



## European Heart Rhythm Association Highlights Occupational Risk of Radiation Exposure in Electrophysiology Procedures

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- Stereotaxis technology included in recommendations to reduce fluoroscopy exposure and described as allowing “near zero exposure” to electrophysiologists
- Clinical data demonstrates significant reduction in radiation exposure for patients undergoing cardiac ablation procedures with Stereotaxis technology

ST. LOUIS, Mo., Feb. 01, 2018 (GLOBE NEWSWIRE) -- Stereotaxis, Inc. (OTCQX:STXS), the global leader in innovative robotic technologies for the treatment of cardiac arrhythmias, announced that the European Heart Rhythm Association (EHRA) has published a consensus document endorsed by the Heart Rhythm Society (HRS) highlighting the occupational risk of radiation exposure in the electrophysiology laboratory and presenting several ways to reduce that exposure.<sup>1</sup>

The occupational hazards to physicians and cath lab workers have been well documented in the literature. The EHRA consensus document states that “electrophysiology and training in electrophysiology may be associated with significant occupational radiation exposure.” Included in a list of recommendations for reduction of fluoroscopy exposure is the use of remote navigation systems such as the Niobe® magnetic navigation system from Stereotaxis.

Unlike most recommendations, which reduce radiation exposure, the EHRA consensus document describes remote navigation systems as allowing for “near zero exposure to operator(s).” The paper states that personnel in the electrophysiology laboratory who are positioned in the control room are protected by both shielding and distance from the x-ray beam, and that radiation exposure in the control room is 1,000 times lower than that seen in the operating room. During robotic navigation procedures utilizing Stereotaxis systems, physicians perform the ablation procedure from the control room, seated, unscrubbed, and protected.

“One of the primary benefits of the Stereotaxis system is reduction of harmful radiation to physicians, staff, and patients,” commented Dr. Sabine Ernst, co-author of the EHRA consensus statement. “The EHRA consensus statement, which was derived from evidence-based data from the literature, recognizes the Niobe remote navigation system for its contribution to making the electrophysiology lab safer by reducing radiation.”

The EHRA consensus paper adds to the list of clinical publications that have documented the significant risk of radiation exposure for physicians that perform interventional procedures. A study on interventional physicians with brain tumors found that 85% of tumors were in the left side of the brain as opposed to the right side, as the physicians usually stand with their left side closer to the x-ray source.<sup>2</sup> It has also been reported that occupational radiation increased the risk for physician and cath lab workers for skin lesions, cataracts, and cancer.<sup>3</sup>

The most common method used by healthcare professionals to protect against radiation exposure while in the electrophysiology lab is the wearing of lead aprons and protective gear. Protective lead aprons may weigh over 20 pounds, and the long term burden of this weight can lead to significant orthopedic problems. A recent survey was published that reported 49% of interventional cardiologists have suffered one or more orthopedic injuries as a direct result of their work in the cath lab, with 9% taking a health-related leave of absence.<sup>4</sup>

Stereotaxis' technology not only protects physicians and healthcare professionals from radiation exposure by removing them from the operating room, but has been shown to allow for reduced x-ray usage and associated radiation exposure for patients. While the EHRA consensus document focused on radiation exposure for healthcare professionals in the electrophysiology laboratory, the document also estimated that a patient undergoing a cardiac ablation procedure is exposed to 15.2 mSv of radiation per procedure. This value is the equivalent to approximately 760 standard chest x-rays (1 mSv = 50 chest X-rays<sup>5</sup>). In an internal systematic review of peer-reviewed publications describing clinical experience with Stereotaxis' remote magnetic navigation compared to manual ablation, comprising 20 publications and 4,567 patients in total, there was an average of 31% reduction in fluoroscopy time in robotic ablation procedures compared to manual ablation procedures.<sup>6</sup> Stereotaxis continues to explore ways to advance its technology to allow even further reductions in radiation exposure for patients.

<sup>1</sup>Sarkozy, et al. Occupational radiation exposure in the electrophysiology laboratory with a focus on personnel with reproductive potential and during pregnancy: A European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS) *EP Europace*, 2017; 19(12):1909–1922.

<sup>2</sup>Roguin A, et al. Brain and Neck Tumors Among Physicians Performing Interventional Procedures *Am J Cardiol* 2013;111:1368-1372.

<sup>3</sup>Andreassi MG, et al. Occupational Health Risks in Cardiac Catheterization Laboratory Workers. *Circ Cardiovasc Interv.* 2016;9(4):e003273.

<sup>4</sup>Klein LW, et al. Occupational health hazards of interventional cardiologists in the current decade: Results of the 2014 SCAI membership survey. *Catheterization and Cardiovascular Interventions.* 2015;86(5):913-24.

<sup>5</sup>Heidbuchel et al. Practical ways to reduce radiation dose for patients and staff during device implantations and electrophysiological procedures, *EP Europace*, Volume 16, Issue 7, 1 July 2014, pages 946-964, <https://doi.org/10.1093/europace/eut409>.

<sup>6</sup>Data on file.

### About Stereotaxis

Stereotaxis is the global leader in innovative robotic technologies designed to enhance the treatment of arrhythmias and perform endovascular procedures. Its mission is the discovery, development and delivery of robotic systems, instruments, and information solutions for the interventional

laboratory. These innovations help physicians provide unsurpassed patient care with robotic precision and safety, improved lab efficiency and productivity, and enhanced integration of procedural information. Over 100 issued patents support the Stereotaxis platform. The core components of Stereotaxis' systems have received regulatory clearance in the United States, European Union, Japan, Canada, China, and elsewhere. For more information, please visit [www.stereotaxis.com](http://www.stereotaxis.com).

*This press release includes statements that may constitute "forward-looking" statements, usually containing the words "believe", "estimate", "project", "expect" or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially from the forward-looking statements. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to raise additional capital on a timely basis and on terms that are acceptable, its ability to continue to manage expenses and cash burn rate at sustainable levels, its ability to continue to work with lenders to extend, repay or refinance indebtedness, or to obtain additional financing, in either case on acceptable terms, continued acceptance of the Company's products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase its systems and the timing of such purchases, competitive factors, changes resulting from healthcare reform in the United States, including changes in government reimbursement procedures, dependence upon third-party vendors, timing of regulatory approvals, and other risks discussed in the Company's periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this release. There can be no assurance that the Company will recognize revenue related to its purchase orders and other commitments in any particular period or at all because some of these purchase orders and other commitments are subject to contingencies that are outside of the Company's control. In addition, these orders and commitments may be revised, modified, delayed or canceled, either by their express terms, as a result of negotiations, or by overall project changes or delays.*

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