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DESCRIPTION

Technical Field of the Invention

[0001] The present disclosure relates to biomedical electrodes, and in particular, to a radiolucent biomedical electrode connector and radiolucent lead wires for performing biomedical monitoring of a patient during imaging procedures.

Background of the Invention

[0002] Electrocardiograph (ECG) monitors are widely used to obtain medical (i.e. biopotential) signals containing information indicative of the electrical activity associated with the heart and pulmonary system. To obtain medical signals, ECG electrodes are applied to the skin of a patient in various locations. The electrodes, after being positioned on the patient, connect to an ECG monitor by a set of ECG lead wires. The distal end of the ECG lead wire, or portion closest to the patient, may include a connector which is adapted to operably connect to the electrode to receive medical signals from the body. The proximal end of the ECG lead set is operably coupled to the ECG monitor and supplies the medical signals received from the body to the ECG monitor.

[0003] A typical ECG electrode assembly may include an electrically conductive layer and a backing layer, the assembly having a patient contact side and a connector side. The contact side of the electrode pad may include biocompatible conductive gel or adhesive for affixing the electrode to a patient's body for facilitating an appropriate electrical connection between a patient's body and the electrode assembly. The connector side of the pad may incorporate a metallic press stud having a bulbous profile for coupling the electrode pad to the ECG lead wire. In use, the clinician removes a protective covering from the electrode side to expose the gel or adhesive, affixes the electrode pad to the patient's body, and attaches the appropriate ECG lead wire connector to the press stud by pressing or "snapping" the lead wire connector onto the bulbous press stud to achieve mechanical and electrical coupling of the electrode and lead wire. Alternatively, ECG connectors that engage via manipulation of a lever or other mechanical locking device may be employed. After use, a clinician then removes the ECG lead wire connector from the pad by pulling or "unsnapping" the connector from the pad or by releasing the lever or other locking mechanism.

[0004] Placement of the electrodes on a patient has been established by medical protocols. A common protocol requires the placement of the electrodes in a 5-lead configuration: one electrode adjacent each clavicle bone on the upper chest and a third electrode adjacent the patient's lower left abdomen, a fourth electrode adjacent the sternum, and a fifth electrode on the patient's lower right abdomen.

[0005] During certain procedures it may be necessary to monitor biological (e.g., ECG) parameters of a patient that is undergoing imaging, such as CT-scan or MRI. Use of conventional ECG connectors and lead wire sets typically associated therewith may have drawbacks in these applications, since they tend to interfere with the imaging systems. In one example, certain components of the ECG connectors and/or lead wires may be detected by the imaging apparatus and consequently may obfuscate the visual images upon which clinicians and surgeons rely. In another example, ferrous and/or magnetic components commonly found in ECG connectors, such as in springs and clips, may be potentially hazardous when used within the intense magnetic field of an MRI scanner. EP2070474 discloses an ECG connector. US 2004/203273 describes a device that electrically connects a connecting line to a medical engineering skin electrode, with a contact member. The contact member has an energy storing element for spring biasing of the contact member into contact with a contact pin of the electrode. US 4674817 describes an electrical connector for connecting a medical electrode terminal on a patient with a lead wire and comprises an electrical contact member that is embedded in a resilient insulating body member. The body member includes first and second cantilevered arms having circuitous arc segments with their concave surfaces facing towards each other to form an open jaw for receiving therebetween the electrode terminal. WO 2008/092098 (A2) discloses a radiolucent ECG connector.

SUMMARY

[0006] In an embodiment in accordance with the present disclosure, there is provided an ECG connector assembly according to claim 1.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] The accompanying drawings are not intended to be drawn to scales. In the drawing, each identical or nearly identical component that is illustrated in various figures is represented by a like numeral. For purposes of clarity, not every component may be labeled in every drawing. Various embodiments of the present disclosure are described hereinbelow with references to the drawings, wherein:

Fig. 1 is an exploded view of a conventional ECG electrode connector;

Fig. 2 is a schematic diagram of the conventional ECG electrode connector of Fig. 12A;

Fig. 3A is a view of an embodiment of a radiolucent ECG electrode connector in an engaged configuration in accordance with the present disclosure;

Fig. 3B is a view of the Fig. 3A embodiment in a disengaged configuration in accordance with the present disclosure;

Fig. 3C is a detail view of a press stud opening of the Fig. 3A embodiment of a radiolucent

ECG electrode connector in accordance with the present disclosure

Fig. 4A is a view of another embodiment of a radiolucent ECG electrode connector in an engaged configuration in accordance with the present disclosure;

Fig. 4B is a view of the Fig. 4A embodiment in a disengaged configuration in accordance with the present disclosure; and

Fig. 5 is a view of another embodiment of a radiolucent ECG electrode connector in accordance with the present disclosure.

Detailed Description of the Preferred Embodiments

[0008] This invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including," "comprising," "having," "continuing," or "involving" and variations thereof herein, is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[0009] Particular embodiments of the present disclosure are described hereinbelow with reference to the accompanying drawings; however, the disclosed embodiments are merely examples of the disclosure, which may be embodied in various forms. Well-known functions or constructions and repetitive matter are not described in detail to avoid obscuring the present disclosure in unnecessary or redundant detail. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosure in virtually any appropriately detailed structure.

[0010] In the drawings and in the descriptions that follow, the term "proximal," as is traditional, shall refer to the end of the instrument that is closer to a user, while the term "distal" shall refer to the end that is farther from a user. In addition, as used herein, terms referencing orientation, e.g., "top", "bottom", "up", "down", "left", "right", "clockwise", "counterclockwise", and the like, are used for illustrative purposes with reference to the figures and features shown therein. Embodiments in accordance with the present disclosure may be practiced in any orientation without limitation. The scope of protection of the present invention is fully determined by the text of the appended claims.

