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

(57) **Abstract:** Certain processes for manufacturing an electrochemical sensor module include etching a Silicon wafer to form precursor sensor bodies, disposing sensor fibers along rows of the precursor sensor bodies, securing a rigid layer over the sensor fibers, dividing the wafer, rigid layer, and sensor fibers into individual precursor sensor bodies, and joining each precursor sensor body to a component body to form sensor modules.



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MANUFACTURING ELECTROCHEMICAL SENSOR MODULES

This application is being filed on 18 May 2012, as a PCT International Patent application in the name of Pepex Biomedical, Inc., 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 Application Serial Number 61/488,512 filed May 20, 2011, the subject matter of which is incorporated by reference in its entirety.

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
5 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
10 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 flowchart illustrating an operational flow for a
15 manufacturing process by which multiple sensor modules may be produced;

FIG. 2 is a top, plan view of an example wafer with features of precursor sensor bodies etched into a surface;

FIG. 3 is a top, plan view of the wafer of FIG. 2 with conductive tracings deposited over the etched features;

20 FIG. 4 illustrates one example implementation of a manufacturing station at which the dispense operation of FIG. 1 is implemented;

FIG. 5 is a top, plan view of the wafer of FIG. 3 with sensor fibers disposed across the etched features;

25 FIG. 6 is a top, plan view of an example rigid layer suitable for use with the wafer of FIG. 5;

FIG. 7 shows the rigid layer of FIG. 6 attached to the wafer of FIG. 5;

FIG. 8 illustrates one example implementation of a cutting station at which the separate operation of FIG. 1 is implemented;

FIG. 9 shows cutting paths superimposed over the rigid layer;

30 FIG. 10 shows one example precursor sensor body divided out from the wafer 120;

FIG. 11 is an end view of an example sensor module including the precursor sensor body of FIG. 10 and an example component body; and

FIG. 12 is a cross-sectional view of the sensor module of FIG. 11 taken through the test chamber of the sensor module.

5

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.

10

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.

15

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).

20

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).

25

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

30

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
5 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
10 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
15 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 disclosure 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,
20 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. Certain types of the elongated electrodes includes a composite
conductive monofilament (CCM) electrode. In other embodiments, the housing can
25 contain additional electrodes having differing enzyme coatings. The analysis cell can be configured for coulometric or amperometric assays.

FIG. 1 is a flowchart illustrating an operational flow for a manufacturing process 100 by which multiple sensor modules may be produced. In some implementations, the manufacturing process 100 uses microfabrication
30 technology to produce multiple precursor bodies of sensor modules on a single wafer. For example, in certain implementations, the manufacturing process 100 produces about 900 sensors on a six-inch diameter substrate. In other

implementations, the manufacturing process 100 can produce greater or fewer sensors on larger or smaller substrate.

The manufacturing process 100 begins at a start module 101, performs any appropriate initialization procedures, and proceeds to a fabricate operation 103. The fabricate operation 103 forms features of one or more precursor sensor bodies in a wafer of substrate 120. In accordance with some aspects, the fabricate operation 103 removes material from the wafer, for example, to form wells and/or channels in the substrate. In some implementations, the fabricate operation 103 removes the material through etching. In other implementations, the fabricate operation 103 removes the material using a laser. In accordance with other aspects, the fabricate operation 103 deposits material into the wafer, for example, to form conductive signal paths or other features.

A dispense operation 105 disposes one or more electrodes along the features of the precursor sensor bodies. In some implementations, the dispense operation 105 disposes a single sensor fiber along the features of multiple precursor sensor bodies. In certain implementations, the dispense operation 105 disposes two sensor fibers (e.g., a working electrode and a counter electrode) along the features of multiple precursor sensor bodies. In certain implementations, the dispense operation 105 disposes three sensor fibers (e.g., a working electrode, a counter electrode, and a reference electrode) along the features of multiple precursor sensor bodies.

An attach operation 107 secures a rigid layer to the wafer 120. In certain implementations, the attach operation 107 secures the rigid layer to the wafer 120 using an organic binder. The rigid layer cooperates with the fabricated substrate 120 to define features (e.g. a test chamber) of the precursor sensor bodies. The rigid layer also secures the electrodes in the precursor sensor bodies. In certain implementations, the binder also provides a seal around the electrodes.

A separate operation 109 divides the wafer into segments so that each segment contains the features of a single precursor sensor body. In certain implementations, dicing tape is applied to the wafer to protect the sensor features during the separate operation 109. In some implementations, the separate operation 107 divides the wafer by cutting the wafer using a shear or other blade. In other implementations, the separate operation 109 divides the wafer using a laser. In still

other implementations, the separate operation 109 divides the wafer by scoring and bending the wafer.

A join operation 111 couples the wafer segment to one or more additional components. When joined, the features of the wafer segment and features of the additional components form a complete sensor body. For example, in certain implementations, joining the wafer and the additional components seals an analysis cell of the sensor body. In certain implementations, joining the wafer and the additional components provides capillary channels from the analysis cell to an exterior of the sensor body. In some implementations, the join operation 111 couples the wafer segment to a molded carrier. In other implementations, the join operation 111 couples the wafer segment to a laminated section.

The manufacturing process 100 performs any appropriate completion procedures and ends at a stop module 113.

FIGS. 2-12 illustrate the steps of the manufacturing process 100 as applied to one example implementation. In the example shown, the manufacturing process 100 is used to form six sensor modules 150. Each sensor module 150 includes a precursor sensor body 140 and a component body 151. The precursor sensor body 140 includes a first (e.g., working) electrode 130 and a second (e.g., counter) electrode 131 disposed in holding structures 122, 123 that extend between opposite ends of the sensor body 150. The electrodes 130, 131 also extend through a test chamber 155 configured to hold a blood sample from a patient. Each precursor sensor body 140 also includes electrode contacts 124, 126 that carry signals from the electrodes 130, 131 to a monitoring system coupled to the sensor module 150. The component body 151 defines a capillary port through which a blood sample may enter the test chamber 155. Certain types of component bodies 151 also include skin-piercing members.

