

Top Swedish Heart Center Confirms PFO-Closure Benefits of NobleStitch™ EL Among Widening Patient Population

Director of Structural Heart Interventions At Linköping University Hospital Chooses HeartStitch® Device For Four Closures In A Week

Los Angeles, California—Tuesday, February 2, 2016—Dr. Niels Erik Nielsen, Director of Structural Heart Interventions at the Linköping University Hospital in Linköping, Sweden, used the suture-based NobleStitch™ EL to perform four successful PFO closures last week among a group of patients who may have presented increased risks with traditional closure.

Dr. N.E. Nielsen performed three of these cases on patients that would not be good candidates for any alternative closure procedures. Dr. Nielsen commented, “Given the risk factors associated with three of these patients, I would not normally recommend closures of the PFO with traditional ‘umbrella’-type implants due to the potential for long and short-term complications that can arise from placing these large metal structures in the heart. This is particularly true in these very young patients, two of which were only 21 years old.”



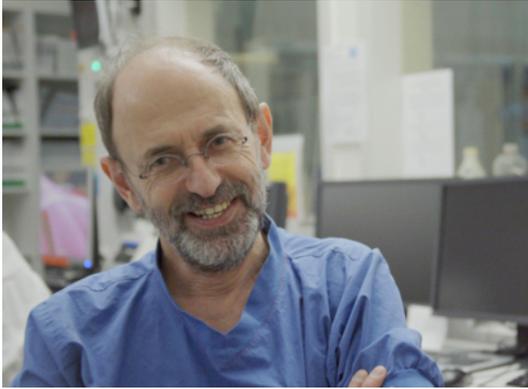
Dr. Nielsen further commented, “In our clinic, NobleStitch™ EL is the primary choice for closing PFO after stroke/TIA, in patients with severe migraine, and now for younger patients for whom the risks would otherwise outweigh the benefits of closure. NobleStitch™ EL is a very attractive method of closing PFO in the larger population of younger patients because you leave only a suture, thereby avoiding the inherent risks associated with implanting other devices that, over the longer life expectancy of these patients, increase every year—for instance stroke, arrhythmia, embolization and/or late erosion. Furthermore some younger patients may need other cardiac interventions later in life, and NobleStitch™ EL does not hinder access to the left atrium if that is required.”

Dr. Nielsen further stated, “Confidence is essential in these procedures. One of the greatest personal benefits to me from the HeartStitch® technology is that I no longer worry about receiving a call from my patient in the first week after closing their PFO. Using a metal umbrella implant, when a call like that comes it is usually attached to a complication and real issues. With NobleStitch™ EL that worry is alleviated, and I feel comfortable immediately after completing the procedure. Bottom line, it allows me to



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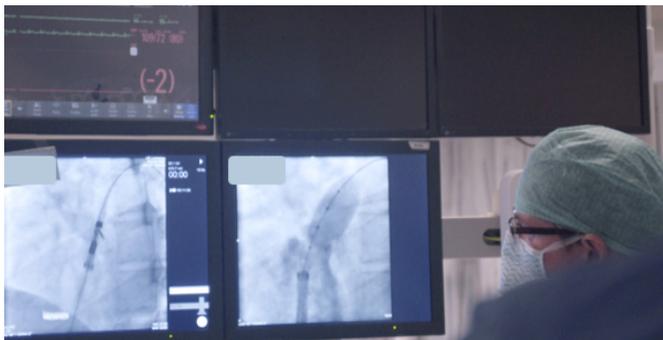
treat a larger population of patients without the inherent risks of serious complications."

Dr. Michael Mullen of St. Barts Hospital in London was also present for the successful procedures, proctoring interventional cardiologist Dr. Jacek Baranowski who performed two of the four cases. Dr. Mullen commented, "This was an excellent day, we were able to successfully treat a diverse group of patients with a wide variety of PFO anatomies. These cases represented a wide demographic,

from very young patients barely 21 years old, to patients in their late 50's. They ranged from very large PFO's of approximately 2cm that would, otherwise, have required a large prosthetic implant, to others with small complex tunnels. Even with my extensive experience, working with NobleStitch™ EL over the past several years, I was impressed by how well it worked in this diverse range of patients. We continue to perfect the technique that we use, and are expanding its suitability to treat the majority of PFO patients with more complex anatomy. NobleStitch™ EL allowed us to effectively close all of these patients."



Dr. Baranowski stated, "I was traditionally opposed to PFO closure in many patients because of the risks—however the suture-based NobleStitch™ EL doesn't share these risks caused by umbrellas. I now believe we should treat these patients—and with the NobleStitch™ EL, I expect we will double the number of patients we perform each year."



Professor Anthony Nobles, CEO of HeartStitch®, was also present for the cases and commented, "When we developed this technology at Nobles Medical Technologies II, we were focused on making the technology less invasive, and we wanted to provide a safe and effective way to close a wide variety of PFO's in the majority of the patients suffering from this debilitating defect.



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Today we saw the fruits of that hard work, and watching the NobleStitch™ EL provide effective closure in such a diverse set of PFO's and patient types was very rewarding."

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.

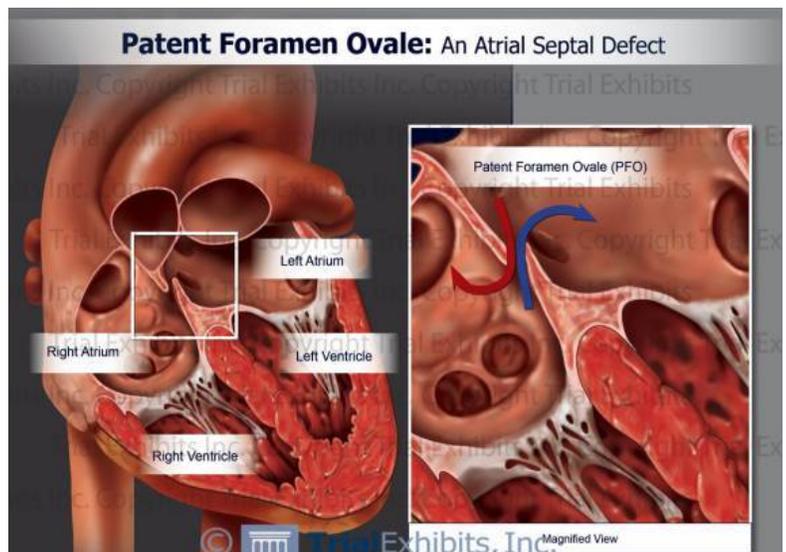
The PFO is formed as a trace of the fetal circulation. When the chambers of a human heart begin to develop, a tunnel is made between the right and left atria, allowing blood to flow directly from the venous circulation to the arterial circulation, circumventing the non-functioning fetal lungs. Following 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





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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

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NobleStitch™ EL for PFO closure

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For more on **HeartStitch®** visit 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

In Kazakhstan

Kazbek Aubakirov

P. +7 777 5009005

kaubakirov@HeartStitch.com