PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Robert Wu
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Palo Alto, CA 94304-1018
United States of America

PCT
WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing (day/month/year) 18 AUG 2016

FOR FURTHER ACTION
See paragraph 2 below

<table>
<thead>
<tr>
<th>Applicant’s or agent’s file reference</th>
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<td>578/492007840</td>
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<table>
<thead>
<tr>
<th>International application No.</th>
<th>International filing date (day/month/year)</th>
<th>Priority date (day/month/year)</th>
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<tr>
<td>PCT/US16/32220</td>
<td>12 May 2016 (12.05.2016)</td>
<td>12 May 2015 (12.05.2015)</td>
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<tr>
<th>International Patent Classification (IPC) or both national classification and IPC</th>
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<td>IPC(8) - A61F 2/24; A61M 25/01, 25/02 (2016.01)</td>
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<td>CPC - A61F 2/24, 2/2418, 2/2427, 2/2436; A61M 25/0015, 25/0043, 25/007, 25/0071, 25/01</td>
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<td>GUIDED DELIVERY SYSTEMS INC.</td>
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1. This opinion contains indications relating to the following items:
   - Box No. I  Basis of the opinion
   - Box No. II  Priority
   - Box No. III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - Box No. IV  Lack of unity of invention
   - Box No. V  Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
   - Box No. VI  Certain documents cited
   - Box No. VII  Certain defects in the international application
   - Box No. VIII  Certain observations on the international application

2. FURTHER ACTION

   If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

   If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

   For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/
Mail Stop PCT, Attn: ISAUS
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Date of completion of this opinion 13 July 2016 (13.07.2016)

Authorized officer Shane Thomas
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (January 2015)
1. With regard to the language, this opinion has been established on the basis of:
   - [x] the international application in the language in which it was filed.
   - [ ] a translation of the international application into __________ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a)).

3. [ ] With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing:
   - [ ] forming part of the international application as filed:
     - [ ] in the form of an Annex C/ST.25 text file.
     - [ ] on paper or in the form of an image file.
   - [ ] furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
   - [ ] furnished subsequent to the international filing date for the purposes of international search only:
     - [ ] in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
     - [ ] on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).

4. [ ] In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Form PCT/ISA/237 (Box No. 1) (January 2015)
Box No. V  Reasoned statement under Rule 43bis.1(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

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<tr>
<th>1. Statement</th>
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<td>Novelty (N)</td>
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<td>Claims</td>
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<td>Inventive step (IS)</td>
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<td>Industrial applicability (IA)</td>
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2. Citations and explanations:
Claims 1 and 13 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest wherein for each pair of adjacent first and second elongate element apertures, the first elongate element extends out of the first elongate element lumen through the first elongate element aperture across the retaining portion transversely with respect to the longitudinal axis and towards the second elongate element aperture, and the first elongate element extends into the second elongate element aperture, loops over the second elongate element, and extends back across the retaining portion and into the first elongate element lumen; retracting the second elongate element from the second elongate element lumen to uncouple the first elongate element from the second elongate element and to open the channel for passage of the first and second tissue anchors; tensioning the uncoupled first elongate element.