[0011] The present invention is directed to an electrode connector suitable for use during patient imaging, such as during a CT-scan or MRI. Commonly available electrode connectors have components which may be detected on the image and/or may become dangerous when

exposed to a particular field, such as a magnetic field.

[0012] One example of a conventional electrode connector 1320 is shown in Fig. 1 and Fig. 2 which includes a housing 1322 having an upper member 1324 and a lower member 1326, and defining an internal cavity 1328 therebetween. Housing 1322 is fabricated from a non-conducting material, e.g., an injection molded polymer which electrically insulates the subject from the conductive element(s) therewithin. Upper member 1324 and lower member 1326 are separate components attached to each other by any suitable method of bonding, such as without limitation, adhesive, ultrasonic welding, or heat welding. Upper member 1324 and lower member 1326 form a non-conductive element of the housing 1322.

[0013] Housing 1322 of the conventional electrode connector includes a lead wire terminal 1330 which is electrically connected to a respective end of lead wire 1304 by any suitable method of connection, including without limitation, crimping, soldering, or welding. Lead wire terminal 1330 is formed of a conductive material, typically a metal such as stainless steel. Housing 1322 supports a contact member 1332 also formed of a conductive material that is electrically connected to a lead wire. In one example, the lead wire is formed of a conductive metals such as tinned copper. In another example, the conductive material of the contact member is a metal such as stainless steel. Contact member 1332 and lead wire terminal 1330 may be integrally formed. Contact member 1332 defines a contact opening 1334 formed therein and in communication with internal cavity 1328 of housing 1322. Contact opening 1334 includes first contact opening portion 1334a and second contact opening portion 1334b. First contact opening portion 1334a defines an internal dimension or diameter which is greater than the corresponding internal dimension or diameter of second contact opening portion 1334b.

[0014] Housing 1322 of conventional electrode connector further includes a lever 1340 pivotably connected thereto. Lever 1340 includes an actuating end 1336. Lever 1340 is biased to a first position by a biasing member 1338, as shown in Fig. 2. Biasing member 1338 is formed of a resilient metal, such as stainless steel. Lever 1340 includes an engaging region 1336a projecting therefrom so as to extend across first contact opening portion 1334a of contact opening 1334 when lever 1340 is in the first position. In use, lever 1340 is actuatable to a second position wherein engaging region 1336a thereof does not obstruct or extend across first contact opening portion 1334a of contact opening 1334. For example, a clinician may apply finger pressure to actuating end 1336 that is sufficient to overcome the biasing force of biasing member 1338, thereby causing engaging region 1336a to move to a second position as herein described.

[0015] Conventional ECG electrode connector 1320 is adapted for connection to a conventional snap-type biomedical electrode (not explicitly shown). A typical snap-type biomedical electrode incorporates an electrode flange or base and male press stud or terminal extending in transverse relation to the electrode base. The male press stud terminal may have a bulbous head whereby an upper portion of the terminal has a greater cross-sectional dimension than a lower portion of the terminal. Accordingly, in use, when lever 1340 of electrode connector 1320 is in the second position, the head of the male press stud terminal of

the snap-type biomedical electrode may be inserted into first contact opening portion 1334a of contact opening 1334 and actuating end 1336, and thus, lever 1340, may be released so that biasing member 1338 moves engaging region 1336a of lever 1340 against the head of the male press stud (not explicitly shown) to push or force the lower portion of the press stud into a second contact opening portion 1334b of contact opening 1334. The biasing force of biasing member 1338 helps to maintain the press stud within second contact opening portion 1334b of contact opening 1334 and thus inhibits removal or disconnection of the biomedical electrode from ECG connector 1320. However, because lead wire terminal 1330, contact member 1332 and biasing member 1338 are metallic, one or more of these components may be detected in the image and/or become dangerous when exposed to a magnetic field.

[0016] Accordingly, one aspect of the present invention provides an electrode connector which may be used during patient imaging. One embodiment of an ECG electrode connector of the present invention is shown in Figs. 3A, 3B, and 3C. In view thereof, and so as not to obscure the present disclosure with redundant information, only those features distinct to ECG electrode connector 1400 will be described hereinafter.

[0017] ECG electrode connector 1400 is configured to facilitate the monitoring of ECG and other biological parameters while the subject patient is undergoing an imaging procedure, such as without limitation, MRI, CT, PET, and the like. Connector 1400 includes a housing 1424 having an interior recessed surface 1431 that includes an opening 1434 defined therein that opens to a patient-facing surface of the housing. Opening 1434 is dimensioned to accept the insertion of a head of a press stud of a patient electrode. Housing 1424 may be formed from any suitable non-conductive material, including polymeric material. The connector 1400 includes an engagement member 1436 having an actuation surface 1439, which may be a contoured pushbutton, and an engaging face 1437. Engagement member 1436 is pivotable about a pivot 1415 to enable the engaging face 1437 to move from a first position whereby engaging face 1437 is closer to a top portion 1425 of opening 1434 and a second position whereby engaging face 1437 is further from a top portion 1425 of opening 1434. By this arrangement, the bulbous head of a press stud that has been introduced into opening 1434 may be captured in opening 1434 between engaging face 1437 and a sidewall of opening 1434. Engagement member 1436 includes a stiffener 1438, that may have an arcuate shape, disposed between engaging face 1437 and pivot 1415.

[0018] The interior recessed surface 1431 of housing 1424 includes a radiolucent conductor 1432 that facilitates the conduction of biological signals between a press stud captured within opening 1434 and a lead wire conductor 1477. Radiolucent conductor 1432 may be included with surface 1431 by any suitable manner, including without limitation, as a conductive coating and/or a conductive material incorporated within housing 1424 or associated portions thereof. In some embodiments, radiolucent conductor 1432 may be formed by dispersing conductive carbon powder over interior recessed surface 1431. The conductive carbon powder is then fused via the application of heat and/or pressure to the polymeric material that forms interior recessed surface 1431. In some embodiments, radiolucent conductor 1432 may be formed by the application of radiolucent conductive ink to interior recessed surface 1431. In other

embodiments, the radiolucent conductor 1432 may comprise a carbon fiber wire fixed to the recessed surface 1431. As shown in Fig. 3C, radiolucent conductor 1432 may extend onto at least a portion of a sidewall 1441 of opening 1434.

