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(54) **Title**: MANUFACTURING ELECTROCHEMICAL SENSOR MODULE

(57) **Abstract**: Certain processes for manufacturing an electrochemical sensor module include molding first and second opposing portions of a sensor module housing onto a carrier; installing an electrode arrangement on the first portion of the sensor module housing; folding the carrier to align the first portion of the sensor module housing with the second portion; and joining the first and second portions of the sensor module housing. The carrier can be advanced amongst different stations that perform the various process steps.

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MANUFACTURING ELECTROCHEMICAL SENSOR MODULE

This application is being filed on 12 November 2009, as a PCT International Patent application in the name of Pepex Biomedical, LLC, a U.S. national corporation, applicant for the designation of all countries except the US, and James L. Say, a citizen of the U.S., applicant for the designation of the US only, and claims priority to U.S. Provisional patent application Serial No. 61/114,856, filed November 14, 2008.

Technical Field

The present disclosure relates to manufacturing systems and processes for producing sensors for measuring bioanalytes and, in particular, to producing sensors using continuous manufacturing systems and processes.

Background

Electrochemical bio-sensors have been developed for detecting analyte concentrations in a given fluid sample. For example, United States Patent Nos. 5,264,105; 5,356,786; 5,262,035; 5,320,725; and 6,464,849, which are hereby incorporated herein by reference in their entireties, disclose wired enzyme sensors for detecting analytes, such as lactate or glucose. Wired enzyme sensors have been widely used in blood glucose monitoring systems adapted for home use by diabetics to allow blood glucose levels to be closely monitored. Other example types of blood glucose monitoring systems are disclosed by United States Patent Nos. 5,575,403; 6,379,317; and 6,893,545.

Conventional manufacturing systems and processes for producing bio-sensors involve web based conductive print technology.

Summary

One aspect of the present disclosure relates to a sensor system that can be manufactured in reduced scale and that can be conveniently handled by consumers.

Another aspect of the present disclosure relates to an electrochemical sensor module for use in a sensor system that can be efficiently manufactured using a continuous manufacturing process such as a continuous insert molding process.

A further aspect of the present disclosure relates to a sensor module including a molded body that defines an analyte analysis cell and also integrates a skin piercing element, such as a lancet or canula, into the molded body.

A variety of additional aspects will be set forth in the description that follows. The aspects can relate to individual features and to combinations of features. It is to be understood that both the forgoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the broad concepts upon which the embodiments disclosed herein are based.

Brief Description of the Drawings

FIG. 1 is a schematic block diagram of a manufacturing system configured to produce sensor modules in accordance with the principles of the present disclosure;

FIG. 2 is a flowchart illustrating an operation flow for an example manufacturing process by which one or more sensor modules can be produced, e.g., using the manufacturing system of FIG. 1;

FIG. 3 is a planar view of a portion of an example carrier that can be indexed through the processing stations of the manufacturing system of FIG. 1 in accordance with the principles of the present disclosure;

FIG. 4 is a top, perspective view of the portion of the carrier of FIG. 3 after sensor module components have been molded onto the body of the carrier in accordance with the principles of the present disclosure;

FIG. 5 is a perspective view of the portion of the carrier of FIG. 4 after a first electrode and a second electrode have been routed onto the molded sensor components in accordance with the principles of the present disclosure;

FIG. 6 is a perspective view of the portion of the carrier of FIG. 5 after the carrier has been rolled or folded along a fold axis to align the first and second sections of the carrier body in accordance with the principles of the present disclosure;

FIG. 7 is a partial, perspective view of the opposite side of the portion of the carrier of FIG. 6 after the opposing components have been secured together in accordance with the principles of the present disclosure;

FIG. 8 is a partial, isometric view of the first sensor module of FIG. 7 after the sensor module has been separated from the carrier in accordance with the principles of the present disclosure;

FIGS. 9 and 10 show another sensor module that can be manufactured in accordance with the principles of the present disclosure;

FIG. 11 is a planar view of a portion of another example carrier that can be indexed through the processing stations of the manufacturing system of FIG. 1 in accordance with the principles of the present disclosure;

FIG. 12 is a top, perspective view of the portion of the carrier of FIG. 11 after sensor module components have been molded onto the body of the carrier in accordance with the principles of the present disclosure;

FIG. 13 is a planar view of the portion of the carrier of FIG. 12 after a first electrode and a second electrode have been routed onto the molded sensor components in accordance with the principles of the present disclosure;

FIG. 14 is a perspective view of the portion of the carrier of FIG. 13 after the carrier has been folded along a fold axis to align the first and second sections of the carrier body in accordance with the principles of the present disclosure; and

FIG. 15 is a perspective view of the opposite side of the portion of the carrier of FIG. 15 after the opposing components have been secured together in accordance with the principles of the present disclosure.

Detailed Description

Reference will now be made in detail to exemplary aspects of the present disclosure which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

The following definitions are provided for terms used herein:

A "working electrode" is an electrode at which the analyte (or a second compound whose level depends on the level of the analyte) is electrooxidized or electroreduced with or without the agency of an electron transfer agent.

A “reference electrode” is an electrode used in measuring the potential of the working electrode. The reference electrode should have a generally constant electrochemical potential as long as no current flows through it. As used herein, the term “reference electrode” includes pseudo-reference electrodes. In the context of the disclosure, the term "reference electrode" can include reference electrodes which also function as counter electrodes (i.e., a counter/reference electrode).

A "counter electrode" refers to an electrode paired with a working electrode to form an electrochemical cell. In use, electrical current passes through the working and counter electrodes. The electrical current passing through the counter electrode is equal in magnitude and opposite in sign to the current passing through the working electrode. In the context of the disclosure, the term "counter electrode" can include counter electrodes which also function as reference electrodes (i.e., a counter/reference electrode).

A “counter/reference electrode” is an electrode that functions as both a counter electrode and a reference electrode.

An "electrochemical sensing system" is a system configured to detect the presence and/or measure the level of an analyte in a sample via electrochemical oxidation and reduction reactions on the sensor. These reactions are converted (e.g., transduced) to an electrical signal that can be correlated to an amount, concentration, or level of an analyte in the sample. Further details about electrochemical sensing systems, working electrodes, counter electrodes and reference electrodes can be found at U.S. Patent No. 6,560,471, the disclosure of which is hereby incorporated herein by reference in its entirety.

"Electrolysis" is the electrooxidation or electroreduction of a compound either directly at an electrode or via one or more electron transfer agents.

An "electron transfer agent" is a compound that carries electrons between the analyte and the working electrode either directly or in cooperation with other electron transfer agents. One example of an electron transfer agent is a redox mediator.

A "sensing layer" is a component of the sensor which includes constituents that facilitate the electrolysis of the analyte. The sensing layer may include constituents such as an electron transfer agent, a catalyst which catalyzes a reaction of the analyte to produce a response at the electrode, or both.

The present invention is directed to a manufacturing system configured to produce one or more sensor modules configured for analyte monitoring (e.g., glucose single-point monitoring, lactate single-point monitoring, etc.). Each sensor module includes a housing containing an analysis cell configured to hold a fluid sample, at least two elongated electrodes arranged to enter the analysis cell, and contacts for electrically connecting the electrodes to external connectors. In a preferred embodiment, the elongated electrodes include a continuously coated working electrode and an uncoated reference electrode. In one embodiment, one or more of the elongated electrodes includes a composite conductive monofilament (CCM) electrode. In other embodiments, the housing can contain additional electrodes having differing enzyme coatings. The analysis cell can be configured for coulormetric or amperometric assays.

In general, each sensor module is produced by a continuous manufacturing system, which includes a manufacture and assembly line in which a preformed carrier travels to different stations along a direction of travel. Components of the sensor modules are formed and/or assembled together at different stations as the carrier progresses through the line. In a preferred embodiment, each sensor module is produced by a “reel to reel” manufacturing system in which the carrier extends between first and second reels. The continuous manufacturing system is particularly suitable for producing very small parts in production quantities of tens of millions of units per year per system.

FIG. 1 is a schematic block diagram of one example continuous manufacturing system 100 configured to produce a sensor module in accordance with the principles of the present disclosure. The manufacturing system 100 includes a carrier 101 extending between a first carrier reel 102 and a second carrier reel 104. The carrier 101 travels along a direction of travel D1 from the first carrier reel 102 to the second carrier reel 104 when indexed by one or both carrier wheels 102, 104. In one embodiment, the carrier 101 is formed from metal. In another embodiment, the carrier 101 is formed from a polymer composition. In other embodiments, however, the carrier 101 can be preformed from any suitable material.

The manufacturing system 100 also includes a molding station 110, an electrode insertion station 130, a folding station 140, a joining station 150, a stamping station 160, and a collection station 170. The carrier 101 passes by each of these stations 110, 130, 140, 150, 160, 170 as the carrier 101 is indexed between the first and second carrier reels 102, 104. Support components of the sensor module are formed at the molding station 110. In general, the molding station 110 overmolds one or more components of each sensor module onto the carrier 101. In a preferred embodiment, the molding station 110 includes an in-line injection molding machine. In various other embodiments, however, different types of molding machines can be used.

Electrodes for use in the sensor modules are created by coating sensor chemistry onto an elongated member (e.g., a composite monofilament) at a coating station 120. In a preferred embodiment, the coating station 120 includes at least two filament reels 106, 108 containing a wound elongated member. Typically, the elongated member includes a continuously conductive elongated member. In one embodiment, the elongated member is a composite monofilament. The elongated member is fed from the first reel 106 to the second reel 108 to continuously coat the elongated member with a layer of sensor chemistry, such as silver chloride, to form a working electrode 122. Accordingly, the second reel 108 contains a wound working electrode 122 when the coating stage is complete. At least a third filament reel 109 contains a wound, uncoated elongated member for forming another electrode 124 (e.g., a reference electrode, a counter electrode, or a reference/counter electrode).

The elongated member to be coated can include a thread, a carbon fiber, a metal wire, or another such elongated member. Preferably, at least a portion of the elongated member is electrically conductive. In certain embodiments, each elongated member can have a composite structure and can include a fiber having a dielectric core surrounded by a conductive layer suitable for forming an electrode. A preferred composite fiber is sold under the name Resistat® by Shakespeare Conductive Fibers LLC. This composite fiber includes a composite nylon, monofilament, conductive thread material made conductive by the suffusion of about a 1 micron layer of carbonized nylon isomer onto a dielectric nylon core material. The Resistat® material is comprised of isomers of nylon to create the basic 2 layer composite thread. However, many other polymers are available for the construction, such as: polyethylene terephthalate, nylon 6, nylon 6,6, cellulose, polypropylene cellulose acetate, polyacrylonitrile and copolymers of polyacrylonitrile for a first component and polymers such as of polyethylene terephthalate, nylon 6, nylon 6,6, cellulose, polypropylene cellulose acetate, polyacrylonitrile and copolymers of polyacrylonitrile as constituents of a second component. Inherently conductive polymers (ICP) such as doped polyanaline or polypyrolle can be incorporated into the conductive layer along with the carbon to complete the formulation. In certain embodiments, the ICP can be used as the electrode surface alone or in conjunction with carbon. The Resistat® fiber is availability in diameters of .0025 to .016 inches, which as suitable for sensor electrodes configured in accordance with the principles of the present disclosure. Example patents disclosing composite fibers suitable for use in practicing sensor modules configured in accordance with the principles of the present disclosure include U.S. Patent Nos. 3,823,035; 4,255,487; 4,545,835 and 4,704,311, which are hereby incorporated herein by reference in their entireties.

The sensing layers provided at working electrodes 122 of sensor modules configured in accordance with the principles of the present disclosure can include a sensing chemistry, such as a redox compound or mediator. The term redox compound is used herein to mean a compound that can be oxidized or reduced. Example redox compounds include transition metal complexes with organic ligands. Preferred redox compounds/mediators include osmium transition metal complexes with one or more ligands having a nitrogen containing heterocycle such as 2, 2'-bipyridine. The sensing material also can include a redox enzyme. A redox enzyme is an enzyme that catalyzes an oxidation or reduction of an analyte. For example, a glucose oxidase or glucose dehydrogenase can be used when the analyte is glucose. Also, a lactate oxidase or lactate dehydrogenase fills this role when the analyte is lactate. In sensor systems, such as the one being described, these enzymes catalyze the electrolysis of an analyte by transferring electrons between the analyte and the electrode via the redox compound. Further information regarding sensing chemistry can be found at U.S. Patent Nos. 5,264,105; 5,356,786; 5,262,035; and 5,320,725, which were previously incorporated by reference in their entireties.

