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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Devices and systems for treating valvular regurgitation

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Cook Medical Technologies, LLC, located in Bloomington, Indiana, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NHLBI Office of Technology Transfer and Development [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479, phone number 301-435-5019, or shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Cook Medical Technologies, LLC: NIH Ref. No. E-027-2013/0 "Devices And Methods for Treating Functional Triscupid Valve Regurgitation" U.S. Provisional Patent Application 61/785,652 filed March 14, 2013, International Patent Application PCT/US2014/025300 filed under the Patent Cooperation Treaty on March 13, 2014, European Patent Application 14723540.2 having an international filing date of March 13, 2014, and U.S. Patent Application 14/776,488 also having an international filing date of March 13, 2014. NIH Ref. No. E-115-2013/0 "Encircling Suture Delivery System For Flexible Circumferential Suture," U.S. Provisional Patent Application 61/834,357 filed June 12, 2013, International Patent Application PCT/US2014/040716 filed under the Patent Cooperation Treaty on June 3, 2014, European Patent Application 14735030.0 having an

international filing date of June 3, 2014 and U.S. Patent Application 14/898,020 also having an international filing date of June 3, 2014. The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive patent License territory may be worldwide and a field of use limited to valvular regurgitation.

The invention embodied in NIH Ref. No. E-027-2013/0 relates to devices and methods for treating functional tricuspid valve regurgitation and related conditions. The devices are adapted for applying force to an area of a patient's heart along or near the atrioventricular groove and can include a tensioning element configured to be delivered by a flexible member guided through a catheter and positioned generally along or near the atrioventricular groove, and a compression member that can be positioned along the tensioning element and over a desired segment of the atrioventricular groove to develop force to be applied to an adjacent area of the heart by selective tensioning of the tensioning element.

The invention embodied in NIH Ref No. E-115-2013/0 relates to devices for delivering encircling implants that can include two separate limbs held together at a distal articulation by the implant being delivered. The implant can comprise a suture and/or a braided tube. The implant can extend through or over the limbs. The implant and at least a distal portion of the limbs can be compressible into a delivery shape that allows for advancement through the lumen of a delivery catheter. When the distal portion of the limbs move out of the delivery catheter, the limbs and implant can resiliently assume a loop shape that is complementary to a shape of a target around which the encircling implant is to be placed. The limbs are then retracted from along the implant to leave the implant in the desired delivery position. The delivery device can be used to place encircling implants around the heart or other targets, and the implant can be tightened to exert compressive force on the target.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NHLBI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404. Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent

permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: September 22, 2017

Michael Shmilovich

Senior Licensing and Patenting Manager

National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development

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