FIGS. 2 and 3 show the results of the fabricate operation 103 implemented on an example wafer 120. In the example shown, the wafer 120 has a rectangular shape. In other implementations, however, the wafer 120 may be round, oblong, square, triangular, or any other shape. In some implementations, the wafer 120 is a Silicon wafer. In other implementations, however, the wafer 120 may be formed from any suitable substrate material.

As shown in FIG. 2, the fabricate operation 103 removes material from the wafer 120 to form features of multiple precursor sensor bodies 140. The fabricate operation 103 forms at least a first row of precursor sensor bodies 140 on the substrate 120. Each row includes features from at least one precursor sensor
5 body 140. In certain implementations, each row includes features from multiple precursor sensor bodies 140. In some implementations, the fabricate operation 103 forms multiple rows of precursor sensor body features. In other implementations, the fabricate operation 103 may form precursor sensor body features in the wafer 120 in other configurations or patterns (e.g., rings, matrices, staggered rows, etc.).

10 In some implementations, the fabricate operation 103 removes material to define one or more wells 121. Each well 121 corresponds to one precursor sensor body 140. The well 121 of each precursor sensor body 140 is configured to form part of the test chamber of a respective assembled sensor body 150. In some implementations, the fabricate operation 103 also removes material to
15 form at least a first channel 122 for each precursor sensor body. In certain implementations, the fabricate operation 103 forms a continuous channel extending across the wafer 120 to form the first channel 122 for each precursor sensor body 140 in the row. In certain implementations, the fabricate operation 103 also forms a second channel 123 extending through one or more of the precursor sensor bodies
20 140 in each row.

In the example shown in FIG. 2, the fabricate operation 103 forms two rows of features of precursor sensor bodies 140. Each row includes features of three precursor sensor bodies 140. For example, the fabricate operation 103 forms a well 121a for each precursor sensor body 140 in the first row and a well 121b for
25 each precursor sensor body 140 in the second row. The fabricate operation 103 also forms a first groove 122a and a second holding groove 123a that extends across the wafer 120 through the first row of precursor sensor bodies 140. The fabricate operation 103 also forms a first groove 122b and a second groove 123b that extends across the wafer 120 through the second row of precursor sensor bodies 140.

30 In some implementations, the fabricate operation 103 deposits material on the wafer 120 to form features of the precursor sensor bodies 140. For example, the fabricate operation 103 may deposit a metal or other conductive material over the wafer 120 to form one or more conductive paths across the wafer

120. As shown in FIG. 3, in some implementations, the fabricate operation 103 forms a first conductive path 124 along the first groove 122 and a second conductive path 126 along the second groove 123. In certain implementations, the conductive paths 124, 126 are broken by the wells 121. In other implementations, the
5 conductive paths 124, 126 pass through the wells 121.

In some implementations, the first conductive path 124 includes at least one contact pad 125 for each precursor sensor body 140 and the second conductive path 126 includes at least one contact pad 127 for each precursor sensor body 140. In certain implementations, each of the conductive paths 124, 126
10 includes two contact pads 125, 127 for each precursor sensor body 140. For example, each conductive path 124, 126 may include a corresponding contact pad 125, 127, respectively, on either side of the well 121.

FIG. 4 illustrates one example implementation of a manufacturing station 134 at which the dispense operation 105 is implemented. The first station
15 134 is configured to deposit one or more sensor fiber electrodes onto the substrate wafer 120. In one example implementation, each sensor fiber electrode includes a composite sensor fiber having a dielectric core, a conductive layer, and a sensing layer. In some implementations, the manufacturing station 134 deposits a single sensor fiber 130 onto the wafer 120 for each row of precursor sensor bodies 140. In
20 other implementations, the manufacturing station 134 disposes multiple sensor fiber electrodes onto the wafer 120 per row of precursor sensor bodies 140. For example, the first station 134 may dispose a first sensor fiber (e.g., working electrode) 130 and a second sensor fiber (e.g., counter electrode) 131 onto each row of the wafer 120.

In some implementations, the composite sensor fibers are dispensed
25 from one or more reels 132 into the grooves 122, 123 defined in the precursor sensor bodies 140. In certain implementations, the first station 134 includes a set of reels 132 for each row of precursor sensor bodies 140. In other implementations, the first station 134 includes multiple sets of reels 132 for each row of precursor sensor bodies 140, each set dispensing one sensor fiber onto a groove. For example, as
30 shown in FIG. 5, a first sensor fiber 130 may be disposed along a first groove 124 and a second sensor fiber 131 may be disposed along a second groove 126 for each row of precursor sensor bodies 140.

In certain implementations, the first station 901 also includes one or more cutting structures 136 that disconnect the dispensed sensor fibers 906 from the reels 910. In some implementations, the cutting structures 914 cut the sensor fibers 130, 131 at extreme ends of the wafer 120. In such implementations, a continuous
5 length of each sensor fiber 130, 131 extends through all of the precursor sensor bodies 140 in one of the rows of precursor sensor bodies 140. In the example shown in FIG. 5, a first continuous length of sensor fiber 130 extends from a first cut end 137 to a second cut end 139. The first cut end 137 is located at a first end of the wafer 120 and the second cut end 139 is located at an opposite end of the wafer 120.
10 Each of the other sensor fibers in FIG. 5 also extend through multiple precursor sensor bodies 140 between opposite sides of the wafer 120.

