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DESCRIPTION

Field of the invention

[0001] The invention relates to inserters and disposables for inserting a subcutaneous element into a subject.

Background and related art

[0002] Medical devices are often used as diagnostic devices and/or therapeutic devices in diagnosing and/or treating medical conditions of patients. For example, a blood glucose meter is used as a diagnostic device to measure blood glucose levels of patients suffering from diabetes. An insulin infusion pump is used as a therapeutic device to administer insulin to patients suffering from diabetes.

[0003] Diabetes mellitus, often referred to as diabetes, is a chronic condition in which a person has elevated blood glucose levels that result from defects in the body's ability to produce and/or use insulin. There are three main types of diabetes. Type 1 diabetes may be autoimmune, genetic, and/or environmental and usually strikes children and young adults. Type 2 diabetes accounts for 90-95% of diabetes cases and is linked to obesity and physical inactivity. Gestational diabetes is a form of glucose intolerance diagnosed during pregnancy and usually resolves spontaneously after delivery.

[0004] Diabetes is managed primarily by controlling the level of glucose in the bloodstream. This level complex as the level of blood glucose entering the bloodstream is dynamic and complex, and is affected by multiple factors including the amount and type of food consumed, and the amount of insulin (which mediates transport of glucose across cell membranes) in the blood. Variation of insulin in the bloodstream that controls the transport of glucose out of the bloodstream also complicates diabetes management. Blood glucose levels are also sensitive to diet and exercise, but also can be affected by sleep, stress, smoking, travel, illness, menses, and other psychological and lifestyle factors unique to individual patients. The dynamic nature of blood glucose and insulin and all other factors affecting blood glucose often require a person with diabetes to forecast blood glucose levels. Therefore, therapy in the form of insulin, oral medications, or both can be timed to maintain blood glucose levels in an appropriate range.

[0005] Management of diabetes is time-consuming for patients because of the need to consistently obtain reliable diagnostic information, follow prescribed therapy, and manage lifestyle on a daily basis. Diagnostic information such as blood glucose is typically obtained from a capillary blood sample with a lancing device and is then measured with a handheld blood glucose meter. Interstitial glucose levels may be obtained from a continuous glucose sensor worn on the body. Prescribed therapies may include insulin, oral medications, or both.

Insulin can be delivered with a syringe, an ambulatory infusion pump, or a combination of both. With insulin therapy, determining the amount of insulin to be injected can require forecasting meal composition of fat, carbohydrates, and proteins along with effects of exercise or other physiological states. The management of lifestyle factors such as body weight, diet, and exercise can significantly influence the type and effectiveness of therapy.

[0006] The use of a medical appliance that can monitor and/or provide insulin to the patient can be beneficial for maintaining proper glucose levels. The use of a medical appliance may involve mounting a pump or sensor assembly on the body and/or clothing and inserting one or more cannula into the body. This however may be difficult for some patients. The loss of motor skills due to old age, diabetes, or the side effects of insulin itself may make it difficult for a patient to properly mount a pump and/or monitor and to properly insert a cannula or sensor into the body. It is therefore of great benefit to simplify the process using a medical appliance to make it less dependent upon the use of fine motor skills. Furthermore, it is of great benefit to provide a reusable inserter that requires only a few simple handling steps to insert the disposable parts like a cannula and/or a sensor.

[0007] International patent application WO 2007031126 A1 discloses an insertion head for medical or pharmaceutical applications, comprising: a base with a lower side which can be placed on organic tissue, an insertion device, movably received by the base, which can be inserted into the tissue, said insertion device being movable in relation to the base from a protected position in which a free end of the insertion device is recessed from the lower side of the base to an insertion position in which the free end projects beyond the lower side a handle projecting from the base and comprising a first handle component and a second handle component, movable in relation to the base and the first handle component, and a coupling that translates a movement of the second handle component into a movement of the insertion device.

[0008] United States patent US 7,879,010 discloses a device for inserting a cannula into tissue, including a cannula, a protective element which can accommodate said cannula, an operating element for moving the cannula out of the protective element, and a holder fixedly connected to the cannula.

[0009] United States patent US 7,815,607 discloses an insertion device for an infusion set, the device including a retention means by which the infusion set can be temporarily held on the device and drive means including a pretensionable spring for providing drive energy for an insertion movement of the infusion set. The infusion set is secured by the retention means by clamping when the retention means is in an engage position and can then be moved, with simultaneous pretensioning of the spring, to an insertion movement starting position. The infusion set is already separated from the retention means at the start of the insertion movement. The infusion set moves through at least part of the insertion movement free of the retention means.