The electrodes (e.g., working electrode and reference electrode) 122, 124 are mounted to the molded components of the sensor module at the insertion station 130. In general, the second reel 108 containing the working electrode and the third reel 109 containing the reference electrode (i.e., or counter electrode or reference/counter electrode) 124 are arranged to feed the electrodes 122, 124 into the insertion station 130, which aligns the electrodes 122, 124 with the molded sensor module components. Typically, the insertion station 130 aligns the elongated members forming the electrodes 122, 124 with the components on the carrier 101 without cutting the elongated members. In other embodiment, additional reels holding wound reference electrodes, counter electrodes, and/or counter/reference electrodes also can be positioned relative to the insertion station 130 to feed the electrodes onto the components without cutting the electrodes. This continuous insertion station 130 allows low cost, high volume production of CCM-type sensor modules at significantly smaller sizes, improved repeatability, and with less process waste than conventional systems and methods.

The folding station 140 arranges the sensor module components into a final configuration in which the components are aligned. In one embodiment, the folding station 140 is configured to bend the carrier 101 to align two sides of the carrier 101. In another embodiment, the folding station 140 is configured to break the carrier along a fold axis to align two sides of the carrier 101. The joining station 150 secures (e.g., presses, welds, molds, heat seals, etc.) the components together to form the sensor module. In one embodiment, the joining station 150 includes a laser welder. In another embodiment, the joining station 150 includes an overmold machine.

The separation station 160 separates the sensor modules from the carrier 101 to produce completed sensor modules. In one embodiment, the separation station 160 includes a stamping machine. In another embodiment, the separation station 160 includes a laser cutting machine. Other types of separation devices also can be used within the scope of the disclosure. The completed sensor modules are accumulated at the collection station 170 after being removed from the carrier 101. The remainder of the carrier 101 is wound onto the second carrier wheel 104.

FIG. 2 is a flowchart illustrating an operation flow for an example manufacturing process 200 by which one or more sensor modules can be produced using the manufacturing system 100 of FIG. 1. Of course, other systems can implement the steps of manufacturing process 200 in accordance with the principles of the present disclosure. The manufacturing process 200 begins at a start module 210, performs any appropriate initialization procedures, and proceeds to a form operation 220.

The form operation 220 produces one or more components of the sensor module onto the carrier 101 (see FIG. 4). For example, the form operation 220 can mold a housing of the sensor module onto the carrier 101. In some embodiments, the form operation 220 produces the housing in a "clamshell" configuration having at least two opposing portions. For example, in form operation 220, the carrier 101 can enter an in-line injection molding machine 110, which simultaneously molds both portions of the housing on the carrier 101 (see FIG. 1). In a preferred embodiment, the two opposing portions are half portions. In other embodiments, however, the opposing portions can be unequal in size and/or shape.

A coat operation 230 adds sensor chemistry to at least one elongated member, such as a monofilament, to produce a first electrode (e.g., a working electrode). In a preferred embodiment, the coat operation 230 continuously coats sensor chemistry on the elongated member at a reel-to-reel coating station. For example, in one embodiment, the elongated member can unwind from a first filament reel, such as reel 106 of FIG. 1, pass through the sensor chemistry, and wind up onto a second filament reel, such as reel 108 of FIG. 1, during the coat operation 230. In one embodiment, the sensor chemistry is continuously coated onto the elongated member. The coated elongated member is referred to as a working electrode.

An insert operation 240 adds the working electrode and a second electrode (e.g., a reference electrode, a counter electrode, or a reference/counter electrode) to the molded components arranged on the carrier 101. Additional electrodes may be added to the molded components in certain embodiments of the sensor modules. The insert operation 240 can feed the electrodes 122, 124 of FIG. 1

from the reels 108, 109, respectively, into the insertion station 130 at which the insert operation 240 can route the electrodes into channels defined in the molded components. The insert operation 240 arranges each electrode to align with a contact element configured to route any signals generated at the electrode out of the sensor module housing.

A fold operation 250 arranges the components and electrodes of each sensor module into a final configuration. For example, the fold operation 250 can align and press together two portions of a sensor module housing to form an enclosure around the coated and uncoated electrodes. A join operation 260 seals together the components of the sensor module. For example, the join operation 260 can weld, glue, melt, fasten, or otherwise secure the components together to form a completed sensor modules. A separate operation 270 removes (e.g., mechanically cuts, stamps, cuts with a laser, etc.) the completed sensor modules from the carrier 101 (FIG. 1). The manufacturing process 200 completes and ends at a stop module 280.

The principles of the application can be further understood by walking through an example application in which a generic sensor module is manufactured. FIG. 3 shows a portion of one example carrier 101 that can be indexed through the different processing stations 110, 120, 130, 140, 150, 160 of the manufacturing system 100 of FIG. 1. The carrier 101 includes a generally flat carrier body 300 defining at least one series of index holes 302 configured to receive index pins to advance the carrier through the system 100. In the example shown, the carrier body 300 defines four series of index holes 302. In other embodiments, however, the carrier body 300 can define greater or fewer series of index holes 302.

The carrier body 300 defines a profile that is configured to support the components of the sensor module. In a preferred embodiment, the carrier body 300 is produced by roll stamping a high-precision profile on a stainless steel or suitable polymer tape and storing the prepared tape on a collector reel, such as the first carrier reel 102. One or more components can be molded to the carrier body 300 as the carrier 101 is indexed. In certain embodiments, multiple components of one sensor module can be molded across the width W1 of the carrier body 300.

The carrier body 300 includes a fold feature 305 that splits the carrier body 300 into a first section 310 and a second section 320 along a fold axis 304. The first section 310 has a width W2 and the second section 320 has a width W3. In a preferred embodiment, the fold feature 305 of the carrier body 300 is a midline fold feature that splits the carrier body 300 along a central axis into two halves (i.e., so that the widths W2, W3 of the first and second sections are about equal). In other embodiments, however, the fold feature 305 can split the carrier body 300 into sections 310, 320 of different sizes.

In general, the fold feature 305 is a weakened or reduced portion of the carrier body 300 at which the carrier body 300 is configured to bend and/or break. In the example shown, the fold feature 305 includes multiple connecting members 307 extending between the first and second sections 310, 320. The connecting members 307 have a tapered center 308 that is configured to bend to enable the carrier body 300 to be folded at the fold feature 305.

Folding the carrier body 300 along the fold axis 304 aligns the first section 310 with the second section 320. Accordingly, the fold feature 305 of the carrier body 300 enables opposing portions of sensor components to be molded onto the first and second sections 310, 320 of the carrier body 300 and subsequently assembled together by folding the carrier body 300 along the fold axis 304. For example, the fold feature 305 enables different housing portions to be molded face-up on opposite sides of the carrier body 300. Additional features can be added to the interior of the sensor module after the support components are molded on the carrier body 300 and prior to folding the carrier body 300.

The carrier body 300 shown in FIG. 3 has a profile configured to support at least two molded components of a sensor module. Each section 310, 320 includes a first support wall 311, 321 and a second support wall 313, 323 connected by a third support wall 315, 325, respectively, to form an "H" shape. The support walls 311, 313, 315 of the first section 310 define first and second gaps 317, 319 within which components of the sensor modules can be molded. The support walls 321, 323, 325 of the second section 320 define first and second gaps 327, 329 within which opposing components of the sensor modules can be molded.

First and second support members 312, 314 protrude into the first gap 317 in the first section 310 from the side walls 311, 313, respectively. Third and fourth support members 316, 318 protrude into the second gap 319 in the first section 310 from the side walls 311, 313, respectively. The support members 312, 314, 316, 318 are configured to provide support for molded components of the sensor module. For example, in FIG. 3, each support member 312, 314, 316, 318 defines an opening at an end opposite the support walls 311, 313 to which a component can be molded. In the example shown, the third support walls 315, 325 of the two sections 310, 320 also define openings to which components or support members can be molded.

FIG. 4 shows the portion of the carrier 101 of FIG. 3 after sensor module components have been molded onto the body 300 of the carrier 101 (e.g., at the mold station 110 of FIG.1). In the example shown, components of two different sensor modules have been molded onto the visible portion of the carrier body 300. Components of a first sensor module 400 have been molded into the first gaps 317, 327 of the first and second sections 310, 320 and components of a second sensor module 400' have been molded into the second gaps 319, 329 of the first and second sections 310, 320.

The first sensor module 400 (FIG. 6) includes a first housing portion 410 molded at the first gap 317 of the first section 310 and a second housing portion 420 molded at the first gap 327 of the second section 320. The first housing portion 410 is formed to be generally complementary to the second housing portion 420. Each of the housing portions 410, 420 defines a depression 415, 425, respectively. When the housing portions 410, 420 are assembled, the depressions 415, 425 align to form an analysis cell within the sensor module 400. In a some embodiment, each depression 415, 425 is about 0.01 inches (0.25 millimeters) to about 0.05 inches (1.27 millimeters) across at a largest dimension and about 0.002 (0.05 millimeters) to about 0.005 inches (0.13 millimeters) deep. In a preferred embodiment, each depression 415, 425 is about 0.03 inches (0.76 millimeters) across at the largest dimension and about 0.003 (0.08 millimeters) deep.

At least one of the housing portions 410, 420 defines a groove 407 to form a sample path between the analysis cell and the exterior of the sensor module 400. In the example shown, the groove 407 is defined in the first housing portion 410. In another embodiment, both housing portions 410, 420 can define channels that align to form the groove 407. Channels configured to hold continuous electrodes also are defined in at least one of the housing portions 410, 420. In the example shown, electrode channels 412, 414 are defined in the first housing portion

410. In the example shown, the electrode channels 412, 414 extend from one end of the housing portion 410, through the anaysis cell, to an opposite end of the housing portion 410. In one embodiment, the electrode channels 412, 414 are V-shaped channels. In other embodiments, however, the channels 412, 414 can have any suitable shape (e.g., U-shaped, squared, etc.). In certain embodiments, corresponding electrode channels can be defined in the second housing portion 420.

In some embodiments, one or both housing portions 410, 420 also can include attachment members configured to secure the housing portions 410, 420 together. For example, one of the housing portions 410, 420 can include pegs or other protrusions configured to mate with openings, depressions, or grooves defined in the other of the housing portions 410, 420. In one embodiment, the first housing portion 410 defines an extended protrusion 405 that is configured to fit within a corresponding channel 426 defined in the second housing portion 420 (e.g., see FIG. 8). In another embodiment, the extended protrusion 405 provides an anchor which can be embedded within a molded or welded section joining the two housing portions 410, 420.

Support members also can be molded onto the carrier body 300 to couple the sensor module components to the carrier body 300 and/or to align the sensor module components on the carrier body 300. In FIG. 4, a first set of connecting support members 332 extend between the support members 312, 314 of the carrier body 300 and the first housing portion 410 to secure the first housing portion 410 to the carrier body 300. A second set of connecting support members 334 extend between the third support member 325 and the second housing portion 420 410 to secure the second housing portion 420 to the carrier body 300. In one embodiment, the connecting support members 334 are integrally formed (see FIG. 6). In other embodiments, the first housing portion 410 can be secured to the third support member 315 of the first section and/or the second housing portion 420 can be secured to support members extending from the walls 321, 323 of the second section 320.

In the example shown, an alignment member 336 is arranged on the third support member 315 of the first section 310. The alignment member 336 defines grooves 325 configured to hold continuous filaments that will form electrodes of the sensor modules. The alignment member 336 has generally the same number of grooves 325 as the first housing portion 410 has electrode channels 412, 414. In FIG. 4, the alignment member 336 defines two grooves 325. The grooves 325 of the alignment member 336 co-axially align with the electrode channels 412, 414 of the first housing portion 410.

