NobleStitch™ EL Receives Approval in Kazakhstan to Treat PFO and to Suture Cardiac Structures

HeartStitch®, Inc. Announced That It Has Received Approval Of Its Registration To Sell The NobleStitch™ EL In Kazakhstan Just After Completing A Successful Congress On PFO Closure In Astana

Astana, Kazakhstan—February 8, 2016—HeartStitch® received approval for the sale of its NobleStitch™ EL in the Republic of Kazakhstan in December, immediately after the technology was presented to more than 100 physicians and technicians from all over Kazakhstan during the inaugural Structural Heart Congress in Astana. Patent Foramen Ovale (PFO)—which is associated with several significant disease states including cryptogenic stroke, transient ischemic attacks (TIA), severe migraine, chronic fatigue syndrome, and complications of spontaneous sub-arachnoid hemorrhage—has historically been closed by open heart surgery or the implantation of large metal discs into the patient’s heart. The NobleStitch™ EL is the first suture-based technology that can close the PFO tunnel without open heart surgery, or leaving a device in the heart.

The NobleStitch™ EL, which HeartStitch manufactures and distributes under an exclusive license from Nobles Medical Technologies II, has been used in several countries around the world—and most recently in Kazakhstan over the last year at the National Scientific Cardio Surgery Center in Astana, Kazakhstan—where it has been used to perform PFO closure in 6 patients successfully.

“This approval now allows us to provide this life-changing technology throughout Kazakhstan as a standard of care. We are very proud to be a part of this project, and will continue to expand our treatment to patients who are at risk from PFO,” commented Dr. Saule Kadirova, the cardiologist who performed the initial 6 patients at the National Scientific Cardio Surgery Center Astana, Kazakhstan.

“After an exciting experience of successful cases performed in Astana over the last year, HeartStitch®, Inc. will now launch sales here in Kazakhstan and expand into its
neighboring CIS countries. It is our goal to provide our citizens with this state-of-the-art treatment for these debilitating disease states, and bring improved healthcare to all Kazakhs," Kazbek Aubakirov, Director of HeartStitch’s ROK operations, commented.

“The recent successful congress generated immediate requests from doctors in several regions of Kazakhstan to purchase the NobleStitch™ EL to treat their patients. This approval will make it possible to sell these critical medical devices to hospitals—not only to treat their patients—but to affirm the market potential within Kazakhstan for HeartStitch®, which was a strategic goal of the collaboration between HeartStitch® and Nazarbayev University,” said Dr. Kanat Baigarin, Vice President of Nazarbayev University and a member of the Board of Directors of HeartStitch®.

“This approval marks the first of many new technologies that HeartStitch® will launch in Kazakhstan. Over the next several years we will continue to release new medical devices and treatments for cardiac disease, many of which will be developed and manufactured here in Kazakhstan. We at HeartStitch® are proud to be part of this project and proud of the results it is bringing to the people of Kazakhstan,” said Professor Anthony Nobles, Chairman and CEO of HeartStitch® and Professor of Biomedical Engineering at the West Sachsen University, Zwickau.
About PFO closure
A PFO is a relatively common heart defect characterized by an unsealed tunnel between the right and left atria of the heart. This defect has been known to be present in anywhere between 10%-25% of people. However, in a number of cases, it is benign.

The PFO is formed as a trace of the fetal circulation. When the chambers of a human heart begin to develop, a tunnel is made between the right and left atria, allowing blood to flow directly from the venous circulation to the arterial circulation, circumventing the non-functioning fetal lungs. Following birth, the pressure differential between the right and left atria changes with newly operational blood flow to the fully functioning lungs. Because of this, the tunnel eventually closes completely within the first few months.

However, in some patients, the foramen ovale fails to seal and stays "patent". In patients with a Patent Foramen Ovale (PFO), the tunnel can reopen under elevated atrial pressure, such as coughing, or straining.

A key issue with PFO is that it gives a pathway for blood clots to pass directly to the arterial circulation without being filtered out by the capillary bed of the lungs. A PFO can also let deoxygenated blood and certain chemicals cross over to the arterial side. The presence of a PFO has been linked to a number of clinical issues, mainly strokes, migraines and chronic fatigue. Developments are being made to solidify the link between PFO and strokes or migraines, and to identify patients that would benefit from PFO closure.

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 and and the Republic of Kazakhstan respectively.

**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](http://www.HeartStitch.com)

For more information, please contact shareholder representatives:

**USA**
Dru Dobbs
P. +1 714 427 6348
F. +1 714 427 6343
[ddobbs@HeartStitch.com](mailto:ddobbs@HeartStitch.com)

**In Kazakhstan**
Kazbek Aubakirov
P. +7 777 5009005
[kaubakirov@HeartStitch.com](mailto:kaubakirov@HeartStitch.com)