[0010] European patent publication EP 1475113 A1 disclsoes a medical device that comprises

a first unit and a releasably attachable second unit. The first unit comprises a mounting surface adapted for application to the skin of a subject, and a needle comprising a distal pointed end adapted to penetrate the skin of the subject. The needle has a first position in which the distal end is retracted relative to the mounting surface, and a second position in which the distal end projects relative to the mounting surface. The second unit comprises actuatable driving means adapted to move the needle from the first position to the second position when the driving means is actuated with the second unit attached to the first unit. By this arrangement the first unit can be applied to the skin of the subject using the second unit as a gripping and handling means, whereafter the driving means can be actuated for insertion of the needle.

[0011] International patent publication WO 2010003886 A1 discloses a device comprising a transcutaneous device and an inserter which transcutaneous device has a mounting surface. The device is upon delivery arranged in a sterile packing which packing functions as inserter and is attached to the transcutaneous device i.e. the packing and the inserter is one integrated unit. A device comprises a transcutaneous device and an inserter. The transcutaneous device comprises a mounting part having a mounting surface and a hard cannula. There is a fluid path leading fluid from a fluid source to the hard cannula. The inserter comprises a packing at least partly covering the transcutaneous device before use. The packing comprises a non-deformable portion which portion cannot be deformed by the user during normal use and a deformable portion which portion can be reduced lengthwise in the direction of insertion during use.

[0012] United States patent application publication US 2004/0133164 A1 discloses an analyte monitor includes a sensor, a sensor control unit, and a display unit. The sensor control unit typically has a housing adapted for placement on skin and is adapted to receive a portion of an electrochemical sensor. The sensor control unit also includes two or more conductive contacts disposed on the housing and configured for coupling to two or more contact pads on the sensor. A transmitter is disposed in the housing and coupled to the plurality of conductive contacts for transmitting data obtained using the sensor. The display unit has a receiver for receiving data transmitted by the transmitter of the sensor control unit and a display coupled to the receiver for displaying an indication of a level of an analyte, such as blood glucose. An inserter having a retractable introducer is provided for subcutaneously implanting the sensor in a predictable and reliable fashion.

[0013] International patent application publication WO 2012108959 A1 discloses an infusion set that includes an inserter pivotally connected to a base. The inserter includes a catheter and an introducer needle. The catheter is movable from a first catheter position disposed substantially entirely within the inserter to a second catheter position in which a free end of the catheter is disposed externally of the inserter and the base. The introducer needle is movable between a first introducer needle position disposed substantially entirely within the inserter and a second introducer needle position in which a free end of the introducer needle is disposed externally of the inserter and the base. An activation button is movable between first and second button positions.

Summary

[0014] The invention provides for a method of using a medical system, a cartridge, an inserter, and a medical system in the independent claims. Embodiments are given in the dependent claims.

[0015] In one aspect the invention provides for a method of using the medical system. The medical system comprises a cartridge and an inserter. In some examples, the inserter is configured to be re-usable rather then a single use diposable inserter.

[0016] The cartridge comprises a housing with an interior volume. The housing comprises a first guiding structure within the interior volume. The cartridge further comprises a cradle for mounting a medical appliance.

[0017] The cradle comprises a subcutaneous element. The subcutaneous element may for example be one or more cannulas and/or one or more sensors. The one or more sensors may for example include a glucose sensor, a lactate sensor, and an oxygen sensor.

[0018] The cradle is within the interior volume. The cradle further comprises an insertion needle. The insertion needle is configured for being actuated to insert the subcutaneous element into the subject.

[0019] The inserter comprises a second guiding structure for mating with the first guiding structure. The first guiding structure and the second guiding structure are configured for guiding a portion of the inserter into the interior volume along an guiding path. The portion of the inserter is configured for removably attaching to the cradle when guided into the interior volume. The inserter further comprises an insertion mechanism for actuating the insertion needle to insert the subcutaneous element into the subject.

[0020] The method comprises the step of moving the portion of the inserter into the interior volume of the housing along the guiding path or in an insertion direction. Moving the portion of the inserter into the interior volume causes the cradle to attach to the portion. The method further comprises the step of removing the portion of the inserter and the cradle from the interior volume.