FIG. 5 shows the portion of the carrier 101 of FIG. 3 after a first electrode 452 and a second electrode 454 have been routed onto the molded sensor components (e.g., at the insertion station 130 of FIG. 1). In the example shown, the electrodes 452,454 are routed on either side of the extended protrusion 405. The first electrode 452 is routed into the first electrode channel 412 and the second electrode 454 is routed into the second electrode channel 414. Accordingly, the electrodes 452, 454 pass through the depression 415 partially forming the analysis cell. Typically, the first electrode 452 is a working electrode formed by coating sensor chemistry onto an elongated member and the second electrode 454 is a reference electrode formed from an uncoated elongated member.

In the example shown, the electrodes 452, 454 extend longitudinally along the first section 310 of the carrier body 300 in continuous strands. Accordingly, the electrodes 452, 454 extend from the first housing portion 410 of the first sensor module 400 to the first housing portion 410' of the second sensor module 400'. The alignment member 336 aids in guiding the electrodes 452, 454 into position on the sensor modules 400, 400'. For example, each electrode 452, 454 can be arranged within a groove 335 of the alignment member 336.

In the example shown, the third support wall 315 of the first section 310 has a depressed or "stepped out" portion to accommodate the alignment member 336 and the electrodes 452, 454. The depressed portion forms a channel 308 (FIG. 6) when the second section 310 of the carrier body 300 is folded over the first section 310. The electrodes 452, 454 are routed through the channel 308 when passing between components of the sensor modules 400, 400'.

FIG. 6 shows the portion of the carrier 101 of FIG. 3 after the carrier 101 has been rolled or folded along the fold axis 304 (FIG. 3) to align the first and second sections 310, 320 of the carrier body 300 (e.g., at fold station 140 of FIG. 1). In one embodiment, the connecting members 307 extending between the first and second sections 310, 320 of the carrier body 300 are broken at their tapered centers 308 along the fold axis 304 as shown in FIG. 6. In other embodiments, however, the connecting members 307 bend sufficiently to enable the first section 310 to align with the second section 320.

The first housing portion 410 of the first sensor module 400 is aligned with the second housing portion 420 in FIG. 6. In one embodiment, the protrusion 405 of the first housing portion 410 fits within the channel 426 of the second housing portion 426. Further, the first housing portion 410' of the second sensor module 400' is similarly aligned with the second housing portion 420' of the second sensor module 400'. In one embodiment, each sensor module 400, 400' defines a gap 460, 460' at which electrodes (e.g., see reference nos. 572, 574 of FIG. 9) can be coupled to the housing in contact with the electrodes.

FIG. 7 is an isometric view of the opposite side of the portion of the carrier 101 shown in FIG. 6 after the opposing components have been secured together (e.g., at joining station 150 of FIG. 1). The carrier body 300 has been broken in half at the centers 308 of the connecting members 307. The index holes 302 of the first and second sections 310, 320 of the carrier body 300 align. The first and second housing portions 410, 420 of the first sensor module 400 also are visibly aligned with each other. When the first housing portion 410 is aligned with the second housing portion 420, the depressions 415, 425 defined in the housing portions 410, 420 form an analysis cell through which the electrodes 452, 454 pass. The groove 407 defined in the first housing portion 410 forms a sample path extending from the analysis cell to an exterior of the sensor module 400. Fluid can be provided to the analysis cell, and hence the portion of the electrodes 452, 454 extending through the analysis cell, through capillary action or wicking.

Furthermore, the first and second housing portions 410, 420 are joined together (e.g., via a weld, an overmold layer, or another joining structure). In a preferred embodiment, the housing portions 410, 420 are secured together using a selective laser weld. For example, in one embodiment, the second housing portion 420, which does not contain active components, such as the electrodes 452,454, is transparent to the laser while the first housing portion 410, which contains the electrodes, is absorptive to the laser energy, thereby establishing an interior plane for a precise laser weld creating a hermetic seal for the analysis cell and related component structures.

FIG. 8 is a partial, isometric view of the first sensor module 400 after the sensor module 400 has been separated from the carrier 101 (e.g., at the separation station 160 of FIG. 1). The first housing portion 410 is shown as transparent in FIG. 1 so that the interior configuration of the sensor module 400 is visible. The electrodes 452, 454 extend through the channels 412, 414 defined in the first housing and through the analysis cell formed by the depressions 415, 425. In FIG. 8, the electrodes 452,454 terminate at the periphery of the housing.

FIGS. 9-15 walk through another application in which another example sensor module 500 (see FIGS. 9 and 10) is manufactured in accordance with the principles of the present disclosure. For example, the sensor module 500 can be fabricated using the manufacturing system 100 of FIG. 1 and/or the manufacturing process 200 of FIG. 2. The sensor module 500 includes a module body 501 having a distal end 502 positioned opposite from a proximal end 503. The module body 501 includes a first housing portion 504 secured to a second housing portion 506 at a part line 506.

The module body 501 includes an analysis cell housing 507 positioned adjacent the distal end 502 and a skin piercing member anchor 508 positioned adjacent the proximal end 503. A flexible linkage 509 mechanically connects the analysis cell housing 507 to the skin piercing member anchor 508. The flexible linkage 509 is configured to allow the analysis cell housing 507 and the skin piercing member anchor 508 to move relative to one another along an axis A that extends through the module body 501 from the proximal end 503 to the distal end 502 (see FIG. 10).

The skin piercing member anchor 508 is configured to slideably secure a skin piercing member (e.g., a cannula, a needle, a lancet, or other structure) 518 within an axially extending passage 514 defined in the analysis cell housing 507. The flexible linkage 509 of the module body 501 preferably has a compressible configuration that enables the flexible linkage 509 to compress axially along the axis A as the skin piercing member anchor 508 moves the skin piercing member 518 from a retracted position to an extended position to pierce the skin of the patient and obtain a fluid sample (e.g., a blood sample).

The analysis cell housing 507 defines an analysis cell 512 (FIG. 10) at which the fluid sample can be analyzed using a sensor structure, such as a wired enzyme sensor arrangement, in fluid communication with the analysis cell 512. The analysis cell 512 has a first end in fluid communication with a capillary slot 513 leading to the passage 514 and an opposite, second end at which a vent 511 is defined. The passage 514 includes a distal end 515 positioned opposite from a proximal end 516 and is configured to transport a fluid sample from a distal end 502 of the module body 501 to the analysis cell 512.

The analysis cell housing 507 also defines first and second electrode mounting structures (e.g., V-grooves) 517, 519 extending from a proximal end of the analysis cell housing to a distal end. First and second electrodes (not shown) extend within the mounting structures 517, 519 across the analysis cell 512 to contact receivers (e.g., receptacles, pads, slots, or other structures) 534, 536 for receiving and retaining electrode contacts 530, 532 (see FIG. 10). The contacts 530, 532 include exposed tips protruding outwardly from the analysis cell housing 507 to enable transmission of signals generated by the electrodes to metering electronics.

Additional details on the sensor module 500, monitoring and delivery systems utilizing the sensor module 500, and monitoring and delivery processes that can be implemented using the sensor module 500 can be found in copending application no. 61/114,844, filed November 14, 2008, and having attorney docket no. 11554.13USP1, the disclosure of which is hereby incorporated by reference herein.

Referring to FIGS. 11-15, the first and second housing portions 504, 506 of the sensor module 500 can be molded on opposite sides of a carrier, such as the carrier 600 of FIG. 11. FIG. 11 shows a portion of one example carrier 600 that can be indexed through the different processing stations 110, 120, 130, 140, 150, 160 of the manufacturing system 100 of FIG. 1. The carrier 600 includes a generally flat carrier body 601 defining a profile that is configured to support the components of the sensor module to be manufactured. One or more components can be molded to the carrier body 601 as the carrier 600 is indexed. In certain embodiments, multiple components of one sensor module can be molded across the carrier body 601.

The carrier body 601 also defines at least one series of index holes 602 configured to receive index pins to advance the carrier through a manufacturing system. In the example shown, the carrier body 601 defines two series of index holes 602. In other embodiments, however, the carrier body 601 can define greater or fewer series of index holes 602. In a preferred embodiment, the carrier body 601 is produced by roll stamping a high-precision profile on a stainless steel or suitable polymer tape and storing the prepared tape on a collector reel, such as the first carrier reel 102 of FIG. 1.

The carrier body 601 includes a fold feature 605 that splits the carrier body 601 into a first section 610 and a second section 620 along a fold axis 604. Folding the carrier body 601 along the fold axis 604 aligns the first section 610 with the second section 620. Accordingly, the fold feature 605 of the carrier body 601 enables opposing portions of sensor components to be molded onto the first and second sections 610, 620 of the carrier body 601 and subsequently assembled together by folding the carrier body 601 along the fold axis 604. .

In general, the fold feature 605 is a weakened or reduced portion of the carrier body 601 at which the carrier body 601 is configured to bend and/or break. In the example shown, the fold feature 605 includes multiple connecting members 607 extending between the first and second sections 610, 620. The connecting members 607 have a tapered center 608 that is configured to bend to enable the carrier body 601 to be folded at the fold feature 605. In a preferred embodiment, the fold feature 605 of the carrier body 601 is a midline fold feature that splits the carrier body 601 along a central axis into two halves. In other embodiments, however, the fold feature 605 can split the carrier body 601 into sections 610, 620 of different sizes.

The carrier body 601 shown in FIG. 11 has a profile configured to support at least two molded components of a sensor module. Each section 610, 620 includes a first support wall 611, 621 and a second support wall 613, 623. One or more support members extend inwardly from the support walls 611, 613, 621, 623 of the each section 610, 620, respectively. The support members are configured to provide support for molded components of the sensor module. The sensor components are molded onto the support members between the support walls 611, 613, 621, 623.

For example, in FIG. 11, the first section 610 includes a first support member 612 extending between the support walls 611, 613 at a first end of the carrier profile. The first section 610 also includes second and third support members

614, 616 extending between the support walls 611, 613 at a position spaced from the first support member 612. A fourth support member 618 also extends inwardly from the second support wall 613. The second section 620 includes a first support member 622 extending between the support walls 621, 623 at the first end of the carrier profile and a second support member 624 extending between the support walls 621, 623 at a position spaced from the first support member 622.

FIG. 12 shows the portion of carrier 600 of FIG. 11 after sensor module components have been molded onto the body 601 of the carrier 600 (e.g., at the mold station 110 of FIG.1). In the example shown, components of a single sensor module 500 have been molded onto the visible portion of the carrier body 601. A first housing portion 504 has been molded onto the support members 612, 614, 616, 618 of the first section 610 of the carrier 600. A second housing portion 506 has been molded onto the support members 622, 624 of the second section 620 of the carrier 600. The first housing portion 504 is formed to be generally complementary to the second housing portion 506.

Each housing portion 504, 506 includes an analysis cell housing section 707, 807, a flexible linkage section 709, 809, and an anchor section 708, 808, respectively. In one embodiment, the analysis cell housing section 707 of the first housing portion 504 defines a depression 712 that at least partially forms the analysis cell 512 when the housing portions 504, 506 are subsequently joined together. In one embodiment, the analysis cell 512 is fully defined by the depression 712 in the analysis cell housing section 707. In another embodiment, a corresponding depression (not shown) is formed in the analysis cell housing section 807 of the second housing portion 506. In a some embodiment, the depression 712 is about 0.01 inches (0.25 millimeters) to about 0.05 inches (1.27 millimeters) across at a largest dimension and about 0.002 (0.05 millimeters) to about 0.005 inches (0.13 millimeters) deep. In a preferred embodiment, the depression 712 is about 0.03 inches (0.76 millimeters) across at the largest dimension and about 0.003 (0.08 millimeters) deep.

The first and second housing portions 504, 506 each define a channel 716, 816 that extends between proximal and distal ends 702, 703, 802, 803 of the housing portion 504, 506, respectively. When the housing portions 504, 506 are subsequently joined together, the channels 716 and 816 form the passageway 514 through which a fluid sample can be transported to the analysis cell 512. In other embodiments, the passageway 514 can be formed entirely by the channel 716 within the first housing portion 504 or the channel 816 within the second housing portion 506.