[0019] ECG electrode connector 1400 includes a lead wire 1475 extending from a proximal (e.g., bottom) end thereof. Lead wire 1475 includes an outer insulator 1476 coaxially disposed about a conductor 1477. Conductor 1477 is formed from radiolucent electrically conductive material, such as conductive carbon or conductive carbon monofilament wire. In some embodiments, conductor 1477 is formed from one or more carbon fibers. A distal portion of the outer insulator is stripped thus exposing a distal portion of conductor 1477'. The exposed portion 1477' of conductor 1477 is operatively joined to radiolucent conductor 1432 of interior recessed surface 1431. Conductor 1477' may be joined by any suitable manner, including without limitation a crimping element 1478 and/or by radiolucent electrically conductive adhesive. In some embodiments, the exposed portion 1477' of conductor 1477 and radiolucent conductor 1432 are integrally formed. A strain relief 1479 surrounds a portion of lead wire 1475 where lead wire 1475 exits the housing 1424

[0020] A resilient member 1470 biases engagement member 1436 towards a first position whereby engaging face 1437 is closer to a top portion 1425 of opening 1434. Lobed resilient member 1470 is positioned between a recess 1428 defined in engagement member 1436 and a saddle 1472 provided by housing 1424. Resilient member 1470 may be formed from a radiolucent elastomer, including without limitation, silicone. Resilient member 1470 may have any shape to provide sufficient force to allow the desired movement of the engagement member 1436. The resilient member 1470 may have any regular or irregular shape, including circle, square, triangle, and clover. In one, one embodiment, resilient member 1470 is a lobed member. In the embodiment shown in Figs. 3A and 3B, lobed resilient member 1470 includes a three-lobe profile having each lobe evenly spaced at about 120° apart, however, a lobed resilient member 1470 in accordance with the present disclosure may include fewer than three lobes, or more than three lobes. Additionally or alternatively, lobed resilient member 1470 may include lobes that are not evenly spaced and/or irregularly placed. The resilient member may be solid throughout, or comprise one or more openings. Lobed resilient member 1470 includes a center opening 1471 defined therein and having a shape that generally corresponds to the contour of the perimeter (e.g., the lobe profile) of lobed resilient member 1470, and/or that may include one or more interior projections 1481. The ratio of the size of opening 1471 to the overall size of the lobed resilient member 1470 determines, at least in part, the resiliency of lobed resilient member 1470 and may facilitate tactile feedback to a user during the actuation/compression and release/extension of the combination of lobed resilient member 1470 and engagement member 1436. For example, and without limitation, cooperative interference between one or more interior projections 1481 as resilient member 1470 is compressed and/or released may generate one or more vibrations that may, in turn, be sensed as tactile feedback by a user's fingertip via actuating surface 1439 and/or via housing 1424.

[0021] During use, a user may apply force to actuating surface 1439 using, e.g., a fingertip, thereby overcoming the biasing force of resilient member 1470 to cause engagement member

1436 to rotate slightly counterclockwise about pivot 1415. In turn, engaging face 1437 moves further from a top surface 1425 of opening 1434 which provides sufficient clearance to enable the introduction of a bulbous head of a press stud into opening 1434. Once the press stud is inserted into opening 1434, the user may remove finger pressure from actuating surface 1439, whereupon the biasing force of resilient member 1470 causes engagement member 1436 to rotate slightly clockwise about pivot 1415, thereby electromechanically engaging the press stud with a portion of opening 1434 and thus, electrically coupling the press stud with radiolucent conductor 1432 and conductor 1477.

[0022] Yet another example of a radiolucent ECG electrode connector 1500 is shown in Figs. 4A and 4B. In view thereof, and so as not to obscure the present disclosure with redundant information, only those features distinct to ECG electrode connector 1500 will be described hereinafter. Radiolucent electrode connector 1500 includes an engagement member 1536 having an actuation surface 1539, which may be a contoured pushbutton, and an engaging face 1537. Engagement member 1536 is pivotable about a pivot 1515 to enable the engaging face 1537 to move from a first position whereby engaging face 1537 is closer to a top portion 1525 of opening 1534 and a second position whereby engaging face 1537 is further from a top portion 1525 of opening 1534. By this arrangement, the bulbous head of a press stud that has been introduced into opening 1534 may be captured between engaging face 1537 and opening 1534.

[0023] A resilient member 1570 biases engagement member 1536 towards a first position whereby engaging face 1537 is closer to a top portion 1525 of opening 1534. Resilient member 1570 may have any shape to provide sufficient force to allow the desired movement of the engagement member 1536. The resilient member 1570 may have any regular or irregular shape, including circle, square, triangle, and clover, and may, but need not be solid throughout. In some examples resilient member 1570 has a generally spherical shape. Spherical resilient member 1570 is positioned between a recess 1528 defined in engagement member 1536 and a saddle 1572 provided by a housing 1524. Spherical resilient member 1570 may be formed from a radiolucent elastomer, including without limitation, silicone. In the example shown in Figs. 4A and 4B, spherical resilient member 1470 may include surface or internal features, such as without limitation, ribs, voids, and/or textures that may facilitate tactile feedback to a user during the actuation/compression and release/extension of the combination of spherical resilient member 1570 and engagement member 1536. In some embodiments resilient member 1570 may have a generally cylindrical shape, a generally ovoid shape, and/or or a compound shape that may include, e.g., a combination spherical, cylindrical, and/or ovoid shape. In some examples, resilient member 1570 may be hollow.

