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HeartStitch® Announces New Director Of Regulatory Affairs And Quality Assurance

Faye Dunn Brings Wide-Ranging Experience To HeartStitch® Management And Manufacturing

Fountain Valley, California—May 25, 2016—Following a detailed search among a field of highly qualified candidates, the HeartStitch® Board of Directors is pleased to announce the appointment of Faye Dunn as director of regulatory affairs and quality assurance. Dunn holds a BS in Medical Microbiology from California State University Long Beach, as well as an MS in Business Organizational Management and an Executive Juris Doctorate. She brings more than 29 years of experience in the medical device and pharmaceutical industries to her work at HeartStitch®, including positions at Boston Scientific and FUJIFILM Medical Systems.

In discussing the appointment, Professor Anthony Nobles, CEO of HeartStitch® stated, "Faye positively impressed us over the course of multiple interviews, and her presence within the company has brought a positive and immediate impact to all of our processes. We were looking for a unique combination of previous experience—including quality management, risk assessment, design controls, and international product registrations. Ours is a very fast-paced environment where creativity and skills in interpersonal dynamics are essential. We are confident after her first few weeks on the job that she will prove a great asset to the company, our physicians, and our shareholders."

President and Member of the HeartStitch® Board of Directors Ben Brosch stated, "Faye Dunn has a broad understanding of medical-device design and production that's particularly valuable to a company of our size, and at this point in our growth cycle. As we ramp up production on our existing devices, and bring an increasing number of new designs through the various phases of prototype development, many of her skills will be put to use. Of course she will be heading up our registrations with the FDA, our European notified body and parallel agencies as we expand our ROW operations. In terms of our manufacturing, her experience in new-product sterilization validation will prove particularly important."

Dunn holds a Regulatory Affairs Certification (RAC) from the Regulatory Affairs Professionals Society, and in addition to her extensive experience resolving compliance issues for medical-device manufacturers, she brings a background in microbiological testing and a proven track record at the FDA to the team at HeartStitch®.

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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.

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, 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.

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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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