[0021] In another embodiment, the cradle comprises an adhesive layer for attaching to an exterior surface of a subject.

[0022] In another embodiment the method further comprises the step of attaching the cradle to the exterior surface of the subject. The method further comprises the step of operating the insertion mechanism to actuate the insertion needle to insert the subcutaneous element into the subject. The method further comprises the step of removing the inserter from the cradle.

[0023] In another embodiment the insertion mechanism comprises a stored energy component for driving the insertion needle into the subject and withdrawal of the insertion needle from the subject. The first guiding structure comprises a rigid element for engaging the stored energy component. The stored energy component is configured for being primed when pressed against the rigid element when the inserter is moved into the interior volume of the housing along the guiding path. The method further comprises priming the stored energy component during the insertion of the portion of the inserter into the interior volume of the housing along the guiding path. This embodiment may be beneficial because the needle is attached to the inserter at the same time that the stored energy component is primed or loaded with energy.

[0024] In another embodiment the cradle comprises a removable needle housing. The insertion needle has an extended position and a retracted position. The insertion needle is within the removable needle housing when in the retracted position. The method further comprises removing the removable needle housing from the cradle after removing the inserter from the cradle. This embodiment may be further beneficial because it provides for a means of disposing of a needle after the insertion has been performed. In some examples the removable needle housing may serve as a disposable sharps container that accompanies the needle.

[0025] In another aspect the invention provides for a cartridge. The cartridge comprises a housing with an interior volume. The housing comprises a first guiding structure within the interior volume for guiding a second guiding structure of an inserter along an guiding path. The cartridge further comprises a cradle for mounting a medical appliance. The cradle comprises a subcutaneous element. The cradle is within the interior volume. The cradle further comprises an insertion needle. The insertion needle is configured for being actuated to insert the subcutaneous element into the subject.

[0026] In another embodiment, the cradle comprises an adhesive layer for attaching to an exterior surface of a subject.

[0027] In another embodiment the first guiding structure comprises a rigid element for engaging the stored energy component of an insertion mechanism of the inserter. In another embodiment the cradle comprises a backing material layer covering the adhesive layer to prevent the adhesive layer from sticking to the interior volume. The housing has an entrance to the interior volume. A portion of the backing material closest to the entrance is attached to the housing. This may be beneficial because a portion of the backing material attached close to the entrance causes the backing material layer to automatically peel off of the adhesive layer as the cradle is removed.

[0028] In another embodiment the attachment of the backing material to the housing is configured to automatically peel the backing from the adhesive layer when the cradle is removed from the housing along the guiding path.

[0029] The portion of the backing material attached to the housing is configured to remain

attached to the housing when the cradle is removed from the housing along the guiding path. This may be beneficial because it reduces the number of pieces that a user of the cartridge needs to dispose of.

[0030] In another embodiment the cradle comprises a removable needle housing. The insertion needle has an extended position and a retracted position. The insertion needle is within the removable needle housing when in the retracted position. The removable needle housing may provide a convenient way of disposing of the insertion needle safely as no sharps container is needed for disposal of the insertion needle.

[0031] In another embodiment the removable needle housing comprises at least one slot that is parallel to the insertion needle. The insertion needle comprises a mechanism attachment point for attaching to the insertion mechanism. The at least one slot provides clearance for a mechanism to actuate the insertion needle.

[0032] In another embodiment the housing is a blister pack. This may be beneficial because it provides an inexpensive and sterile packaging for the needle within the housing.

[0033] In some examples, the blister pack may be made of plastic and/or metal based materials. It may be vacuum formed or injection molded.

[0034] In another embodiment the housing has an opening to the interior volume.

[0035] In another embodiment the housing comprises a lid for sealing the opening. The lid may also be referred to as a lid seal or lidding seal. In some examples, the lid is a foil that provides a germ proof or sterile seal. In some examples the lid is attached to the housing via hot melt, thermos, ultrasonic or laser welding

[0036] In another embodiment the lid is formed from any one of the following: aluminum foil, plastic, paper, and combinations thereof.

[0037] In another embodiment the interior volume is sterile.

[0038] In another embodiment the opening is planar.

[0039] In another embodiment the interior volume has a rectangular profile perpendicular to the guiding path. The opening is tilted with respect to the rectangular profile.

