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(54) APPARATUS FOR THE MANUFACTURE OF MEDICAL DEVICES

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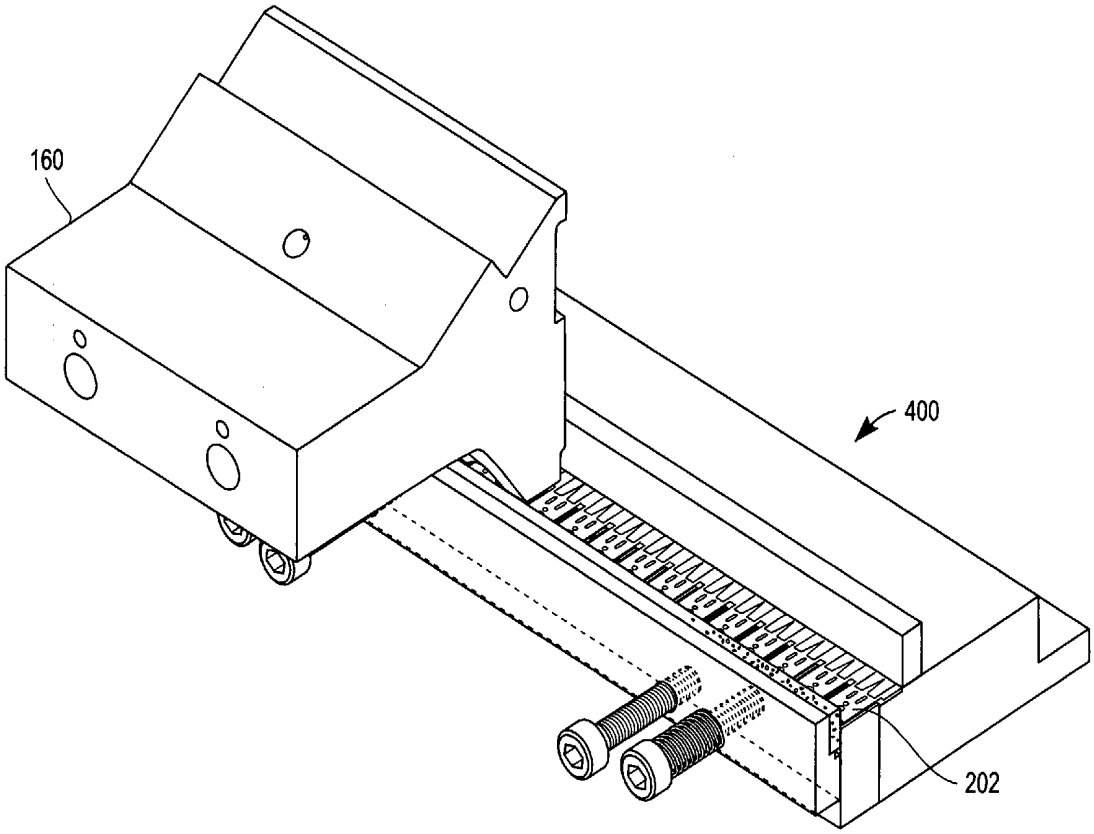
(57) **ABSTRACT**

The determination of analyte concentration in physiological samples is of ever increasing importance to today's society. Such assays find use in a variety of applications, including clinical laboratory testing, home testing, etc., where the results of such testing play a prominent role in the diagnosis and management of a variety of disease conditions. An apparatus is described herein which may be used for the manufacture of medical devices which include an integrated lancet and sensor.



