DOCUMENT MADE AVAILABLE UNDER THE PATENT COOPERATION TREATY (PCT)

International application number: PCT/US2016/032220

International filing date: 12 May 2016 (12.05.2016)

Document type: Certified copy of priority document

Document details:
- Country/Office: US
- Number: 62/160,595
- Filing date: 12 May 2015 (12.05.2015)

Date of receipt at the International Bureau: 22 May 2016 (22.05.2016)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a),(b) or (b-bis)
May 21, 2016

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 62/160,595
FILING DATE: May 12, 2015
RELATED PCT APPLICATION NUMBER: PCT/US16/32220

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US 62/160,595

Certified by

[Signature]

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office
SCORE Placeholder Sheet for IFW Content

Application Number: 62160595  
Document Date: 05/12/2015

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

• Drawing

At the time of document entry (noted above):
• USPTO employees may access SCORE content via eDAN using the Supplemental Content tab, or via the SCORE web page.
• External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: August 26, 2013
Device & Method for Releasing Catheters from Cardiac Structures

Background of the Invention
Functional mitral valve regurgitation (FMR) and heart failure (HF or CHF) are responsible for significant morbidity, mortality and cost to the healthcare system. Methods and devices have been developed to accomplish ventriculoplasty on the left ventricle of the human heart for patients suffering from FMR and/or CHF, during which anchors are placed within the left ventricular myocardium in the sub-annular region between the mitral annulus and the papillary muscles. A tether is slidably coupled to the anchors and subsequently cinched in order to reduce the mitral annulus, creating mitral valve competence. In addition, the LV wall dimension is reduced, relieving wall stress and facilitating LV reverse remodeling.

In order to accomplish ventriculoplasty via a trans-femoral transcatheter approach, it is advantageous to place a template in the subannular region through which anchors can be delivered into the LV myocardium. This template, or guide tunnel (GT), can be indexed to landmarks and held in place by a number of methods, including mechanical interference with the LV wall, direct attachment to the LV wall, or other means. One advantageous method of direct attachment involves threading the tether around latches in the GT itself, such that the process of delivering anchors into the wall also attaches the GT to the wall.

In order to remove the GT after the anchors have been placed, the latches would have a means to release the tether. The latches could be opened, for example, by releasing a pull wire that secures one end of the latches, allowing the tether to escape through the open ends of latches as the GT is removed.

A more advantageous embodiment would cause the latches themselves to withdraw into the wall of the GT such that they are completely removed from the region of the LV wall and the tether. With this embodiment there would be no ability for the latches to snag on the tether, anchors or other structures.

Brief Description of the Drawings
Figure 1 depicts the short axis view of the left ventrical (LV), showing the aortic outflow tract and the LV chamber.
Figure 2 shows the same short axis view of the LV, with a guide (G) across the aortic valve (AV) and tangent to the LV wall.
Figure 3 depicts a guide tunnel (GT) catheter deployed from the G and extending around and alongside the LV wall. Radiopaque markers and windows are disposed along the outer radius of the GT wall, through which catheters can be deployed.
Figure 4 depicts a delivery catheter (DC) deployed from the GT through a window, and in contact with the LV wall.
Figure 5 depicts a short axis view of the LV with the G and GT in place, and in which DCs were used to deploy anchors into the myocardium to a predetermined depth from the first two windows. A DC is shown exiting the third window in order to deploy the next anchor. The anchors are slidably connected to a tether, which is laced behind latches in the GT.
Figures 6a, 6b, 6c depict one embodiment of a GT catheter and detail views of its distal and proximal ends.
Figures 7a, 7b, 7c illustrate a detail view of the GT with a latch in the closed configuration, with the latchwire removed, and with the latch open, respectively.
Description of the Invention
The current invention is directed toward removing a catheter from a body organ generally, after it has been located and fixed into position during an interventional procedure, for instance in a cath lab procedure. Specifically, the current invention is especially well suited to removing a template catheter, or Guide Tunnel (GT) from the subannular region of the left ventricle (LV) of the heart.

An illustrative procedure will be described in the following figures, though it should be appreciated that the current invention can be employed in many other procedures as well. Referring to Figure 1, a cath lab procedure involving a patient’s LV typically employs fluoroscopy and, among other views, a short axis view of the LV. Figure 1 shows the short axis of the left side of the heart (10) with the surrounding myocardium (11), endocardium (12), LV chamber (13) and aortic outflow tract and aortic valve (14).

In Figure 2 a Guide catheter (20), with a distal opening (21) is inserted across the aortic valve (14) and placed tangent to the endocardium (12). Subsequently a GT catheter (30) is placed (Figure 3) against or near the endocardium (12). The GT can be used as a template device, using windows (31) and radiopaque markers (32) to direct the placement of devices, such as anchors, into the myocardium of the LV. Finally, (Figure 4) a Delivery Catheter (DC) (40) is tracked up GT (30) such that the distal tip (41) exits a preferred window (31) and contacts endocardium (12). Advancing Delivery Catheter (40) further causes it to penetrate endocardium (12) to a desired depth.

After a first anchor (50), secured to a tether (70), is delivered (Figure 5) into endocardium (12), subsequent Delivery Catheters (40) are indexed to adjacent windows (31) to deliver subsequent device components such as links (60, 61) and additional anchors (51). As the delivery catheters deploy anchors into the myocardium, the tether (70) becomes laced around latches (33), fixing GT (30) to the LV wall (11, 12) and maintaining its location with respect to anatomical features. After the last device components have been delivered, GT (30) must be detached from the LV (11) wall and removed through Guide (20).