[0040] In some examples the housing has a pie shaped profile. A pie shaped profile is a profile that is similar in shape to a sector of a circle or is triangular in shape. The pie shape may have the advantage that is minimizes storage volume and simplifies the handling for the user.

[0041] In another embodiment the opening is tilted with respect to the rectangular profile between 20° and 60°.

[0042] In another embodiment the housing is at least partially formed by a thermal formed plastic.

[0043] In another embodiment the thermal formed plastic is any one of the following: polyvinyl chloride, polychlorotrifluoroethylene, cyclic olefin copolymers, and cyclic olefin polymers.

[0044] In another embodiment the first guiding structure is formed in a first sidewall of the interior volume.

[0045] In another embodiment the rigid structure is formed from a portion of the first sidewall.

[0046] In another embodiment the interior volume has as second sidewall opposing the first sidewall. The sidewall comprises a supplementary guiding structure.

[0047] In another embodiment the supplementary guiding structure is aligned with the guiding path.

[0048] In another embodiment the first guiding structure is aligned with the guiding path.

[0049] In another aspect the invention provides for an inserter. The inserter comprises a second guiding structure for mating with the first guiding structure of a cartridge. The second guiding structure are configured for guiding a portion of the inserter into the interior volume along an guiding path defined by the first guiding structure. The cartridge comprises a cradle. The portion of the inserter is configured for removably attaching to the cradle when guided into the interior volume. The cradle comprises an insertion needle. The inserter further comprises an insertion mechanism for actuating the insertion needle to insert the subcutaneous element into the subject.

[0050] In another embodiment the insertion mechanism comprises an energy storage component for driving the insertion needle into the subject and out of the subject. The first guiding structure comprises a rigid element for engaging the energy storage component. The energy storage component is configured for being primed when pressed against the rigid element when the inserter is moved into the interior volume of the housing along the guiding path.

[0051] In another embodiment the inserter comprises a cover. The second guiding structure is a first groove in the cover. The insertion mechanism comprises a sliding element for sliding within the first groove. The sliding element is configured for priming the energy storage component when moved along the first groove.

[0052] In another embodiment the inserter further comprises an additional guiding structure. The additional guiding structure is a second groove in the cover. The additional guiding structure is aligned with the guiding path.

[0053] In another embodiment the additional guiding structure mates with the supplementary guiding structure.

[0054] In another embodiment the insertion mechanism comprises a button for activating the insertion mechanism when the stored energy component is primed.

[0055] In another embodiment the insertion mechanism comprises a safety element which may also be referred to as a safety or safety mechanism. The safety element extends through the adhesive layer when the stored energy component is primed. The inserter has a mounting surface. The mounting surface is flush with the adhesive layer. The safety element is configured for being depressed flush with the mounting surface when the stored energy component is primed. The insertion mechanism is locked unless the safety element is depressed flush with the mounting surface. This may be beneficial because it may prevent the insertion mechanism from being activated when the inserter is not attached to a subject.

[0056] In another aspect the invention provides for a medical system. The medical system comprises a cartridge according to an embodiment. The medical system further comprises an inserter according to an embodiment.

[0057] In another embodiment the medical system comprises a medical appliance for mounting into the cradle.

[0058] In another embodiment the subcutaneous element comprises at least one cannula. The medical appliance comprises a pumping system. The pumping system comprises any one of the following: an insulin pump for pumping insulin through the at least one cannula, a glucagon pump for pumping glucagon through the at least one cannula, and combinations thereof.

[0059] In another embodiment the subcutaneous element comprises a glucose sensor. The medical appliance comprises a continuous glucose monitor.

[0060] In another embodiment a cradle with one or two cannulas and/or a sensor could be present in a single cradle. In one example the inserter could insert two cannulas at the same time. In another example a cannula and one or more sensors could be inserted at the same time. In another example two cannulas and one or more sensors could be inserted at the same time. In these examples, the inserter mechanism cold actuate multiple insertion needles. In other examples a single needle is used to insert multiple subcutaneous elements.

[0061] In other words a single cradle might have multiple subcutaneous elements that can be inserted by a single inserter.

[0062] In another embodiment the portion of the inserter is configured for forming a snap-fit to removably attach to the cradle when guided into the interior volume.

[0063] It is understood that one or more of the aforementioned embodiments of the invention

may be combined as long as the combined embodiments are not mutually exclusive.

