CONTROLLED STEERING FUNCTIONALITY FOR IMPLANT-DELIVERY TOOL

Abstract: A catheter (14), advanced toward an anatomical site, has a proximal end and a steerable distal end. An anchor (32, 2332) is advanced through the catheter. An anchor driver (36) drives the anchor out of the catheter's distal end (104), anchoring the anchor at the site. A first constraining member (1602, 1652) engages tissue, and inhibits, after the anchor has been driven out of the catheter and before the anchoring, movement of at least the anchor driver's distal end, on a first axis between the anchor driver's distal end and a site at which the first constraining member engages the tissue. A second constraining member (26) inhibits, after the anchor has been driven out of the catheter and before the anchoring, movement of at least the anchor driver's distal end, on a second axis. Other embodiments are also described.
— with international search report (Art. 21(3))
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/10; A61F 2/24 (2014.01)
USPC - 623/2,36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 17/10; A61F 2/24 (2014.01)
USPC - 623/2,36

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 2011/0166649 A1 (GROSS, A, et al.) July 7, 2011: figures 6, 11, 17, 20; paragraphs [0093], [0100], [0206], [0235], [0244], [0259], [0283], [0308], [0309], [0319], [0349], [0351], [0368], [0376], [0383], [0394], [0404], [0410], [0422], [0425], [0461]</td>
<td>1-1 1</td>
</tr>
<tr>
<td>Y</td>
<td>US 2007/01 12425 A1 (SCHALLER, L, et al.) May 17, 2007; figures 13, 14; paragraphs [0010], [0042], [0069],[0105], [0113], [0126]</td>
<td>1-1 1</td>
</tr>
</tbody>
</table>

Date of the actual completion of the international search: 20 March 2014 (20.03.2014)

Date of mailing of the international search report: 09 APR 2014

Name and mailing address of the ISA/US

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Form PCT/ISA/210 (second sheet) (July 2009)
**INTERNATIONAL SEARCH REPORT**

**Box No. II**  
**Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following **reasons**:

1. [ ] Claims Nos.:  
   Because they relate to subject matter not required to be searched by this Authority, namely:

2. [ ] Claims Nos.:  
   Because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:  
   Because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III**  
**Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

- **Group I** Claims 1-11 are directed toward an apparatus for use with a subject.
- **Group II** Claims 12-24, 66-77 and 89-90 are directed toward an apparatus configured for providing percutaneous access to a body of a subject.
- **Group III** Claims 25-47 are directed toward an apparatus for use with a subject, with a catheter transluminal advanceable into a heart of the subject.

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos. 1-11.