Each channel 716, 816 includes a first section 713, 813, a second section 714, 814, and a third section 715, 815, respectively. The first sections 713, 813 of the channels 716, 816 have a frustro-conical shape configured to allow blood or other fluid to enter the passageway 514 formed by the channels 716, 816. The second section 714, 814 of the channels 716, 816 extend between the first sections 713, 813 and the depression 712. The third sections 715, 815 of the channels 716, 816 extend from the depression 712 to the opposite end of the analysis cell housing section 707, 807.

The second sections 714, 814 have diameters generally sufficient to enable sliding movement of a piercing member, such as piercing member 518 of FIG. 10, and to enable passage of a sample fluid alongside the piercing member 518. The third sections 715, 815 have diameters that are less than the diameters of the second sections 714, 814. In one embodiment, the diameters of the third sections 715, 815 are sized to enable sliding movement of the piercing member 518, but to inhibit passage of a sample fluid alongside the piercing member 518.

The analysis cell housing section 707 of the first housing portion 504 also can define electrode channels 717, 719 in which first and second continuous electrodes (not shown) can be routed through the analysis cell housing section 807. In one embodiment, the electrode channels 717, 719 are V-shaped channels. In other embodiments, however, the channels 717, 719 can have any suitable shape (e.g., U-shaped, squared, etc.). In certain embodiments, corresponding electrode channels 717, 719 can be defined in the second housing portion 506.

In one embodiment, the analysis cell housing section 707 of the first housing portion 504 defines cavities or slots 734, 736 at which the electrodes are exposed to contact 530, 532 extending through the analysis cell housing section 707. These contacts 530, 532 include exposed tips that extend outwardly from the first housing portion 504 to enable electrical coupling to processing and/or metering electronics. Accordingly, signals generated at the electrodes can be forwarded to such electronics via the contacts 530, 532.

In some embodiments, these contacts 530, 532 can be coupled to the carrier 600 on which the housing portions 504, 506 are molded prior to the manufacturing process. For example, in FIG. 11, the contacts 530, 532 are coupled to support members 614, 616 of the first section 610 of the carrier 600. Accordingly, the first housing portion 504 can be overmolded around the contacts 530, 532 to embed the contacts 530, 532 in the first housing portion 504. In other embodiments, however, these contacts 530, 532 are inserted into the slots 734, 736 at the completion of the manufacturing process.

In some embodiments, one or both housing portions 504, 506 also can include attachment members configured to secure the housing portions 504, 506 together. For example, one of the housing portions 504, 506 can include a peg or other protrusion configured to mate with an opening, depression, or groove, or slot defined in the other of the housing portions 504, 506. In one embodiment, the first housing portion 504 defines an extended protrusion 725 that is configured to fit within a corresponding slot 825 defined in the second housing portion 506 (e.g., see FIG. 13).

FIG. 13 shows the portion of the carrier 600 of FIG. 12 after a first electrode 552 and a second electrode 554 have been routed onto the molded sensor components (e.g., at the insertion station 130 of FIG. 1). In the example shown, the electrodes 552,554 are routed through channels 717, 719 of the first housing portion 504. Accordingly, the electrodes 552, 554 pass through the depression 712 partially forming the analysis cell 512. Typically, the first electrode 552 is a working electrode formed by coating sensor chemistry onto an elongated member and the second electrode 554 is a reference electrode formed from an uncoated elongated member.

FIG. 14 is an isometric view of the portion of the carrier 600 after the carrier 600 has been rolled or folded along the fold axis 605 (FIG. 11) to align the first and second sections 610, 620 of the carrier body 600 (e.g., at fold station 140 of FIG. 1). In one embodiment, the connecting members 607 extending between the first and second sections 610, 620 of the carrier body 600 are broken at their tapered centers 608 along the fold axis 604 as shown in FIG. 14. In other embodiments, however, the connecting members 607 bend sufficiently to enable the first section

610 to align with the second section 620 without breaking the carrier 600 into two sections.

The first housing portion 504 of the sensor module 500 is aligned with the second housing portion 506 in FIG. 14. In one embodiment, the protrusion 725 of the first housing portion 504 fits within the slot 825 of the second housing portion 506. When the first housing portion 504 is aligned with the second housing portion 506, at least the depressions 712 defined in the first housing portion 504 forms an analysis cell 512 through which the electrodes 552, 554 pass. The channels 716, 816 defined in the first and second housing portions 504, 506 form the sample path 514 extending through the analysis cell 512. Fluid can be provided to the analysis cell 512, and hence the portion of the electrodes 552, 554 extending through the analysis cell, through capillary action or wicking.

The first and second housing portions 504, 506 are joined together (e.g., via a weld, an overmold layer, or another joining structure). In a preferred embodiment, the housing portions 504, 506 are secured together using a selective laser weld. For example, in one embodiment, the second housing portion 506, which does not contain active components, such as the electrodes 552,554, is transparent to the laser while the first housing portion 504, which contains the electrodes 552, 554, is absorptive to the laser energy, thereby establishing an interior plane for a precise laser weld creating a hermetic seal for the analysis cell and related component structures.

FIG. 15 is an isometric view of the portion of the carrier 600 shown in FIG. 14 after the opposing components have been secured together (e.g., at joining station 150 of FIG. 1). The carrier body 600 has been broken in half at the centers 608 of the connecting members 607. The index holes 602 of the first and second sections 610, 620 of the carrier body 600 align. The first and second housing portions 504, 506 of the sensor module 500 also are visibly aligned with each other.

Additional features can be added to the interior of the sensor modules 400, 500 after the support components are molded on the carrier body 300, 600 and prior to folding the carrier body 300, 600. For example, in certain embodiments, a piercing member (e.g., needle cannula 518 of FIG. 10) can be added to the sensor module (e.g., sensor module 500 of FIGS. 9 and 10) to aid in obtaining a fluid sample. In other embodiments, additional features can be added to the sensor module after completion of the manufacturing process (e.g., manufacturing process 200 of FIG. 2). For example, in certain embodiments, an reservoir containing insulin or another drug can be added to the sensor module after the sensor module has been separated from the carrier. Of course, the piercing member also can be added to the sensor module after separation from the carrier.

Additional details regarding example sensor modules that can be manufactured using the systems and processes disclosed herein can be found in copending application Serial Nos. 61/114,829 and 61/114,844 (having attorney docket nos. 11554.11USP1 and 11554.13USP1), filed November 14, 2008, the disclosures of which are hereby incorporated herein by reference.

The above specification provides examples of how certain aspects may be put into practice. It will be appreciated that the aspects can be practiced in other ways than those specifically shown and described herein without departing from the spirit and scope of the present disclosure. For example, various sensor modules having different structures can be manufactured by changing the profile of the carrier.

CLAIMS:

1. A method of manufacturing an electrochemical sensor module, the method comprising:

molding first and second opposing portions of a sensor module housing onto a carrier, the first portion including a depression that at least partially forms an analysis cell when the first portion is aligned with the second portion;

installing an electrode arrangement on the first portion of the sensor module housing at an installation station, wherein the electrode arrangement is arranged in fluid communication with the analysis cell when the first portion is aligned with the second portion;

folding the carrier to align the first portion of the sensor module housing with the second portion at a folding station; and

joining the first and second portions of the sensor module housing at a joining station.

2. The method of claim 1, further comprising advancing the carrier between the stations.

3. The method of claim 1, wherein molding first and second opposing portions of the sensor module housing comprises injection molding the first and second opposing portions.

4. The method of claim 1, wherein molding first and second opposing portions of the sensor module housing comprises molding at least the first portion to define a channel extending from the depression to an exterior of the first portion, wherein the channel at least partially defines a passageway leading to the analysis cell when the first portion is aligned with the second portion.

5. The method of claim 1, wherein installing the electrode arrangement comprises installing at least one continuous monofilament to the first portion of the senor module housing.

6. The method of claim 1, wherein installing the electrode arrangement comprises unwinding the electrode arrangement from at least a first reel.

7. The method of claim 1, wherein folding the carrier comprises breaking the carrier along a fold axis.

8. The method of claim 1, wherein joining the first and second portions includes welding together the first and second portions.

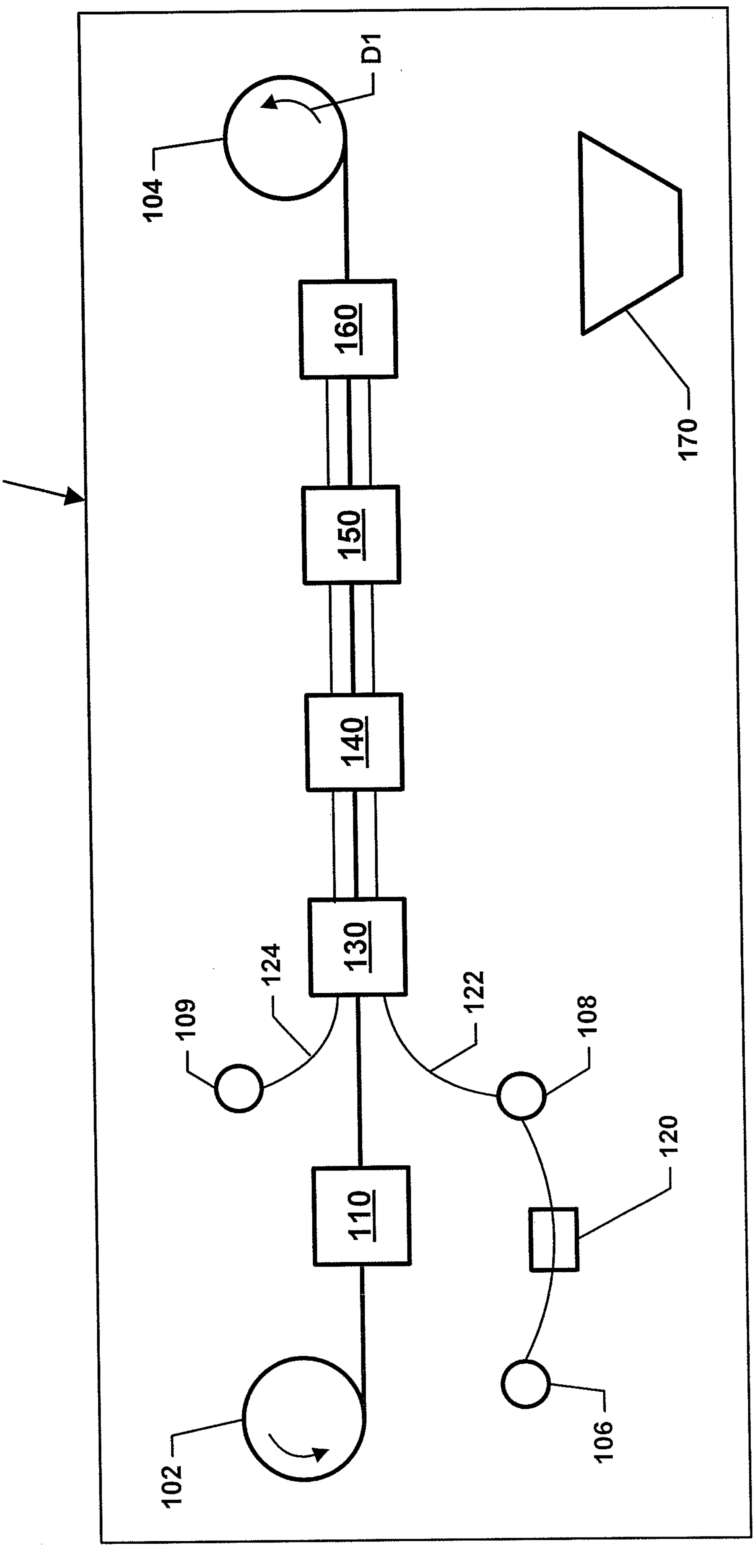
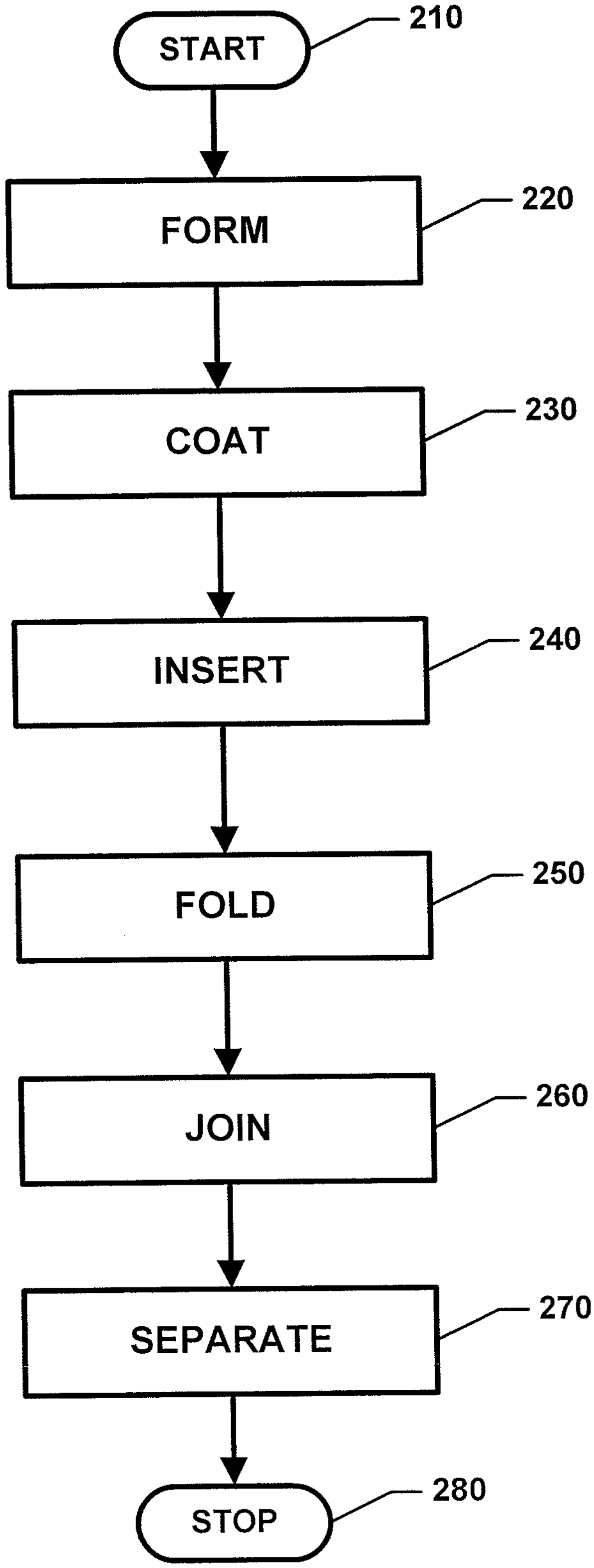