[0024] Fig. 5 shows in another example similar to the electrode connector shown in Figs. 3A, 3B, and 3C. In view thereof, and so as not to obscure the present disclosure with redundant information, only those features distinct to ECG electrode connector 1600 will be described hereinafter. As seen in Fig. 5, opening 1634 which is dimensioned to accept the insertion of a head of a press stud of a patient electrode is bounded on at least one side by a conductor 1677. Conductor 1677 may have any size and shape as long as at least a portion of the

conductor extend into opening 1634 along at least a portion of sidewall 1634. In one example, conductor 1677 extends through opening 1634 to completely cover at least a portion of the circumference of the opening 1634. Conductor 1677 may be made of a radiolucent conductive material such as a conductive polymer or a conductive carbon. A radiolucent leadwire (not shown) formed of a conductive carbon may be positioned in a passageway 1699 of the connector housing and joined to conductor 1677. In use, once an electrode stud is positioned in opening 1634 and engagement member 1636 is released, engagement face 1637 captures the electrode stud between the engagement face 1637 and a portion of conductor 1677.

[0025] According to one aspect of the invention, the radiolucent electrode connectors of the present invention are advantageous because they need not be removed from a patient before imaging reducing the time required to administer often critical procedures. The radiolucent electrode connectors of the present invention may also increase patient safety by reducing or eliminating the dangers associated with imaging conventional electrode connectors. Moreover, the radiolucent electrode connectors of the present invention may allow ECG patient monitoring during imaging.

[0026] It will be understood that various modifications, alterations, and improvements will readily occur to those skilled in the art. Further variations of the above-disclosed and other features and functions, or alternatives thereof, may be desirably combined into many other different systems, instruments and applications. Various presently unforeseen or unanticipated alternatives, modifications, variations or improvements therein may be subsequently made by those skilled in the art.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

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- [US2004203273A \[0005\]](#)
- [US4674817A \[0005\]](#)
- [WO2008092098A2 \[0005\]](#)

EKG-ELEKTRODEKONNEKTOR

PATENTKRAV

1. EKG-konnektorenhed (1400), der omfatter:
 - et hus (1424), der har en indre forsænket overflade (1431), hvor der deri er placeret en åbning
 - 5 (1434), der er dimensioneret til operativt at modtage en EKG-elektrodepudes trykknapp;
 - en radiolucent leder (1432), der er placeret på mindst en del af den indre forsænkede overflade (1431);
 - en radiolucent trådleder (1477), der strækker sig fra en proksimal ende af huset (1424) og er operativt koblet til den radioluciente leder (1432);
 - 10 et indgrebselement (1436), der er drejbart placeret på den indre forsænkede overflade (1431) og har en indgrebsflade (1437) og en drejetap (1415), hvor indgrebselementet (1436) kan dreje mellem en første position, hvorved indgrebsoverfladen (1437) er tættere på en øvre del af åbningen, (1434), og en anden position, hvorved indgrebsfladen (1437) er længere væk fra den øvre del af åbningen (1434), hvor trykknappen kan opfanges i åbningen (1434) mellem indgrebsfladen (1437) og en sidevæg af åbningen
 - 15 (1434);
 - indgrebselementet (1436) endvidere indbefatter et bueformet afstivningselement (1438), der er placeret mellem en ende af indgrebsfladen (1437) distalt fra drejetappen og indgrebselementets (1436) drejetak (1415), og hvor det bueformede afstivningselement (1438) og indgrebsfladen (1437) danner en lukket form, der omgiver ovennævnte åbning (1434), hvor den lukkede form er større end åbningen (1434),
 - 20 og hvor den lukkede form definerer en åbning til modtagelse af trykknappen;
 - hvor kombinationen af åbningen (1434) i huset (1424) og åbningen, der er defineret af det bueformede afstivningselement (1438) og indgrebsfladen (1437), tilvejebringer tilstrækkeligt frirum til indføring af trykknappen; og
 - et radiolucent elastisk element (1470), der er konfigureret til at forspænde indgrebselementet
 - 25 (1436) mod den første position.
2. EKG-konnektorenhed (1400) ifølge krav 1, hvor det radioluciente elastiske element (1470) indbefatter en flerhed af sløjfer.
3. EKG-konnektorenhed (1400) ifølge krav 1, hvor det radioluciente elastiske element (1470) indbefatter en midteråbning (1471), der er defineret deri.
- 30 4. EKG-konnektorenhed (1400) ifølge krav 1, hvor det radioluciente elastiske element (1470) indbefatter ét eller flere fremspring (1481), der samvirkende interfererer for at generere taktilt feedback, når indgrebselementet (1436) bevæges mellem den første position og den anden position.
5. EKG-konnektorenhed (1400) ifølge krav 1, hvor det radioluciente leder (1432) strækker sig på mindst en del af sidevæggen af åbningen (1434).
- 35 6. EKG-konnektorenhed (1400) ifølge krav 1, hvor det radioluciente leder (1432) er dannet ud af carbon.
7. EKG-konnektorenhed (1400) ifølge krav 1, hvor det radioluciente leder (1432) er dannet ud af ledende carbonpulver placeret over og smeltet sammen med den indre forsænkede overflade (1431).

- 2 -

8. EKG-konnektorenhed (1400) ifølge krav 1, hvor det radiolucente elastiske element (1470) har en form, der er udvalgt fra gruppen bestående af i alt væsentligt sfærisk, i alt væsentligt cylindrisk, eller i alt væsentligt oval.
 9. EKG-konnektorenhed (1400) ifølge krav 1, hvor indgrebselementets (1436) drejbare akse er
- 5 vinkelret på planet af den indre forsænkede overflade (1431).