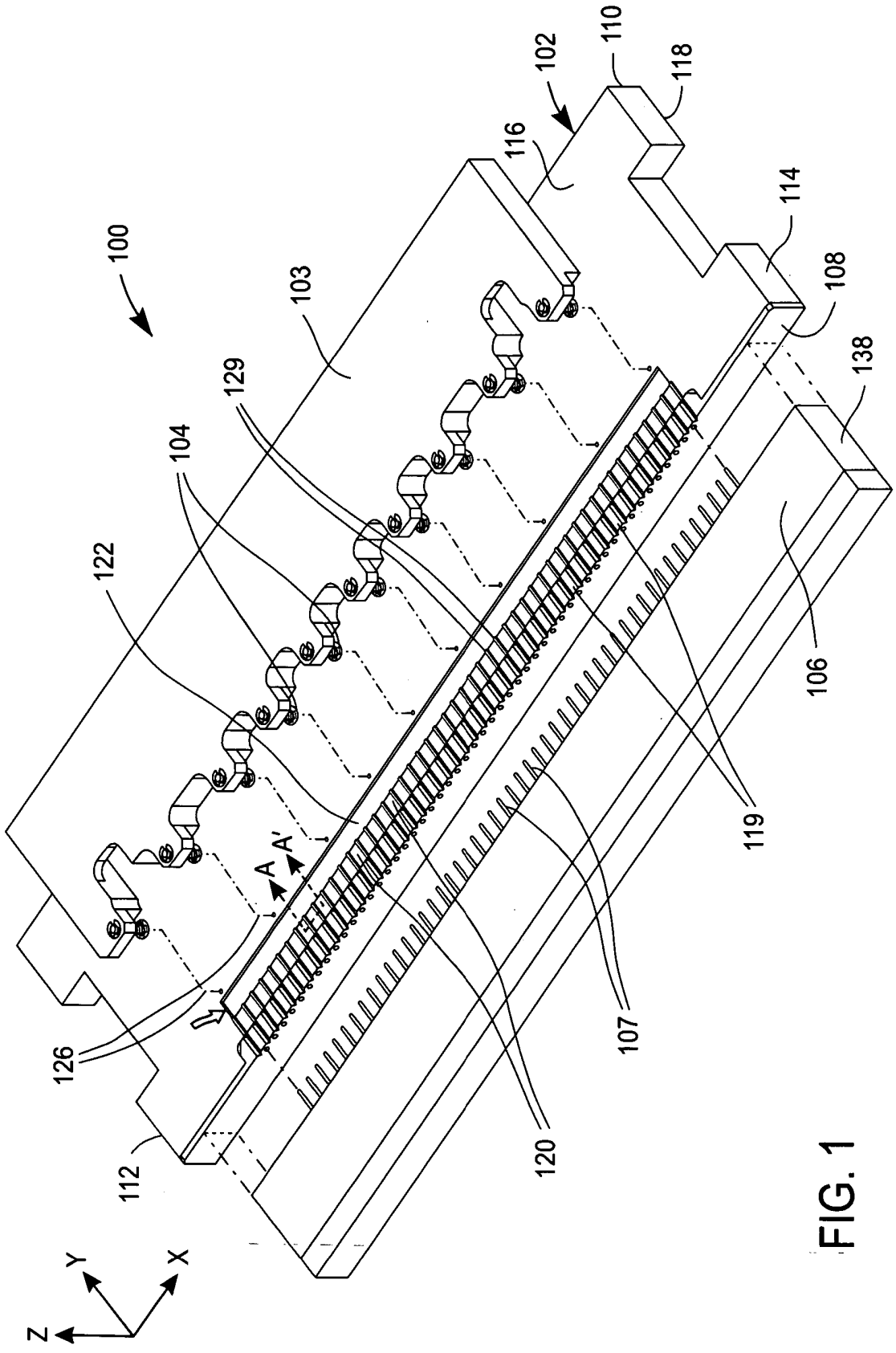

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FIG. 1

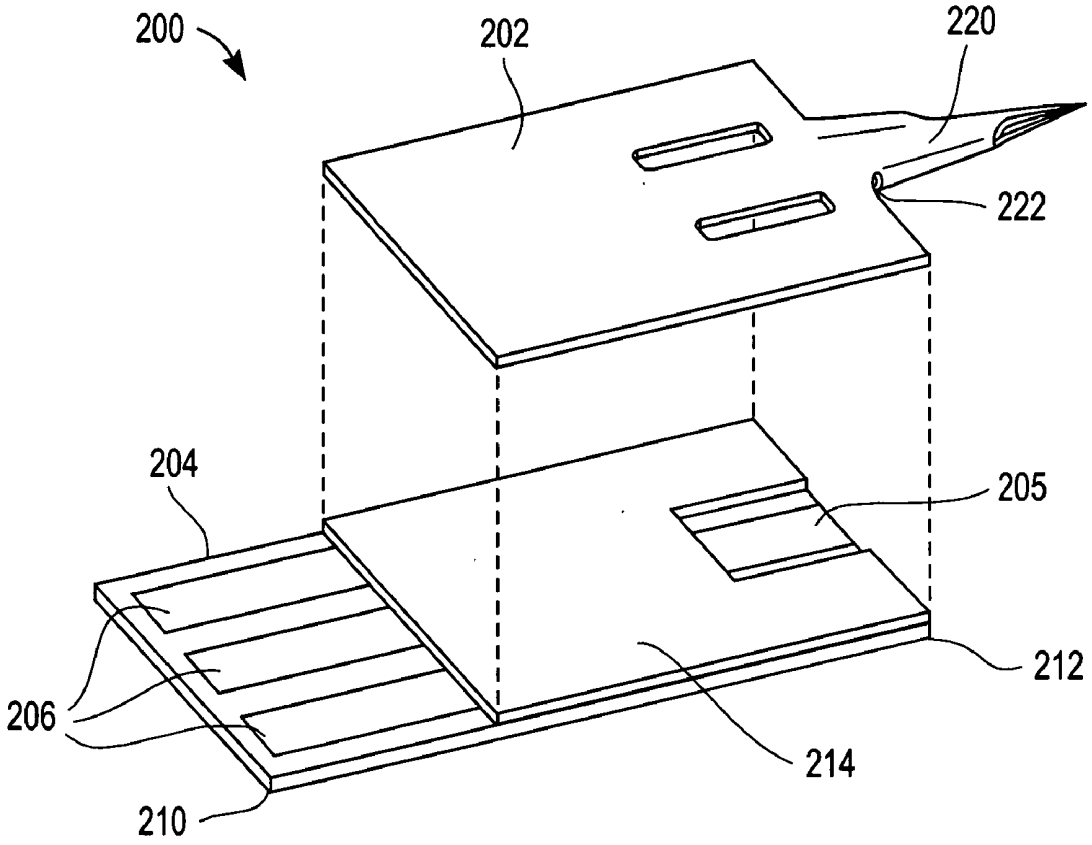

FIG. 2A

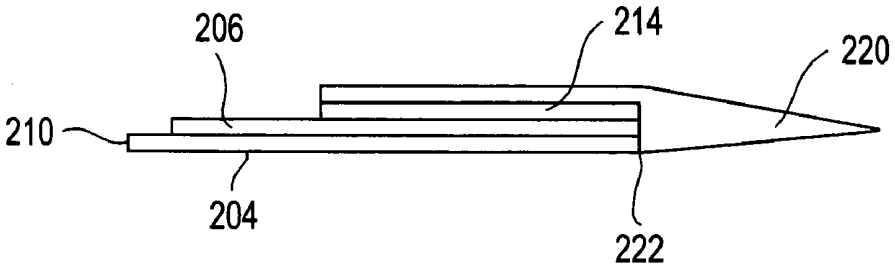

FIG. 2B

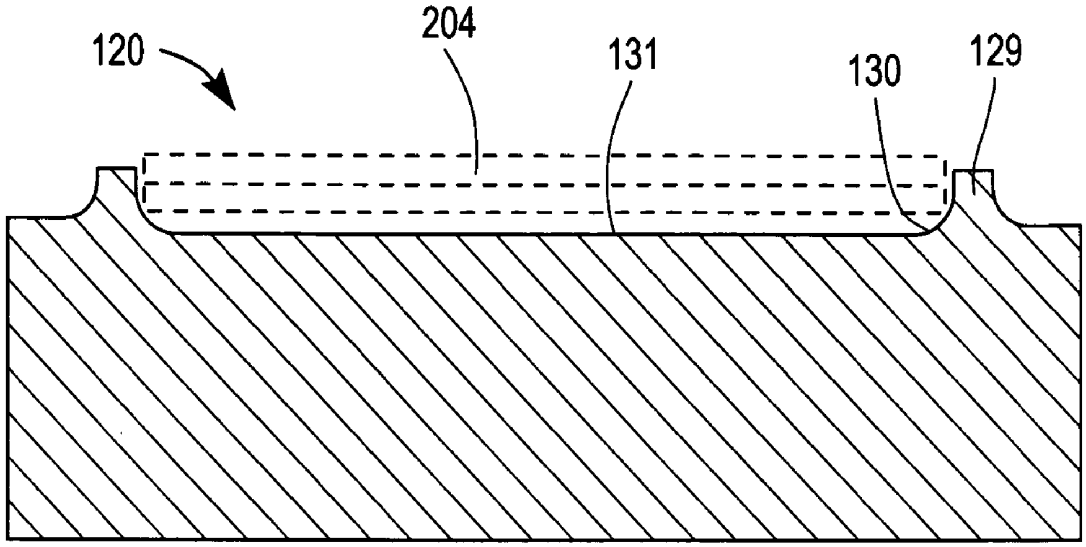

FIG. 3A

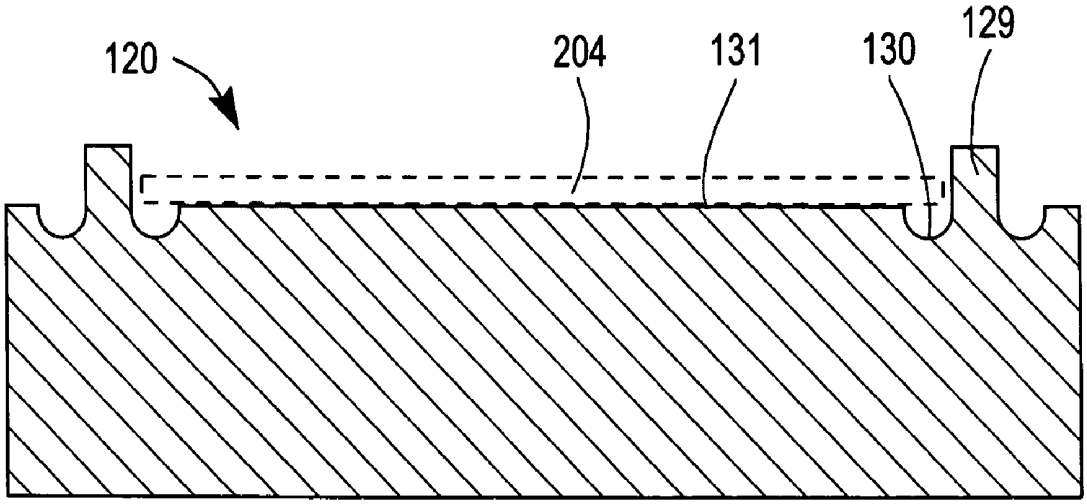

FIG. 3B

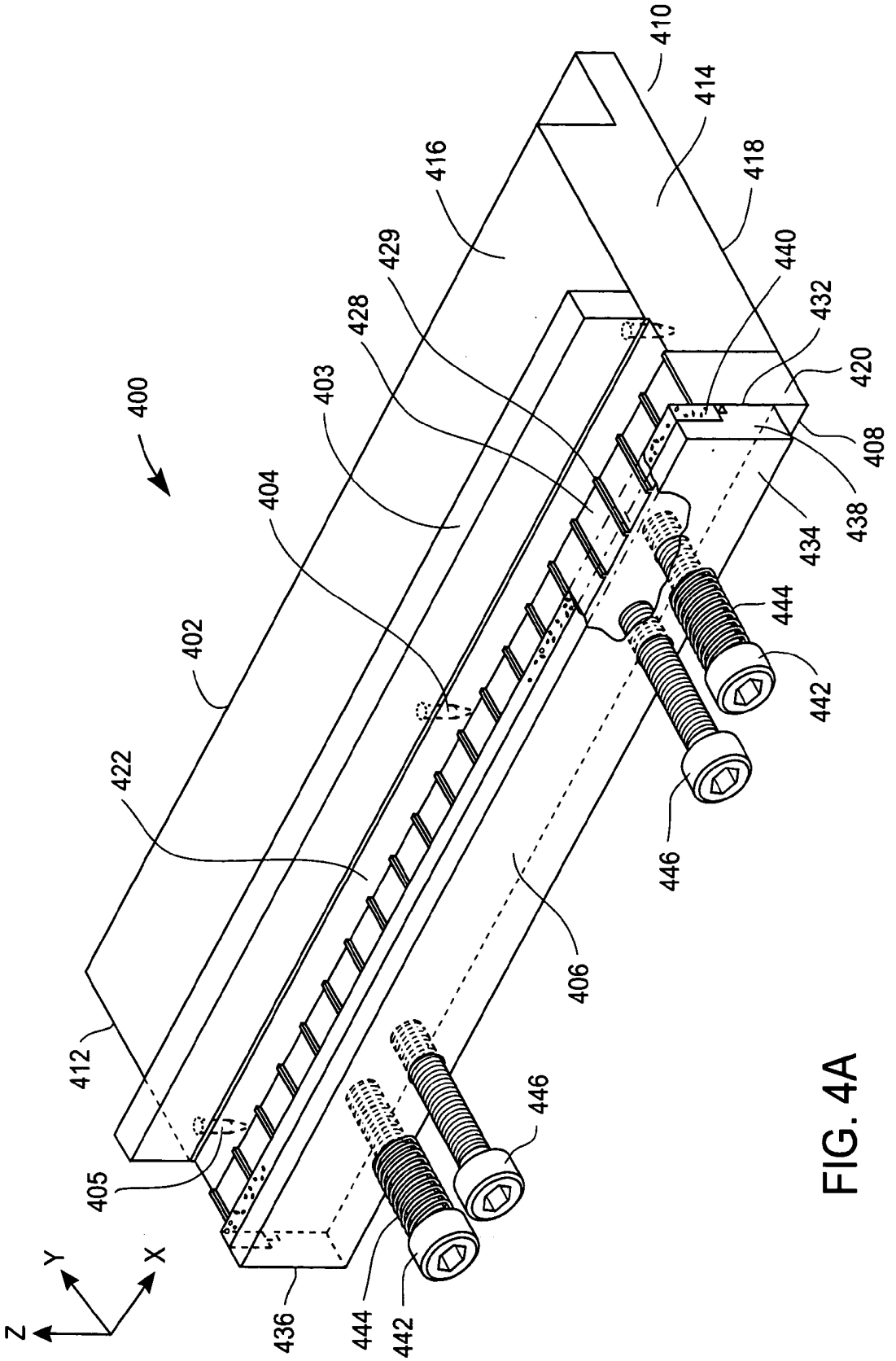
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FIG. 4A

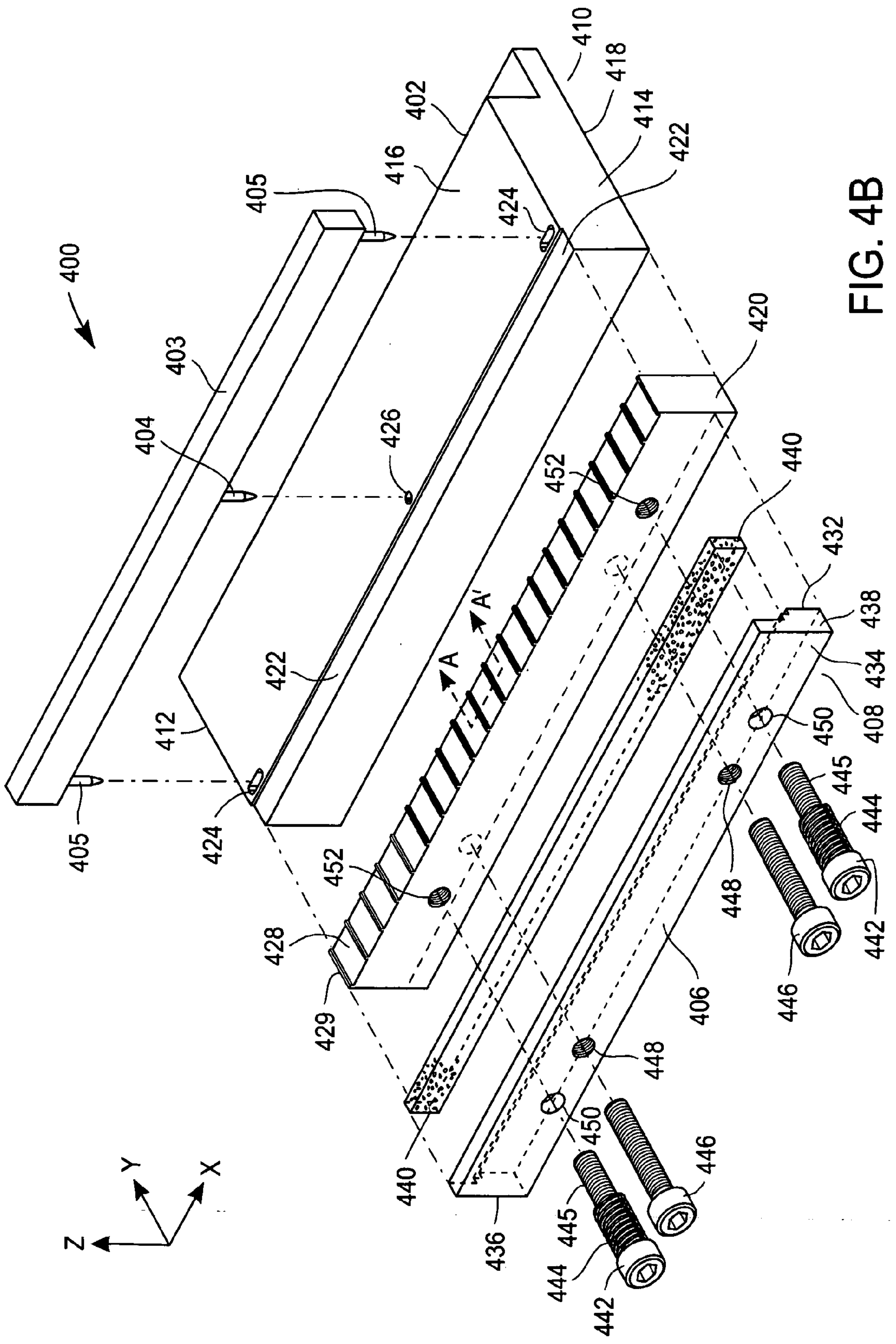
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FIG. 4B

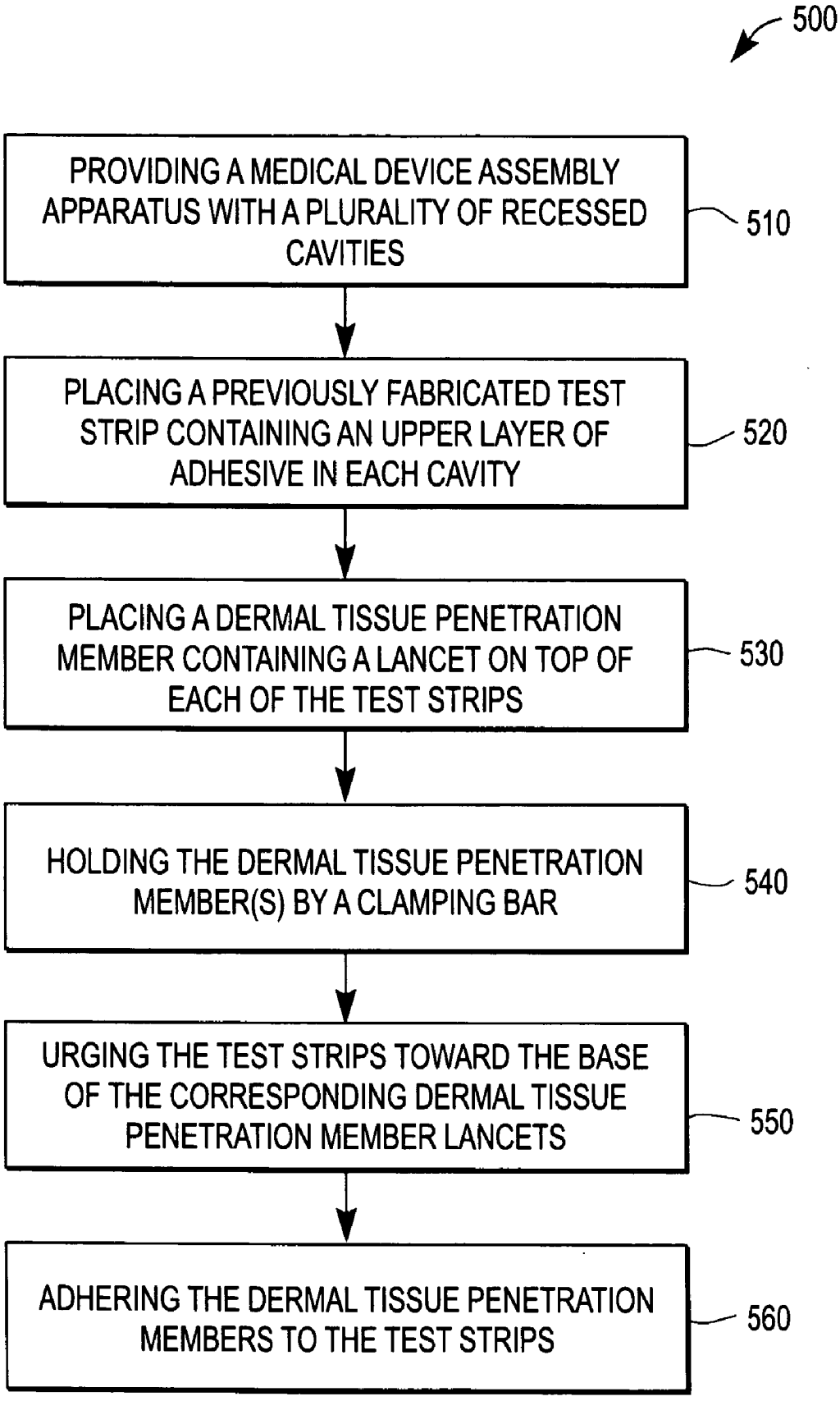
500
PROVIDING A MEDICAL DEVICE ASSEMBLY APPARATUS WITH A PLURALITY OF RECESSED CAVITIES
510
PLACING A PREVIOUSLY FABRICATED TEST STRIP CONTAINING AN UPPER LAYER OF ADHESIVE IN EACH CAVITY
520
PLACING A DERMAL TISSUE PENETRATION MEMBER CONTAINING A LANCET ON TOP OF EACH OF THE TEST STRIPS
530
HOLDING THE DERMAL TISSUE PENETRATION MEMBER(S) BY A CLAMPING BAR
540
URGING THE TEST STRIPS TOWARD THE BASE OF THE CORRESPONDING DERMAL TISSUE PENETRATION MEMBER LANCETS
550
ADHERING THE DERMAL TISSUE PENETRATION MEMBERS TO THE TEST STRIPS
560