**Remark on Protest**  
[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2009)
The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include a first constraining member configured to engage tissue of the subject, and to inhibit, after the anchor has been driven out of the distal end of the catheter and before the anchor has been anchored, movement of at least the distal end of the anchor driver, on a first axis, between (1) the distal end of the anchor driver and (2) a site at which the first constraining member engages the tissue of the subject; and a second constraining member configured to inhibit, after the anchor has been driven out of the distal end of the catheter and before the anchor has been anchored, movement of at least the distal end of the anchor driver, on a second axis, which are not present in Groups I-II; the special technical features of Group II include a first catheter having a steerable distal end portion, and comprising a first coupling at a longitudinal site of the first catheter, configured to be advanced transluminally into a subject; a second catheter having a steerable distal end portion configured to be advanced through the first catheter in any rotational orientation of the second catheter with respect to the first catheter, and to be advanced out of a distal end of the first catheter, the second catheter comprising a second coupling at a longitudinal site of the second catheter, the second coupling being configured to be advanced through the first catheter to the first coupling, and to be automatically intracorporeally locked to the first coupling upon the second catheter assuming a given rotational and longitudinal alignment with respect to the first catheter, the first coupling and the second coupling defining a distal locking mechanism having an unlocked state in which the first coupling is not locked to the second coupling, and in which the second catheter is rotatable and longitudinally slidable within the first catheter, and a locked state in which the first coupling is locked to the second coupling, and in which the longitudinal site of the second catheter is (1) inhibited from rotating with respect to the longitudinal site of the first catheter, and (2) longitudinally slidable with respect to the longitudinal site of the first catheter; a first handle, coupled to a proximal end of the first catheter; a second handle, coupled to a proximal end of the second catheter; and a proximal locking mechanism, comprising: a first coupling, coupled to the first handle; and a fourth coupling, coupled to the second handle, and configured to be locked to the third coupling, the third coupling and the fourth coupling defining a proximal locking mechanism having an unlocked state in which the third coupling is not locked to the fourth coupling, and a locked state in which the third coupling is locked to the fourth coupling, and in which the proximal end of the second catheter is (1) inhibited from rotating with respect to the proximal end of the first catheter, and (2) inhibited from longitudinally sliding with respect to the proximal end of the first catheter, which are not present in Groups I and II-VI; the special technical features of Group III include an electrode, configured to be coupled to a subject; a catheter, transluminally advanced into a heart of the subject; an implant, advanceable through the catheter into the heart of the subject, and comprising a sleeve shaped to define a lumen therethrough; a channel, slidable within the catheter, a distal end portion of the channel being slidable within the lumen of the sleeve; a tissue anchor slidable through the channel and into the lumen of the sleeve, and comprising (1) a distal electrically-conductive helical tissue-engaging element, configured to be screwed through the sleeve from the lumen, and to be anchored to a tissue of the heart of the subject, and (2) a proximal electrically conductive coupling head that is electrically coupled to the tissue-engaging element, and is configured to not pass through the sleeve; an electrically-conductive anchor driver, having a proximal end, and a distal end that is mechanically and electrically coupleable to and decoupleable from the coupling head; a control unit, electrically coupleable to the electrode, and electrically coupleable to the tissue-engaging element via the coupling head and the anchor driver, comprising a display, and circuitry configured, while the electrode is in contact with the subject and the tissue-engaging element is in contact with the tissue of the heart of the subject, to receive an electrical signal from the electrode and from the tissue-engaging element, and indicate via the display a position of the tissue-engaging element with respect to the heart of the subject, which are not present in Groups I-III and IV-VI; the special technical features of Group IV include a primary lumen along the longitudinal axis, the lateral wall of longitudinal axis, and within the lateral wall, and having a distal steerable portion; a pull-wire disposed within the secondary lumen; and a pull-ring coupled to the distal steerable portion of the tubular member such that the pull-ring circumscribes the primary lumen, shaped to define a receptacle, coupled to a distal portion of the pull-wire, the distal portion of the pull-wire being disposed within the receptacle, the disposition of the distal portion of the pull-wire in the receptacle facilitating the coupling of the pull-wire to the pull-ring, which are not present in Groups I-III and V-VI; the special technical features of Group V include an implant structure configured to treat a native atrioventricular valve of a patient, the implant structure comprising a sleeve having a lumen and at least a proximal end, the proximal end being shaped so as to define an opening; a longitudinal element, having a distal end that is slidable within the lumen and slidable out of the lumen via the opening; and a closure element coupled to the implant structure in a vicinity of the at least one end, comprising a flap having (1) an open state and (2) a closed state in which the lumen is in reduced fluid communication with outside of the implant structure compared to when the flap is in the open state, and configured to be biased toward assuming the closed state, the apparatus being configured such that when the distal end of the longitudinal element is disposed within the lumen and distal to the closure element, the flap is retained in the open state, and sliding of the distal end of the longitudinal element proximal to the closure element closes the flap, which are not present in Groups I-IV and VI; the special technical features of Group VI include a flexible, elongate anchor driver having a proximal end, and a distal end that is configured to be reversibly coupled to the tissue anchor, and advanced transluminally to the tissue of the subject, and being configured to transfer rotational force to the proximal end to the tissue anchor and a tool comprising a distal portion that is coupleable to the proximal end of the anchor driver, a proximal portion, rotatably coupled to the distal portion, and having a rest rotational position with respect to the distal portion, a variable-resistance mechanism, configured to progressively inhibit rotation of the proximal portion with respect to the distal portion, correspondingly with a rotational distance, from the rest rotational position, of the proximal portion with respect to the distal portion, which are not present in Groups I-V.
**Continued from Previous Supplemental Box**

The common technical features of Groups I-V are a steerable catheter/tubular member/lumen.

However, these common technical features are disclosed by US 2011/0166649 A1 to Gross, et al. (hereinafter 'Gross'). Gross discloses a steerable catheter/tubular member/lumen (steerable catheter 421; abstract: paragraph [0382]).

Since the common technical features are previously disclosed by the Gross reference, the common features are not special and so Groups I-V lack unity.

The common technical features of Groups I, III and VI are a tissue anchor, configured to be advanced through the catheter; an anchor driver having a distal end that is reversibly couplable to the tissue anchor, and configured to drive the tissue anchor through the catheter and out of the distal end of the catheter, and to anchor the tissue anchor at the anatomical site.

However, these common technical features are disclosed by the Gross. Gross discloses a tissue anchor, configured to be advanced through the catheter (at least first and second tissue anchors; claim 38); an anchor driver having a distal end that is reversibly couplable to the tissue anchor, and configured to drive the tissue anchor through the catheter and out of the distal end of the catheter, and to anchor the tissue anchor at the anatomical site (anchor configured to be advanced through the lumen of the tube, wherein the anchor is configured to be advanced through a portion of the implant at the first location in response to steering the distal portion of the tube toward the first location by applying the force to the first one of the longitudinal guide members, and wherein the first one of the longitudinal guide members is configured to be decoupled from the implant subsequent to the anchoring of the anchor to tissue of the patient; claim 10).

Since the common technical feature is previously disclosed by the Gross reference, the common features are not special and so Groups I, III and VI lack unity.