Figure 6a shows a preferred embodiment of GT (30) configured to facilitate its removal, with a distal end (34) (Figure 6b) containing windows (32) and latches (33), and a proximal end (Figure 6c) containing port (35) and port (36) to control the release of latches (33). The latches themselves (Figure 7a) are comprised of polymer tabs (37), a lumen (38a) through which is routed a fiber latch cable (38b) that is looped over tabs (37) and around a latchwire (39b) residing in a lumen (39a). Latch cable (38b) is then tensioned and secured by cap to maintain the tabs (37) in a closed position.

The latches are opened by first removing latchwire (39) (Figure 7b) by retracting the cap of port (35) (Figure 6c) to which the proximal end of latchwire (39) is attached, then retracting the cap of port (36) that secures the proximal end of latch cable (38b), such that the loops of latch cable (38b) over tabs (37) are withdrawn (Figure 7c) into lumen (38a). GT (30) is then free of tether (70) (not shown), and GT (30) may be removed.
PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2
This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

**INVENTOR(S)**

<table>
<thead>
<tr>
<th>Given Name (first and middle [if any])</th>
<th>Family Name or Surname</th>
<th>Residence [City and either State or Foreign Country]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huu</td>
<td>Nguyen</td>
<td>San Jose, CA</td>
</tr>
<tr>
<td>Rob</td>
<td>Kolmel</td>
<td>Burlingame, CA</td>
</tr>
<tr>
<td>Tiffany</td>
<td>Mirchandani</td>
<td>San Jose, CA</td>
</tr>
<tr>
<td>David Scott</td>
<td>Baron</td>
<td>Sunnyvale, CA</td>
</tr>
<tr>
<td>Russel</td>
<td>Sampson</td>
<td>Palo Alto, CA</td>
</tr>
</tbody>
</table>

Additional inventors are being named on the separately numbered sheets attached hereto.

**TITLE OF THE INVENTION (500 characters max):**

Device and Method for Releasing Catheters from Cardiac Structures

**Direct all correspondence to:**

☑ Form or individual Name: Russel Sampson

Address: 2355 Calle de Luna

City: Santa Clara  State: CA  Zip 95054

**ENCLOSED APPLICATION PARTS (check all that apply):**

☐ Application Data Sheet. See 37 CFR 1.76.

☐ Drawing(s) Number of Sheets 7

☐ Specification (e.g., description of the invention) Number of Pages 2

**FEES Due:** Filing fee of $260 ($130 for small entity) ($65 for micro entity). If the specification and drawings exceed 100 sheets of paper, an application size fee is also due, which is $400 ($200 for small entity) ($100 for micro entity) for each additional 50 sheets or fraction thereof. See 37 U.S.C. 41(i) and 37 CFR 1.16(f).

**METHOD OF PAYMENT OF THE FILING FEE AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT:**

☐ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.

☐ Applicant must attach form PTO/358/USA or B or equivalent.

☐ A check or money order made payable to the Director of the United States Patent and Trademark Office is enclosed to cover the filing fee and application size fee (if applicable).

☐ Payment by credit card. Form PTO-208B is attached.

☐ The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: 0300.

**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 10 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and for suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the invention was made by an agency of the U.S. Government. The U.S. Government agency name is _______________________________

☐ Yes, the invention was made under a contract with an agency of the U.S. Government. The name of the U.S. Government agency and Government contract number are _______________________________

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

SIGNATURE ___________________________ DATE 05/12/15

TYPED OR PRINTED NAME ___________________________ REGISTRATION NO. ________________
(if appropriate)

TELEPHONE 650 245 8228 DOCKET NUMBER ___________________________
<table>
<thead>
<tr>
<th><strong>Electronic Acknowledgement Receipt</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EFS ID:</strong> 22329458</td>
</tr>
<tr>
<td><strong>Application Number:</strong> 62160595</td>
</tr>
<tr>
<td><strong>International Application Number:</strong></td>
</tr>
<tr>
<td><strong>Confirmation Number:</strong> 8847</td>
</tr>
<tr>
<td><strong>Title of Invention:</strong> Device &amp; Method for Releasing Catheters from Cardiac Structures</td>
</tr>
<tr>
<td><strong>First Named Inventor/Applicant Name:</strong> Huu Nguyen</td>
</tr>
<tr>
<td><strong>Correspondence Address:</strong> Russel Sampson  2355 Calle de Luna  650 245 8278 <a href="mailto:rsampson@gdsmed.com">rsampson@gdsmed.com</a></td>
</tr>
<tr>
<td><strong>Filer:</strong> Russel Sampson</td>
</tr>
<tr>
<td><strong>Filer Authorized By:</strong></td>
</tr>
<tr>
<td><strong>Attorney Docket Number:</strong></td>
</tr>
<tr>
<td><strong>Receipt Date:</strong> 12-MAY-2015</td>
</tr>
<tr>
<td><strong>Filing Date:</strong></td>
</tr>
<tr>
<td><strong>Time Stamp:</strong> 23:32:42</td>
</tr>
<tr>
<td><strong>Application Type:</strong> Provisional</td>
</tr>
</tbody>
</table>

**Payment information:**

<table>
<thead>
<tr>
<th>Submitted with Payment</th>
<th>yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment Type</td>
<td>Credit Card</td>
</tr>
<tr>
<td>Payment was successfully received in RAM</td>
<td>$130</td>
</tr>
<tr>
<td>Document Number</td>
<td>Document Description</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>1</td>
<td>Provisional Cover Sheet (SB16)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Drawings-other than black and white line drawings</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Specification</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Fee Worksheet (S806)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Warnings:**

This is not a USPTO supplied Provisional Cover Sheet SB16 form.

The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing.

Information:

Total Files Size (in bytes): 675706
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.
Short axis view of LV

Figure 4
Short axis view of LV

Figure 5