In some implementations, the dispose operation 105 also includes disposing a binder over the fiber sensors 130, 131. In certain implementations, the binder is an organic binder that is configured to permanently attach a rigid layer to
15 the silicone substrate 120. In certain implementations, the binder also provides a thin film that forms a seal around the sensor fibers 130, 131.

FIGS. 6 and 7 illustrate an example implementation of a rigid layer 128 suitable to be secured to the wafer 120 to form the precursor sensor bodies 140. The rigid layer 128 defines a plurality of apertures 129. In some implementations,
20 the rigid layer 128 defines apertures 129 that align with the wells 121 of the wafer 120 to form the test chambers 155 of the precursor sensor bodies 140 (see FIG. 7). In certain implementations, the rigid layer 128 also defines apertures 129 that align between the wells 121 of the wafer 120 to expose the contact pads 125, 127 of the precursor sensor bodies 140 (see FIG. 7). Accordingly, a monitoring system can
25 access signals generated by the electrodes via the contact pads 125, 127.

FIG. 8 illustrates one example implementation of a cutting station 138 of the manufacturing system. The cutting station 138 is configured to separate the precursor bodies 140 of the sensor modules 150 from each other by cutting the wafer 120 and the continuous lengths of the composite sensor fibers 130, 131. For
30 example, FIG. 9 shows cutting paths 139 superimposed over the rigid layer 128. The cutting paths 139 define the boundaries of the precursor sensor bodies 140.

The cutting station 138 includes at least one cutting tool 136. In some implementations, the cutting station 138 includes a single cutting tool 136 that

moves along the wafer 120. In other implementations, the cutting station 138 includes multiple cutting tools 136. For example, the cutting tools 136 may be positioned in a fixed pattern and pressed through the wafer 120. In certain implementations, the cutting station 138 applies dicing tape to a top of the wafer 120
5 along dividing lines that define the boundaries of the precursor sensor bodies 140. The dicing tape may protect the sensor fibers 130, 131 or other features while the wafer is segmented.

In some implementations, the wafer 120 and sensor fibers 130, 131 are cut using the same cutting tool 136. In certain implementations, the wafer 120
10 and the sensor fibers 130, 131 are cut with a laser. In certain implementations, the wafer 120 and sensor fibers 130, 131 are cut with a knife or other bladed instrument. In certain implementations, the wafer 120 and sensor fibers 130, 131 are cut with a nipper. In certain implementations, the wafer 120 and sensor fibers 130, 131 are cut with pneumatic shears. In other implementations, the wafer 120 and sensor fibers
15 130, 131 are cut using different tools. For example, the wafer 120 may be cut with a laser and the sensor fibers 130, 131 may be cut using a nipper.

FIG. 10 shows one example segment divided out from the wafer 120. The segment defines a precursor sensor body 140 a first sensor fiber 130 and a second sensor fiber 131 extending through a test chamber 155. Cut ends of the
20 sensor fibers 130, 131 are located at opposite sides of the test precursor sensor body 140. The aperture 129 in the rigid layer 128 provides access to the test chamber 155. Apertures 129 in the rigid layer 128 on either side of the test chamber 155 provide access to the contact pads 125, 127. The contact pads 125, 127 are located at positions offset from the cut ends of the electrodes 130, 131.

FIGS. 11 and 12 show the result of the join operation 111 of the
25 manufacturing process 100 of FIG. 1. The join operation 111 attaches the precursor sensor body 140 to a component body 151 to form a sensor module 150. In some implementations, the component body 151 includes a molded carrier. In other implementations, the component body 151 includes a laminated member. Joining
30 the precursor sensor body 140 and the component body 151 closes the test chamber 155.

The component body 151 defines a passage 152 extend at least from one end of the component body 151 to the test chamber aperture 129 in the rigid

layer 128 of the precursor sensor body 140. The passage 152 provides an inlet at one end of the sensor module 150 that leads to the test chamber 155. In some implementations, the component body 150 includes a skin-piercing member that is configured to extend and retract through the passage 152 to take the blood sample.

5 Additional details regarding example sensor fibers suitable for use in sensor modules manufactured as described above can be found in U.S. Patent Nos. 5,264,105; 5,356,786; 5,262,035; and 5,320,725, the disclosures of which are incorporated by reference herein. Further examples of sensor fibers are described in U.S. Application Nos. 13/129,325, filed May 13, 2011, and titled "Electrochemical
10 Sensor Module," the disclosure of which is incorporated by reference herein. Other examples of sensor fibers are described in PCT Publication Nos. WO 2009/032760 and WO 2009/051901, the disclosures of which are incorporated by reference herein. Additional details regarding example sensor modules can be found in U.S. Provisional Application No. 61/430,384, filed January 6, 2011, and titled "Sensor
15 Module with Enhanced Capillary Flow," the disclosure of which is 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
20 from the spirit and scope of the present disclosure.

CLAIMS:

1. A method of installing sensors in sensor modules, the method comprising:
providing a first wafer and a continuous length of at least a first composite sensor fiber;
removing material from the first wafer to form features of a plurality of precursor sensor bodies;
disposing at least the first composite sensor fiber across the features of the precursor sensor bodies;
coupling a rigid body to the first wafer;
separating the coupled first wafer and rigid body into a plurality of precursor sensor bodies by cutting the first wafer, the rigid body, and the first composite sensor fiber into segments.
2. The method of claim 1, further comprising depositing conductive tracings on the first wafer prior to disposing the first composite sensor fiber across the features of the precursor sensor bodies.
3. The method of claim 1, further comprising:
providing a continuous length of a second composite sensor fiber; and
disposing the second composite sensor fiber across the features of the precursor sensor bodies adjacent to the first composite sensor fiber;
wherein separating the coupled first wafer and rigid body into a plurality of precursor sensor bodies also includes cutting the second composite sensor fiber into segments.
4. The method of claim 3, wherein the segments of the first composite sensor fiber form working electrodes and the segments of the second composite sensor fiber form counter electrodes.
5. The method of claim 1, wherein removing material from the first wafer to form features of a plurality of precursor sensor bodies comprises etching the first wafer to form the features.