FIG. 1

FIG. 2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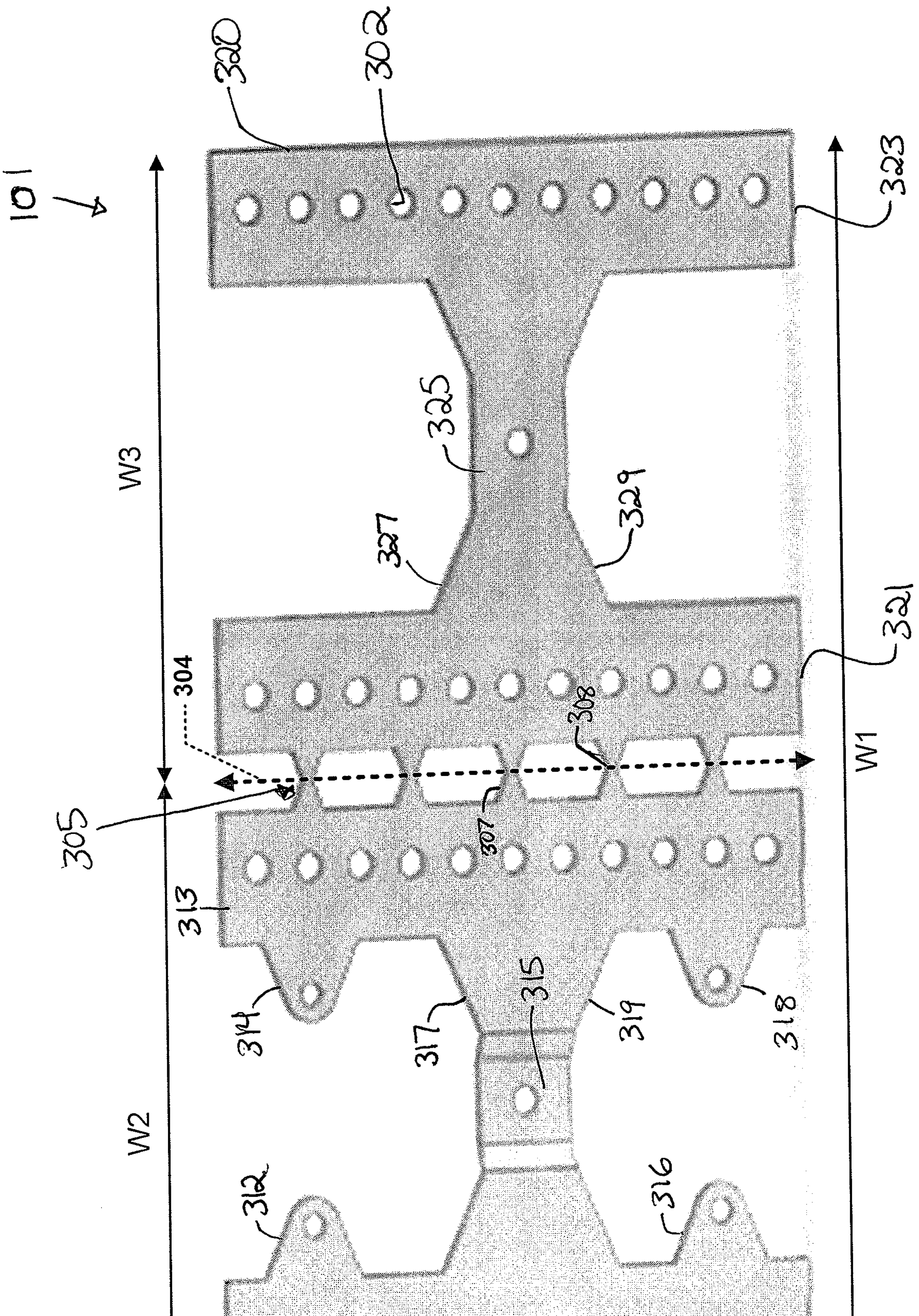
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310
302

FIG. 3

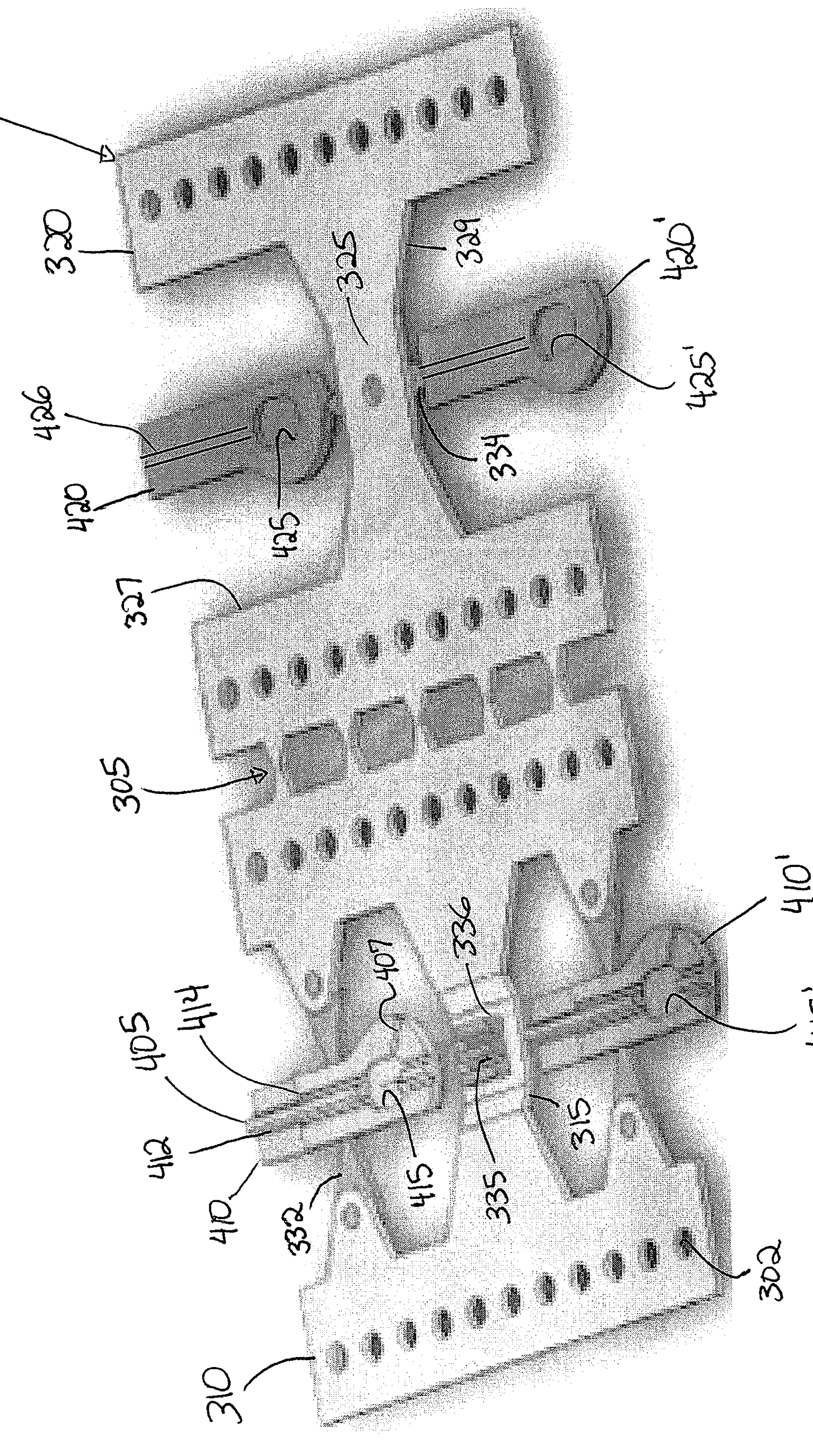
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FIG. 4