FIG. 5

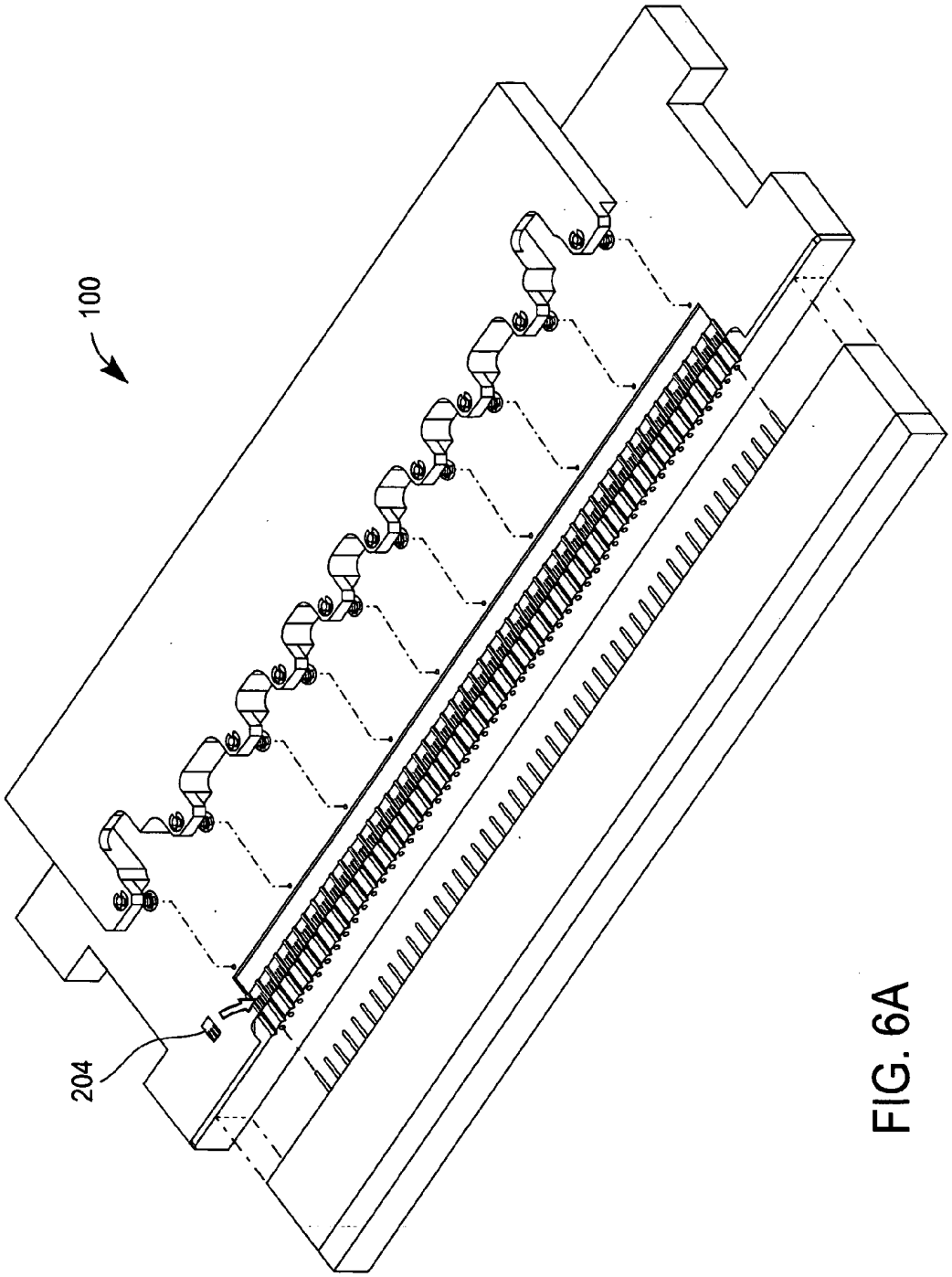

FIG. 6A

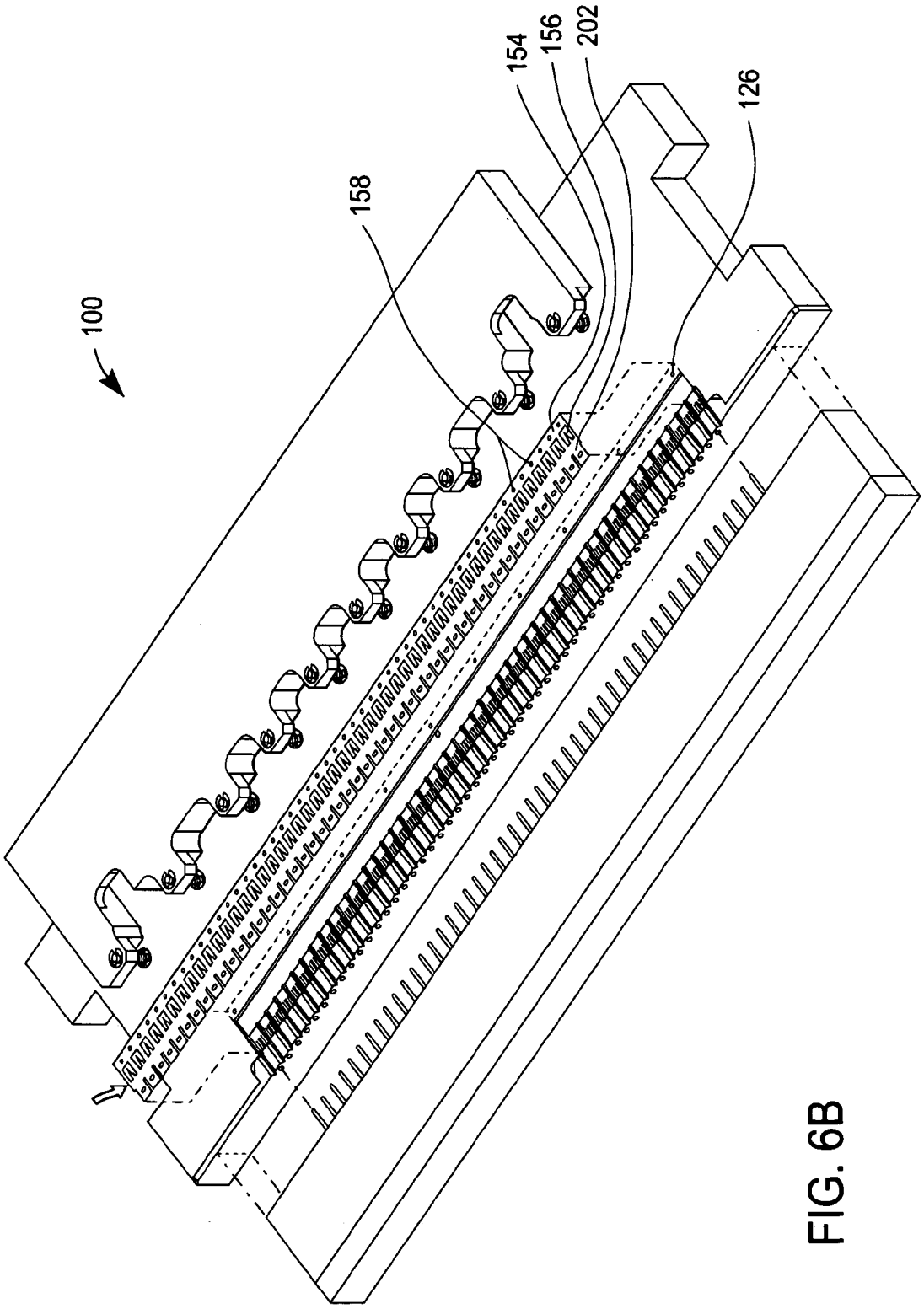

FIG. 6B

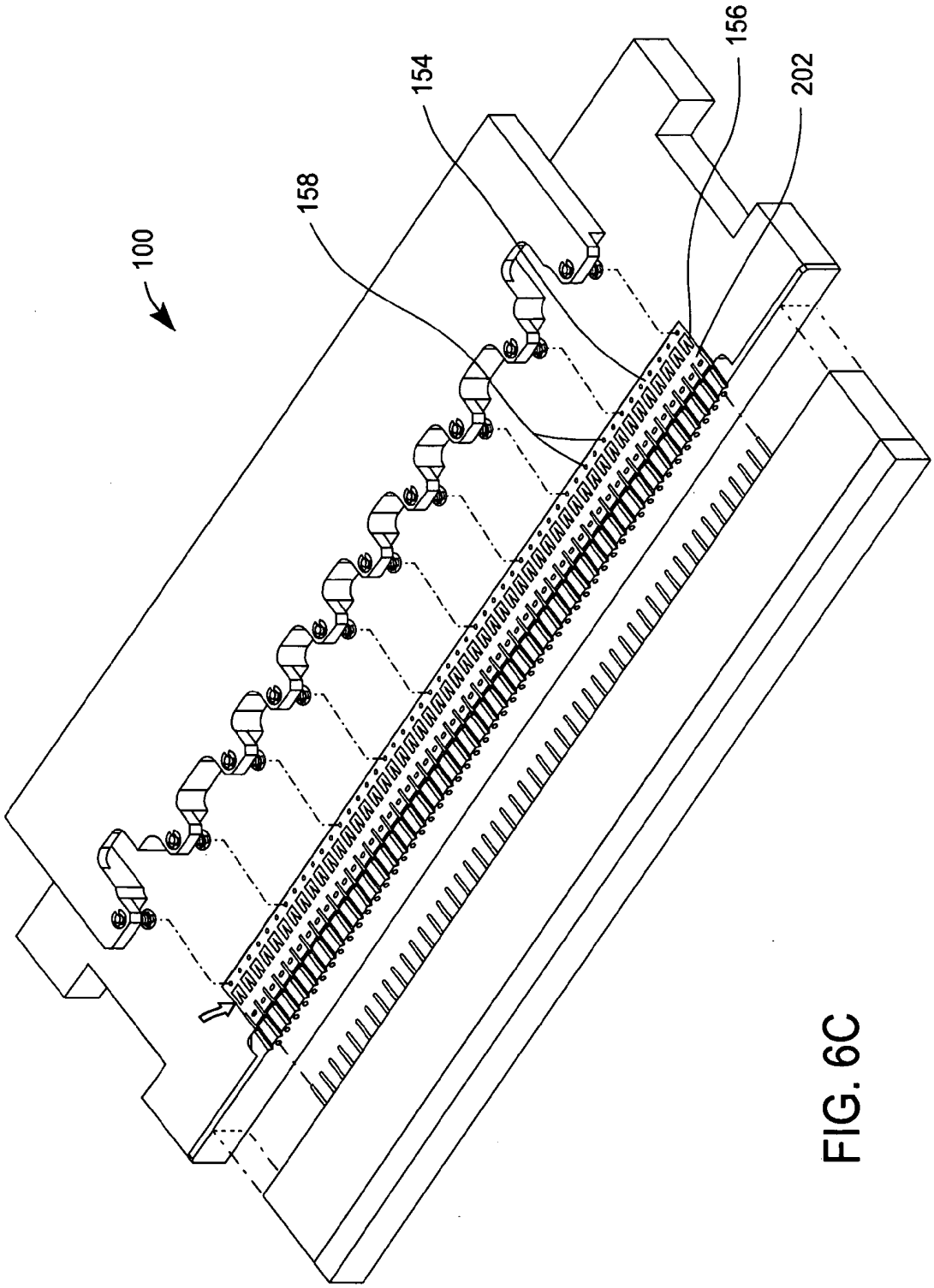

FIG. 6C

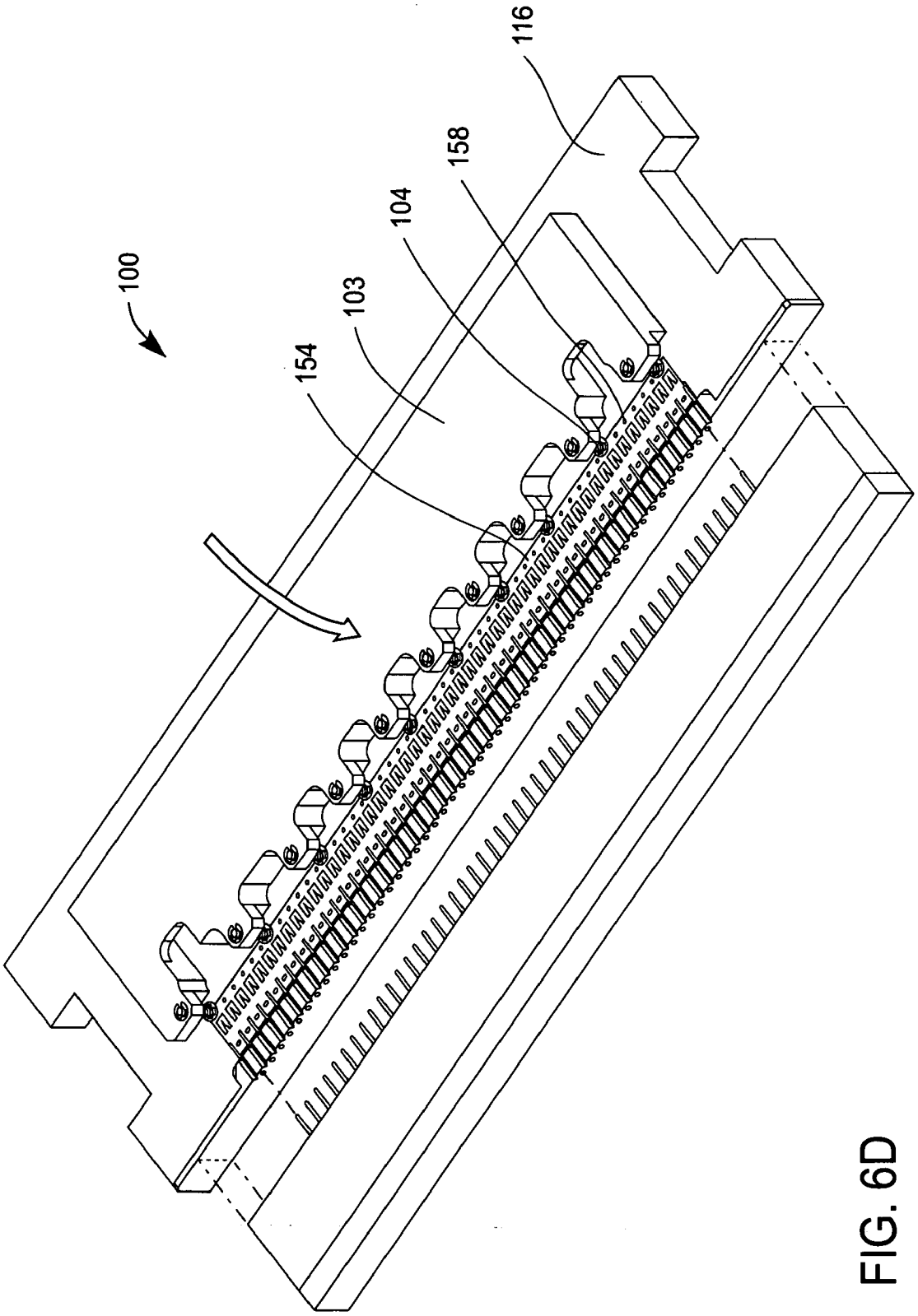

FIG. 6D

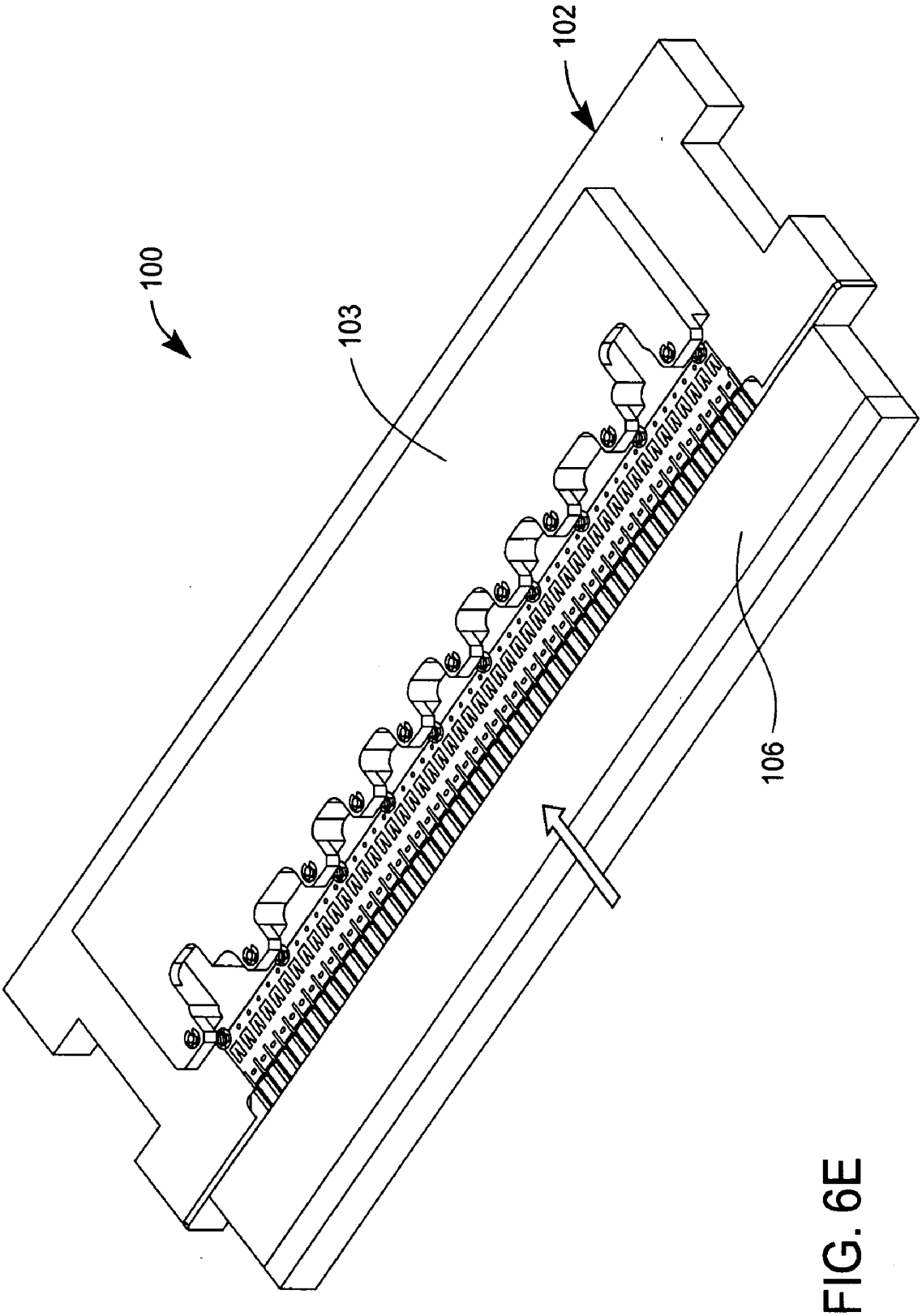

FIG. 6E

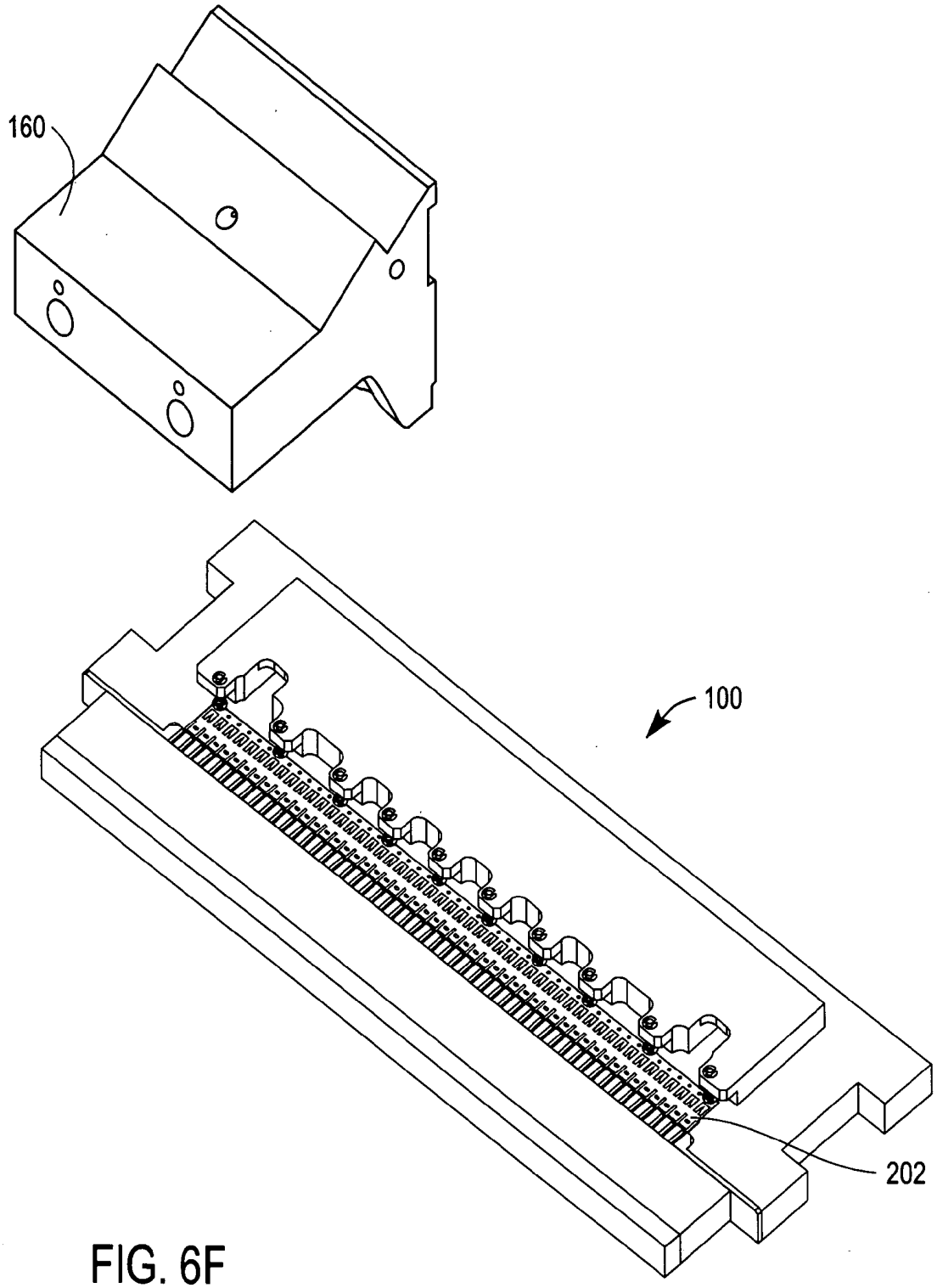

