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HeartStitch® Expands Sales of NobleStitch™ EL To Italy

Patient In Successful, First-Italian Case Avoids Nitinol Disc and Antiplatelet Drugs

Fountain Valley, California—April 20, 2016—Prof. Cesare Greco, Associate Professor of Cardiology, Sapienza University of Rome, consulting with renowned Prof. Carlo Gaudio of the Policlinico Umberto 1, Rome, Italy successfully performed the first-ever NobleStitch™ EL PFO closure in the country. Reported in (<http://m.ilmessaggero.it/primopiano/articolo-1640429.html>). This marks the official sales launch for HeartStitch® and its structural heart products in Italy.

HeartStitch® VP of Sales and Marketing Dirk Segers, working in conjunction with Kardia, Milano, brought Dr. Michael Mullen, Cardiologist St. Bartholomew's Hospital, London and member of the HeartStitch® clinical advisory board, to Rome to proctor the Italian team of interventional cardiologists at the famed Policlinico Umberto 1 Cardiac Center. The center had previously used large metal implants to treat Patent Foramen Ovale (PFO)—a condition that is associated with strokes, severe migraine, and chronic fatigue. These implants are known to have several potential complications, albeit rare, that can lead to stroke, erosion, migration, perforation, and death. To avoid these potential side effects many patients prefer to go untreated; HeartStitch® technology leaves nothing but a surgical suture to close the PFO tunnel.

Prof. Cesare Greco, Chief of the Department of Heart and Big Vessels at Policlinico Umberto I, Rome, commented, "This system is revolutionary. It allows secure PFO closure without implanting the Nitinol disc that would have been 2.5cm in the atria of the heart, to be left forever in the patient. This 45-minute procedure also avoided the need for the 2 antiplatelet drugs we would have had to use with the metal implants; this is an important advance."

Dr. Michael Mullen commented, "I am grateful to Prof. Gaudio and Prof. Cesare Greco, his colleagues and staff for the opportunity to work with them on this historic first case in Italy. We achieved successful closure in a 52-year-old-female who had a very short PFO tunnel—a condition that in the past we would not have attempted with this technology. However, with the new techniques we have developed over the last year, I was confident that we could achieve closure in this case. Successfully closing the PFO without a metal implant in a patient who had already suffered a previous stroke at her age was a victory for the patient. She will not have the concern of side effects associated with the metal implants, and will not have to take the regiment of antiplatelet drugs that would have been mandatory with a metal implant."

Dirk Segers, Vice President of Sales and Marketing for HeartStitch®, stated, "It was a pleasure to bring the NobleStitch™ technology to Italy, and to work with such a great



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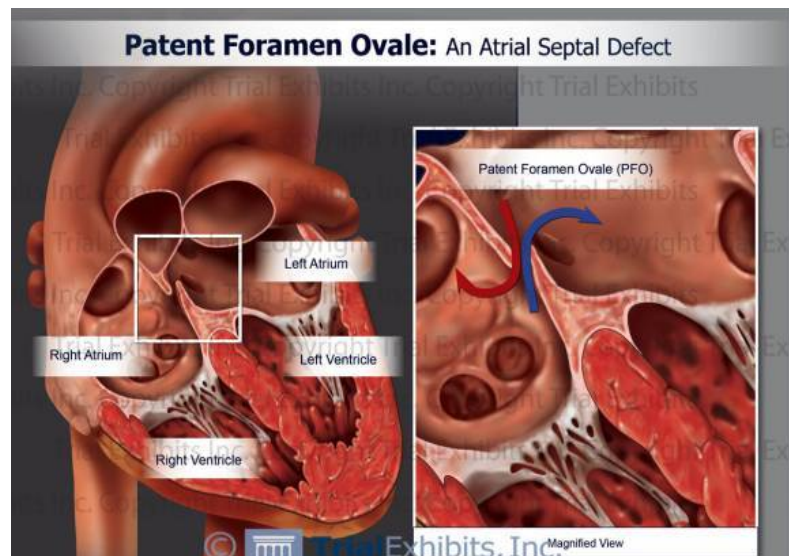
team. This is our first sale in Italy, and we look forward to growing our experience here at the Policlinico Umberto 1 with Prof. Gaudio and his colleagues, and to expand throughout Italy.”

Professor Anthony Nobles, CEO of HeartStitch® stated, "We continue to grow our distribution throughout Europe, and Italy was a crucial step for us in our sales plan. We continue to learn from our growing customer base, and with each case we improve our training techniques and expand the indications for our suture technology. I am personally proud to be able to bring NobleStitch™ to Italy, a country that has been a big part of my life—and of the development process of our suturing technology.”

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 27%-38% 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 stokes,



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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 innovative suture-based systems for remotely providing suture repair of structural heart defects and other vascular structures.

The HeartStitch[®] TA and HeartStitch[®] MR are FDA cleared for vascular suturing in the United States. HeartStitch[®] manufactures and markets the NobleStitch[™] EL under 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 the Republic of Kazakhstan, respectively.

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

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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