US 2008/0173730 A1 (STARKSEN) discloses a method for performing a procedure inside a heart (method for securing implants to heart tissue; abstract) comprising: positioning a catheter adjacent to heart tissue (advancing a catheter to a first region of heart tissue; abstract), wherein the catheter comprises a longitudinal axis (horizontal axis; figure 31), a first elongate element lumen (interior of tubular member 3102), a second elongate element lumen (interior of tubular member 3106), a tissue anchor lumen (interior of tubular member 3104), and a plurality of apertures (3101, 3108) along the longitudinal axis (as shown), wherein the plurality of apertures comprise a first elongate element aperture (3101), a second elongate element aperture (3108), a plurality of retaining portions between adjacent first and second elongate element apertures (portions between apertures 3101 and 3108); a first elongate element (3120) within the first elongate element lumen (as shown); wherein for the pair of adjacent first and second elongate element apertures (3101, 3108), the first elongate element (3120) extends into the first elongate element lumen through the first elongate element aperture across the retaining portion (tether 3120 (first elongate element) extends into aperture 3101 (first elongate element aperture) in tubular member 3106 (first elongate lumen) and across the portion of tubes 3102 and 3104 between (retaining portions) apertures 3101 and 3108; figure 31) transversely with respect to the longitudinal axis (the tether 3120 includes a transverse extending portion; figure 31) and towards the second elongate element aperture (extends towards aperture 3108; figure 31), and the first elongate element extends into the second elongate element aperture (tether extends through (into) aperture 3108; figure 31), and extends back across the retaining portion (as shown); deploying a first tissue anchor and at least a second tissue anchor into the heart tissue (anchor portions 3112 and 3114 are hooked into the heart tissue; abstract; paragraph [0081]), wherein the first elongate element couples the first tissue anchor to at least the second tissue anchor (as shown; figure 31), tensioning the first elongate element (pulling tether 3120; paragraph [0081]); removing the catheter from the heart (withdrawing after implantation; abstract; paragraph [0081]). In an alternative interpretation, Starksen discloses deploying a first tissue anchor and at least a second tissue anchor into the heart tissue (implant 3100 includes tube 3102 with anchor portions 3112 and 3114, and tube 3104 with anchor portions 3116 and 3118; figure 31; paragraph [0081]), wherein a tether (3120) couples the first tissue anchor to at least the second tissue anchor (as shown; figure 31).

US 2009/0054624 A1 (MILLSHEIMER) discloses an implant delivery system comprising: a catheter (72; figure 8) comprising a longitudinal axis (along the length of body 72; figure 8), a first elongate element lumen (84; figure 8), a second elongate element lumen (82), and a plurality of apertures (77, 79) along the longitudinal axis (as shown), wherein the plurality of apertures comprise first elongate element apertures (77, 79), a plurality of retaining portions between adjacent first elongate element apertures (portion between 77 and 79); a first elongate element (83) within the first elongate element lumen (at 86 as shown); the first elongate element (85) extends into the first elongate element lumen through the first elongate element aperture across the retaining portion (as shown; figure 8) transversely with respect to the longitudinal axis (includes a transverse extending portion extending through 77) and the first elongate element loops over (loops around 84; figure 8).

US 5,919,207 A (TAHERI) discloses an implant delivery system comprising: a catheter (19; figure 4) comprising a longitudinal axis (axis along the length of catheter 19), a first elongate element lumen (22), a second elongate element lumen (25), a tissue anchor lumen (28), a first elongate element (31) within the first elongate element lumen (as shown); and a second elongate element (31) within the second elongate element lumen (as shown).

US 5,355,316 A (MARTIN) discloses an implant delivery system comprising: a catheter (20; figure 8) comprising a longitudinal axis (as shown), a first elongate element lumen (44), a second elongate element lumen (46), a tissue anchor lumen (48), and a plurality of apertures (55, 82, 84) along the longitudinal axis (as shown), wherein the plurality of apertures comprise first elongate element apertures (82), second elongate element apertures (84), and tissue anchor apertures (55), wherein the catheter comprises a plurality of retaining portions each between adjacent tissue anchor apertures and between adjacent first and second elongate element apertures (portions between holes 56, 82, 84).

***Continued Within the Next Supplemental Box***.
Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-***Continued from Box V: Citations and Explanations-***-

Nonetheless, it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine Starkson's multiple tubes defining multiple lumens and first elongated element looping through apertures to include Metsheimer's looping bail, Tehen's first and second elongated elements, and Martin's multiple apertures in each of the three lumens because the structures of each reference are incompatible and therefore lack a motivation to combine; furthermore the prior art fails to disclose a triple lumen catheter, each lumen having multiple longitudinal apertures, with the looping combination between the first and second elongate elements for any surgical or medical use; furthermore, Starkson's multiple lumens are not circumferential lumens of a catheter, they are coaxial lumens of connected tube anchors and the first elongate element is a tether; it would require more than routine skill in the art to create the claimed structure.

Claims 2-12 and 14-20 meet the criteria set out in PCT Article 33(2)-(3), because of dependency on claims 1 and 13.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.