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- (71) Applicant: ORFORD HOLDINGS SA [CH/CH]; Av. des Alpes 104, CH-1820 Montreux (CH).
- (72) Inventors; and
- (71) Applicants (for US only): SPENCE, Paul, A. [CA/US]; 5818 Orion Road, Louisville, KY 40222 (US). TOMP-

KINS, Landon, H. [US/US]; 1314 Bluegrass Parkway, La Grange, KY 40031 (US).

(74) Agent: ROONEY, Kevin, G.; Wood, Herron & Evans LLP, 2700 Carew Tower, 441 Vine Street, Cincinnati, OH 45202-2917 (US).

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(54) Title: MITRAL VALVE DOCKING DEVICES, SYSTEMS AND METHODS

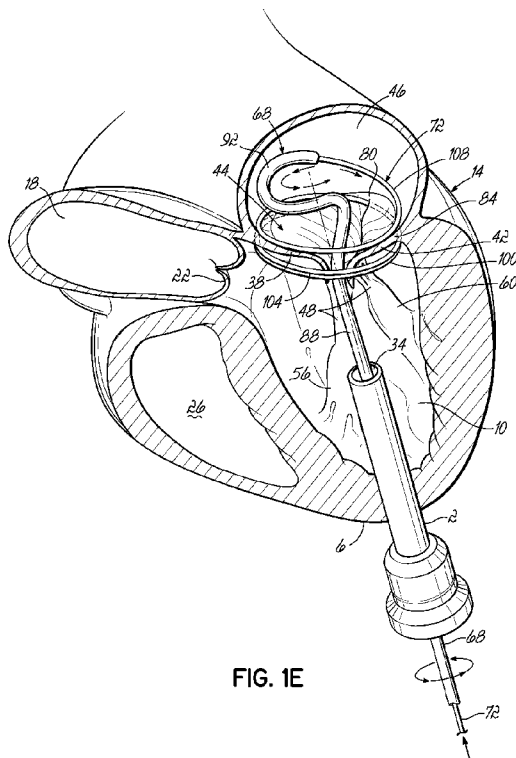
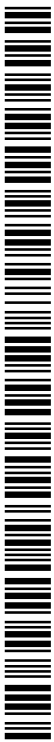


FIG. 1E

(57) Abstract: Various systems, devices and methods associated with the placement of a dock or anchor (72) for a prosthetic mitral valve (120). The anchor (72) may take the form of a helical anchor having multiple coils (104, 108) and/or a stent-like structure. Various methods include different levels of minimal invasive procedures for delivering the prosthetic valve anchor (72) and prosthetic valve (120), as well as tissue anchors for plication or other purposes to the mitral valve position in the heart (14).



TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61F 2/06, 2/24; A61M 31/00 (2013.01) USPC - 623/ 2.11, 2.17, 2.18, 2.36, 2.37; 604/500 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): A61F 2/06, 2/24; A61M 31/00 (2013.01) USPC: 623/ 2.11, 2.17, 2.18, 2.36, 2.37; 604/500 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Google/Google Scholar; DialogPro; Pubmed/Medline: mitral, bicuspid, atrioventricular, valve, prosthetic, prosthesis, implant, coil, curve, helical, helix, spiral, screw, corkscrew, anchor, guide catheter, docking, straighten, activate, annuloplasty, shape memory, hooks, claws, prongs, grooves, snare		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0234318 A1 (LOULMET, D et al.) September 17, 2009; figures 14a; figures 3, 14a, 22a-c; paragraphs [0045]-[0046], [0054], [0056]-[0057], [0073]-[0075], [0092], [0110], [0117]-[0118], [0125]-[0126]	1-17, 22-42
Y	US 2011/0137397 A1 (CHAU, M et al.) June 9, 2011; figures 23, 79, 83; paragraphs [0090], [0098]-[0100], [0129], [0176]	1-17, 22-42
E, X	WO 2013/114214 A2 (SPENCE, PA et al.) August 8, 2013; figures 1a-f; paragraphs [00104]-[00116]	1-17, 22-42
A	US 2007/0232898 A1 (HUYNH, R et al.) October 4, 2007; figures 4; paragraphs [0043]-[0047]	1, 22
A	US 2007/0244553 A1 (RAFIEE, N, et al.) October 18, 2007; figures 6a-b, 10-17; paragraphs [0068]; [0070]-[0077], [0094]	1, 22
A	US 6971998 B2 (ROSENMAN, DC et al.) December 6, 2005; figures 2-4; column 6, lines 3-35; column 11, lines 52-67	1, 22
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 28 October 2013 (28.10.2013)		Date of mailing of the international search report 05 NOV 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB13/00593

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:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-17 and 22-42 are directed toward a system for docking and method of implanting a mitral valve prosthesis in the heart of a patient.