DRAWINGS

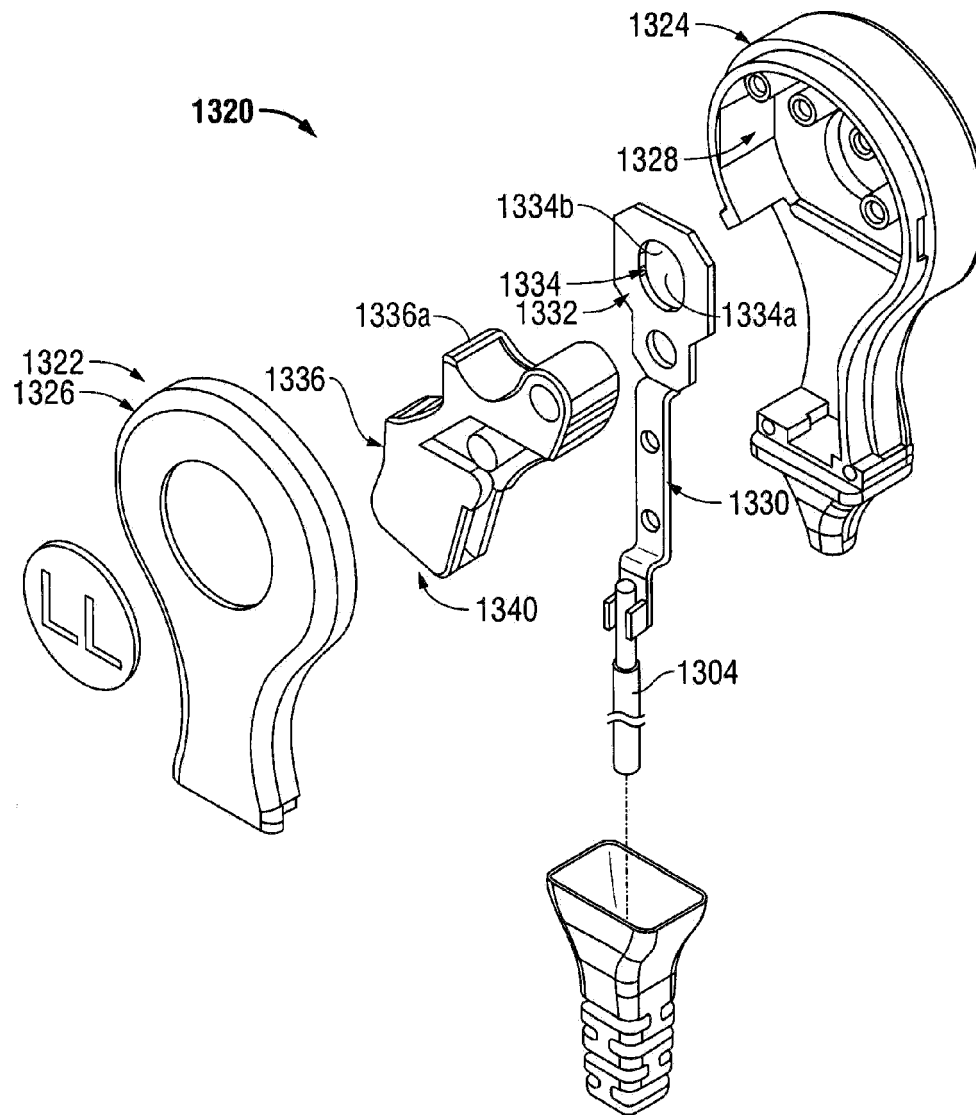


Fig. 1
Prior Art

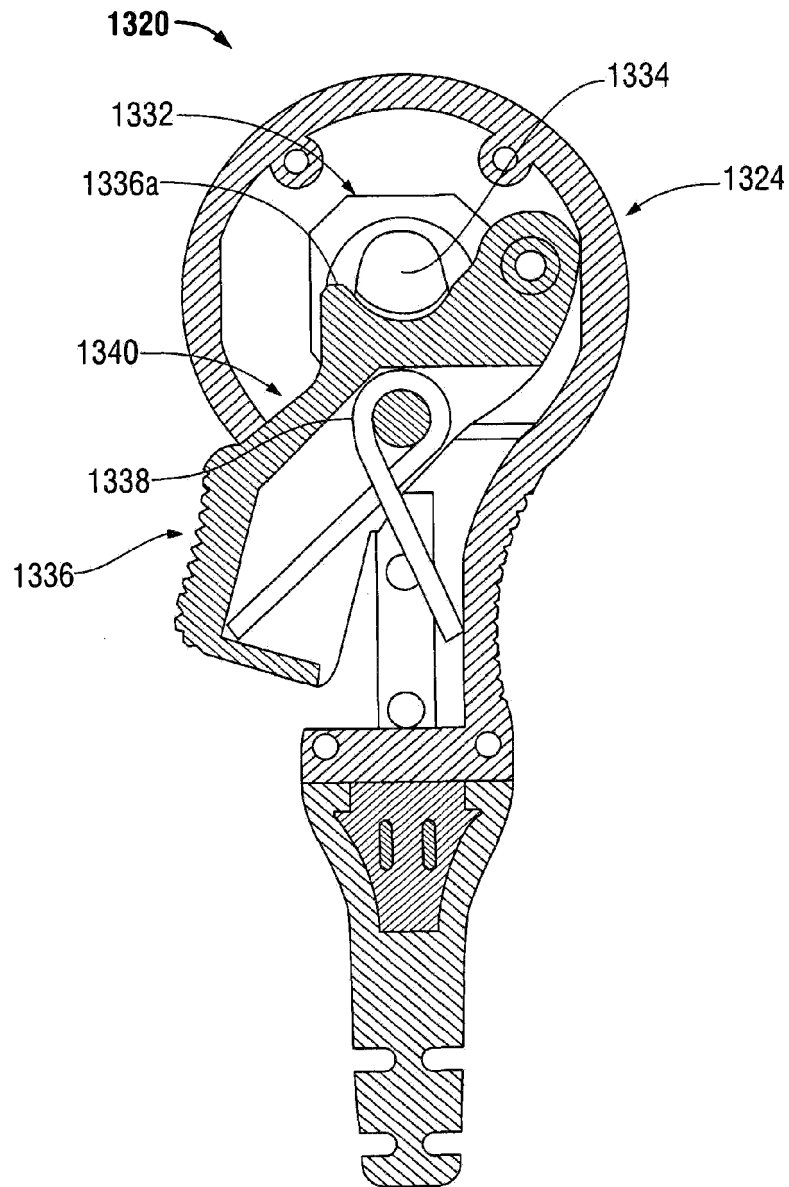


