DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent Commercialization 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, is contemplating the grant of a worldwide exclusive 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 Transmural Systems, LLC, a limited liability company incorporated under the laws of the State of Massachusetts and having its principle place of business in Andover, Massachusetts.

The contemplated exclusive license may be limited to caval-aortic devices for aortic valve replacement.

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: 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 Patenting 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 technology pertains to devices and methods for transcatheter correction of cardiovascular abnormalities and more 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. When the device is not deformed into the radially compressed configuration, 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 license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, 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: September 1, 2015.

Richard U. Rodriguez,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

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