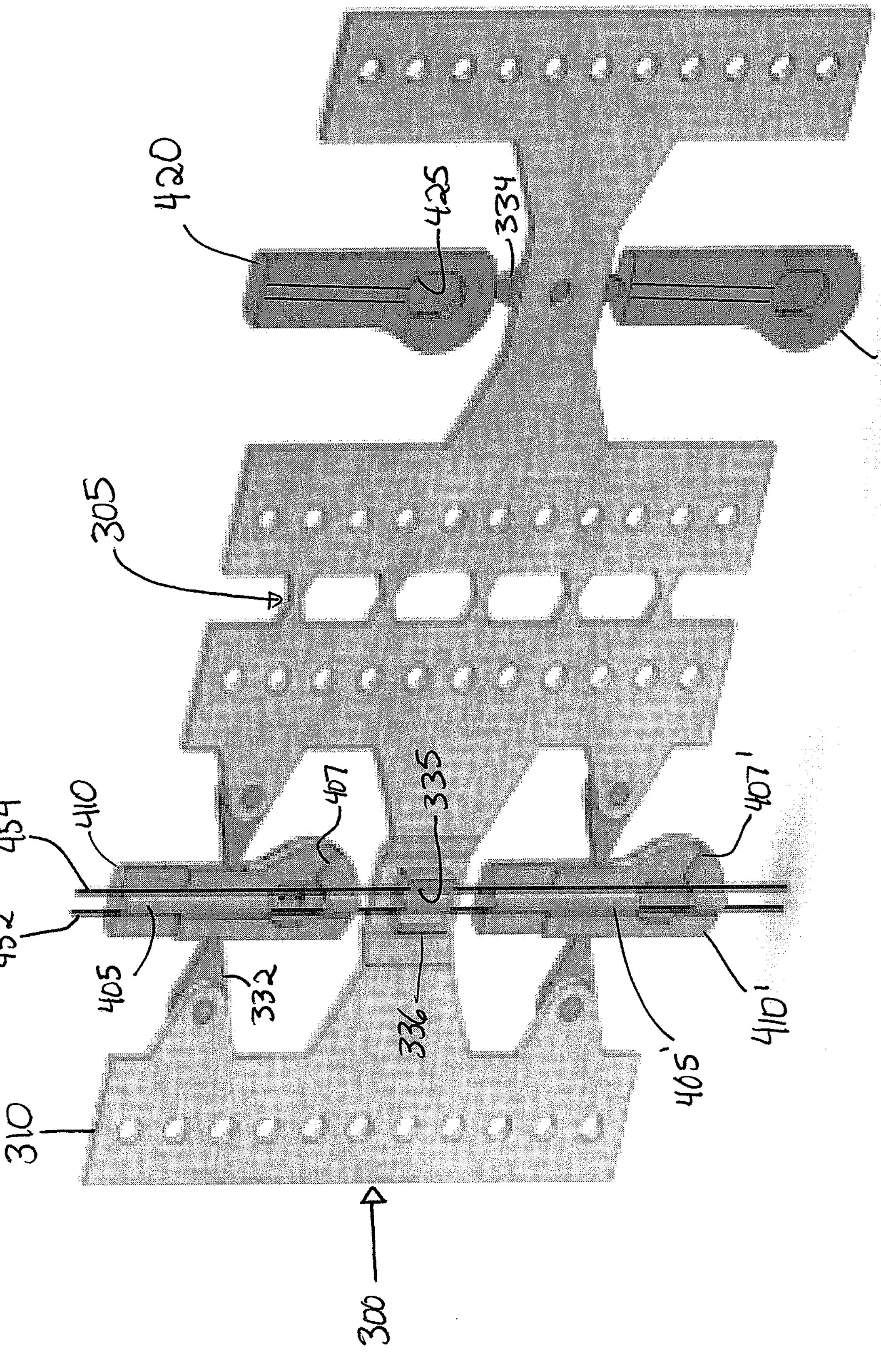
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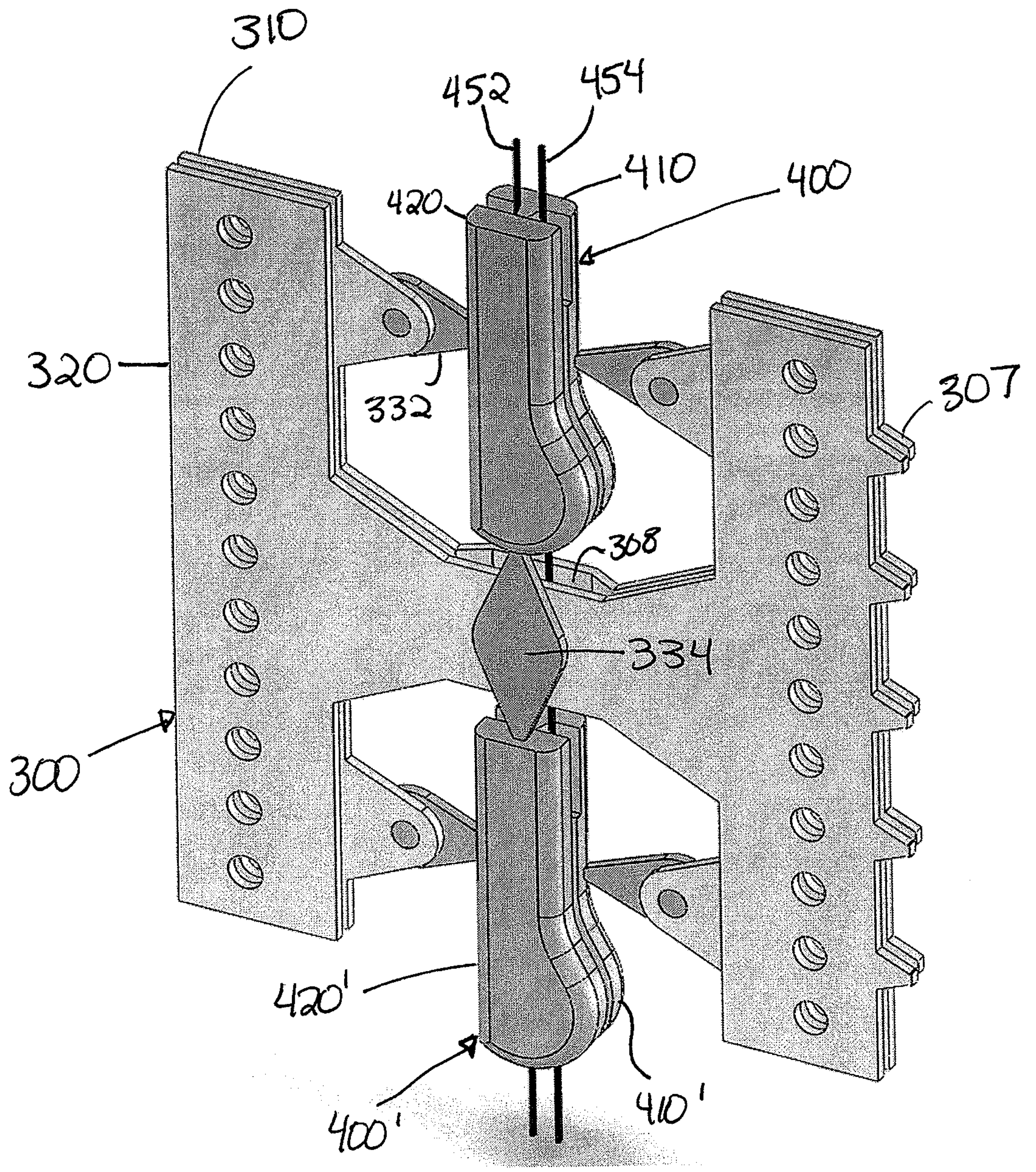
FIG. 5