Fig. 2
Prior Art

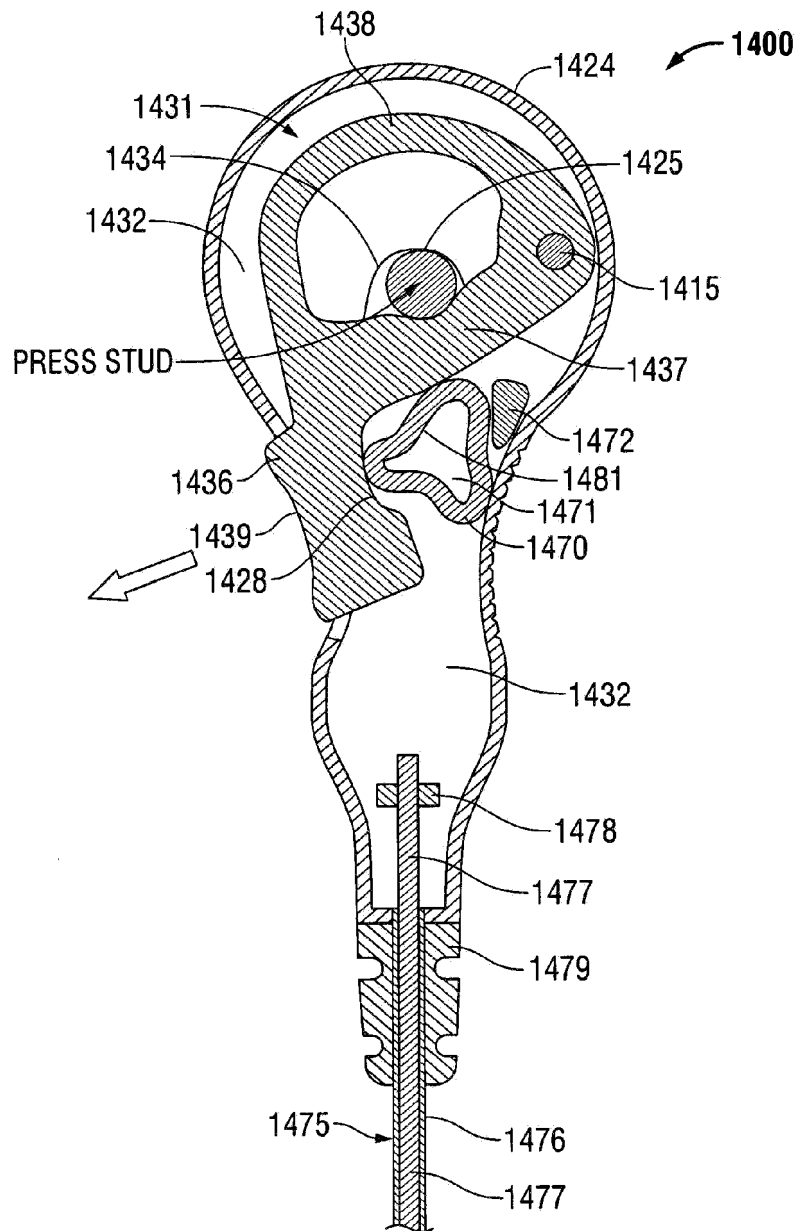


Fig. 3A

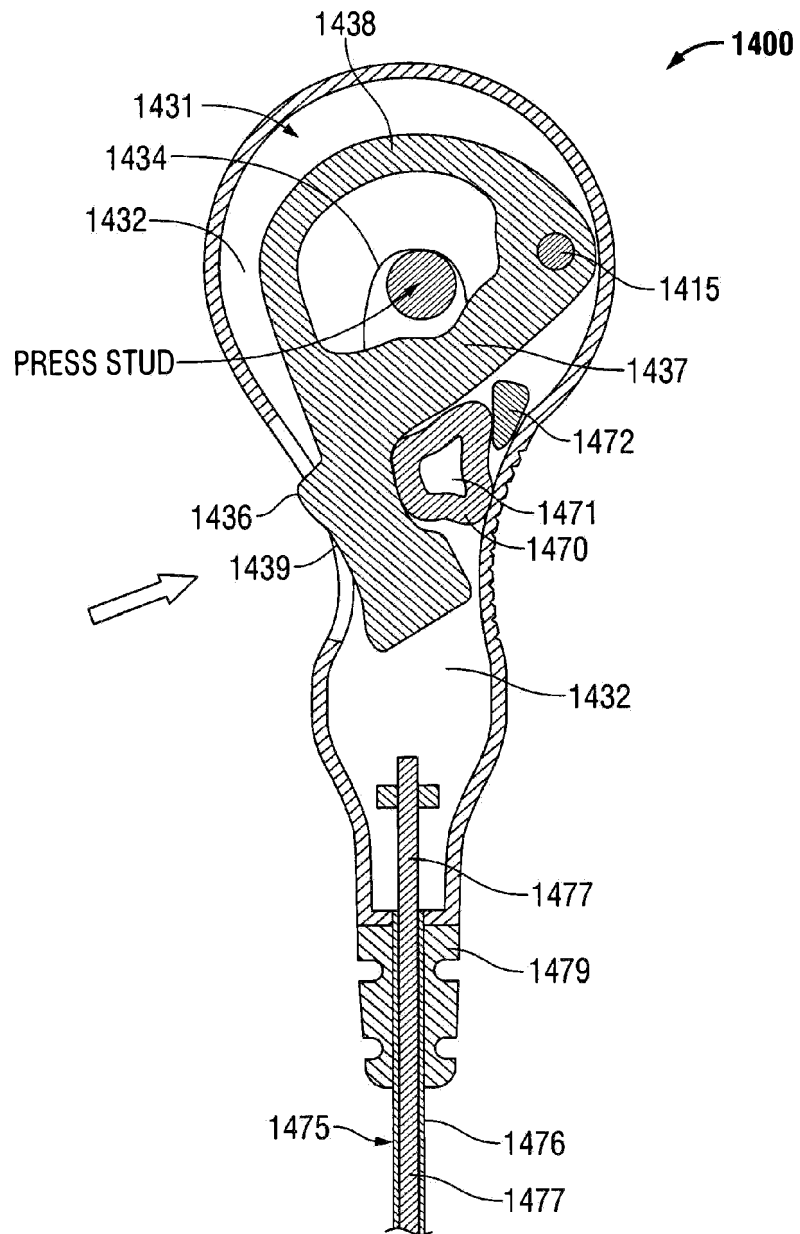


