[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent Commercialization License: Cerclage Annuloplasty Devices for Treating Mitral Valve Regurgitation.

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:

NIH REF NO.	PATENT APPLICATION NO.	FILING DATE	TITLE
E-048-2009/0-US-01	61/157,267	March 4, 2009	Cerclage Locking Device And Delivery System
E-048-2009/0-PCT-02	PCT/US2010/026245	March 4, 2010	Cerclage Locking Device And Delivery System
E-048-2009/0-US-03	13/254,160	March 4, 2010	Cerclage Locking Device And Delivery System
E-108-2010/0-US-01	61/383,061	September 15, 2010	Methods and Devices For Transcatheter Cerclage Annuloplasty

NIH REF NO.	PATENT APPLICATION NO.	FILING DATE	TITLE
E-108-2010/0-PCT-02	PCT/US2011/51748	September 15, 2011	Methods and Devices For Transcatheter Cerclage Annuloplasty
E-108-2010/0-EP-03	11760945.3	September 15, 2011	Methods and Devices For Transcatheter Cerclage Annuloplasty
E-108-2010/0-US-04	13/824,198	March 15, 2013	Methods and Devices For Transcatheter Cerclage Annuloplasty

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 cerclage annuloplasty devices for treating mitral valve regurgitation.

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 30 days from date of publication of notice 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 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:

E-048-2009

The invention relates to a device that can be used to non-invasively secure surgical suture loops when combined with a percutaneous delivery system. It has been shown to be effective in correcting mitral valve regurgitation (MVR) in an animal model. During the procedure, a guidewire is percutaneously conveyed to the atrium of the heart and is used to secure the "cerclage" suture encircling the mitral valve annulus, which is delivered using a delivery catheter. The locking device is advanced over the suture by the delivery catheter and it permanently secures the suture and maintains the tension on the annulus once the delivery system is removed. This locking device, in combination with the percutaneous procedure, allows for more complete coaptation of the valve leaflets and correction of MVR without the need for open heart surgery and its associated risks. The locking device is also adjustable, allowing the user to vary the tension on the suture if further tightening or loosening is required. It is also MRI compatible and all follow-up studies can be performed under MRI. This invention demonstrated its ability to correct MVR in animals where the locking device was observed to maintain the correct position and tension after implantation. This device has the potential to replace the traditional loop and knot method used for surgical correction of MVR, and may also be useful for other conditions that require permanently secured suture loops.

E-108-2010

The invention relates to techniques and devices for cardiovascular valve repair, particularly annuloplasty techniques and devices in which tensioning elements are

positioned to treat regurgitation of the mitral valve or tricuspid valve. More specifically, the technology pertains to a new device for myocardial septal traversal ("cerclage reentry") that also serves to capture (ensnare) and externalize the traversing guidewire. The focus of the invention is to avoid a phenomenon in cardiac surgery known as "trabecular entrapment." The device features an expandable and collapsible mesh deployed in the right ventricle to simplify capture of a reentering guidewire during transcatheter cerclage annuloplasty. The wire mesh exerts pressure against trabecular-papillary elements of the tricuspid valve to displace them against the right ventricular septal wall. By abutting the right ventricular reentry site of the cerclage guidewire, trabecular entrapment is avoided. The device comprises a shaft having a distal loop which provides a target in the interventrical myocardial septum through which a catheter-delivered tensioning system is guided. The loop ensnares the catheter-delivered tensioning system as it reenters the right ventricle or right atrium. The expandable and collapsible mesh is disposed within the right ventricle such that the catheter-delivered tensioning system is directed from the ventricular septum into the right ventricular cavity through only a suitable opening in the mesh and such that the catheter delivered tensioning system is captured or ensnared within the mesh opening.

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

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

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