FIG. 6



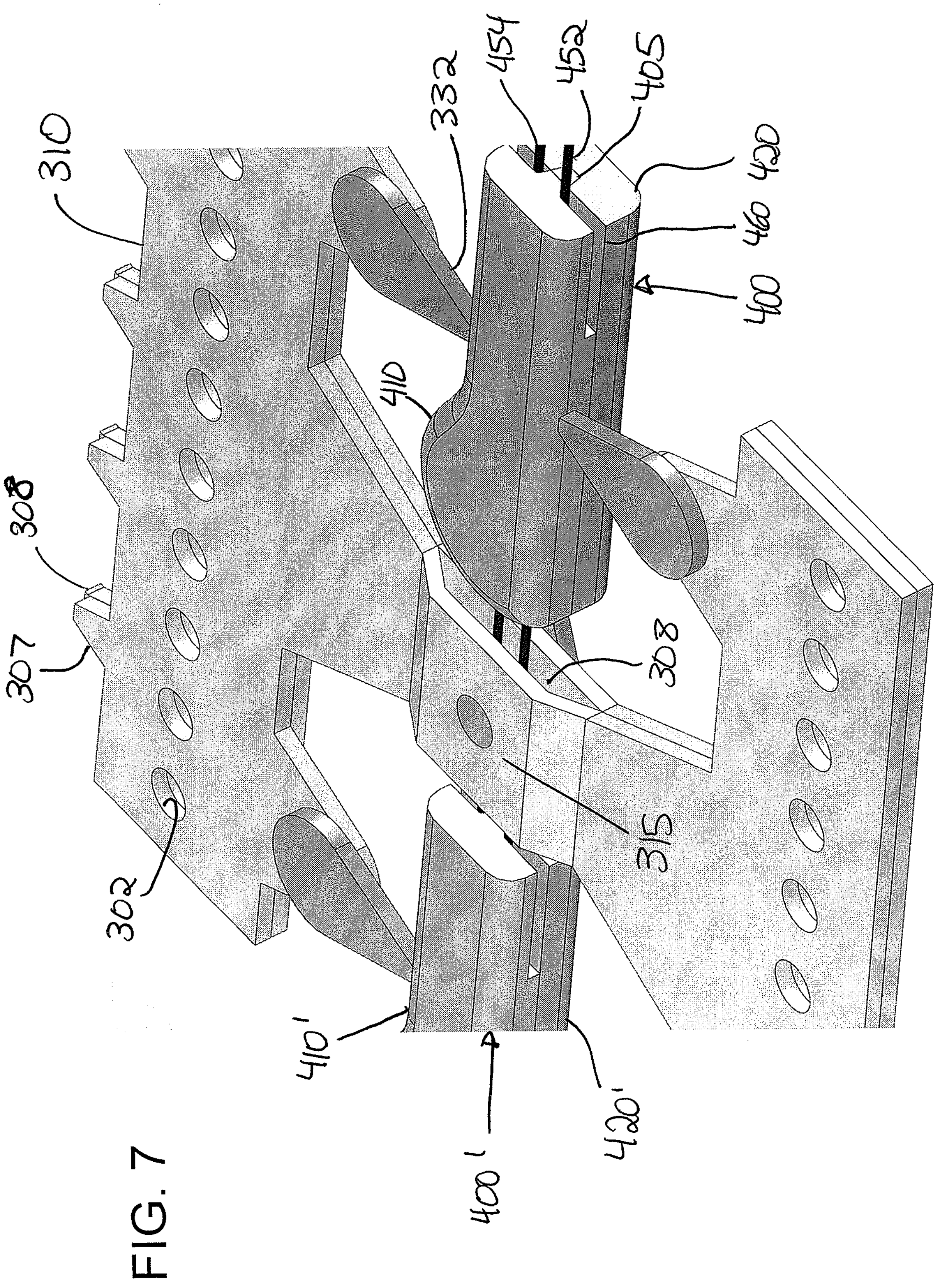

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FIG. 7

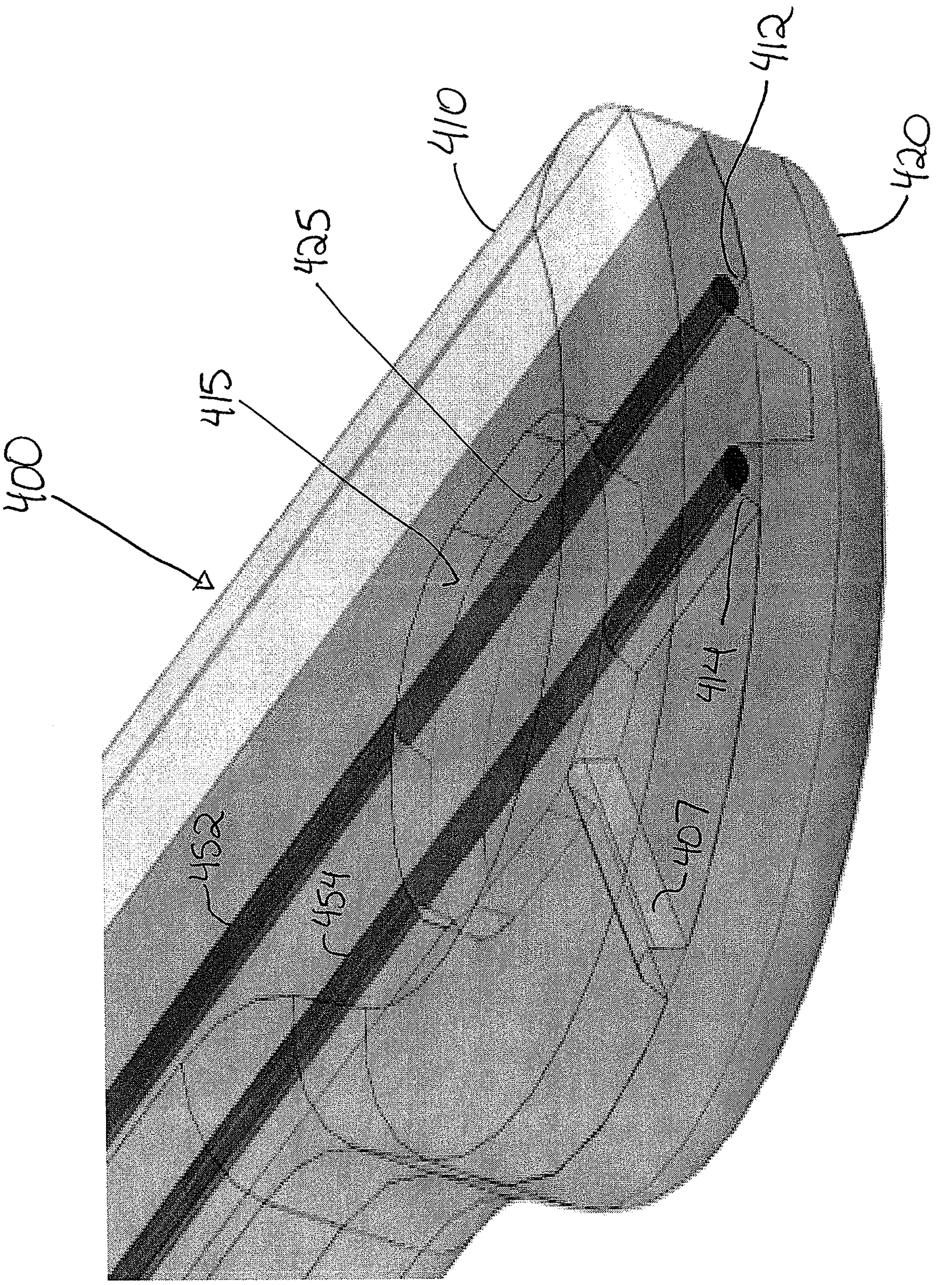


FIG. 8

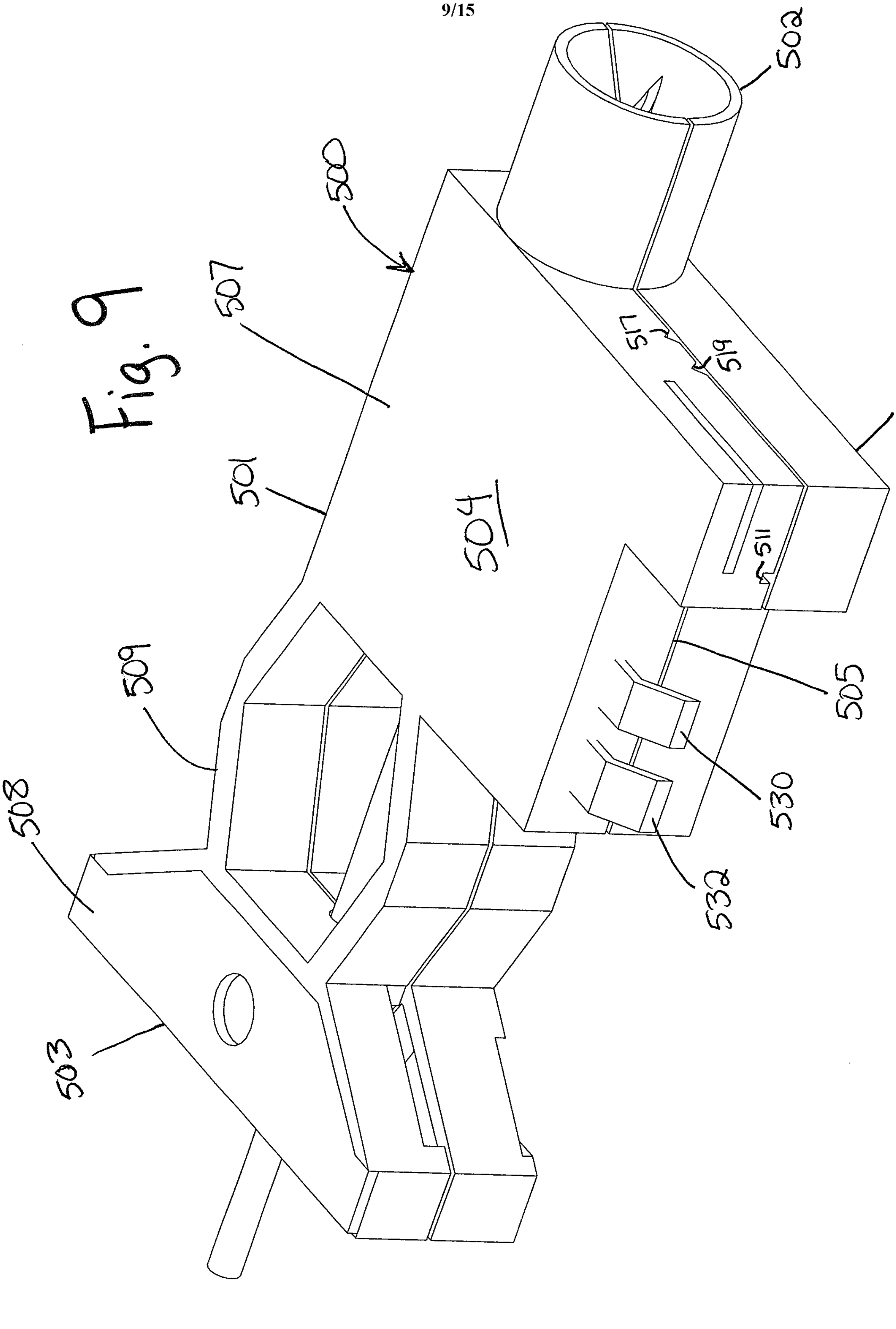
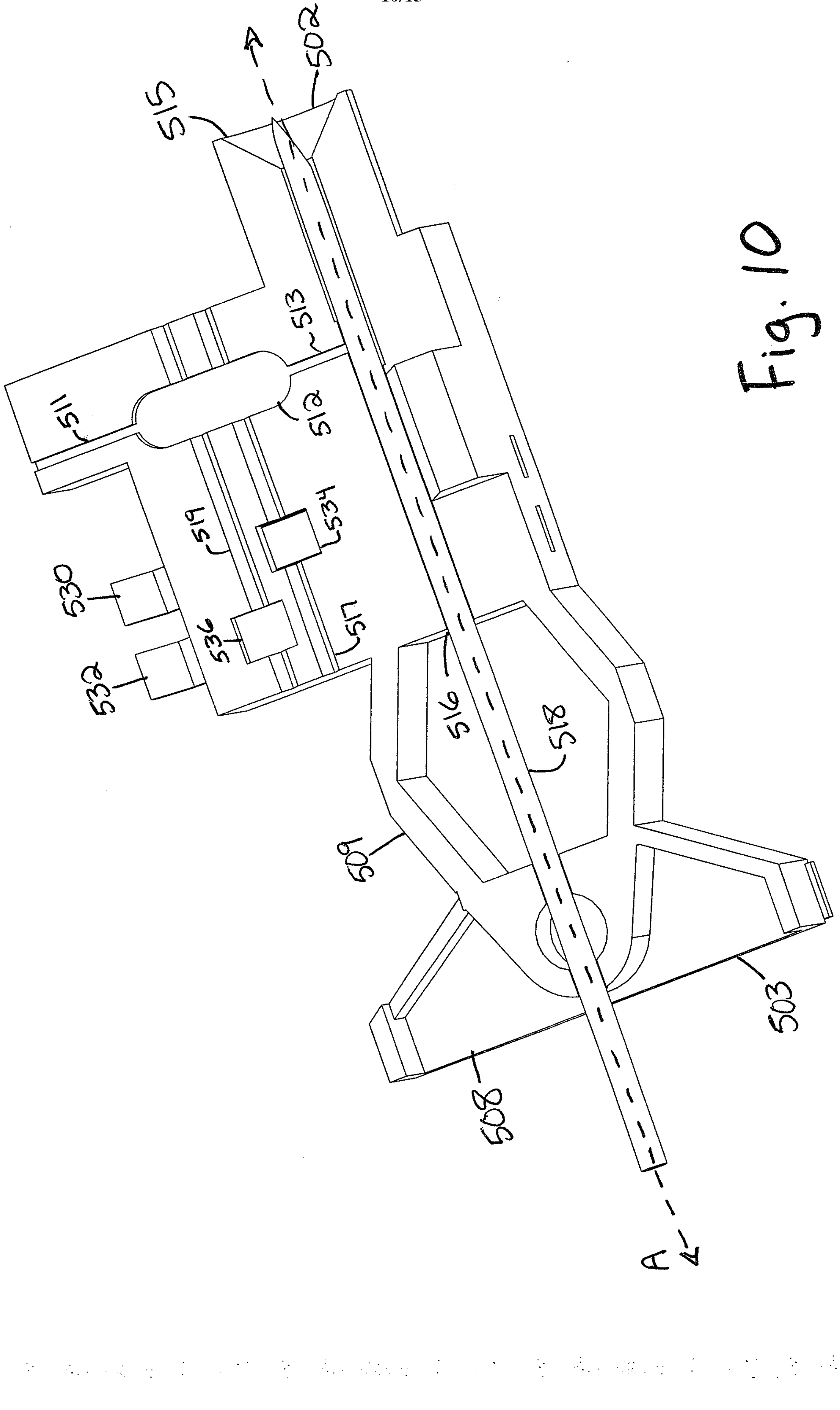


Fig. 9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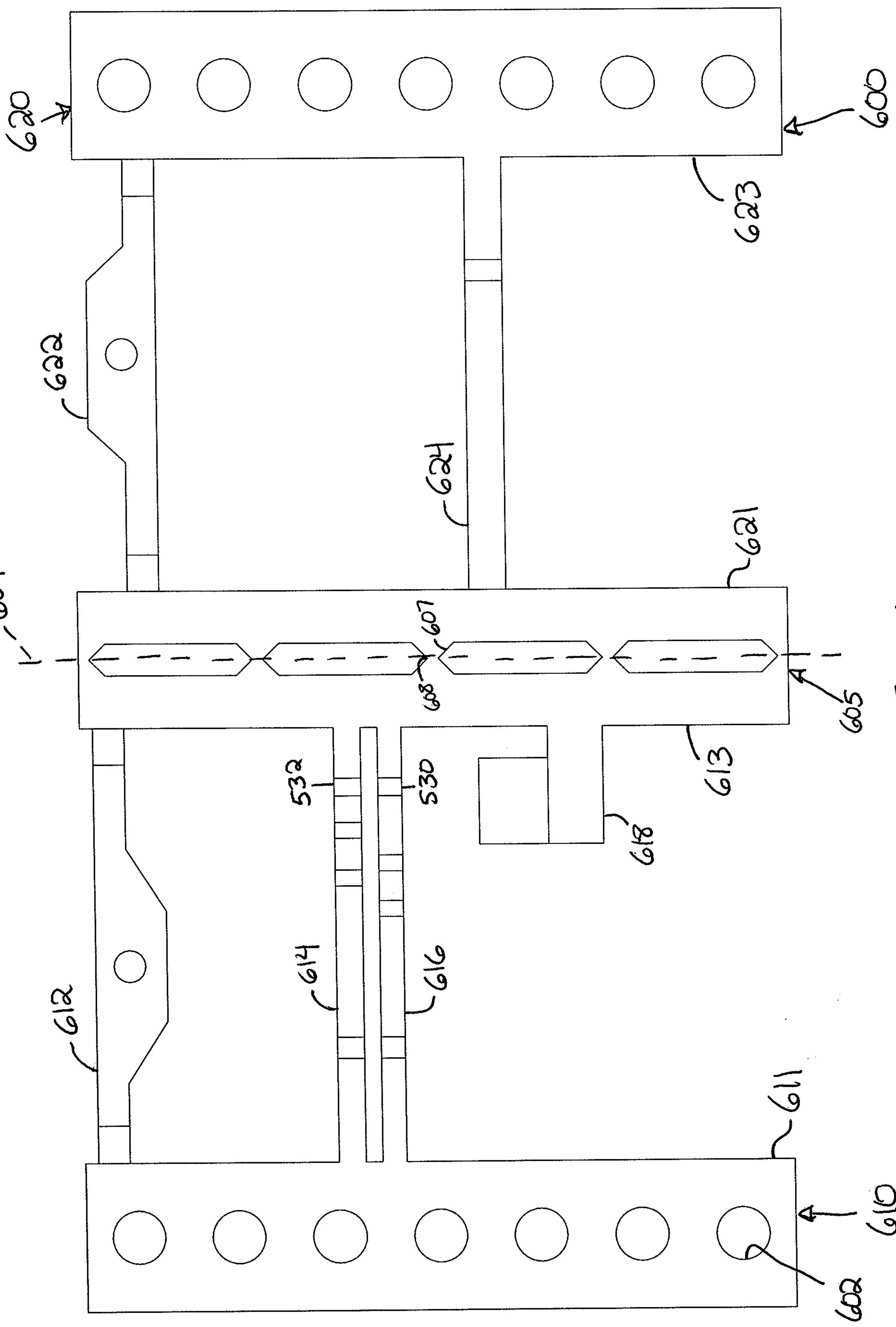
503
508
A