FIG. 6F

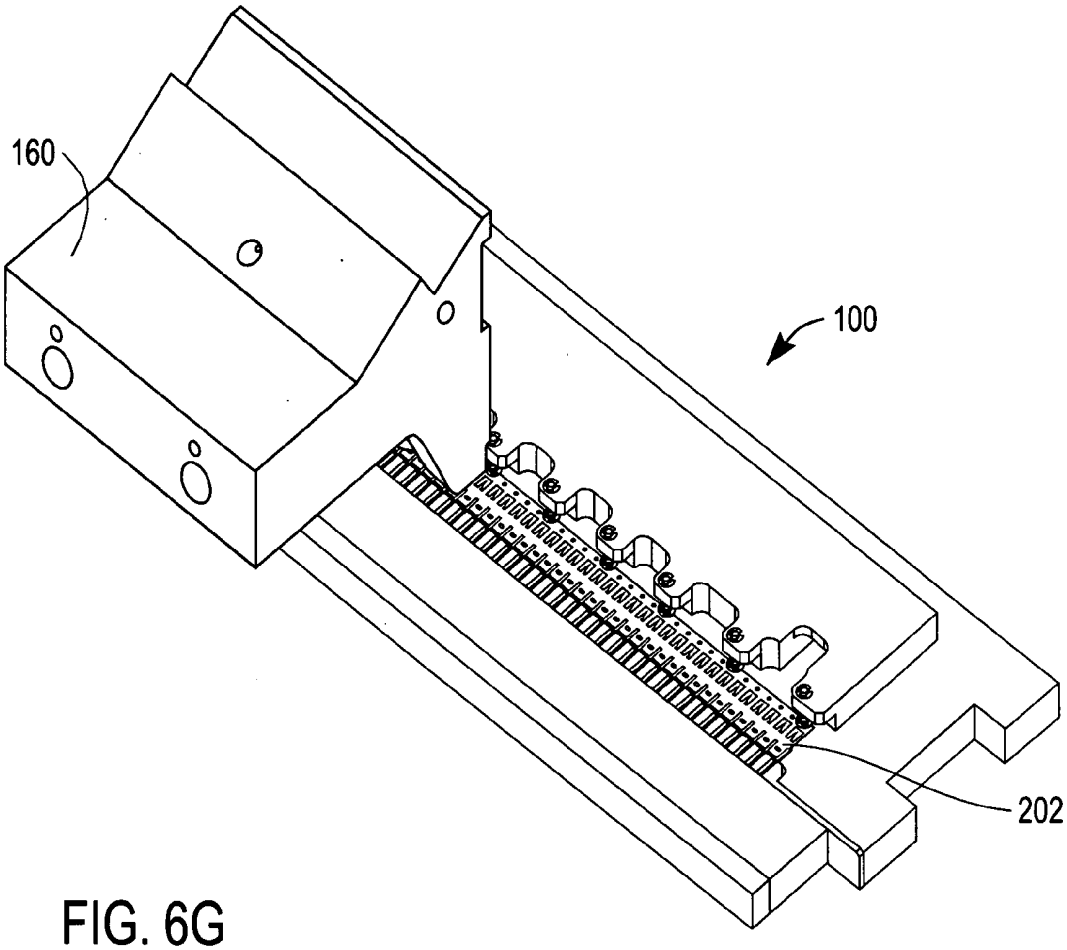

FIG. 6G

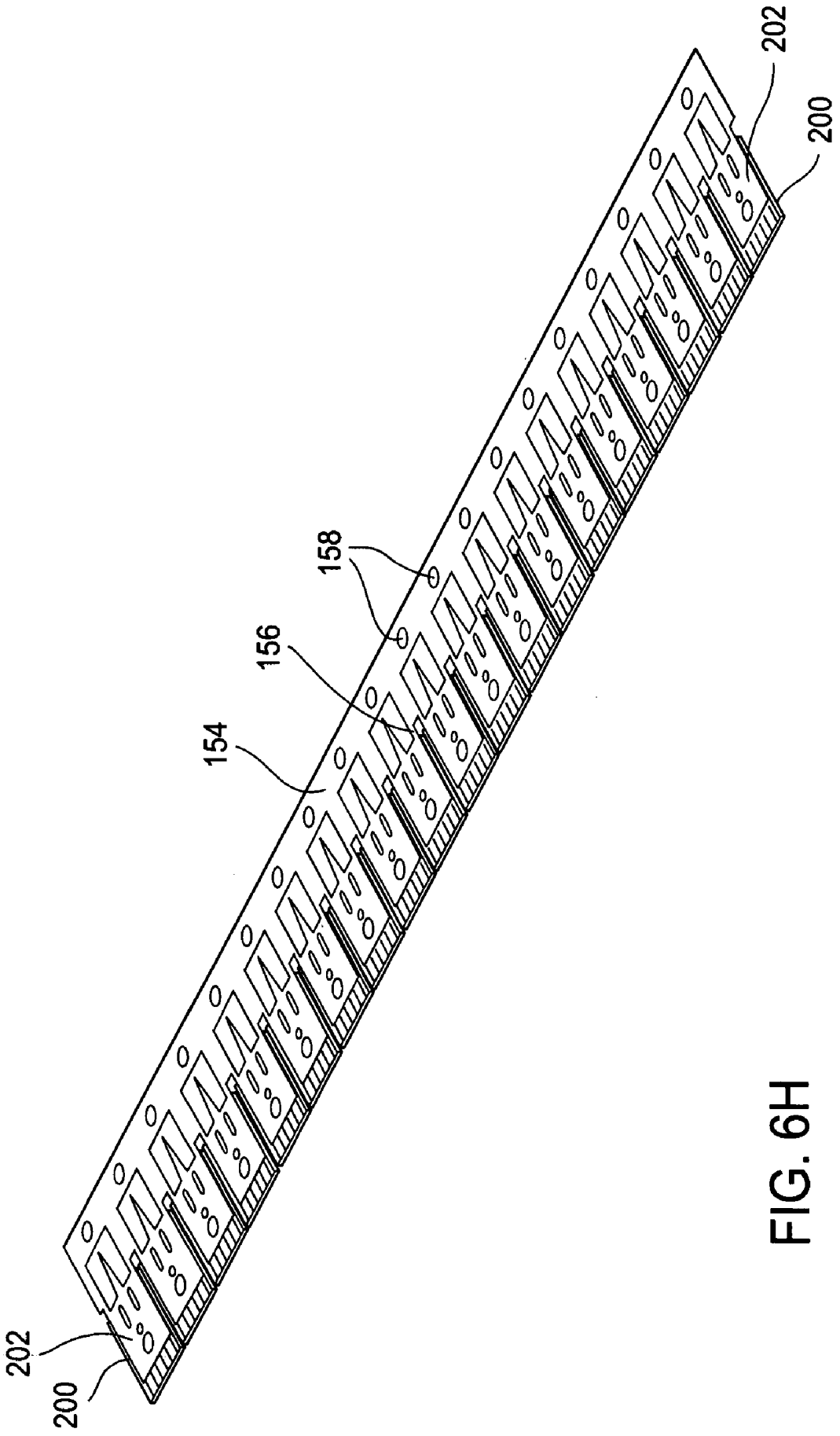

FIG. 6H

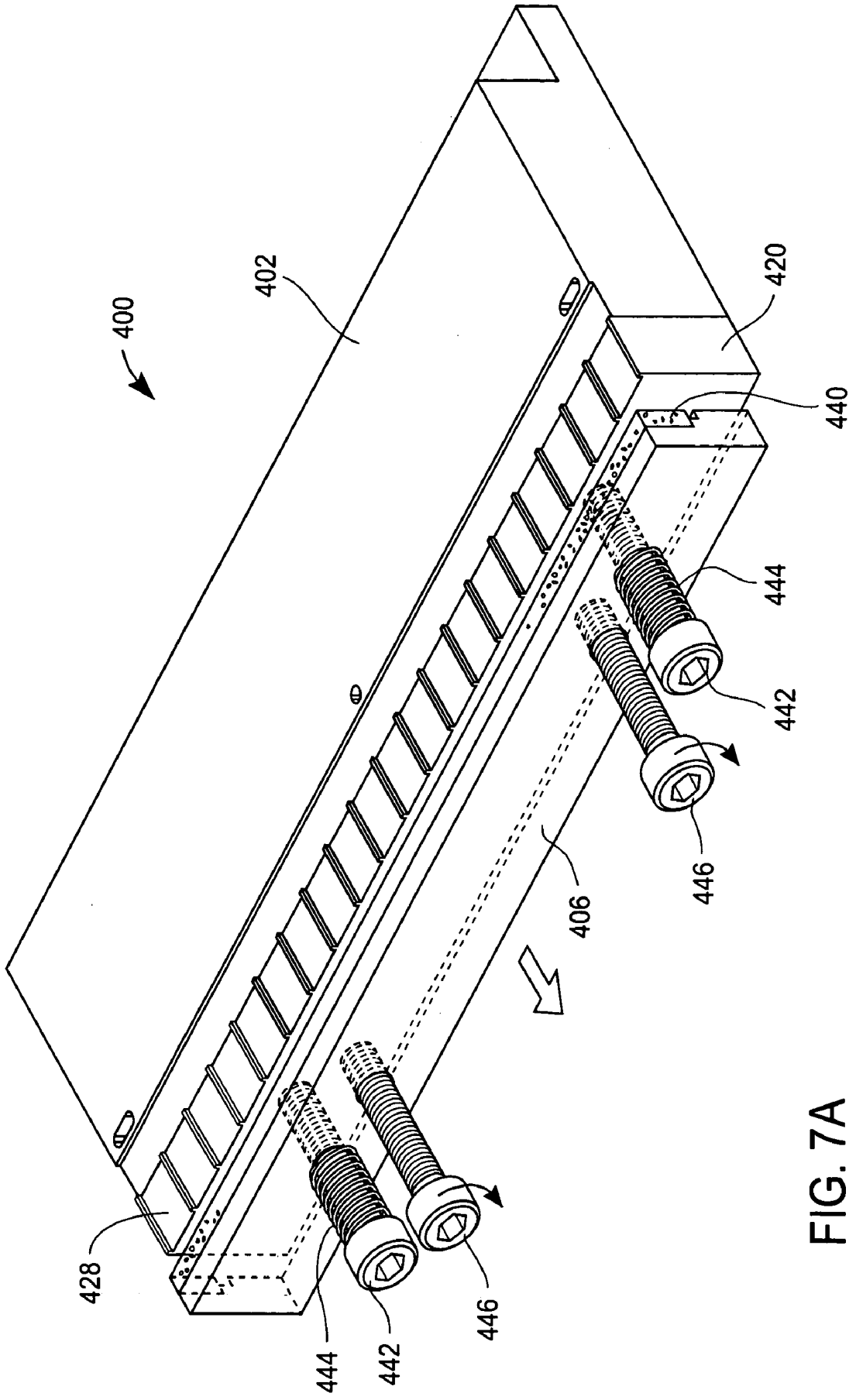

FIG. 7A

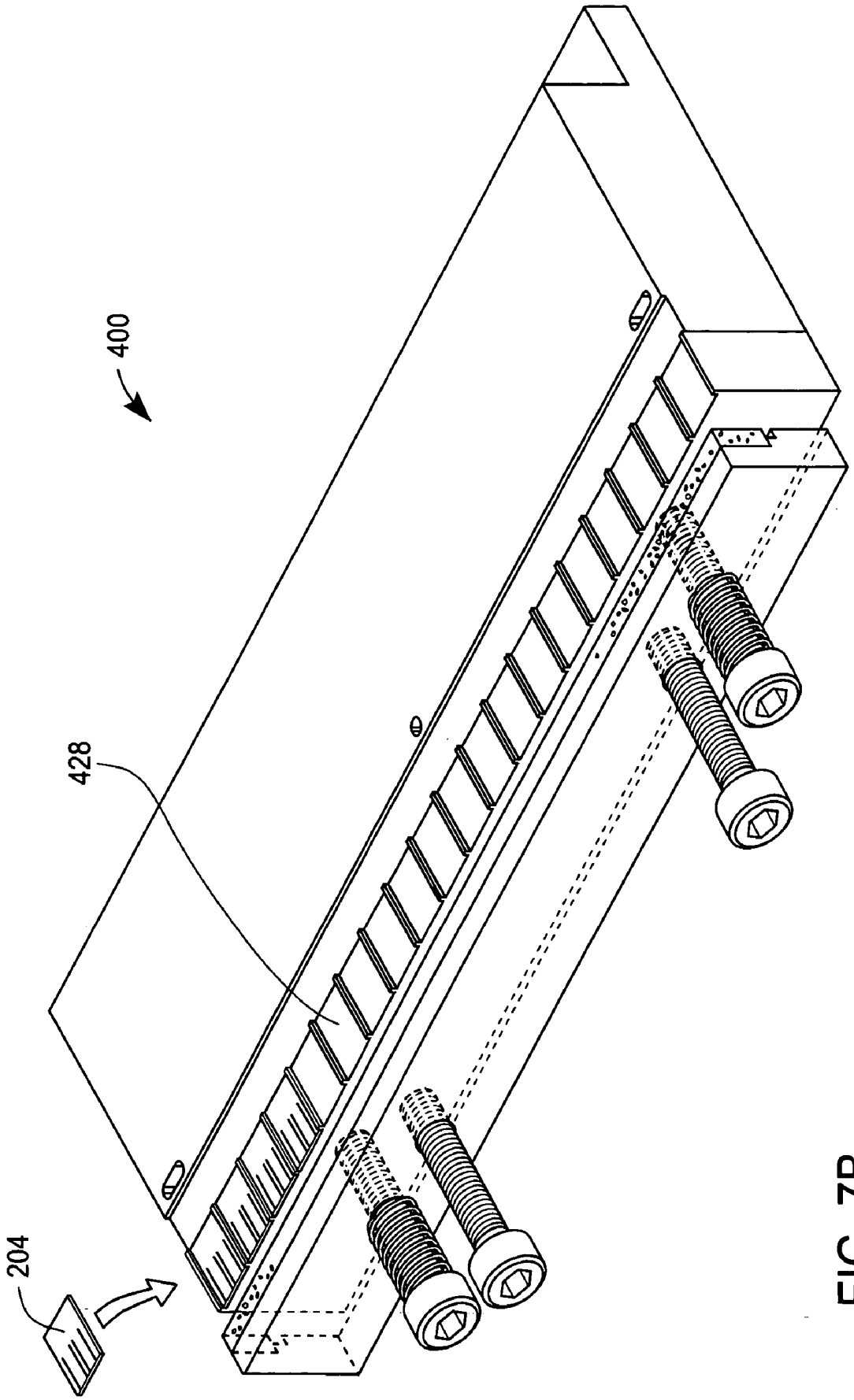

FIG. 7B

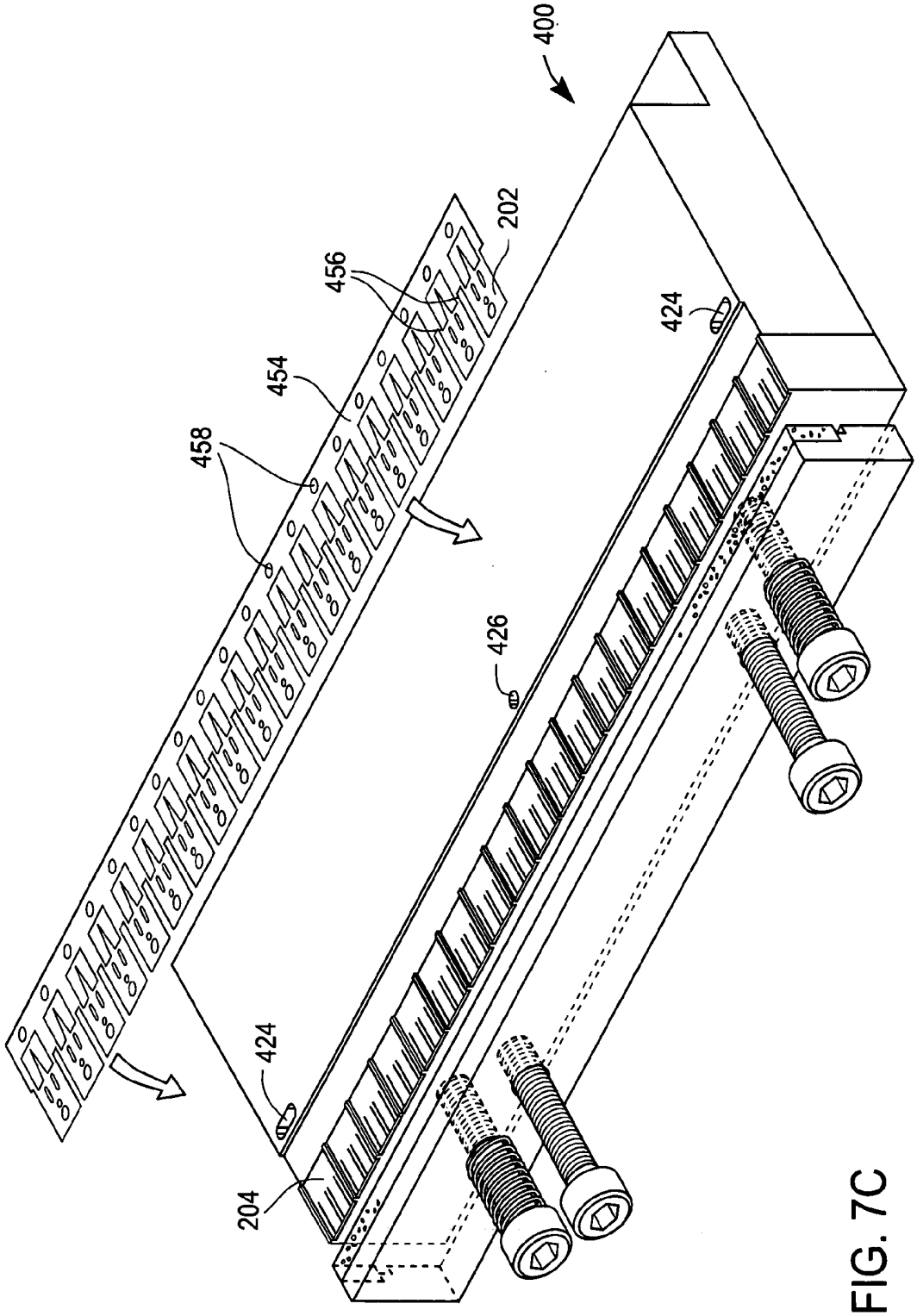

FIG. 7C

