[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: 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 No. or APPLICATION No.	FILING DATE	TITLE
E-249-2006/0-US-01	60/858,716	November 14, 2006	A Device To Protect Coronary Arteries Against Compression During Transcatheter Mitral Valve Annuloplasty (PMVA)
E-249-2006/1-US-01	60/932,611	May 31, 2006	"
E-249-2006/2-PCT-01	PCT/US2007/023876	November 13, 2007	"
E-249-2006/2-EP-02	07861997.0	November 13, 2007	Transcatheter Coronary Sinus Mitral Valve Annuloplasty Procedure And Coronary Artery And Myocardial Protection Device
E-249-2006/2-US-03	8,211,171	November 13, 2007	"
E-249-2006/2-US-04	9,271,833	November 13, 2007	"
E-249-2006/3-US-01	15/056,599	February 29, 2016	Transcatheter Coronary Sinus Mitral Valve Annuloplasty Procedure and Coronary Artery and

			Myocardial Protection Device with "Landing Zone"

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.

DATES: Only written comments and/or applications for a license that are received by NIH at the address indicated below on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of any unpublished patent application, inquiries, objections to this notice, comments and other requests relating to the contemplated license should be directed to: Michael Shmilovich, Esq., CLP, 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: This notice is published in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7 (a)(1)(i).

Mitral regurgitation (MR) is amongst the most common valvular heart disorders, with an estimated prevalence of approximately 1.7% in the United States, increasing with age to approximately 9.3% in those over the age of 75. MR is classified as primary (also known as "organic") when principally due to a structural or degenerative abnormality of the mitral valve (MV), whether of the leaflets, chordae tendineae, papillary muscles, or mitral annulus. Secondary (also known as functional) MR occurs in the absence of organic MV disease, usually from left ventricular (LV) dysfunction. It is more common

than primary MR and is associated with a worse prognosis (compounded by the underlying cardiomyopathy), and (in contrast to primary MR) the benefits of MV surgery are uncertain. The MV consists of two leaflets (anterior and posterior) sitting within the annulus (see picture below). The posterior mitral leaflet originates from the left atrial (LA) endocardium. A subvalvular apparatus, comprising two papillary muscles (anterolateral and posteromedial) arising from the LV myocardium and the chordae tendineae, supports the leaflets. LV dilation due to ischemic or nonischemic cardiomyopathy secondarily impairs leaflet coaptation of a structurally normal MV, resulting in secondary MR. Specifically, LV dysfunction and remodeling lead to apical and lateral papillary muscle displacement, resulting in leaflet tethering, dilation and flattening of the mitral annulus, and reduced valve closing forces.

The subject mitral repair system devices are primarily intended to treat secondary mitral regurgitation. The proposed mitral cerclage with coronary artery protection is an approach capable of overcoming many of the problems that exist with existing devices namely allowing a larger subset of patients to be treated compared to other coronary sinus devices, providing a full annuloplasty type device which is flexible enough to preserve annular motion, reduce hospitalization costs and shorten recovery time. The associated method closely resembles the surgical placement of a full annuloplasty ring.

E-249-2009/0-2

Catheter-based mitral valve regurgitation treatments that use coronary sinus trajectory or coronary sinus implant can have unwanted effects because the coronary sinus and its branches have been found to cross the outer diameter of major coronary arteries in a majority of humans. As a result, pressure applied by any prosthetic device in the

coronary sinus (such as tension on the annuloplasty device) can compress the underlying coronary artery and induce myocardial ischemia or infarction. This invention pertains to devices and methods that avoid constricting coronary artery branches during coronary sinus-based annuloplasty. These devices and methods protect coronary artery branches from constriction during trans-sinus mitral annuloplasty. The device protects a coronary vessel from compression during mitral annuloplasty by extending an annuloplasty element, such as a tensioning device, at least partially through the coronary sinus over a coronary artery. The device is a surgically sterile bridge configured for placement within the coronary sinus at a location where the coronary sinus passes over a coronary artery, so that the protection device provides a support for a mitral annuloplasty element, such as a compressive prosthesis, including a tension element when it is placed under tension. The protection device has an arch of sufficient rigidity and dimensions to support the tensioning element over the coronary artery, redistribute tension away from an underlying coronary artery, and inhibit application of pressure to the underlying artery, for example when an annuloplasty tension element is placed under tension during mitral annuloplasty. In particular, the protective device can be a support interposed in the coronary sinus between the annuloplasty device and the coronary artery. The device may be substantially tubular so that the tensioning element is contained within the protective device and supported in spaced relationship to the coronary artery. An arch may be configured to extend between a proximal end and a distal end that are substantially collinear with one another so that the ends form stabilizing members such as feet that retain the bridge in position over the coronary artery.

Another embodiment of the cerclage protection device is a combination with a cerclage tension element that can be used to facilitate transcatheter mitral valve implantation. The transcatheter strategy includes a "valve-in-ring" wherein a cerclage annuloplasty is first performed. During the same session or during a separate procedure, a transcatheter mitral valve implantation could be performed that would take advantage of the cerclage annuloplasty system to serve as a visual and a mechanical "landing zone" for mitral valve implantation. A cerclage annuloplasty ring would allow outward expansion of the mitral valve to achieve fixation. However, without the cerclage protection device in place, such a strategy would cause compression of an entrapped coronary artery. This new embodiment of the protection device protects coronary arteries not from extrinsic compression but from "inside-out" compression, thereby allowing cerclage to be the first step for transcatheter mitral valve implantation. It also allows the latter to be employed as second-stage adjunct or bailout for inadequate cerclage mitral valve annuoplasty.

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 § 404.7. The prospective exclusive license may be granted unless, within fifteen (15) 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 § 404.7.

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 17, 2017

Michael Shmilovich

Office of Technology Transfer and Development

National Heart, Lung, and Blood Institute

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