Fig. 3B

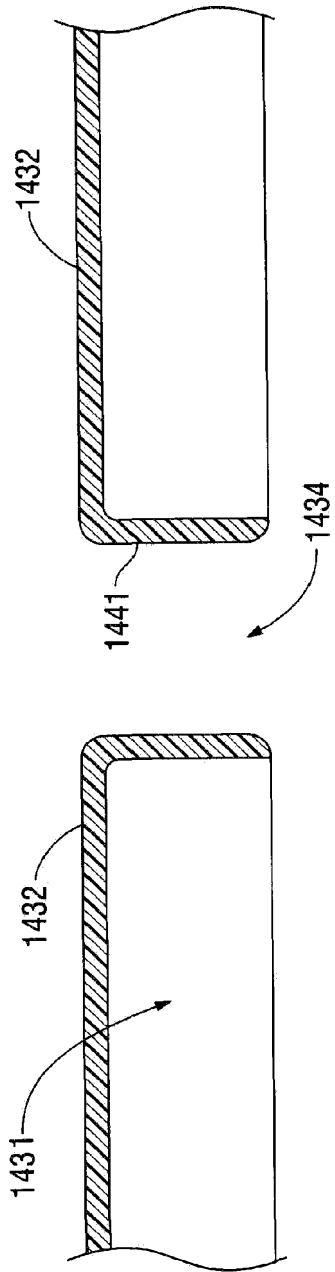


Fig. 3C

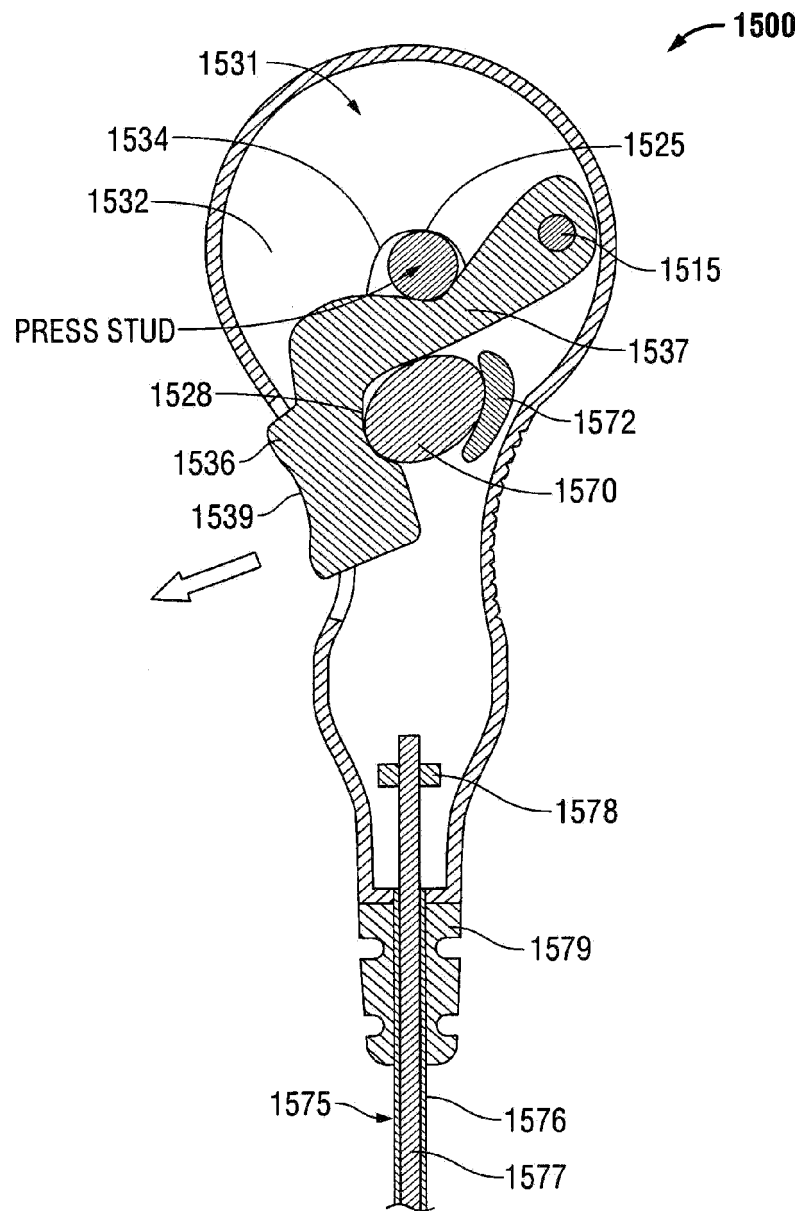


