

FOR IMMEDIATE RELEASE



**SUCCESSFUL TRANSAPICAL ACCESS AND CLOSURE CLINICAL TEST
PERFORMED IN 6 COSECUTIVE INVIVO PROCEDURES USING THE
HEARTSTITCH TA**

Paris, France – March 8, 2016 – Dr. Michael Mullen, Cardiologist St. Bartholemews Hospital, London and **Dr. Yuriy Pya**, CEO and Chief of the National Research Center for Cardiac Surgery (NRCCS), Astana, Kazakhstan, successfully performed 6 in vivo tests of **HeartStitch TA** <http://heartstitch.net/heartstitchta.html>, remotely placing suture into the apex of the heart, to facilitate large bore access to the left ventricle for the treatment of structural heart defects. This collaboration between cardiology and cardiac surgery provided HeartStitch the valuable procedural technique and training knowledge required to finalize the design of the HeartStitch TA prior to clinical use.

Assisting in the procedure was Dr. Timur Lesbekov, cardiac surgeon at NRCCS, Astana and Prof. Anthony Nobles. The procedures collectively took approximately 4 hours to complete and led to refinements in the HeartStitch TA procedure and design that will be implemented this month. HeartStitch expects to perform further in vivo and ex vivo tests in April incorporating the input from this successful set of tests before First-In-Man clinical use of the HeartStitch TA which is expected to be performed in Astana, Kazakhstan within a few months following completion of the final tests.

Dr. Mullen commented, “We have been working on this device for some time and today we wanted to test the device performance under extreme and challenging conditions to assure its safety. Dr. Pya brought the perspective of the cardiac surgeon to procedure which proved to be critical in the technique we have been using.” Further commenting, “This technology, which is based on the same successful suture technology we use in PFO closure, shows tremendous promise in allowing access and secure closure of the apex of the heart using only suture, the same technique currently used by surgeons in open heart procedures.”

Dr. Pya stated, “I was very pleased with the procedures and impressed with the HeartStitch TA device. As surgeons, I am familiar with the benefits and outcomes of using suture rather than a bulky metal implant. These procedures today confirmed the potential for safe and effective access and closure of the apex using the HeartStitch device. I am very excited about the potential clinical benefit it will bring to my patients, allowing the less invasive approach to performing life

saving structural heart procedures.”

Professor Anthony Nobles, CEO of **HeartStitch** who assisted on the cases, stated "The HeartStitch TA performed incredibly well. More importantly the input from our clinical investigators gave us essential feedback to prepare for the clinical use of the HeartStitch TA. We have implemented their feedback in the procedural technique and in the device design. After completing the required testing, we will look forward to testing the final design and technique in the upcoming tests and the subsequent clinical cases in Astana, Frankfurt and in the UK."

About Transapical Access and Closure

Transapical Access and Closure is the technique of entering the left ventricle of the beating heart with an access device such as a cannula or sheath that allows the physician to access the chambers of the heart directly to perform procedures on the internal structures of the heart such as the valves, Left Atrial Appendage (LAA) and the septum. After completion of the procedure the access device is removed and the apical hole is closed using sutures. This technique allows for the use of larger devices and more direct control during the procedure as compared to the femoral or other remote vascular access which limits the size and increases the complexity of the devices used. Transapical Access and Closure can be performed in an open surgical setting, a limited thoracotomy which is a small incision between the ribs or percutaneously through a puncture in the intercostal space between the ribs.

About HeartStitch:

HeartStitch, Inc. was founded by Prof. Anthony Nobles with the intent of leveraging its technologies in the structural heart marketplace. HeartStitch is focused on the innovative suture-based systems for remotely providing suture repair of structural heart defects and other vascular structures.

HeartStitch manufactures and markets the NobleStitch EL under and exclusive license. NobleStitch EL is FDA cleared for vascular suturing in the United States and CE Marked for cardio-vascular suturing and PFO closure in the European Union.

HeartStitch® is a registered trademark of HeartStitch, Inc..

HeartStitch® TA for cardiac suturing and transapical access and closure

Covered by or for use under U.S. and international patents including one or more of U.S. Patent Nos. 5860990, 6117144, 6245079, 6551331, 6562052, 6733509, 7004952, 7090686, 7803167, 8197497, 8348962, 8469975, 8496676, and 8709020.

HeartStitch® MR for suturing an anatomical valve

Covered by or for use under U.S. and international patents including one or more of U.S. Patent Nos. 5860990, 6117144, 6245079, 6551331, 6562052, 6733509, 7004952, 7090686, 7803167, 8197497, 8348962, 8469975, 8496676, 8709020, and 8771296.

NobleStitch™ EL for PFO closure

Covered by or for use under U.S. and international patents including one or more of U.S. Patent Nos. 5860990, 6117144, 6245079, 6551331, 6562052, 6733509, 7004952, 7090686, 7803167, 8197497, 8197510, 8246636, 8348962, 8372089, 8469975, 8496676, 8709020, and 9131938.

For more on **HeartStitch** visit www.HeartStitch.com

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