40-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Catheter-based myotomy devices and systems.

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 Septune, Inc., located in San Juan, Puerto Rico, 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 30 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., MS, CLP

Acting Director, phone number 301-435-5019 or shmilovm@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 license to Septune, Inc.:

NIH REF NO.	PATENT No. or APPLICATION No.	FILING DATE	TITLE
E-194-2025-0-US-01	63/890,784	September 30, 2025	Electrosurgical Myotomy Catheter System
E-166-2022-0-US-01	63/383,012	November 9, 2022	Myotomy Catheter System And Methods For A Myotomy Catheter System
E-166-2022-0-PC-01	PCT/US2023/079114	November 8, 2023	Myotomy Catheter System And Methods For A Myotomy Catheter System

E-166-2022-0-US-02	19/127,710	November 8, 2023	Myotomy Catheter System And Methods For A Myotomy Catheter System
E-166-2022-0-EP-01	23821091.8	November 8, 2023	Myotomy Catheter System And Methods For A Myotomy Catheter System

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 in a field of use limited to catheter-based myocardial myotomy systems for the treatment of cardiovascular disease.

The invention described in E-194-2025 for which we currently have a provisional patent application covers a variable-depth electrosurgical myotomy catheter system configured to perform a longitudinal endomyocardial myotomy, also referred to as septal scoring along the midline endocardium (SESAME). The catheter system is configured to slice the "septal hump" causing symptomatic left ventricular outflow tract obstruction in hypertrophic cardiomyopathy (HCM), a common congenital heart disease in adults and children. The system may have further applications in creating space to allow non-surgical transcatheter mitral valve implantation (TMVR), which excludes more than half of TMVR candidates, and potentially reduces left ventricular stiffness causing heart failure with preserved ejection fraction (HFpEF), a widely prevalent disease.

The invention described in E-166-2022, for which we now have pending national stage applications in the US and Europe, pertains to a controlled-depth myotomy catheter system configured to perform a longitudinal endomyocardial myotomy (also referred to as septal scoring along the midline endocardium (SESAME)) precisely and reproducibly with less operator skill than previous SESAME procedures, less reliance on image guidance, and lowered procedure times. SESAME is conventionally accomplished by navigating a 0.014" guidewire under x-ray fluoroscopy and ultrasound guidance via a retrograde transaortic guiding catheter through the interventricular septum. A straight rigid engagement guidewire engages the basal septum either mechanically or electrosurgically to allow a 0.014" microcatheter to enter the basal septum. The

instant invention replaces the 0.014” engagement guidewire is with a 0.014” curved-tip guidewire navigated through the septal myocardium towards the apex until it exits the myocardium and reenters the left ventricular chamber. The trajectory may be confirmed by ultrasound. The intracameral guidewire tip is ensnared to allow positioning of an inner-curvature-denuded laceration surface resembling the “flying- V” used for other procedures such as laceration of the anterior mitral leaflet to prevent outflow obstruction (LAMPOON). The “flying-V-like” configuration includes insulating microcatheters on both free limbs of the lacerating guidewire. Once positioned, the laceration surface is electrified under traction to accomplish SESAME. Currently, SESAME also requires general anesthesia and advanced imaging including combinations of transthoracic, transesophageal, and intracardiac ultrasound, even within the left ventricular chamber, as well as biplane fluoroscopy. Ultrasound imaging windows across the chest wall, from the esophagus, and even within heart chambers are usually insufficient to give high confidence in the guidewire position along its whole trajectory. As explained previously, the uncertain depth of endomyocardial scoring via conventional SESAME may result in too shallow a laceration (resulting in therapeutic failure) or too deep a laceration (resulting in ventricular septal defect or free wall rupture). Conversely, the device disclosed in E-166-2022 addresses these issues by providing a controlled-depth laceration. The myotomy catheter system may be referred to as a transcatheter articulated heart incision instrument (TAHINI) catheter system. The TAHINI catheter system includes an incision catheter and an anchor stabilization and orientation catheter system configured to stabilize and properly orient the incision catheter. The anchor stabilization and orientation catheter system includes one or more anchors that are configured to be positioned in the heart to guide the incision catheter to perform SESAME. The anchor(s) may include mural anchors that enter or traverse the wall of the heart (e.g., the septum) and/or endocameral stabilizing hoops (that stabilize the catheter within a heart chamber, such as the left ventricle). The incision catheter may include an articulated cutting tool (e.g., a lacerator/blade that can be insulated from other metal components

and electrified to perform electrosurgery) that, when deployed, is angled relative to the septal myocardium (e.g., tangential) such that traction-withdrawal along an anchored guidewire causes the cutting tool to embed deeply into the septal myocardium.

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 thirty (30) 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: April 9, 2026

Michael Shmilovich,

Acting Director,

National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development

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