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HeartStitch® Launches German Sales of NobleStitch™ EL

Expansion Marked By First Five PFO Closures

Frankfurt, Germany—May 2, 2016—Prof. Dr. Horst Sievert of the Cardiovascular Center, Frankfurt, successfully completed five PFO closures using the NobleStitch™ EL—marking the official sales release of the NobleStitch™ device in Germany.

Dr. Michael Mullen, Cardiologist St. Bartholomew's Hospital, London, and member of the HeartStitch® clinical advisory board, and Prof. Anthony Nobles, CEO of HeartStitch®—proctored Prof. Sievert and his team at the CVC Heart Center in Frankfurt on the NobleStitch™ EL PFO closure system. This followed the first cases successfully performed in Germany last year by Dr. Michael Mullen and Prof. Sievert: the first, a week before the CSI Frankfurt Congress; and the second, a live case performed during the Congress and in front of more than 850 physicians from around the world.

Prof. Sievert requested to use the NobleStitch™ EL, and selected a series of patients with history of stroke. Eight patients were scheduled for the initial training and use of the NobleStitch™ EL. Five patients were candidates for the NobleStitch™ and three patients had Atrial Septal Defects (ASD) with little or no PFO tunnel detected. One of these three was a pure ASD and not a candidate for the NobleStitch™ EL and the remaining 2 were selected to close or reduce the ASD to use a smaller implant. The five PFO cases were all successfully closed including one with an additional septal fenestration (an additional hole in the septal wall).

Prof. Dr. Horst Sievert, Chief of Cardiology, Cardiovascular Center, CVC, Frankfurt, has watched the evolution of this technology through its development over the last few years in HeartStitch's association with his annual CSI Congress held in Frankfurt, Germany. During the recent CSI congress in Dubai Prof. Sievert discussed the importance of closing a PFO without leaving a device behind in the atria as very appealing. This most recent version of the NobleStitch™ EL has an advanced ease of use which surpasses the previous design. Nobles received numerous positive comments from staff following the recent cases performed at CVC Center in Frankfurt. Prof. Nobles stated "We experienced several perfect closures without residual shunts, which the staff had not expected from a suture-based device." They also utilized the devices in some defects that would normally not be a candidate for this technology due to the lack of sufficient tunnel to close. The NobleStitch™ EL allows doctors to maintain the alternative of device closure as a back up in these types of cases, and they were able to close two of these three unique cases with little to no shunt, and reduce the ASD in two others."



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Dr. Mullen commented, "This was an incredible day. We saw so many variations of anatomy and had many unique challenges. In the PFO cases that met our criteria for closure we achieved acute closure using our standard technique. In the cases where the anatomy was challenging, we developed and implemented new techniques, and were able to come up with advancements to the technology that will allow us to overcome certain anatomical difficulties in the future. These will potentially allow us to treat a greater patient population."

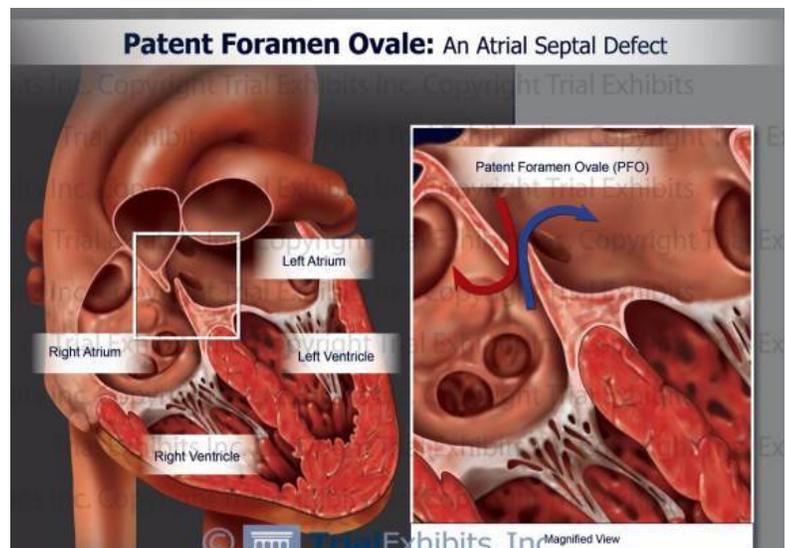
Dirk Segers, Vice President of Sales and Marketing for HeartStitch®, stated, "It was a pleasure to bring the NobleStitch™ technology to Prof. Sievert, who is recognized as a leader in the structural heart field, and the most prominent authority on PFO in Germany. Within the European Union, Germany is the largest market for our HeartStitch® products, and CVC is one of the largest and most important accounts. I look forward to growing the relationship with Prof. Sievert and CVC."

Professor Anthony Nobles, CEO of HeartStitch® stated, "I have had the pleasure of presenting HeartStitch's technologies over the past several years to the CSI Congress at Prof. Sievert's invitation. It is a great honor for me to see him perform the NobleStitch™ PFO closure first hand. I was very impressed with his ability to quickly learn and implement a technology so seamlessly. Prof. Sievert also provided significant feedback that will help us expand our product world-wide. HeartStitch® is committed to this type of collaboration with industry leaders and our customer base."

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





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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 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 from Nobles Medical technologies II, Inc. 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.

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