Brief description of the drawings

[0064] In the following embodiments of the invention are explained in greater detail, by way of example only, making reference to the drawings in which:

Fig. 1A
illustrates an example of a cartridge;
Fig. 1B
further illustrates the example of Fig. 1A;
Fig. 1C
further illustrates the example of Fig. 1A;
Fig. 2
illustrates an example of a medical system comprising an inserter and the cartridge of Fig. 1;
Fig. 3
shows the medical system of Fig. 2 after the inserter has been inserted into the cartridge;
Fig. 4
shows the inserter of Fig. 2 after it has been placed on the surface of a subject;
Fig. 5
shows the inserter of Fig. 2 as it is being removed from a cradle;
Fig. 6
shows a removable needle housing being removed from the cradle of Fig. 5;
Fig. 7
illustrates a method of operating a medical system as is shown in Figs. 1 through 6;
Fig. 8
shows an exploded view of an inserter;
Fig. 9
shows an assembly drawing of the inserter of Fig. 8;
Fig. 10
shows a further assembly drawing of the inserter of Fig. 8;
Fig. 11
shows a further assembly drawing of the inserter of Fig. 8;
Fig. 12
shows a further assembly drawing of the inserter of Fig. 8;
Fig. 13
shows a further assembly drawing of the inserter of Fig. 8; and
Fig. 14
shows a further assembly drawing of the inserter of Fig. 8;
Fig. 15
shows an example of a cradle with a removable needle housing attached;

Fig. 16
shows an enlarged region of Fig. 15;
Fig. 17
shows an assembly drawing of a removable needle housing;
Fig. 18
shows a cross sectional view of the removable needle housing Fig. 17;
Fig. 19
shows a further cross sectional view of the removable needle housing of Fig. 17;
Fig. 20
shows a view of an inerter;
Fig. 21
shows a further view of an inerter;
Fig. 22
shows a further view of an inerter;
Fig. 23
shows a cross sectional view of an inserter that is mounted on a cradle;
Fig. 24
shows an enlarged region of Fig. 23;
Fig. 25
illustrates an example of how a removable needle assembly interfaces with an inserter;
Fig. 26
shows an insulin pump mounted on a cradle: and
Fig. 27
shows an exploded view of the insulin pump and cradle of Fig. 26.

Detailed Description

[0065] Like numbered elements in these figures are either equivalent elements or perform the same function. Elements which have been discussed previously will not necessarily be discussed in later figures if the function is equivalent.

[0066] Figs. 1A, 1B, and 1C are three different views which illustrates an example of a cartridge 100. The cartridge 100 has an opening 102 in a housing 103. The opening 102 provides access to an interior volume 104 of the cartridge 100. There is a sealing surface surface 105 which can be used to attach a lid or a lidding seal such as a metal and/or plastic foil.

[0067] There is a first guiding structure 106 and a supplementary guiding structure 108. The first guiding structure is shown as being formed as part of a first side wall 107. The supplementary guiding structure 108 is show as being formed as part of a second side wall 109. In this example both guiding structures 106, 108 are identically formed. They are both

ridges of solid material which are aligned with an guiding path 110. The Fig. shows how the supplementary guiding structure 108 extends into the interior volume 104. In this example the cartridge 100 is formed from a blister pack or thermoformed plastic. The first guiding structure 106 extends into the interior volume 104 in the same way that the supplementary guiding structure 108 does.

[0068] Within the interior volume 104 there is a cradle 112. The cradle has attached to it a movable needle housing 114 that houses a needle. There is a slot 115 which a mechanism can use to enter and actuate the needle within the removable needle housing 114. On the underside of the cradle 112 there is a backing material 116 which protects a an adhesive layer. The backing material 116 is attached to the interior volume 104 at an attachment point 118. In this case it is the portion of the backing material 116 that is closest to the opening 102. As the cradle 112 is removed from the housing 103 the backing material 116 is peeled off from the cradle 112 exposing the adhesive layer.

[0069] Fig. 2 shows an example of an inserter 200 being inserted into the cartridge 100 along the guiding path 110. The inserter 200 and the cartridge 100 are part of a medical system 201. The inserter 200 can be seen as having a cover 202. There is a button 204 on the inserter 200 to fire an insertion mechanism which is contained within the cover 202. In Fig. 2 there can be seen a second guiding structure 206 which is formed as a first groove in the cover 202. This second guiding structure 206 mates with the first guiding structure 106. Within the second guiding structure 206 is a sliding element 208 which is used to charge or prime an energy storage element within the inserter 200. A portion 203 of the inserter 200 is inserted into the cartridge 100. As this is done, the sliding element 208 pushes against the first guiding structure 106 which is a rigid element. This pushes the sliding element 208 back and primes the insertion mechanism. On the far side of the cover 202 there is also an additional guiding structure which mates with the supplementary guiding structure 108. There is also a groove in the cover 202 that is used to help align and make the inserter 200 better follow the guiding path 110.