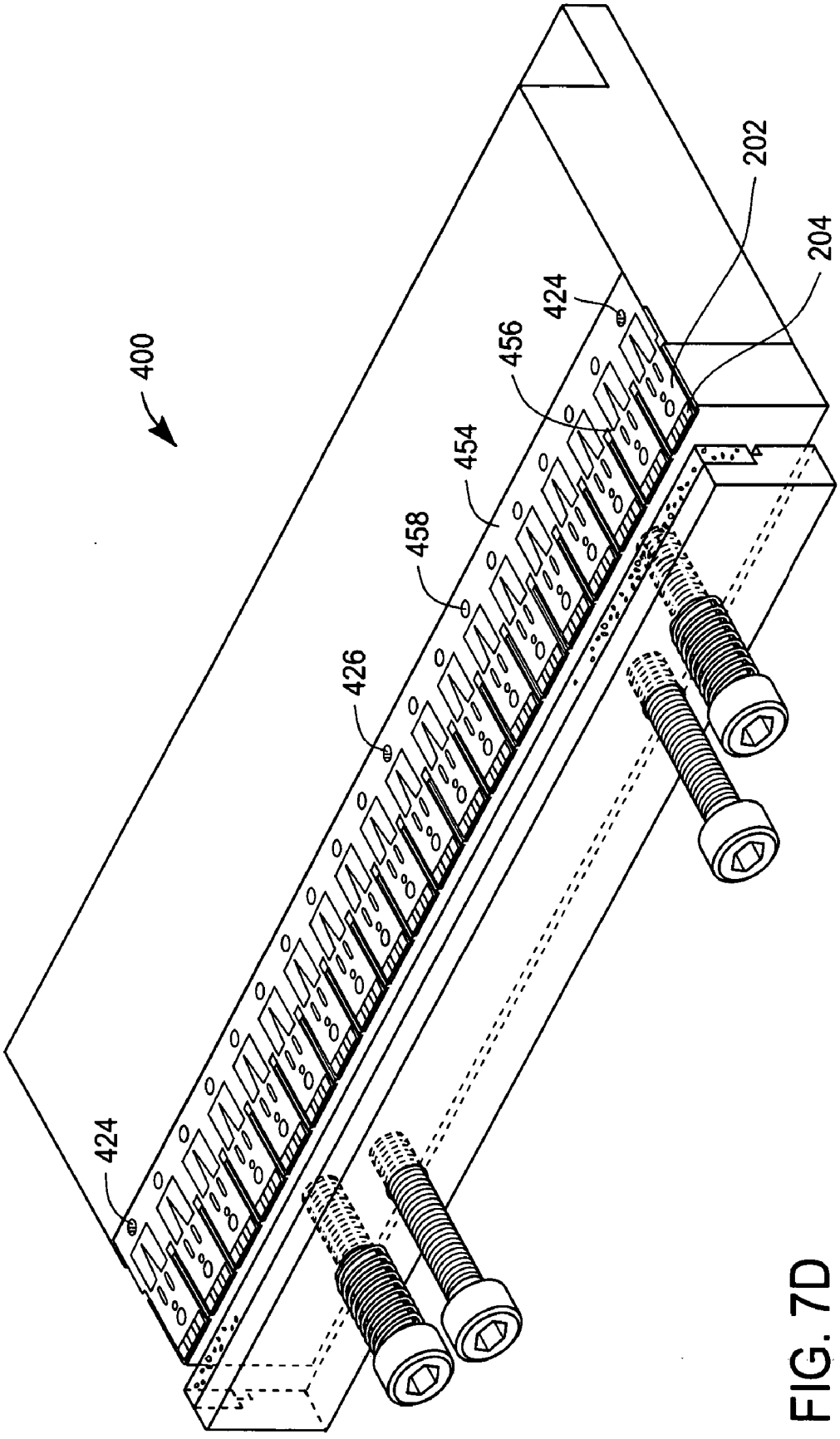

FIG. 7D

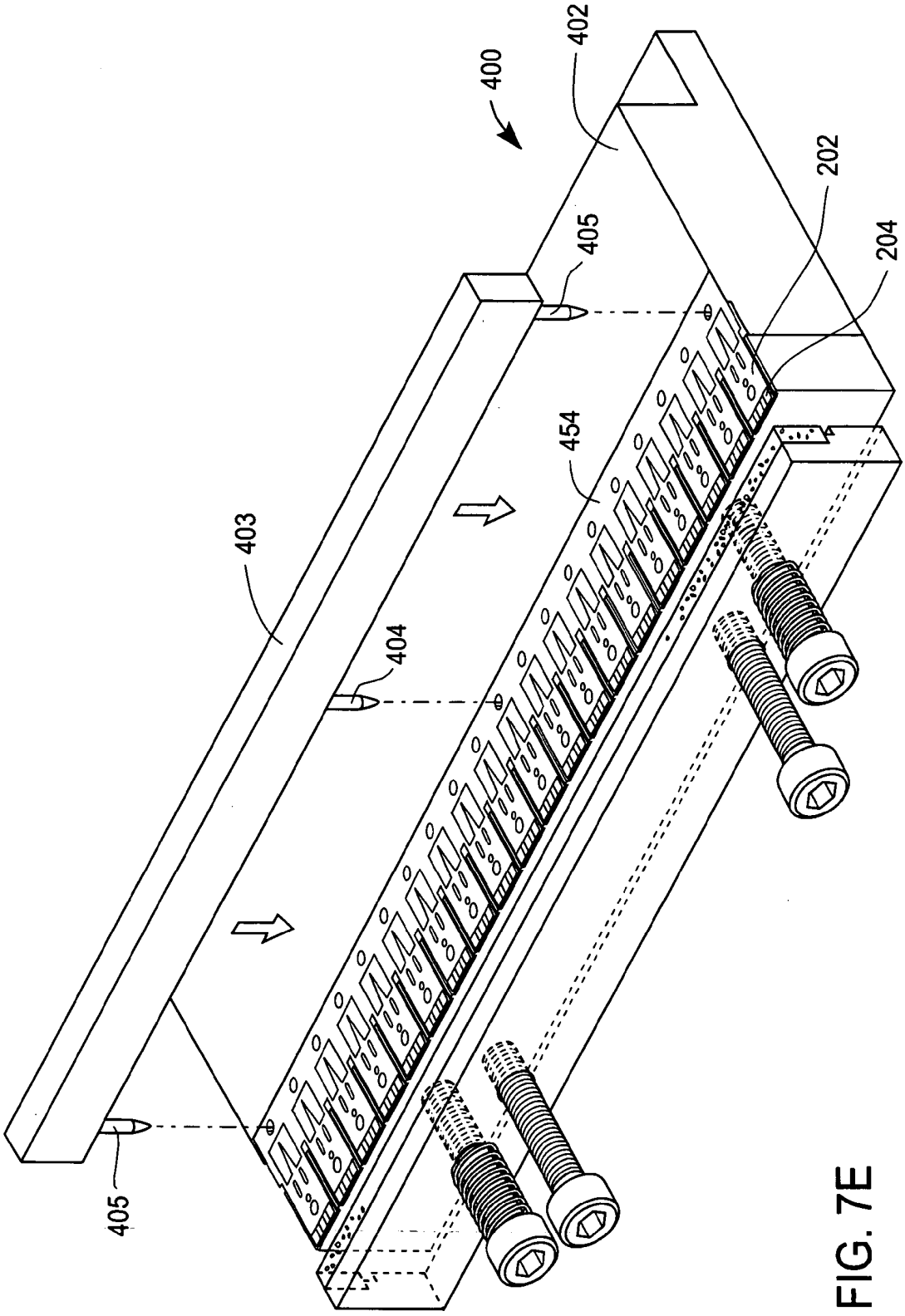

FIG. 7E

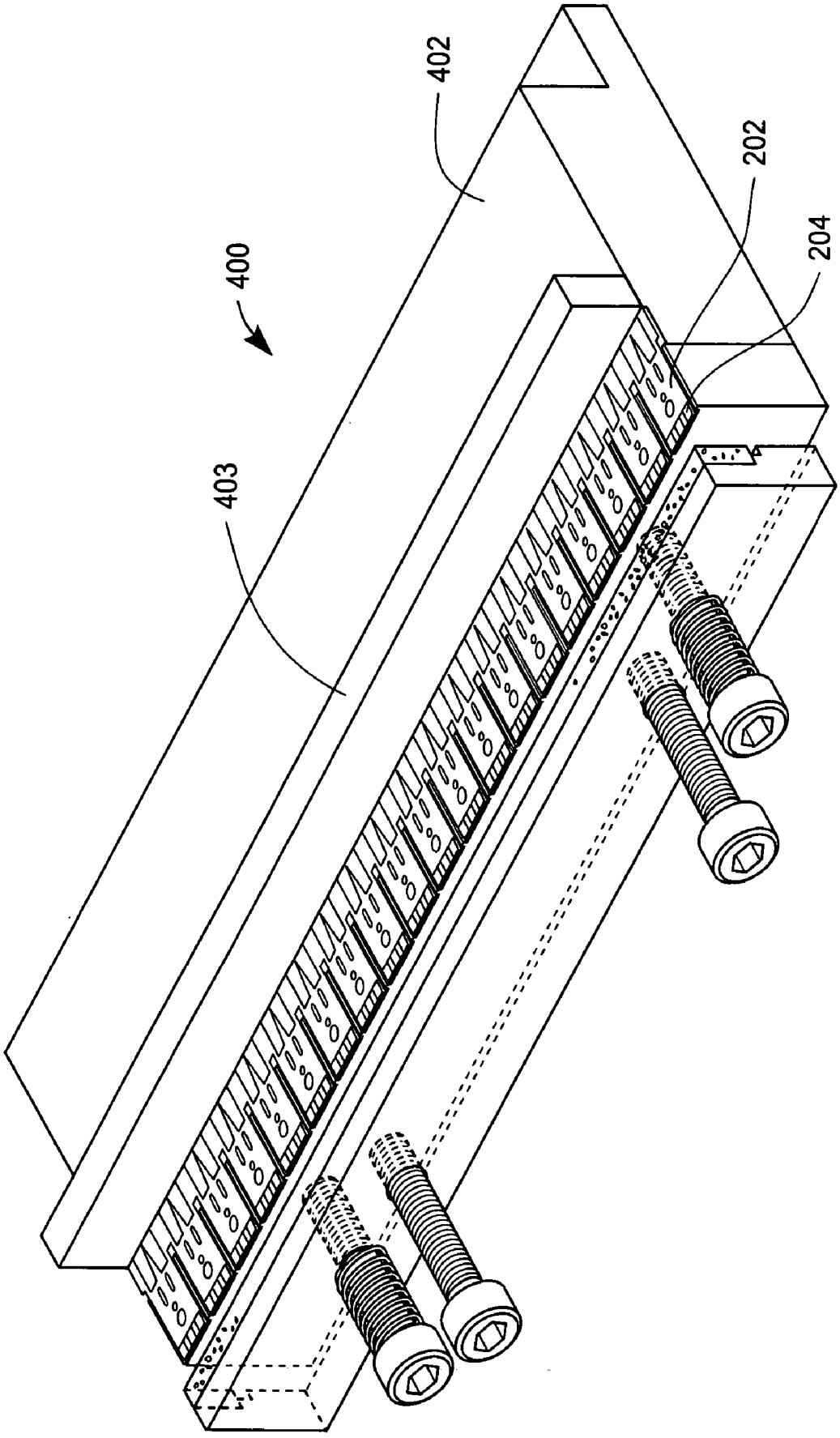

FIG. 7F

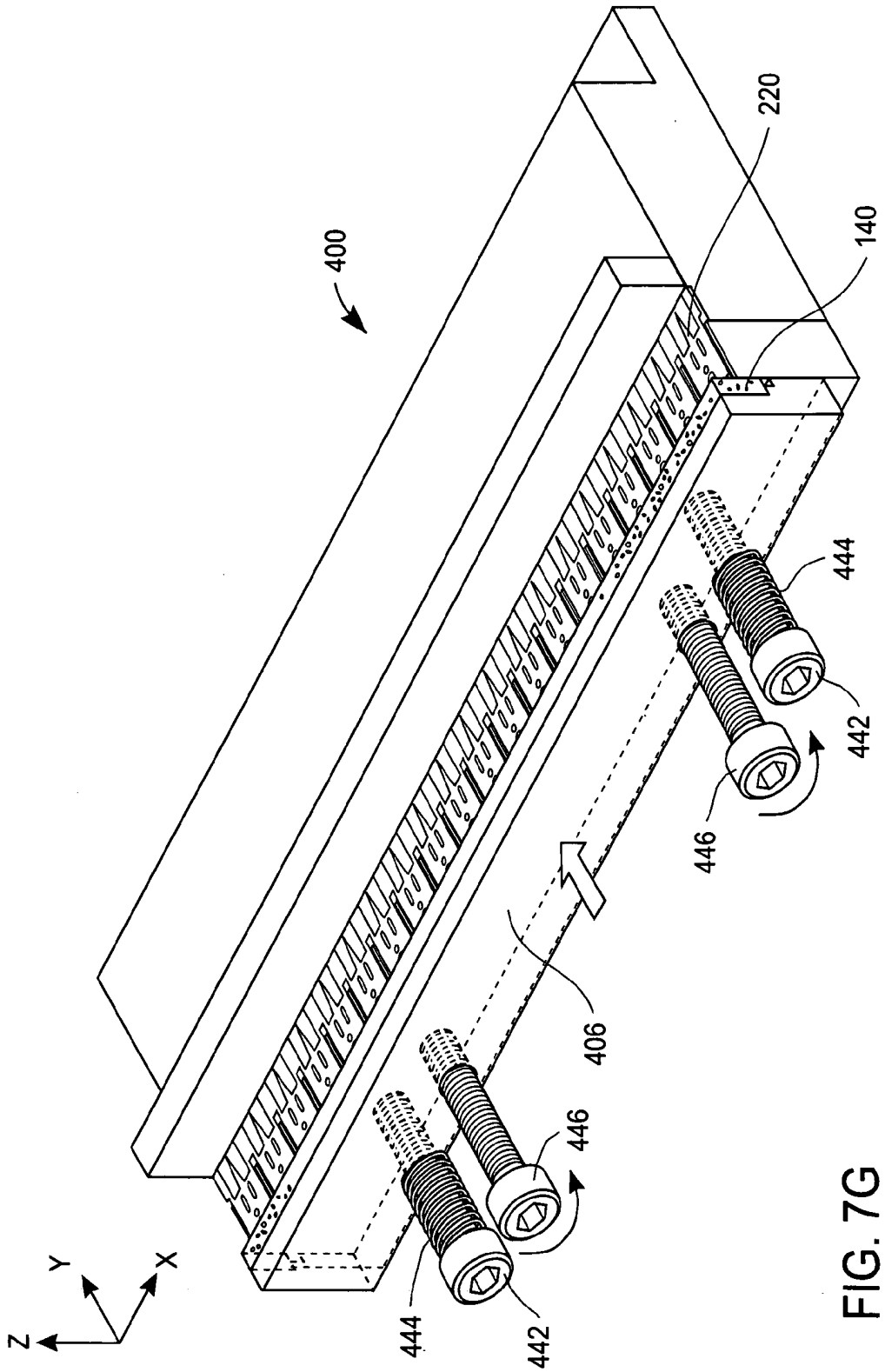

FIG. 7G

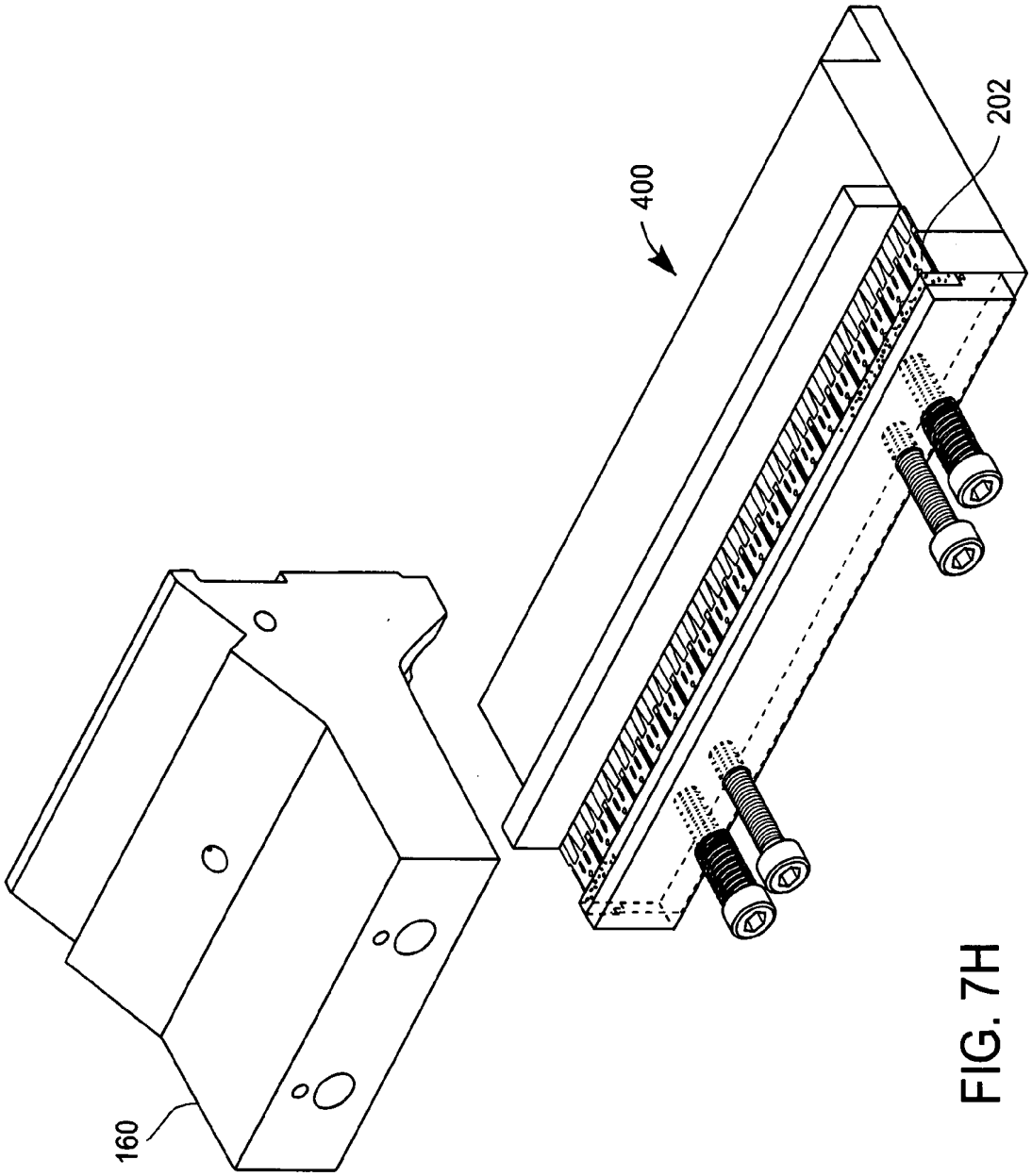

FIG. 7H

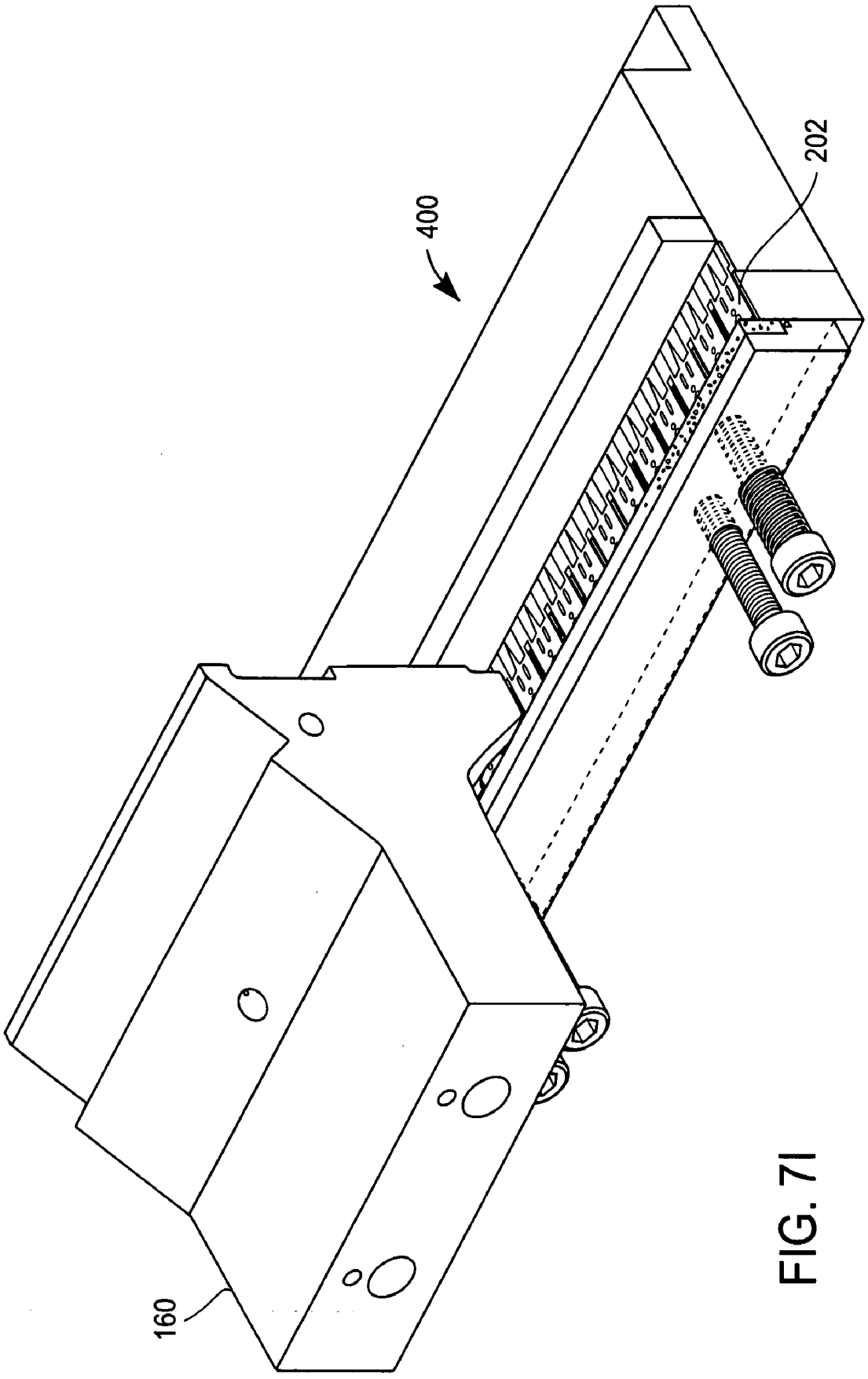

FIG. 7I

APPARATUS FOR THE MANUFACTURE OF MEDICAL DEVICES

BACKGROUND OF THE INVENTION

[0001] The present invention relates, in general, to medical devices containing an integrated lancet and sensor and, more particularly, to an assembly apparatus for use in manufacturing such medical devices.