6. The method of claim 1, wherein removing material from the first wafer to form features of a plurality of precursor sensor bodies comprises removing the material to form a well for each precursor sensor body to be formed.
7. The method of claim 6, wherein coupling the rigid body to the first wafer comprises aligning apertures in the rigid body with the wells defined in the first wafer to form test chambers.
8. The method of claim 7, further comprising joining each of the precursor sensor bodies to a component body that closes the respective test chamber.
9. The method of claim 1, further comprising joining each of the precursor sensor bodies to a component body that includes a skin-piercing member.
10. The method of claim 1, wherein removing material from the first wafer to form features of the precursor sensor bodies comprises forming multiple rows of the features of the precursor sensor bodies, each row including features of multiple precursor sensor bodies.

FIG. 1

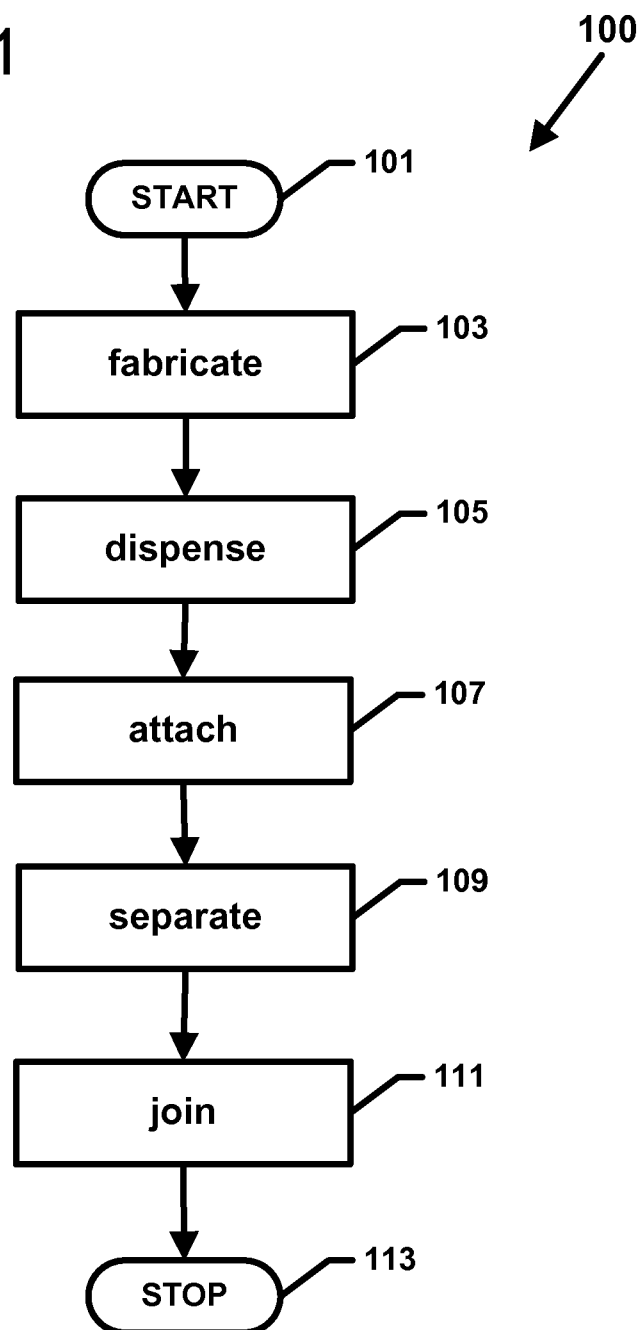


FIG. 2

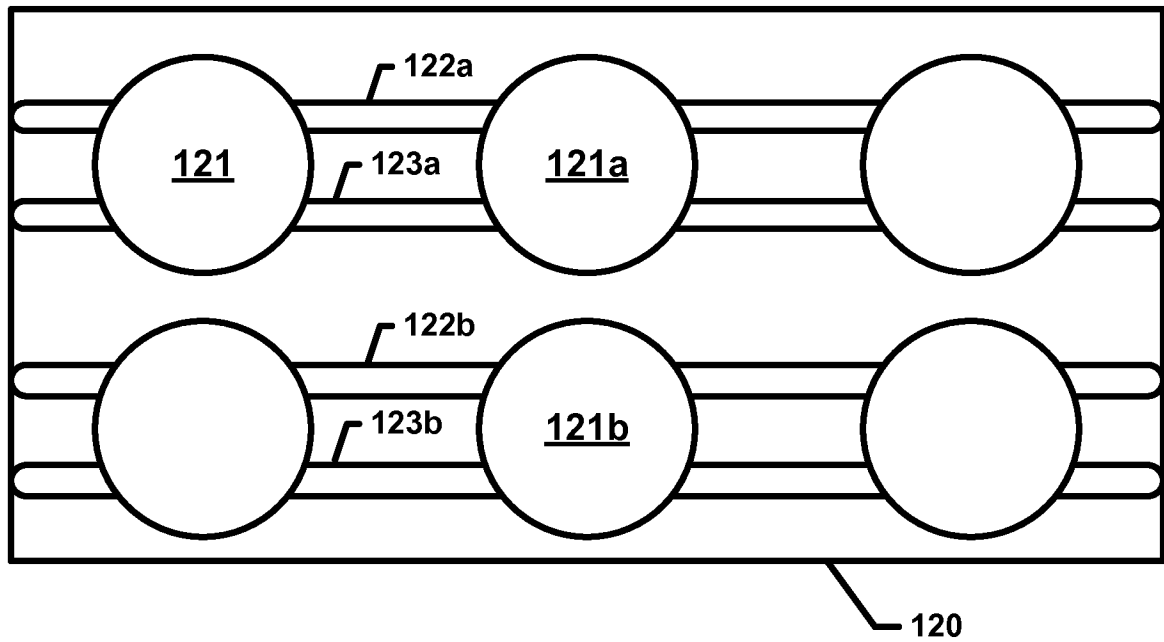


FIG. 3

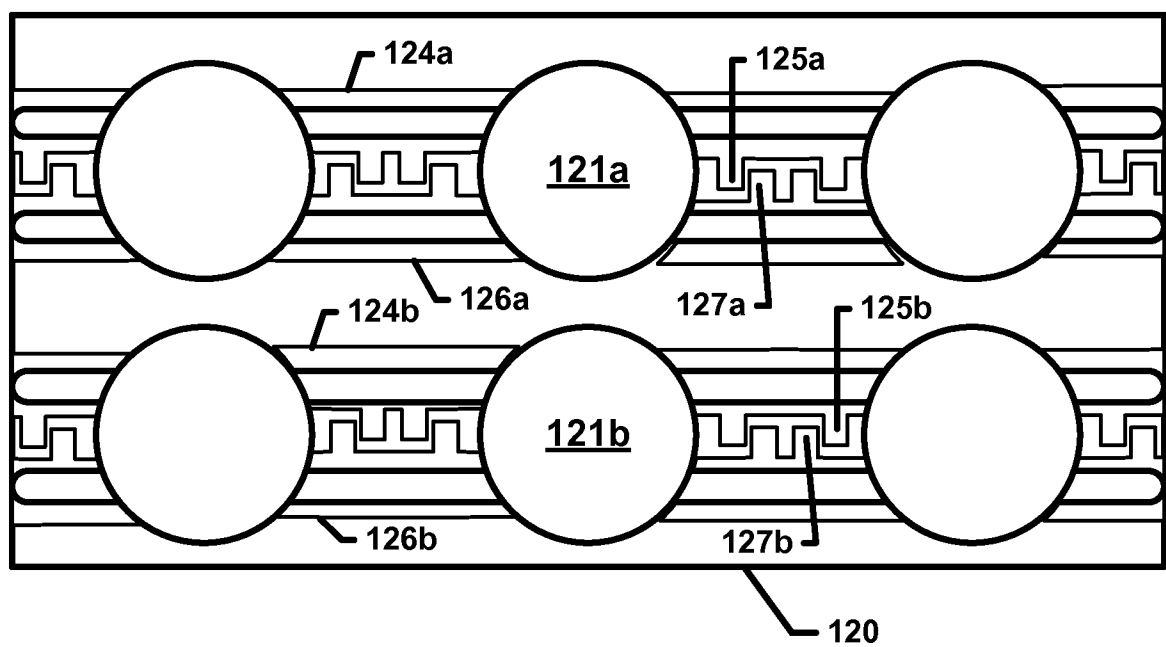


FIG. 4

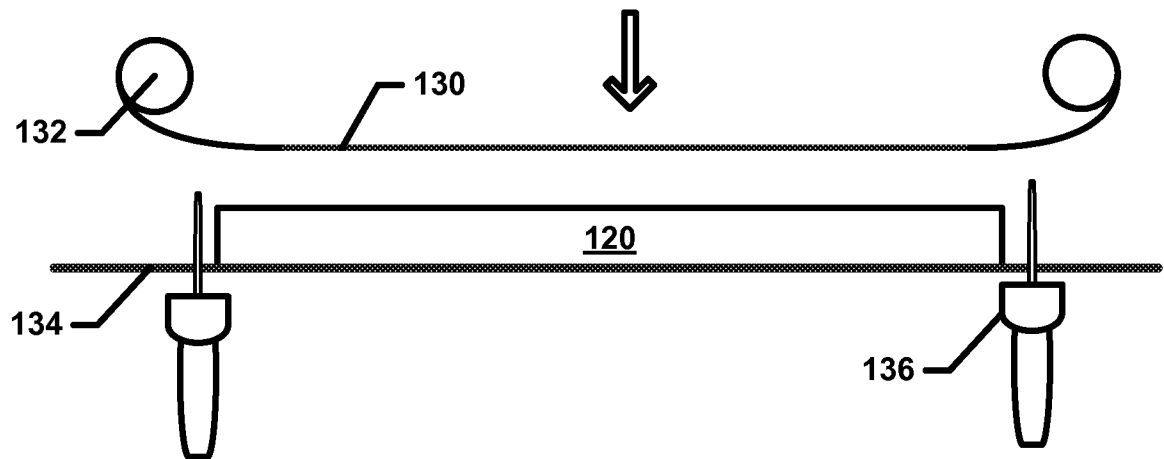


FIG. 5

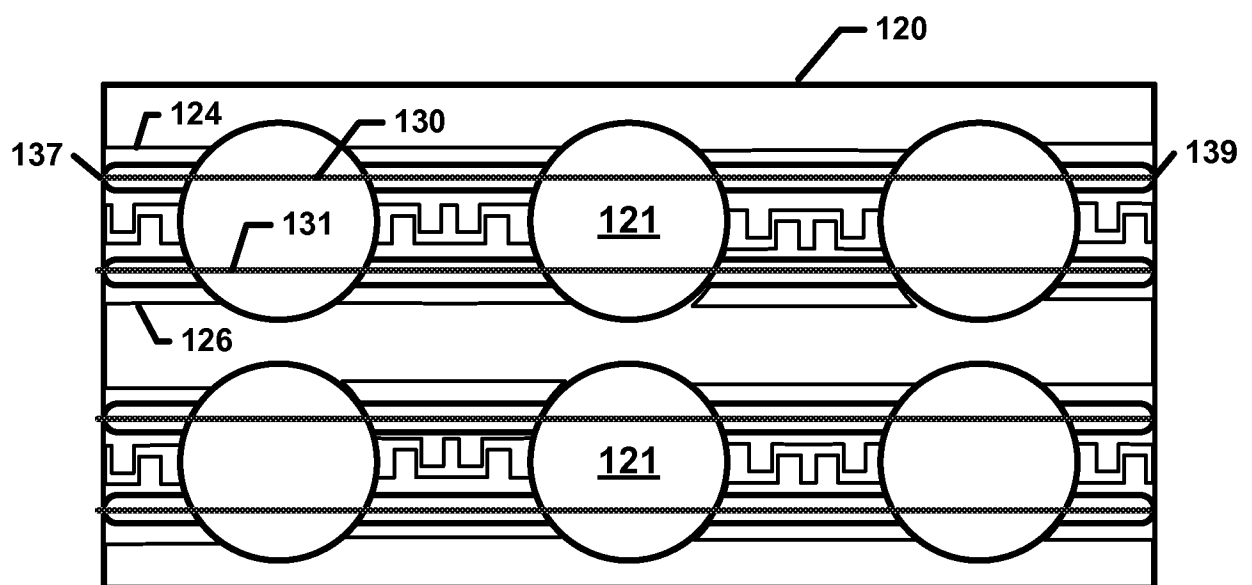


FIG. 6

