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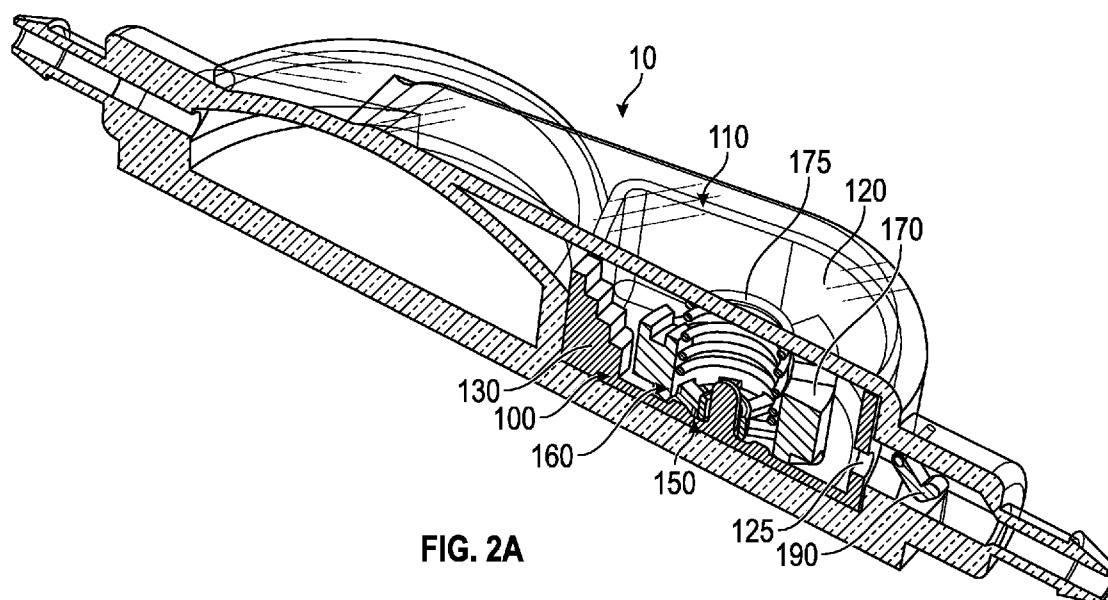


FIG. 2A

(57) Abstract: An implantable valve device includes a valve unit having a flow limiter in operative association with a dial for controlling a flow of material through a lumen in communication with the valve unit. The dial includes a dial indicator viewable through cross-sectional imaging for determining and/or otherwise verifying a "pressure setting" of the valve unit. The valve unit can include a housing that encapsulates the dial therein and provides one or more reference indicators that enable a practitioner to determine an orientation of the valve unit and further clarify the position of the dial indicator. The valve unit can be interrogated through conventional non-invasive cross-sectional imaging methods such as ultrasound.



LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI,
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- *with international search report (Art. 21(3))*
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/60182

A. CLASSIFICATION OF SUBJECT MATTER

IPC - INV. A61M 27/00 (2023.01)

ADD. A61M 39/22 (2023.01)

CPC - INV. A61M 27/006

ADD. A61M 27/002, A61M 27/00, A61M 39/22

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)

See Search History document

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

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 4,676,772 A (HOOVEN) 30 June 1987 (30.06.1987) Entire document.	1-7, 13 ----- 11-12, 14
X -- Y	US 2021/0330947 A1 (HP BIOPROTESES LTDA et al.) 28 October 2021 (28.10.2021) Entire document.	1-3, 8-10 ----- 14
Y	US 4,081,635 A (MOORE) 28 March 1978 (28.03.1978) Entire document.	11-12
A	US 10,967,158 B1 (POPFLOW, LLC) 06 April 2021 (06.04.2021) Entire document.	1-14
A	US 2018/0126147 A1 (HAKIM) 10 May 2018 (10.05.2018) Entire document.	1-14
A	US 2018/0001064 A1 (DEPUY SYNTHES PRODUCTS, INC) 04 January 2018 (04.01.2018) Entire document	1-14
A	US 2018/0133444 A1 (INTEGRA LIFESCIENCES SWITZERLAND SARL) 17 May 2018 (17.05.2018) Entire document.	1-14

☐ Further documents are listed in the continuation of Box C.☐ 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

"D" document cited by the applicant in the international application

"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

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/60182

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 searched, the appropriate additional search fees must be paid.

Group I: claims 1-14, drawn to a dial for a valve device

Group II: claims 15-21, drawn to method of imaging a valve

The inventions listed as Groups I - II 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:

---- see extra 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 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

International application No.

PCT/US 23/60182

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

Group II includes the special technical features of method steps including particular use steps (claim 15) capturing, at a cross-sectional imaging device, a cross-sectional image of the valve device including the position of the dial indicator viewable within the cross-sectional image; and determining, based on the cross-sectional image of the dial indicator, the position of the dial based on the position of the dial indicator viewable within the cross-sectional image, not required by Group I.

Group I-II are related to an apparatus (Group I) and method(s) of using the apparatus (Group II). These groups therefore share the technical features of the apparatus of claim 1, however, these shared technical features fail to provide a contribution over the prior art of US 4,676,772 A (HOOVEN). As per claim 1, Hooven describes a valve device (Abstract), including: a dial having a dial indicator (thread screw member 31 and permanent magnet 72 or wrench 70, FIG. 2, col 7, ln 9-10: "permanent magnet 72"; col 5, ln 62- col 6, ln 5: "As is best seen in FIGS. 6 and 7, the magnetic wrench 70 is positioned above the screw member 31 such that pins 71a-71d are received within four of the twelve circular recesses 62 in the upper surface of screw member 31. Such engagement of the pins and recesses allows vertical motion of the wrench relative to the screw member, while at the same time assuring that rotation of one results in rotation of the other. Thus, by rotating the magnetic wrench, the vertical position of the screw member, and hence the contact force existing between ball 29 and valve seat shoulder 54, may be continuously adjusted"), the dial and the dial indicator being moveable between a plurality of positions (about shoulder 56 with serrations 78, FIGS. 2, 6, col 6, ln 22-35 "To prevent inadvertent or unintentional rotation of the magnetic wrench, the valve includes an annular member 77 formed of a magnetic material embedded in shoulder 56 directly beneath the magnetic wrench 70. In the absence of a strong externally applied magnetic field, the magnetic wrench 70 will be pulled downwardly into contact with step 56 by reason of the attraction between magnet 72 to annular member 77 to the position shown in Fig. 6. As illustrated in Fig. 2, the upper surface of step 56 is provided with a plurality of serrations 78 which serve to increase the friction between the lower surface of the wrench and the casing top 30 to prevent inadvertent rotation of the magnetic wrench when in this position"), the dial being configured such that a position of the plurality of positions of the dial is viewable through cross-sectional imaging of the dial indicator (magnetic imaging of dial indicator 72 allows position of dial/dial indicator to be viewed via tool 80, FIG. 3, col 6, ln 36-40, "To allow accurate and non-invasive determination of magnetic wrench position, a position sensor 80, constructed in accordance with the invention, is provided and is illustrated in FIGS. 3 and 4"; alternatively, note intended use as dial indicator is a permanent magnet and housing is polymeric (col 3, ln 60-64, col 7, ln 9-10) therefore have different densities that are distinguishable in various medical scans).

Thus, Groups I-II lack unity of invention because they do not share a same or corresponding special technical feature providing a contribution over the prior art.