[0002] The determination of analyte concentration in physiological samples is of ever increasing importance to today's society. Such assays find use in a variety of applications, including clinical laboratory testing, home testing, etc., where the results of such testing play a prominent role in the diagnosis and management of a variety of disease conditions. Analytes of interest include glucose for diabetes management, cholesterol for monitoring cardiovascular conditions, drugs for monitoring levels of therapeutic agents, and identifying illegal levels of drugs, and the like. In response to this growing importance of analyte concentration determination, a variety of analyte concentration determination protocols and devices for both clinical and home testing have been developed.

[0003] In determining the concentration of an analyte in a physiological sample, a physiological sample must first be obtained. Obtaining and testing the sample often involves cumbersome and complicated procedures. Unfortunately, successful manipulation and handling of test elements, such as test strips, lancing members, meters and the like is, to a great extent, dependent on the visual acuity and manual dexterity of the user, which in the case of people with diabetes is subject to deterioration over the course of the disease state. In extreme cases people that have significant loss of sight and sensation, testing procedures can become significantly difficult and require additional assistance from ancillary devices or personnel.

[0004] A typical procedure for making a glucose measurement with the use of a test strip involves the following actions or steps (but not necessarily in the order given): (1) removing supplies from a carrying case, (2) removing a lancing device loading cap or door, (3) removing and disposing of a used lancet from the lancing device, (4) inserting the lancet in the lancing device, (5) twisting off a protective cap from the lancet, (6) replacing the lancing device cap, (7) cocking the lancing device, (8) opening a test strip vial/container, (9) removing a strip from the container and inserting or interfacing it with a meter, (10) holding a lancing device to the skin, (11) firing the lancing device, (12) removing the lancing device from the skin, (13) extracting a sample, (14) applying sample to the test strip and obtaining results of the measurement; (15) disposing of the test strip, (16) cleaning the test site, and (17) returning supplies to the carrying case. Of course, certain glucose measurement systems and protocols may involve fewer or more steps.

[0005] One manner of reducing the number of actions is by the use of integrated medical devices that combine multiple functions in order to minimize the handling of sensor and/or lancing components that may lead to contamination of the components and/or injury to the user. An example of such an integrated medical device that includes a test strip and lancet is described in International Application No. PCT/GB01/05634 (published as WO 02/49507 on Jun. 27, 2002) and U.S. patent application Ser. No. 10/143,399, both of which are fully incorporated herein by reference.

[0006] Technological advancements have been made in test strip fabrication in which both sensor and lancing functions and the structures to provide such functions are provided on a single fully integrated medical device, as described in the aforementioned U.S. patent application Ser. No. 10/143,399. Integrated medical devices are typically in the form of strips. Web-based methods can be used to make such fully integrated medical devices. In these methods, the integrated medical devices are singulated after fabrication prior to being collectively packaged in a cartridge, magazine, cassette or the like. Examples of web-based methods for making such medical devices are disclosed in U.S. patent application Ser. No. 10/142,409 and European Patent Application EP 1360932 A1, both of which are fully incorporated herein by reference. These web-based methods, however, require expensive equipment that requires substantial manufacturing floor space. In web-based methods, the alignment of the sensor and lance can also change during the manufacturing process.

[0007] Still needed in the field, therefore, is an inexpensive and simple method of fabricating an integrated medical device containing a lancet and a test strip. This method should also produce integrated medical devices in which the sensor and lance are precisely aligned.

SUMMARY OF THE INVENTION

[0008] In one embodiment of the present invention, an integrated medical device assembly apparatus includes: a body with a proximal end, a distal end, a detachable clamping bar and a pusher plate. In this embodiment of the invention the proximal end of the assembly apparatus includes a plurality of recesses for receiving and removably retaining a plurality of test strips. In an integrated medical device assembly according to the present invention the pusher plate may include a plurality of spring-loaded protrusions for contacting the plurality of test strips retained within the recesses. In an integrated medical device assembly apparatus according to the present invention, the pusher plate may include a resiliently deformable band adapted to force the plurality of test strips retained into the recesses. In an integrated medical device assembly apparatus according to the present invention, the clamping bar includes at least one pin for attaching to the body.

[0009] In one embodiment of the present invention an integrated medical device for use in detecting the presence of analytes in blood includes a test strip manufactured using a web process: a first heat activated bonding layer positioned over the first test strip substrate and a tissue penetration member bonded to the test strip by heating the bonding layer. In this embodiment of the present invention, the tissue penetrating member is affixed to the test strip by positioning the test strip and bonding layer in a recessed cavity, placing the tissue penetration member over the bonding layer, clamping the tissue penetration member in place using a clamping bar, forcing the test strip into the recess using a pusher plate and heating the test strip, bonding layer and penetration member to a predetermined temperature. In an integrated medical device according to one embodiment of the present invention the predetermined temperature is

between 95° C. and 150° C. In an integrated medical device according to one embodiment of the present invention the tissue penetration member includes a lancet. In an integrated medical device according to one embodiment of the present invention, a notch in the distal end of the heat activated bonding layer, a first side of the test strip and a first side of the tissue penetration member form a chamber positioned to receive fluid from the lancet.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings (wherein like numerals represent like elements), of which:

[0011] **FIG. 1** is a partially exploded perspective view of an integrated medical device assembly apparatus according to an embodiment of the present invention;

[0012] **FIGS. 2A and 2B** are perspective and side views, respectively, of a medical device that can be used with exemplary embodiments of the assembly apparatus according to the present invention; and

[0013] **FIGS. 3A and 3B** are cross-sectional side views of a portion of the medical device assembly apparatus of **FIG. 1B** along A-A' in the direction of the arrows, representing exemplary embodiments of assembly apparatus recesses.

[0014] **FIGS. 4A and 4B** are perspective and exploded perspective views, respectively, of an integrated medical device assembly apparatus according to an exemplary embodiment of the present invention;

[0015] **FIG. 5** is a flow chart illustrating a sequence of steps in a process for manufacturing an integrated medical device using the assembly apparatuses according to exemplary embodiments of the present invention;

[0016] **FIGS. 6A-6H** are schematic, perspective views depicting stages of a process for manufacturing medical devices according to the present invention; and

[0017] **FIGS. 7A-7I** are schematic, perspective views depicting stages of a process for manufacturing medical devices according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] **FIG. 1** is an exploded perspective view of a medical device assembly apparatus **100** according to an exemplary embodiment of the present invention. Assembly apparatus **100** includes a body **102**, a detachable clamping bar **103** with a plurality of locating pins **104**, and a detachable test strip pusher plate **106** with a plurality of spring-loaded protrusions **107**. Assembly apparatus **100** is generally rectangular in shape and can be formed of metal or any material that can withstand a temperature ranging from about 95° C. to 150° C.

[0019] **FIGS. 2A and 2B** are perspective and side views, respectively, of an exemplary integrated medical device **200** that can be manufactured using assembly apparatus **100** according to one aspect of the present invention. Integrated medical device **200** includes a test strip **204** and a dermal tissue penetration member **202**. Test strip **204** has a reaction area **205** and electrical contacts **206** that terminate on a proximal end **210** of integrated medical device **200**. Electrical contacts **206** are made of any suitable conductive material, such as gold, silver, platinum or carbon. Dermal tissue penetration member **202** includes a lancet **220** adapted to pierce a user's skin and draw blood into reaction area **205**. Dermal tissue penetration member **202** is adhered to test strip **204** by an adhesive layer **214**. This adhesive layer **214** can be heat seal or pressure sensitive adhesive. Lancet **220** includes a lancet base **222** that terminates at the distal end **212** of the assembled test strip. Further descriptions of integrated medical devices that can be manufactured using assembly apparatus **100** according to the present invention are in the aforementioned International Application No. PCT/GB01/05634 and U.S. patent application Ser. No. 10/143,399. In addition, dermal tissue penetration member **202** can be fabricated, for example, by a progressive die-stamping technique, as disclosed in the aforementioned International Application No. PCT/GB01/05634 and U.S. patent application Ser. No. 10/143,399.

[0020] Referring again to **FIG. 1**, body **102** of assembly apparatus **100** includes a first side **108**, a second side **110**, a first end **112**, a second end **114**, an upper surface **116** and a lower surface **118**. First side **108** includes a plurality of protrusion guides **119** which may be, for example, hollow, tubular-shaped for the plurality of protrusions **107** to move through. The function of protrusions **107** is to move through protrusion guides **119** thereby pushing strips positioned in recess **120** into alignment with dermal tissue penetration members **202** during the manufacturing process, as will be described in more detail below (see **FIGS. 5 and 6**E). The cross section of protrusion guides **119** are shaped to accommodate the cross-sectional shape of protrusions **107**.

[0021] Adjacent to protrusion guides **119** is a plurality of recesses **120** and groove **122** which may be, for example, elongate in shape, on upper surface **116** running from first end **112** to second end **114** (i.e., in the X direction of **FIG. 1**) substantially parallel to first side **108**. Adjacent to groove **122** are a plurality of locating pin receiving holes **126**. The function of locating pin receiving holes **126** is to align and secure clamping bar **103** through locating pins **104** to body upper surface **116**, as will be described in more detail below (see **FIGS. 5, 6C** and 6D).

[0022] Recesses **120** each contain at least one recess wall **129** approximately perpendicular to groove **122** (i.e., in the Y direction, see **FIG. 1**). Recess **120** is configured (e.g., sized, shaped and/or orientated) to receive and to removably retain a test strip **204** (illustrated in **FIGS. 2A and 2B** as part of integrated medical device **200**) at least partially therein. The number of recesses **120** can range from 10 to 100 or more and more usually ranges from 20 to 50. The width of recess **120** (i.e., in the X direction) is marginally larger (e.g., about 1-3%) than the width of test strip **204** such that test strip **204** fits snugly therein. This snug fit beneficially minimizes side-to-side movement of the strip during the integrated medical device assembly process (see **FIG. 5**) such that alignment between test strip **204** and dermal tissue penetration member **202** in the X direction is maintained.

[0023] Recesses **120** can be formed by processes known to those skilled in the art including, but not limited to, spark erosion and electrical discharge machining (EDM). Types of

EDM include, for example, wire, sinker and small hole EDM. Cross-sectional side views of recess **120** are shown in **FIGS. 3A and 3B**. Recess **120** includes at least one corner **130** which, in the embodiment of **FIG. 3A** is a rounded inner corner bounded by recess wall **129** and a recess base surface **131**. An exemplary embodiment of recess **120** is shown in cross-section in **FIG. 3A**. In this embodiment, test strip **204** within recess **120** contacts a region on corner **130** but does not contact recess base surface **131**. In other words, test strip **204** is held remote from recess base surface **131** by corner **130** which may be, for example, a rounded inner corner. **FIG. 3B** illustrates another exemplary embodiment of recess **120** in which corners **130** are wire eroded to form a depression of approximate semi-circular cross section bounded by recess wall **129** and recess base surface **131** to allow test strip **204** to lie flat within recess **120**. This beneficially allows close contact of test strip **204** with recess base surface **131**, ensuring complete and even adhesion between test strip **204** and dermal tissue penetration member **202** during the heat seal step in process **500** (see **FIGS. 5, 6F** and 6G).

[**0024**] **FIGS. 4A and 4B** are perspective and exploded perspective views, respectively, of a medical device assembly apparatus **400** according to another exemplary embodiment of the present invention. Assembly apparatus **400** includes a body **402**, a detachable clamping bar **403** with a central locating pin **404**, two outer locating pins **405** and a detachable spring-loaded test strip pusher plate **406**. Assembly apparatus **400** is generally rectangular in shape and can be formed of metal or any material that can withstand a temperature ranging from about 95° C. to 150° C.

[**0025**] Assembly apparatus body **402** includes a first side **408**, a second side **410**, a first end **412**, a second end **414**, an upper surface **416** and a lower surface **418**. Second side **410** can include a stepped shape for securing assembly apparatus **400** in a heat-sealing apparatus prior to the integrated medical device assembly process. Adjacent to first side **408** is an elongate recess-containing member **420** and an elongate groove **422** on upper surface **416** running from first end **412** to second end **414** (i.e., in the X direction, see **FIGS. 4A and 4B**) substantially parallel to recess-containing member **420**. Adjacent to groove **422** are outer locating pin slots **424** near to each of first and second ends **412** and **414**. Also adjacent to groove **422** in substantially the center of body **402** is a central locating pin receiving hole **426**. The function of outer locating pin slots **424** and central locating pin receiving hole **426** is to align and secure clamping bar **403** through central locating pin **404** and outer locating pins **405** to body upper surface **416**, as will be described in more detail below (see **FIGS. 5, 7E** and 7F).

[**0026**] Recess-containing member **420** includes a plurality of recesses **428** each containing at least one recess wall **429** approximately perpendicular to groove **422** (i.e., in the Y direction, see **FIGS. 4A and 4B**). Recess **428** is configured (e.g., sized, shaped and/or orientated) to receive and to removably retain a test strip **204** (illustrated in **FIGS. 2A and 2B** as part of integrated medical device **200**) at least partially therein. The number of recesses **428** can range from 10 to 100 and more and usually ranges from 20 to 50. The width of recess **428** (i.e., in the X direction) is marginally larger (e.g., about 1-3%) than the width of test strip **204** such that test strip **204** fits snugly therein. This snug fit beneficially minimizes side-to-side movement of the strip during the integrated medical device assembly process (see **FIG. 5**) such that alignment between test strip **204** and dermal tissue penetration member **202** in the X direction is maintained.