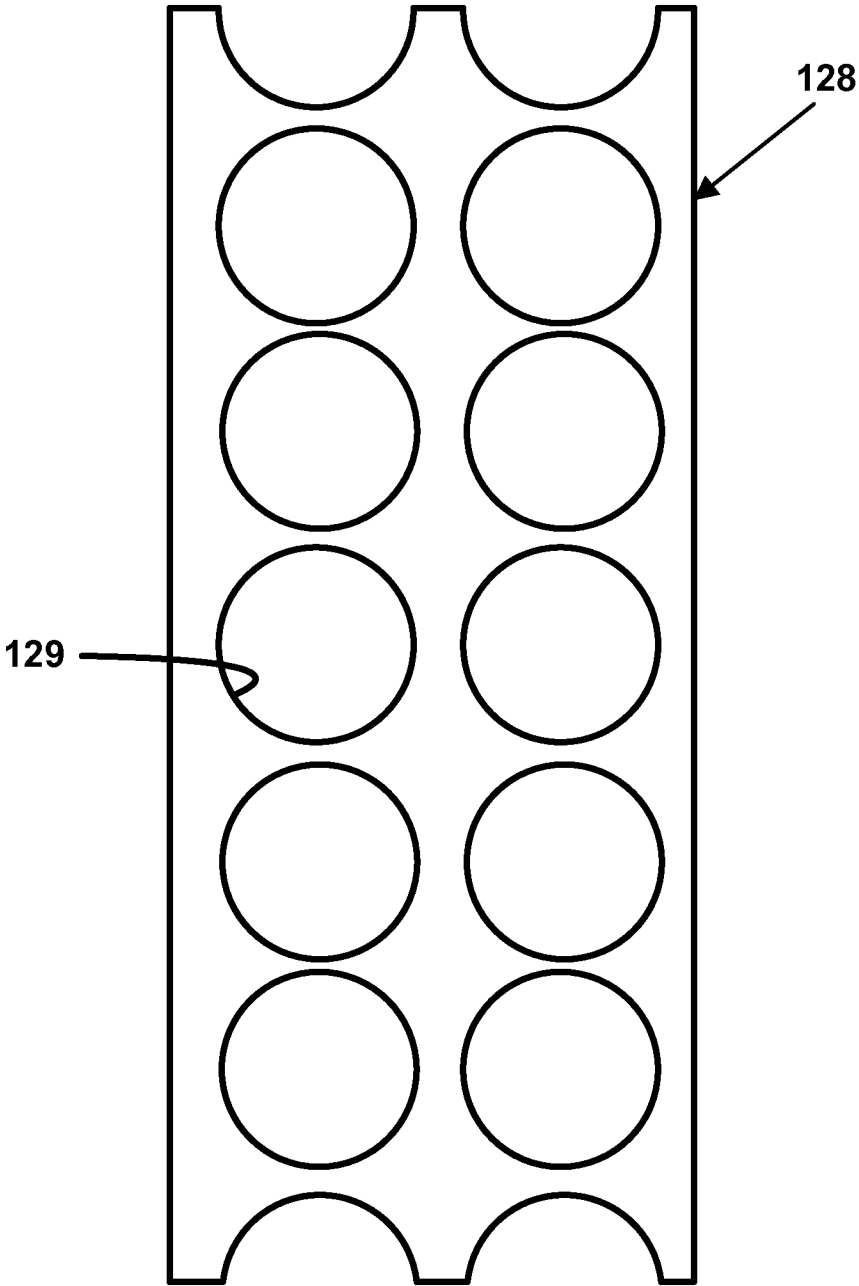


FIG. 7

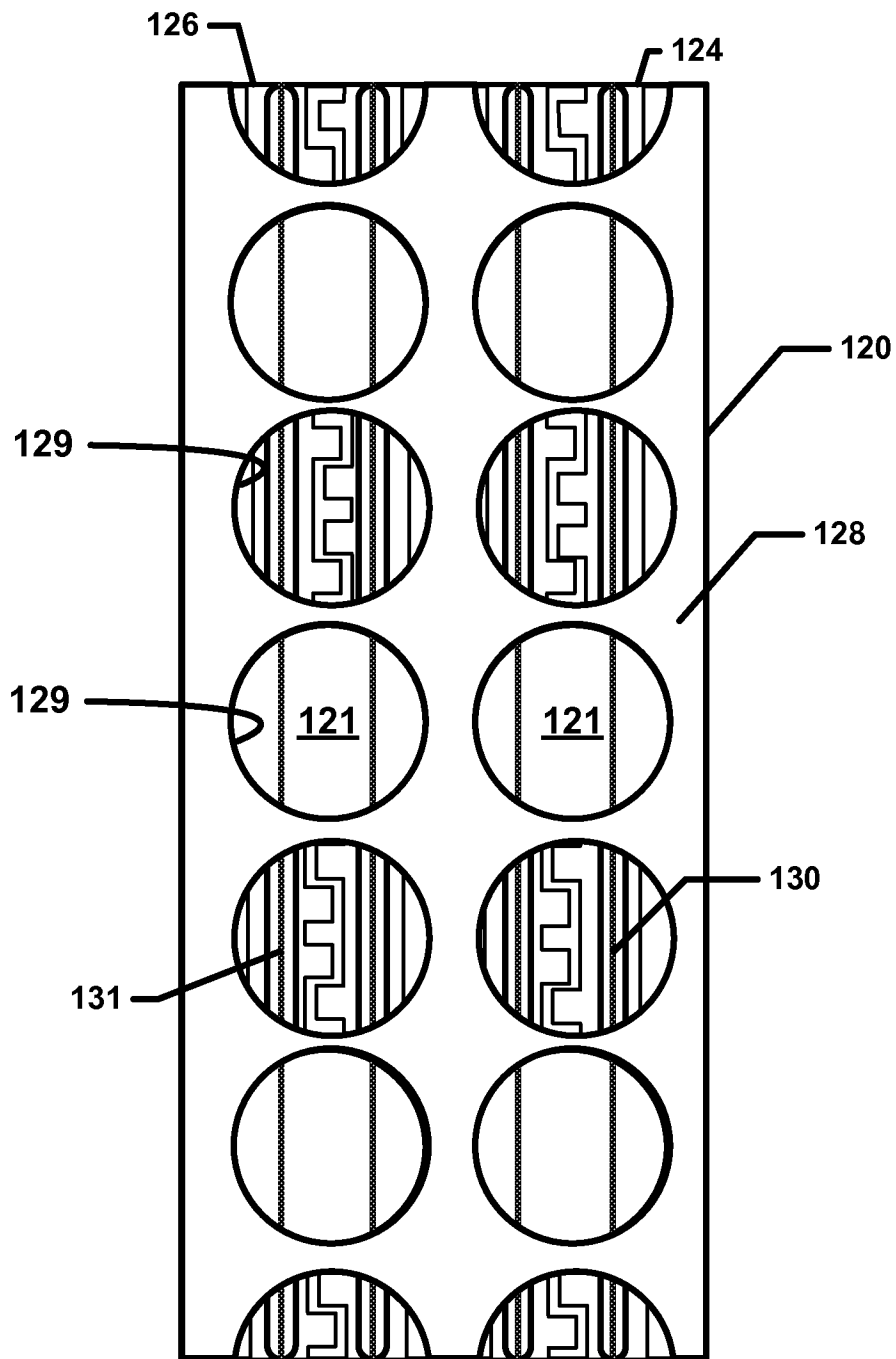


FIG. 8

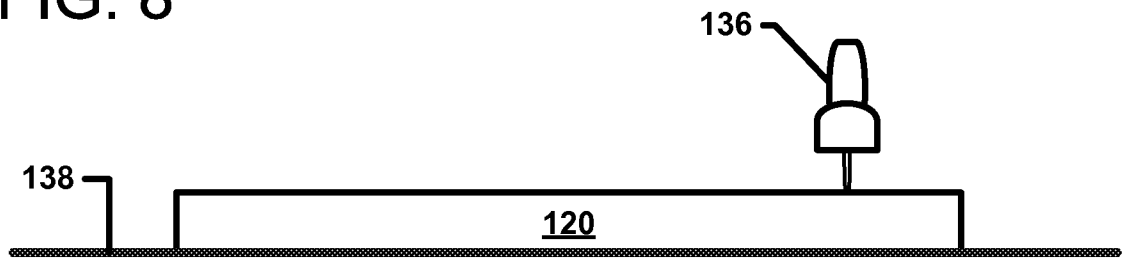


FIG. 9

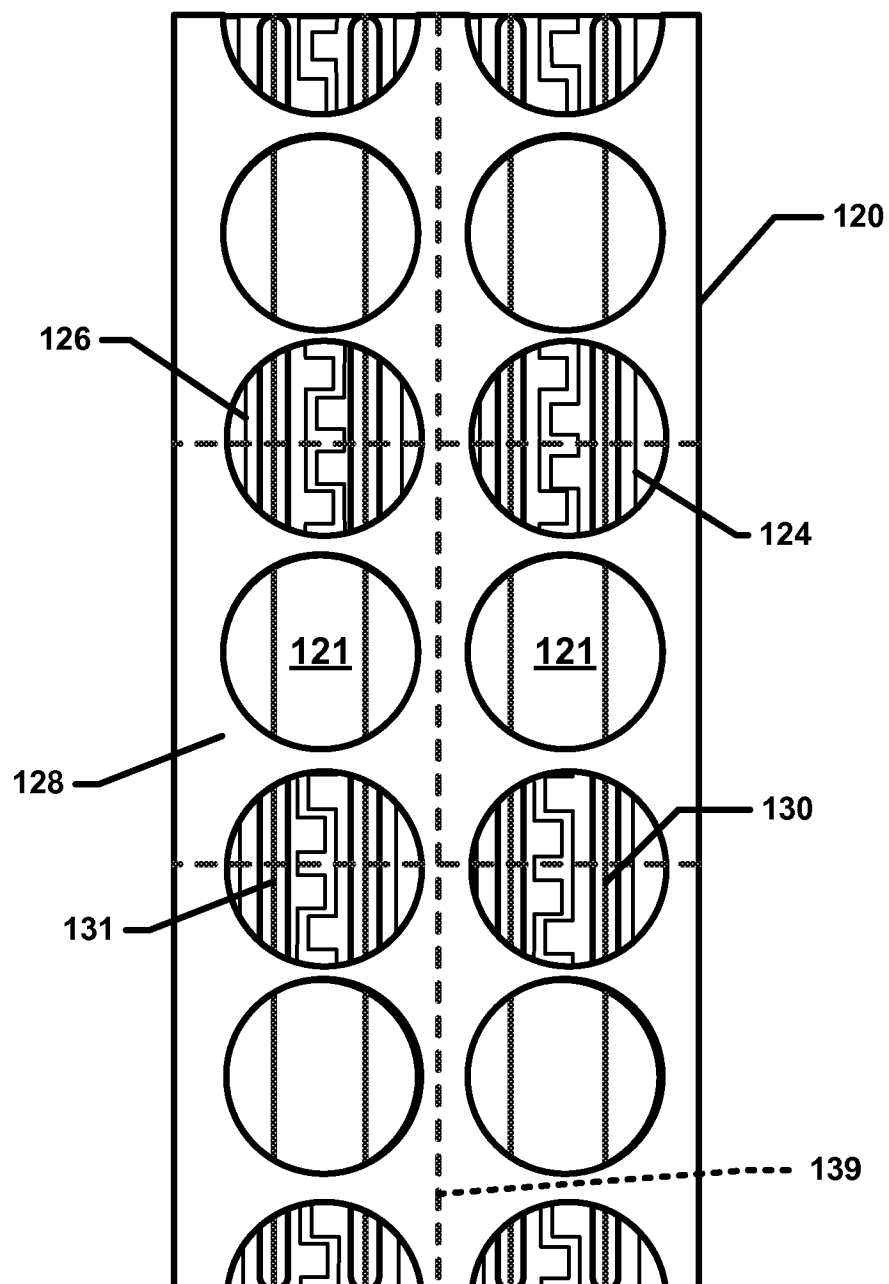


FIG. 10

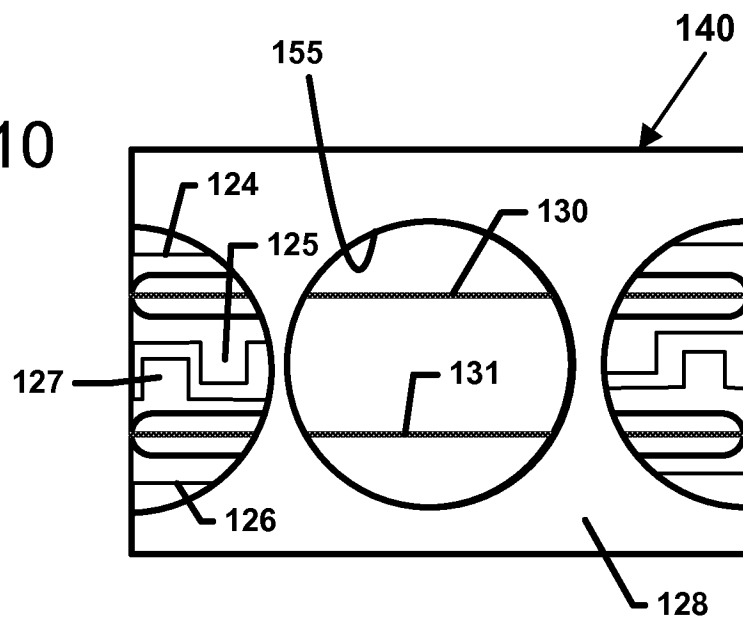


FIG. 11

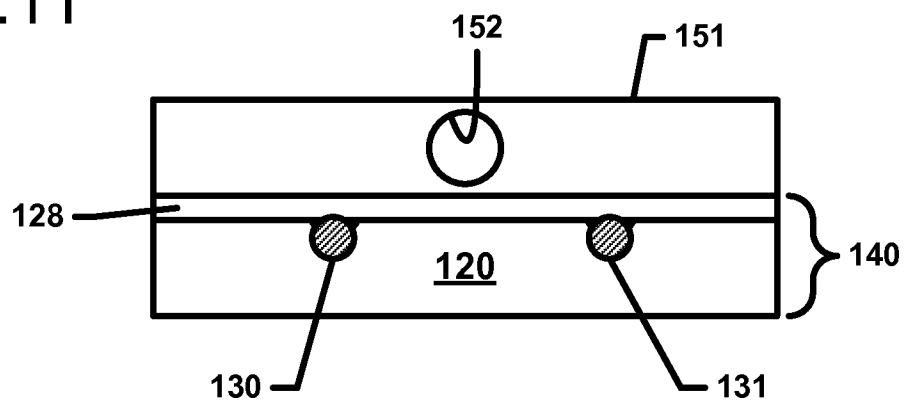


FIG. 12