[0070] Fig. 3 shows the inserter 200 after it has been fully inserted into the cartridge 100. The cradle 112 including the removable needle housing 114 has been snap-fit into the inserter 200. As the inserter 200 is withdrawn in the opposite direction to the guiding path 110 the cradle 112 is automatically removed. The backing material 116 is also automatically peeled off of the adhesive layer on the underside of the cradle 112.

[0071] Fig. 4 shows the inserter 200 after it has been completely removed from the cartridge 100. The sliding element 208 is no longer visible within the groove that forms the second guiding structure 206. It has been depressed into the energy storage component and is now hidden by the cover 202. The cradle 112 is on the underside of the inserter 200. The cartridge 200 shown in Fig. 4 could be attached to a subject by simply placing the inserter 200 on the surface or skin of a subject. Not shown in Fig. 4 is a safety element mechanism which is only engaged when the inserter 200 is placed on a surface. The square box 400 is representative of the surface 400 of the subject, which the inserter 200 is being placed on The square box

400 may also represent a surface of the inserter for mounting on the subject.

[0072] Fig. 5 shows the inserter 200 being removed from the cradle 112. The insertion mechanism has been actuated and the inserter 200 is then able to be easily slid apart from the cradle 112. The cradle 112 is adhered to an adhesive layer 400' which again adheres to the surface 400 of the subject.

[0073] Fig. 6 shows the removable needle housing 114 being removed from the cradle 112. The needle is within the removable needle housing 114. The removable needle housing 114 functions as a sharps container and the removable needle housing 114 can simply be thrown away.

[0074] Fig. 7 shows a flowchart which illustrates a method of operating the medical system 201 shown in Figs. 1-6. First in step 700 a portion 203 of the inserter 200 is moved into the interior volume 104 along the guiding path 110. After the inserter has be moved along the guiding path 110 the cradle 112 to attaches to the inserter 200. Next in step 702 the portion 203 of the inserter 200 and the cradle 112 are removed from the interior volume 104. Next in step 704 the cradle 112 is attached to an exterior surface of a subject via the adhesive layer 400'. Next in step 706 the insertion mechanism is operated to actuate the insertion needle to insert a subcutaneous element into the subject. Finally in step 708, as is shown in Fig. 5, the inserter 200 is removed from the cradle 112.

[0075] Fig. 8 shows an exploded view of some components of the inserter 200. The cover 202 is comprised of a top cover 202' and a bottom cover 202". The bottom cover 202" also comprises some fixed elements of the insertion mechanism 800. In the components there can be seen the sliding element 208 which is used to prime the insertion mechanism 800. When the sliding element 208 is depressed it charges, loads, or primes a drive spring 806 or a stored energy component 806. The spring 806 is used to drive a drive arm 808 which forces a needle driver 810 in a downward motion. The needle driver 810 is able to go through the slots 115 of the disposable needle enclosure 114. After the drive arm 808 has been depressed the retraction spring 804 withdraws the drive arm 808 back up again to remove the needle from the subject. The spring 806 is stronger than the retraction spring 804. As the drive spring 806 drives the needle driver 810 towards the subject it also applies force to and charges the retraction spring 804. The drive spring 806 is then released from the mechanism and the spring 804 is able to return the drive arm 808 and the needle drive 810 to its original starting position. The component 204 is a button which is actuated through the top cover 202'. The component 812 is a safety element which prevents activation of the insertion mechanism 800 unless the bottom cover 202" is placed on a surface such as a subject.

[0076] Fig. 9 shows a top view of the assembled insertion mechanism 800 of Fig. 8. The sliding element 208 has a sloped surface 14. This is used to engage an end point 816 of the driver spring 806. As the sliding element 208 is moved back the sloped surface 814 lifts the end point 816 and deposits it on a connection point 818 of the drive arm 808. When the drive arm 808 reaches a fully depressed position the end point 816 is forced off of the connection

point 818 by a release element 820. In Fig. 8, it can be seen that in the bottom cover 202" there are a number of structures. The sloped component labeled 820 is the release element. The release element disengages the end point 816 from the connection point 818 when the drive arm 808 has been fully depressed. After the end point 816 has been disengaged from the connection point 818 the retraction spring 804 is then able to lift the drive arm 808 back into its original position.