Fig. 10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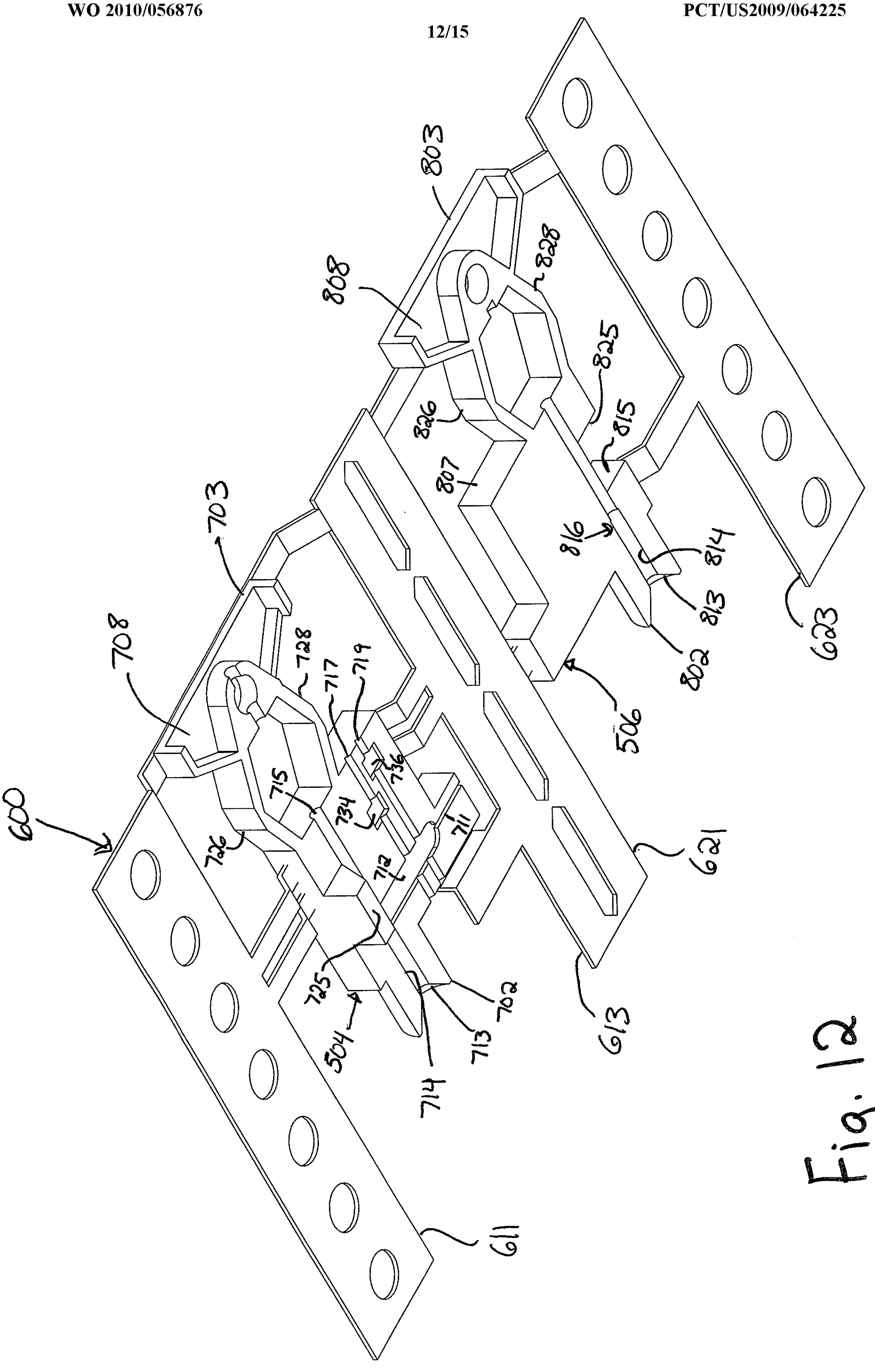
532

Fig. 11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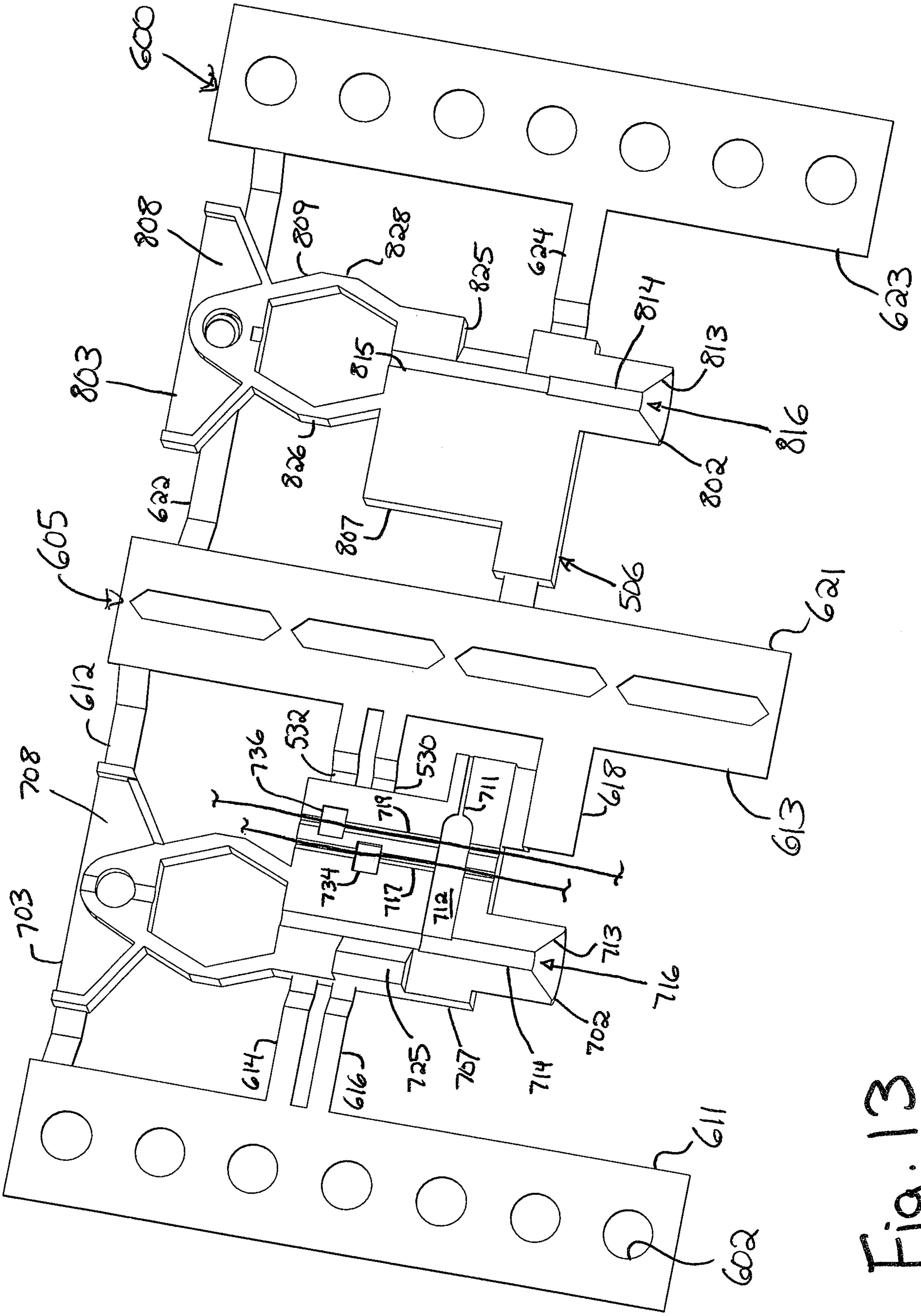
623

Fig. 12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611
602

Fig. 13

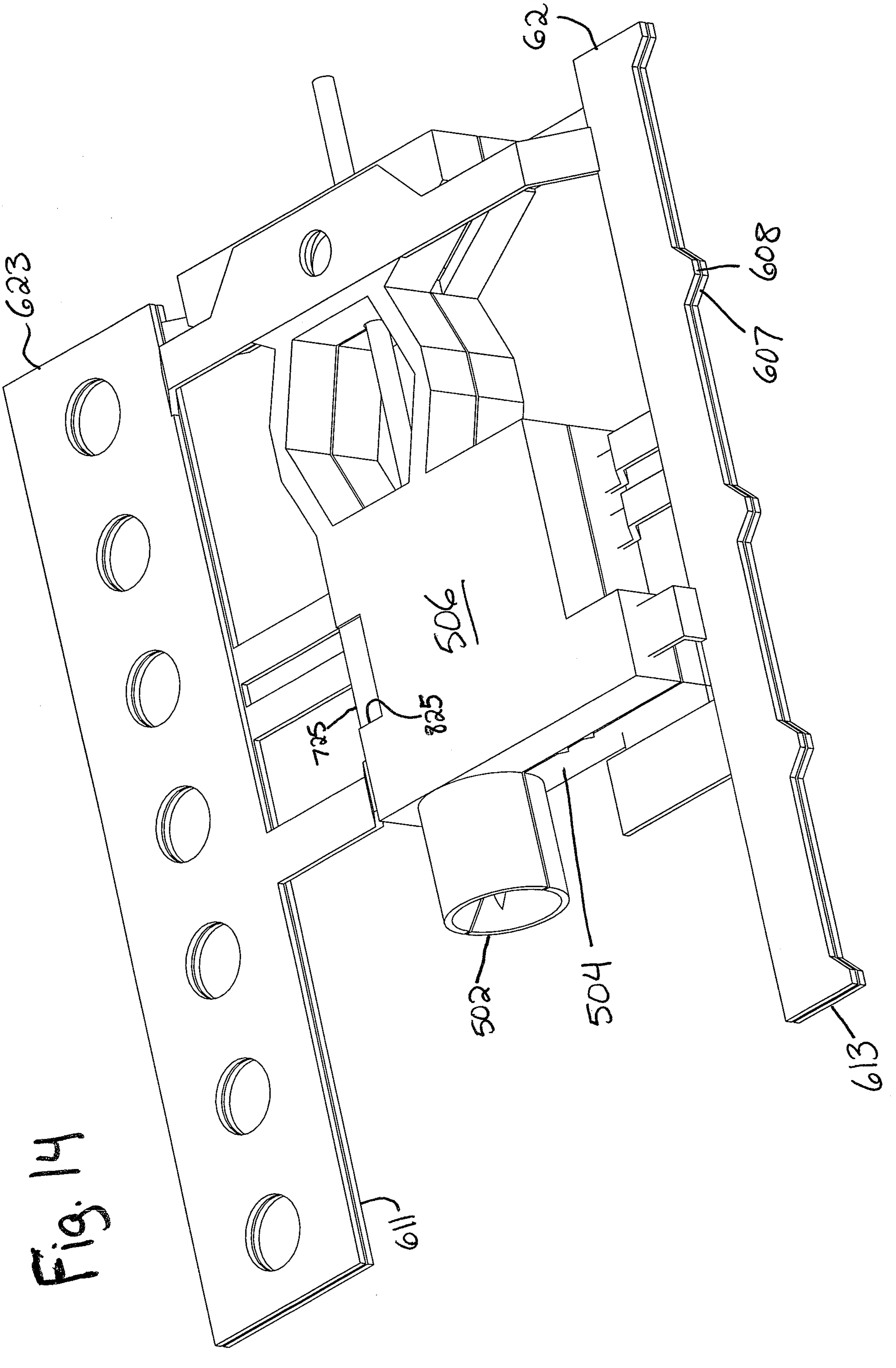

Fig. 14

Fig. 15