Fig. 4A

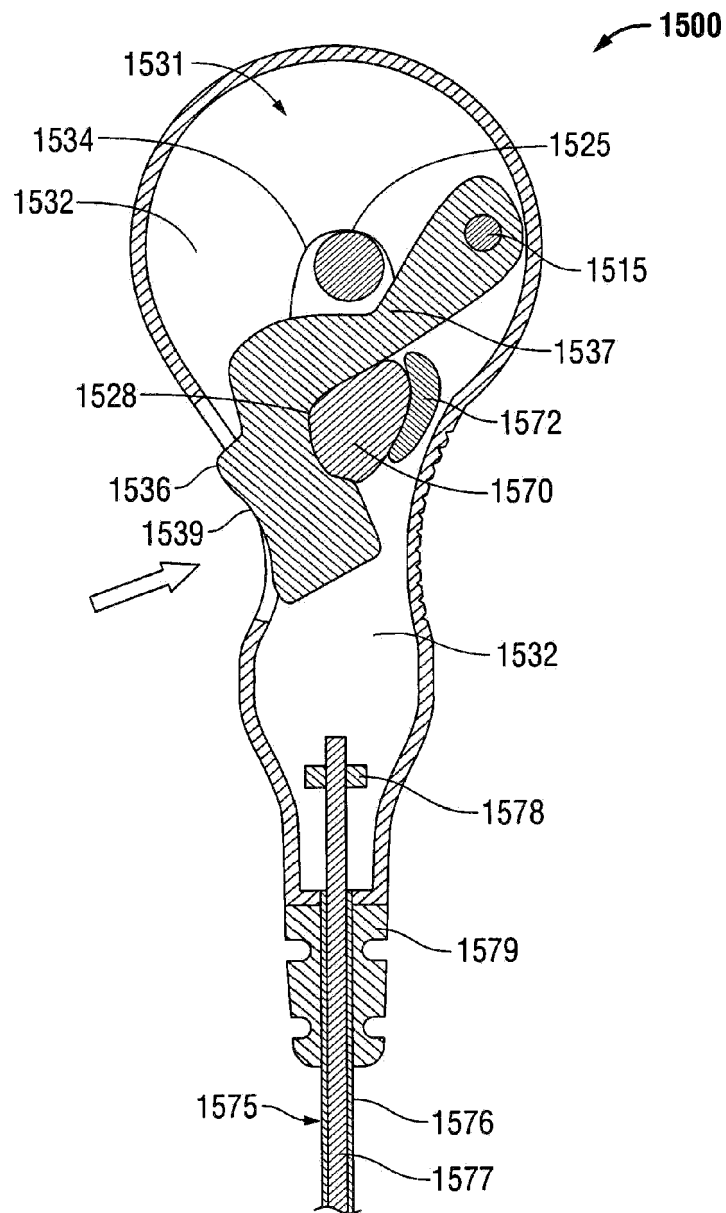


Fig. 4B

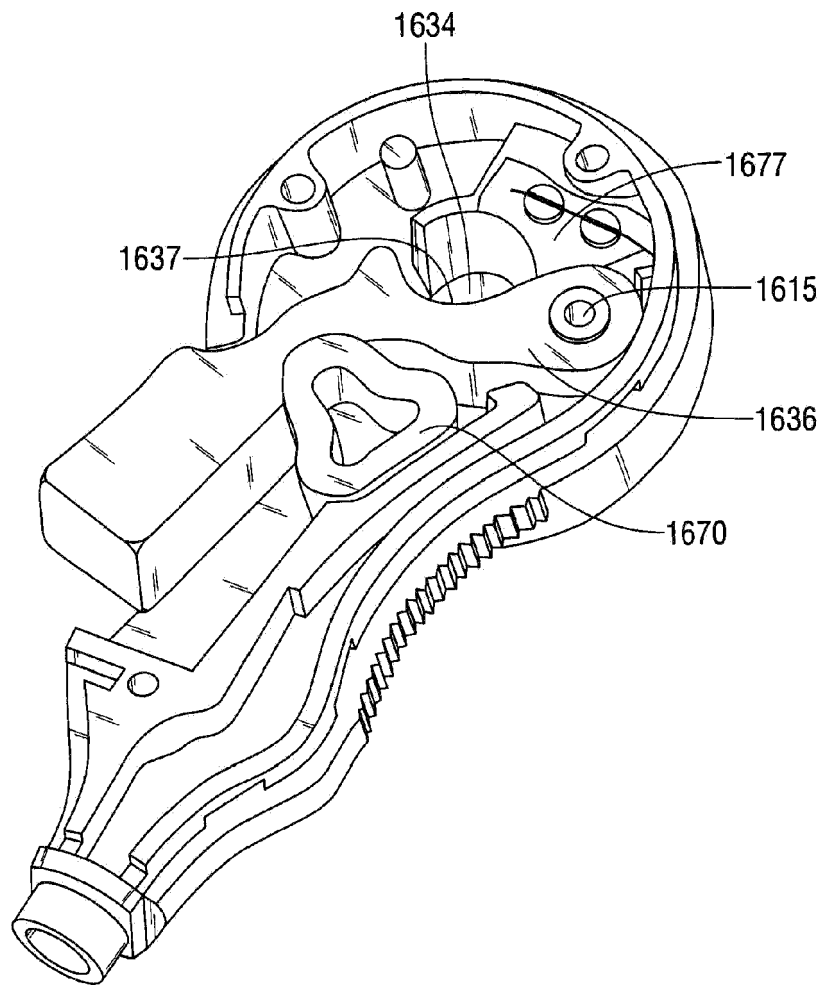


Fig. 5