[**0027**] Recess-containing member **420** is securely attached to body **402** by means or processes known to those skilled in the art including, for example, bolting, dowelling and welding. Recess-containing member **420** is fabricated separately from body **402** so that recesses **428** can be formed by processes known to those skilled in the art including, but not limited to, spark erosion and electrical discharge machining (EDM). Types of EDM include, for example, wire, sinker and small hole EDM. The exemplary embodiments of recess **428** shown in **FIGS. 3A and 3B** can also be used in assembly apparatus **400**.

[**0028**] Referring again to **FIGS. 4A and 4B**, pusher plate **406** includes a plate proximal side **432** facing recess-containing member **420**, a plate distal side **434**, a first end **436** and a second end **438**. Plate proximal side **432** includes a resiliently deformable band **440** along the entire length of plate **406** from first end **436** to second end **438** and extending to approximately half the height and width of pusher plate **406**. Deformable band **440** contacts test strips **204** as pusher plate **406** is urged against recess-containing member **420**, as will be described below (see **FIGS. 5 and** 7G).

[**0029**] Deformable band **440** can be formed of any resiliently deformable material known to those skilled in the art including, but not limited to, Styrofoam materials, elastomeric materials, silicone materials, latex materials, polymeric materials, polyurethane materials and any combination thereof. Deformable band **440** is detachably adhered to pusher plate **406** with semi-permanent adhesive to allow for removal when deformable band **440** is no longer functional, is soiled or is damaged. Any suitable adhesive known to those skilled in the art can be employed for this purpose including, but not limited to, pressure sensitive adhesives, cold-seal adhesives, heat-seal adhesives and releasable adhesives available from, for example, 3M, Basic Adhesives and Avery Dennison.

[**0030**] Referring to **FIG. 4B**, pusher plate **406** further includes at least one outer screw **442** with a spring **444** in surrounding relation to outer screw threads **445** and at least one inner screw **446**. A non-threaded outer screw plate hole **450** allows movement of pusher plate **406** relative to outer screw **442**. Outer screw **442** is anchored in recess-containing member **420** through an outer screw threaded body hole **452** that is aligned with non-threaded outer screw plate hole **450**. Inner screws **446** can move through the width of pusher plate **406** by threaded inner through screw hole **448**. Outer screw(s) **442** and inner screw(s) **446** are positioned inward from first end **436** and second end **438** approximately one quarter and one third of the length, respectively, of pusher plate **406** running in the X direction. Outer screw **442** and inner screw **446** are also positioned in pusher plate **406** below deformable band **440** such that movement of pusher plate **406** with respect to recess-containing member **420** on outer screw **442** and inner screw **446** is not impeded by deformable band **440**. Outer screw threaded body holes **452** are also included in recess-containing member **420** for receiving outer screws **442**. Outer screws **442** are screwed into recess-containing member **420** through outer screw threaded body holes **452** to a depth sufficient to allow movement of plate pusher **406** away from recess-containing

member **420** and to allow compression of springs **444**. Inner screws **446** can touch but do not penetrate recess-containing member **420**.

[**0031**] **FIG. 5** is a flow chart illustrating a sequence of steps in a process **500** for manufacturing a plurality of integrated medical devices according to an exemplary embodiment of the present invention. Process **500** is described below utilizing **FIGS. 6A-6I** and 7A-7I (schematic, perspective views depicting various stages of process **500**). Process **500** will first be described utilizing assembly apparatus **100** shown in **FIGS. 6A-6I** and then will be described utilizing assembly apparatus **400** shown in **FIGS. 7A-7I**.

[**0032**] Process **500** includes first providing an assembly apparatus **100**, as set forth in step **510** of **FIG. 5** (see **FIG. 1**). The provided assembly apparatus **100** includes a body **102**, a clamping bar **103** with a plurality of locating pins **104**, and a pusher plate **106** with a plurality of protrusions **107** which may be, for example spring-loaded. Body **102** further includes a first side with a plurality of protrusion guides **119** for the protrusions **107** to move therethrough. Adjacent to protrusion guides **119** is a plurality of recesses **120** configured to receive and to removably retain test strips **204** at least partially therein.

[**0033**] Next, as set forth in step **520**, a previously fabricated test strip **204** with an exposed upper heat seal adhesive layer is placed in each recess **120** in assembly apparatus **100** (see **FIG. 6A**). Test strips **204** used in this process can be manufactured, for example, by web processes as disclosed in U.S. patent application Ser. Nos. 10/143,399 and 10/142,409 or by screen printing processes as disclosed in International Application No. PCT/GB03/04656 (published as WO 04/040287 on May 13, 2004).

[**0034**] As set forth in step **530**, a set of 10 to 50 dermal tissue penetration members **202** attached to a common bandolier **154** through tabs **156** is next placed on top of test strips **204** in assembly apparatus **100** such that at least one bandolier hole **158** is aligned with at least one locating pin receiving hole **126** (see **FIGS. 6B-6C**).

[**0035**] Subsequently, clamping bar **103** is attached to body upper surface **116** by placing locating pins **104** through bandolier holes **158** and locating pin receiving holes **126**, thereby securing bandolier **154** (see **FIGS. 6D**), as set forth in step **540**. Locating pins **104** beneficially securely hold bandolier **154** in place to ensure that there is minimal movement of dermal tissue penetration members **202** in the X, Y and Z directions during step **560** (see below).

[**0036**] As set forth in step **550**, pusher plate **106** is urged toward body **102**, causing test strips **204** to be pushed toward body **102** in the Y direction by protrusions **107** (not shown). Protrusions **107** continue to push test strips **204** until the reaction areas on test strips **204** are aligned with a lancet base **222** (see **FIG. 6E**; strips and lancet base not shown). Movement of protrusions **107** in the Y direction is optionally guided by protrusion guides **119**. Protrusions **107** are spring loaded to accommodate variations in test strip length while ensuring that the strips are fully pushed against lancet base **222**.

[**0037**] Next, assembly apparatus **100** is placed in a heat sealing apparatus and dermal tissue penetration members **202** are adhered to test strips **204** by a heat sealer **160**, as set forth in step **560** (see **FIGS. 6F-6G**). Any heat sealer known to those skilled in the art can be used in this step. Heat sealer **160** seals 2 to 20 medical devices at a time and more usually seals 5 to 10 at one time. Typical temperature, pressure and dwell times (i.e., time that the heat sealer contacts the dermal tissue penetration member) for heat sealer **160** range from 95-150° C., 15-40 N per lancet, and 1-5 seconds, respectively. The assembled integrated medical devices **200** attached to bandolier **154** (see **FIG. 6H**) are then removed from assembly apparatus **100** for further processing, i.e. for singulation by cutting through tabs **156** that connect dermal tissue penetration member **202** to the bandolier **154**.

[**0038**] When assembly apparatus **400** is used in process **500**, process **500** includes first providing an assembly apparatus **400**, as set forth in step **510** of **FIG. 5** (see **FIG. 7A**). The provided assembly apparatus includes a body **402**, a clamping bar **403** with a central locating pin **404** and outer locating pins **405** for attaching clamping bar **403** to body **402**, and a pusher plate **406** which may be, for example spring-loaded. Body **402** includes a recess-containing member **420** containing a plurality of recesses **428** for receiving test strips therein. The pusher plate **406** includes an optional resiliently deformable band **440** for contacting the test strips during the manufacturing process. Pusher plate **406** further includes at least one outer screw **442** with a spring **444** in surrounding relation to outer screw threads **445** and at least one inner screw **446**. Pusher plate **406** can move relative to outer screw **442**. Outer screw **442** is anchored in recess-containing member **420** and remains stationary during process **500**. Inner screw **446** moves through pusher plate though a threaded inner screw hole **448** and touches but does not penetrate recess-containing member **420**. In step **510**, pusher plate **406** has been moved away from recess-containing member **420** by turning inner screws **446** clockwise. This allows placement of test strips **204** into recesses **428** (see step **520**). Turning inner screws clockwise causes inner screws **446** to push against recess-containing member **420**, resulting in movement of pusher plate **406** away from recess-containing member **420** and compression of springs **444**. Pusher plate **406** is now spring-loaded in preparation for assembling integrated medical devices.

[**0039**] Next, as set forth in step **520**, a previously fabricated test strip **204** with an exposed upper heat seal adhesive layer is placed in each recess **428** in assembly apparatus **400** (see **FIG. 7B**).

[**0040**] As set forth in step **530**, a set of 10 to 50 dermal tissue penetration members **202** attached to common bandolier **454** through tabs **456** is next placed on top of test strips **204** in assembly apparatus **400** such that at least one bandolier hole **458** is aligned with central locating pin receiving hole **426** and at least one outer locating pin slot **424** (see **FIGS. 7C-7D**).

[**0041**] Subsequently, clamping bar **403** is attached to body upper surface **416** by placing central locating and outer locating pins **404** and **405** through bandolier holes **458** and outer locating pin slots **424** and central locating pin receiving hole **426**, thereby securing bandolier **454** (see **FIGS. 7E-7F**), as set forth in step **540**. Central locating pin **404** fits securely into body **402** of assembly apparatus **400**, whereas at least one outer locating pin **405** fits into outer locating pin slots **424** in body **402**, allowing outer locating pins **405** to move as needed during the manufacturing process. Central

locating pin **404** beneficially securely holds bandolier **454** in place to ensure that there is minimal movement of dermal tissue penetration members **202** in the X direction during step **560**. The combination of a fixed central locating pin **404** and moveable outer locating pins **405** beneficially improves the alignment tolerance for the dermal tissue penetration members relative to the test strips by allowing the penetration members to move on either side of the central locating pin rather than moving the entire length of the bandolier. This configuration therefore effectively halves the alignment tolerance in the X direction.

[**0042**] As set forth in step **550**, test strips **204** are pushed toward body **402** in the Y direction by pusher plate **406** such that the reaction area on test strips **204** are aligned with lancet base **222** (see **FIG. 7G**; strips and lancet base not shown). Movement of pusher plate **406** in the Y direction is achieved by turning inner screws **446** counter-clockwise to release springs **444**. As pusher plate **406** moves in the Y direction, deformable band **440** contacts test strips **204**, subsequently pushing strips into position. Deformable band **440** beneficially accommodates variations in test strip length while ensuring that the strips are fully pushed against the base of lancet **220**.

[**0043**] Next, assembly apparatus **400** is placed in a heat sealing apparatus and dermal tissue penetration members **202** are adhered to test strips **204** by a heat sealer **160**, as set forth in step **560** (see **FIGS. 7H-7I**). Any heat sealer known to those skilled in the art can be used in this step. Heat sealer **160** seals 2 to 20 medical devices at a time and more usually seals 5 to 10 at one time. Typical temperature, pressure and dwell times (i.e., time that the heat sealer contacts the dermal tissue penetration member) for heat sealer **160** range from 95-150° C., 15-40 N per lancet, and 1-5 seconds, respectively. The assembled integrated medical devices **200** attached to bandolier **154** (see **FIG. 6H**) are then removed from assembly apparatus **400** for further processing, i.e. for singulation by cutting through tabs **156** that connect dermal tissue penetration member **202** to the bandolier **154**.

[**0044**] Each of the steps of process **500** can be performed, for example, either manually by a user or with the aid of a mechanical and/or electrical device.

[**0045**] Once apprised of the present disclosure, one skilled in the art will recognize that a variety of medical devices can be beneficially manufactured according to the present invention. Such medical devices include, but are not limited to, integrated medical devices that include a combination of a test strip and a lancet, examples of which are described in the aforementioned International Application No. PCT/GB01/05634 (published as WO 02/49507 on Jun. 27, 2002) and U.S. patent application Ser. No. 10/143,399, both of which are fully incorporated herein by reference. One skilled in the art will also recognize that such test strips may have, but are not limited to, an electrochemical or photometric configuration. For illustrative purposes only, medical devices in various figures of the present disclosure were depicted as having an electrochemical configuration.

[**0046**] Moreover, those skilled in the art will appreciate that medical devices according to embodiments of the present invention can be adapted for the measurement of, for example, glucose, ketones, glycated albumin, coagulation parameters and cholesterol of a sample.

[**0047**] In addition, one skilled in the art will also recognize that medical devices according to the present invention may be contained within a combined sample collection and metering system designed for in-situ testing. Examples of such systems designed for in-situ testing are disclosed in International Patent Application No. PCT/US01/07169 (published as WO 01/64105 A1 on Sep. 7, 2001) and International Patent Application No. PCT/GB02/03772 (published as WO 03/015627 A1 on Feb. 27, 2003), each of which is fully incorporated herein by reference.

[**0048**] It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

1. An integrated medical device assembly apparatus comprising:

a body including:

a proximal end; and

a distal end;

a detachable clamping bar; and

a pusher plate,

wherein the proximal end includes a plurality of recesses for receiving and removably retaining a plurality of test strips.

2. The integrated medical device assembly apparatus of claim 1, wherein said pusher plate includes a plurality of spring loaded protrusions for contacting said plurality of test strips retained within said recesses.

3. The integrated medical device assembly apparatus of claim 2, wherein said pusher plate includes a resiliently deformable band adapted to force said plurality of test strips retained into the recesses.

4. The integrated medical device assembly apparatus of claim 3, wherein said clamping bar includes at least one pin for attaching to said body.

5. An integrated medical device for use in detecting the presence of analytes in blood, said integrated medical device comprising:

a test strip manufactured using a web process;

a first heat activated bonding layer positioned over said first test strip substrate;

a tissue penetration member affixed to said test strip by positioning said test strip and bonding layer in a recessed cavity, placing said tissue penetration member over said bonding layer, clamping said tissue penetration member in place using a clamping bar, forcing said test strip into said recess using a pusher plate and heating said test strip, bonding layer and penetration member to a predetermined temperature.

6. An integrated medical device according to claim 5 wherein said predetermined temperature is between 95° C. and 150° C.

7. An integrated medical device according to claim 6, wherein said tissue penetration member includes a lancet.

8. An integrated medical device according to claim 7, wherein a notch in the distal end of said heat activated bonding layer, a first side of said test strip and a first side of said tissue penetration member form a chamber positioned to receive fluid from said lancet.

* * * * *

专利名称(译)	用于制造医疗装置的设备		
公开(公告)号	US20060006574A1	公开(公告)日	2006-01-12
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[标]申请(专利权)人(译)	LANG David K制作 JOHN ALLEN JOHNSON JOHN		
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外部链接	Espacenet USPTO		

摘要(译)

生理样品中分析物浓度的测定对当今社会的重要性日益增加。此类测定可用于多种应用，包括临床实验室测试，家庭测试等，其中此类测试的结果在多种疾病状况的诊断和管理中起重要作用。本文描述了一种装置，其可用于制造包括集成刺血针和传感器的医疗装置。