



- (51) **International Patent Classification:**
A61F 2/24 (2006.01)
- (21) **International Application Number:**
PCT/US2019/058638
- (22) **International Filing Date:**
29 October 2019 (29.10.2019)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
62/754,066 01 November 2018 (01.11.2018) US
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- (81) **Designated States** (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,

(54) **Title:** IMPLANT HOLDER ASSEMBLY WITH ACTUATOR FOR HEART VALVE REPAIR AND REPLACEMENT

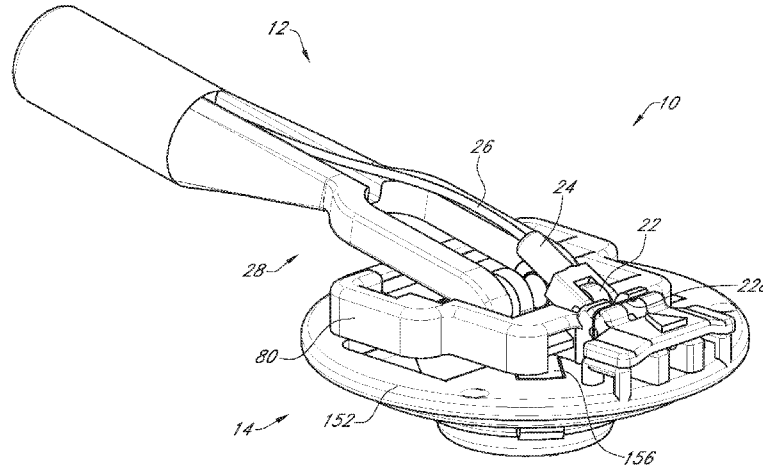


FIG. 4A

(57) **Abstract:** An articulating implant holder system for heart valve repair or replacement has an implant configured to be secured to a heart valve annulus, an implant holder secured to the implant, an articulating handle assembly comprising a handle, a swivel pivotably secured to the handle at a first location and a connector pivotably secured to the swivel at a second location, an actuating cable secured between the handle and the connector to cause the swivel to move from a first position to a second position, and a latch removably secured to the implant holder. A plurality of sizer heads are configured to correspond to different sizes of heart valve annuluses and each of the plurality of sizer heads has a latching feature. A latching feature of the swivel is configured to removably snap on to the latching feature of each of the plurality of sizer heads and is configured to permanently snap on to the latch.



WO 2020/092418 A3

SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, 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, KM, ML, MR, NE, SN, TD, TG).

Published:

- *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))*

(88) Date of publication of the international search report:

23 July 2020 (23.07.2020)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/058638

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:

see additional sheet

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 an 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.:

1-14

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.

INTERNATIONAL SEARCH REPORT

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| International application No PCT/US2019/058638 |
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| A. CLASSIFICATION OF SUBJECT MATTER INV. A61F2/24 ADD. | | |
| 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) A61F | | |
| 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) EPO-Internal, WPI Data | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | WO 2009/033173 A1 (EDWARDS LIFESCIENCES CORP [US]; KEIDAR YARON [IL] ET AL.) 12 March 2009 (2009-03-12) paragraphs [0065] - [0089]; figures 15A-21B ----- | 1-14 |
| A | US 2018/116795 A1 (CONKLIN BRIAN S [US] ET AL) 3 May 2018 (2018-05-03) paragraphs [0052] - [0086]; figures 3-17 ----- | 1-14 |
| A | WO 2007/143077 A2 (MEDTRONIC INC [US]; RYAN TIMOTHY R [US] ET AL.) 13 December 2007 (2007-12-13) page 24, line 26 - page 25, line 12; figure 11 ----- | 1-14 |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex. | | |
| * 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 | Date of mailing of the international search report | |
| 27 January 2020 | 24/06/2020 | |
| Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016 | Authorized officer Chevalot, Nicolas | |

INTERNATIONAL SEARCH REPORT

Information on patent family members

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| International application No PCT/US2019/058638 |
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-14

An articulating implant holder system for heart valve repair or replacement, comprising: an implant configured to be secured to a heart valve annulus; an implant holder having a bottom portion and a top portion, the implant secured to the bottom portion of the implant holder; an articulating handle assembly comprising a handle and a swivel, the swivel having a latching feature, the handle pivotably secured to the swivel at a first location, a connector pivotably secured to the swivel at a second location different from the first location, and an actuating cable secured between the handle and the connector to move the swivel from a first position relative to the handle to a second position relative to the handle; a latch removably secured to the implant holder; and a plurality of sizer heads configured to correspond to different sizes of heart valve annuluses, each of the plurality of sizer heads having a latching feature: wherein the latching feature of the swivel is configured to removably snap on to the latching feature of each of the plurality of sizer heads: and wherein the latching feature of the swivel is configured to permanently snap on to the latch.

2. claims: 15-19

An articulating implant holder system for heart valve repair, comprising: an annuloplasty ring configured to be secured to a heart valve annulus: an implant holder having a bottom portion and a top portion, the annuloplasty ring secured to the bottom portion of the implant holder; an articulating handle assembly comprising a handle and a swivel, the swivel having a latching feature, the handle pivotably secured to the swivel at a first location, a connector pivotably secured to the swivel at a second location different from the first location, and an actuating cable secured between the handle and the connector to move the swivel from a first position relative to the handle to a second position relative to the handle; and a latch removably secured to the implant holder; wherein the latch is secured to the top portion of the implant holder by a release suture that is accessible to cutting from above by a surgeon; and wherein the latching feature of the swivel is configured to permanently snap on to the latch.

3. claim: 20

An articulating implant holder system for heart valve repair, comprising: an annuloplasty ring configured to be secured to a heart valve annulus: an implant holder having a

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

bottom portion and a top portion, the annuloplasty ring secured to the bottom portion of the implant holder; and an articulating handle assembly comprising a handle and a swivel, the swivel having a latching feature, the handle pivotably secured to the swivel at a first location, a connector pivotably secured to the swivel at a second location different from the first location, and an actuating cable secured between the handle and the connector to move the swivel from a first position relative to the handle to a second position relative to the handle; wherein the articulating handle assembly is mounted on the top portion of the implant holder and is secured by a suture, the suture threaded across a suture mount of the swivel that forms a single cutting point gap, down through the implant holder, and back up through the implant holder to a base of the swivel opposite the suture mount to secure the swivel to the implant holder and to permit release of the articulating handle assembly from the implant holder at a single cutting point at the suture mount.
