the enhancements offered by the CARTO<sup>(R)</sup> 3 System have been developed to streamline and simplify workflow in the EP lab."

One of the leaders of the recent external evaluations, Vivek Y. Reddy, M.D. offered praise for the CARTO<sup>(R)</sup> 3 System.

"The CARTO<sup>(R)</sup> 3 System is an exciting technology that represents a major step forward for electrophysiologists. I was especially impressed with the Fast Anatomical Mapping [FAM] feature. I was able to create a map quickly and the accuracy was excellent," said Vivek Y. Reddy, M.D., Director, Cardiac Arrhythmia Service, The Zeng and Michael A. Wiener Cardiovascular Institute, The Marie-Josee and Henry R. Kravis Center for Cardiovascular Health. Dr. Reddy is also Professor of Medicine, [Mount Sinai School of Medicine](#) in New York City. "In addition, I was pleased with how the system merged with our CT scan. Overall, the evaluation was a great experience for the whole lab team who enjoyed the new quick system set up."

The CARTO<sup>(R)</sup> 3 System is the latest in a series of innovations from Biosense Webster. In recent months, the company has launched the [NAVISTAR<sup>\(R\)</sup> RMT THERMOCOOL<sup>\(R\)</sup>](#) Catheter in the U.S. and Europe and the [EZ STEER<sup>\(R\)</sup> THERMOCOOL<sup>\(R\)</sup> Bi-Directional Catheter](#) in the U.S.

Earlier this year, the FDA approved the NAVISTAR<sup>(R)</sup> THERMOCOOL<sup>(R)</sup> Catheter, including its bidirectional EZ STEER<sup>(R)</sup> Catheter platform, as safe and effective for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation

when used with the CARTO<sup>(R)</sup> System. The [NAVISTAR<sup>\(R\)</sup> THERMOCOOL<sup>\(R\)</sup> Catheters](#) are the first and the only ablation catheters approved by the FDA for the treatment of AFib.

Dr. Reddy is compensated for his time as a consultant to Biosense Webster.

***About Biosense Webster, Inc.***

Biosense Webster, Inc., a [Johnson & Johnson](#) company, pioneered electrophysiology diagnostic catheters more than 30 years ago and continues to lead the industry as an innovative provider of advanced diagnostic, therapeutic and mapping tools. As the leader in navigation systems and ablation therapy, Biosense Webster, Inc.'s technology includes the largest installed base of navigation systems worldwide in leading hospitals and teaching institutions. With proprietary products such as the CARTO<sup>(R)</sup> XP System, the CARTOSOUND(TM) Image Integration Software Module, the THERMOCOOL<sup>(R)</sup> Irrigated Tip Catheter and the LASSO<sup>(R)</sup> Circular Variable Mapping Catheter, the company is changing the way electrophysiologists diagnose and treat arrhythmias.

For more information about Biosense Webster, visit [www.biosensewebster.com](http://www.biosensewebster.com).

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