[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive Evaluation License: Caval-Aortic Devices for Aortic Valve Replacement

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive evaluation option license to practice the inventions embodied in: HHS Ref. No. E-553-2013/0, U.S. Provisional Patent Application No. 61/863,071, filed August 7, 2013; International Patent Application PCT/US2013/072344 filed November 27, 2013 entitled "Transvascular And Transcameral Device Access And Closure," to Mehr Medical LLC, having its principle place of business in Andover Massachusetts.

The contemplated exclusive license may be limited to caval-aortic devices for aortic valve replacement. Upon the expiration or termination of the start-up exclusive evaluation license, Mehr will have the right to execute a start-up exclusive patent commercialization license with no greater field of use and territory than granted in the evaluation license.

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

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq. Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; E-mail: shmilovm@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The invention pertains to devices and methods for transcatheter correction of cardiovascular abnormalities and most specifically for the delivery of prosthetic valves to the heart. Featured is a device implant for closing a caval-aortic iatrogenic fistula created by the introduction of a transcatheter device from the inferior vena cava into the abdominal aorta. The occlusion device includes an expandable transvascular implant with an elastomeric surface capable of extending between a vein and artery which conforms to the boundaries of an arteriovenous fistula tract between the artery and vein. A guidewire channel is disposed within the occlusion device wherein the channel also has elastomeric wall surfaces that conform or can be expanded to the area so that it occludes the channel when the guidewire is not present. The implant is resiliently deformable into a radially compressed configuration for delivery through the catheter but when not deformed into the radially compressed configuration at least the distal end of the device is radially enlarged relative to the intermediate neck whereby the distal end forms an enlarged distal skirt, such as a disk or button shaped member. A polymer coating on the radially enlarged distal end conforms to the endoluminal aortic wall for deployment against an internal wall of the artery.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive evaluation option license, and a

subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, the NIH 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 404.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: March 3, 2014.

Richard Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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