Group II: Claims 18-21 and 43-44 are directed toward a device for docking a mitral valve prosthesis and a method of implanting a mitral valve prosthesis in the heart of a patient

-Continued Within the Next Supplemental Page-

- 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. 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.:
1-17 and 22-42

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.

-***-Continued from Box No. III: Observations where unity of invention is lacking-***-

Group III: Claim 45 is directed toward a helical anchor wherein the helical anchor includes a distal end portion and the distal end portion is formed to extend downward and radially outward relative to a next adjacent coil such that the distal end portion is spaced from the next adjacent coil and is configured to be delivered between the commissures of the native mitral valve.

Group IV: Claims 46-47 are directed toward a helical anchor wherein the plurality of coils include an upper, atrial coil adapted to be placed above the native mitral valve annulus and a lower, ventricular coil adapted to be placed below the native mitral valve annulus, wherein the upper coil is adjacent the lower coil, and further comprising a gap between the upper and lower coils creating a space prior to implantation of the coils such that the upper and lower coils do not trap mitral leaflet tissue upon implantation.

Group V: Claim 48 is directed toward a helical anchor wherein the plurality of coils include an upper, atrial coil adapted to be placed above the native mitral valve annulus and a lower, ventricular coil adapted to be placed below the native mitral valve annulus, and further comprising an extension extending out of a plane of the upper coil and spaced from the upper coil so as to engage the wall of the atrium and provide stabilization upon implantation in the heart.

Group VI: Claims 49-50 are directed toward a helical anchor wherein the plurality of coils include a plurality of upper, atrial coils and a plurality of lower, ventricular coils, the upper, atrial coils adapted to be placed above the native mitral valve annulus and extend upwardly to adjustably position the mitral valve prosthesis at a desired height relative to the mitral valve annulus.

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 coil guide catheter including a stem portion and a distal portion connected to the stem portion at a first curved shape, the distal portion having a second curved shape configured to generally follow the curvature of the mitral valve annulus, said first and second curved portions capable of being delivered in straightened configurations and activated to the first and second curved shapes within the heart proximate the mitral valve, and a helical anchor adapted to be received in and delivered from the coil guide catheter, the helical anchor formed as multiple coils having a preformed, coiled configuration after being delivered from the coil guide catheter and adapted to support a prosthetic mitral valve upon being fully delivered from the coil guide catheter and implanted with coil portions above and below the mitral valve annulus, which are not present in Groups II-VI; the special technical features of Group II include directing a stent delivery catheter to the mitral valve position within the heart of the patient, extending a stent dock from the stent deliver catheter, expanding an atrial portion of the stent dock in the left atrium such that the atrial portion engages the wall of the left atrium, expanding a valve retaining portion of the stent dock against the leaflets of the native mitral valve, and implanting the mitral valve prosthesis within the valve retaining portion such that the mitral valve prosthesis is supported by the stent dock, which are not present in Groups I and III-VI; the special technical features of Group III include wherein the helical anchor includes a distal end portion and the distal end portion is formed to extend downward and radially outward relative to a next adjacent coil such that the distal end portion is spaced from the next adjacent coil and is configured to be delivered between the commissures of the native mitral valve, which are not present in Groups I-II and IV-VI; the special technical features of Group IV include wherein the plurality of coils include an upper, atrial coil adapted to be placed above the native mitral valve annulus and a lower, ventricular coil adapted to be placed below the native mitral valve annulus, wherein the upper coil is adjacent the lower coil, and further comprising a gap between the upper and lower coils creating a space prior to implantation of the coils such that the upper and lower coils do not trap mitral leaflet tissue upon implantation, which are not present in Groups I-III and V-VI; the special technical features of Group V include wherein the plurality of coils include an upper, atrial coil adapted to be placed above the native mitral valve annulus and a lower, ventricular coil adapted to be placed below the native mitral valve annulus, and further comprising an extension extending out of a plane of the upper coil and spaced from the upper coil so as to engage the wall of the atrium and provide stabilization upon implantation in the heart, which are not present in Groups I-IV and VI-VI; the special technical features of Group VI include wherein the plurality of coils include a plurality of upper, atrial coils and a plurality of lower, ventricular coils, the upper, atrial coils adapted to be placed above the native mitral valve annulus and extend upwardly to adjustably position the mitral valve prosthesis at a desired height relative to the mitral valve annulus, which are not present in Groups I-V.

The common technical feature of Groups I-VI is a mitral valve. However, this common technical features is disclosed by US 2011/0106247 A1 to Miller, et al. (hereinafter 'Miller'). Miller discloses a mitral valve (mitral valve of the patient; figure 4; paragraph [0121]).

Since the common technical feature is previously disclosed by the Miller reference, the common feature is not special and so Groups I-VI lack unity.

The common technical features of Groups I and III-VI are coils; and helical anchors. Miller discloses coils (coiled implant; paragraph [0127]); and helical anchors (helical tissue anchors; paragraph [0109]).

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