[0077] Fig. 10 shows a perspective side view of the assembly drawing in Fig. 9. In particular in Fig. 10 it can be seen how the sloped surface 814 engages the end point 816. Fig. 10 also is useful for illustrating the function of the safety element 812. Unless the safety element 812 is properly engaged the switch or button 204 is not able to function. At the end point of the safety element 812 is a sensing point 1000. When the sensing point 1000 touches a surface such as the surface of the subject it causes the sensing point to become flush with a mounting surface 1001 and the entire safety element 812 lifts up. The dashed region labeled 1002 is shown in an expanded view in Fig. 11. The safety element 812 has a notched region 1100 which locks the button 204 in place. When the safety element 812 is free and the sensing point 1000 is not touching anything the notched region 1100 falls into place and locks the position of the button 204. When the sensing point 1000 is placed on a surface it lifts the safety element 812 and the button 204 is free to move. The mechanism may then be activated. In Figs. 9, 10 and 11 the insertion mechanism 800 has not yet been primed.

[0078] Fig. 10 and 11 further shows a release pin 1004. The release pin 1004 extends through the arm 808 and is supported by the button 204. When the button 204 is depressed the arm 808 is able to be actuated.

[0079] Fig. 12 shows a side view of the insertion mechanism 800 before it has been primed. The sliding element 208 has been pushed back by the first guiding structure 106. The end point 816 has been lifted by the sloped edge 814 above the connection point 818 of the drive arm 808. It can be seen that the button 204 is holding the arm 808 of the spring above the connection point 818. When the button 204 is depressed the release pin 1004 no longer holds the drive arm 808 such that the arm 808 can move downwards.

[0080] Fig. 13 shows the same view of the insertion mechanism 800 of Fig. 12 but at a slightly different angle and position. In Fig. 13 it can be seen how the release button 204 holds the drive arm 808 in an upper position. When the button 204 is depressed the drive arm is no longer supported and the drive spring or stored energy component 806 is able to drive and actuate the drive arm 808.

[0081] Fig. 14 shows how the end point 816 of the drive spring 806 is disengaged from the connection point 818 of the drive arm 808. As the drive arm 808 is depressed the end point 816 of the drive spring 806 comes in contact with a curved surface 1400 of the release element 820. As the drive arm 808 reaches its fully depressed position the curved surface 1400 physically pushes the end point away and off of the connection point 818. At this point the drive spring 806 is no longer engaged and the retraction spring 804 is able to drive the drive

arm 808 back into its original position.

[0082] Fig. 15 shows an example of a cradle 112 with a removable needle housing attached. The box labeled 1500 shows a zoomed region which is shown in greater detail in Fig. 16. Fig. 16 shows how the adhesive layer 400' is attached to the cradle 112. The backing material 116 is shown as being attached to the adhesive layer 400'.

[0083] Fig. 17 shows an assembly drawing of the removable needle housing 114. The removable needle housing comprises an insertion needle 1700 and a cannula 1702. The cannula 1702 could be replaced by additional or different subcutaneous elements such as a sensor and/or additional cannulas. The insertion needle 1700 has a mechanism attachment point 1704 for attaching to an insertion mechanism. A portion of a mechanism may be inserted through the slit 115 and may be used to press against the mechanism attachment point 1704 to actuate the needle.

[0084] Fig. 18 shows a cross sectional view of the removable needle housing 114 of Fig. 17. In this cross sectional view, the needle is shown before being inserted into a subject. In Fig. 18, the insertion needle is in the retracted position 1800.

[0085] Fig. 19 shows a further cross sectional view of the removable needle housing 114 of Fig. 17. In this Fig., the insertion needle 1700 has been driven into a subject. When the insertion needle 1700 is withdrawn, the cannula 1702 will be left within the subject. In Fig. 19 the insertion needle is shown in the extended position 1900.

[0086] Figs. 20, 21, and 22 show further views of the inserter 200. In Figs. 20 and 21 an additional guiding structure 2000 can be seen. It is able to mate with the supplementary guiding structure 108 shown in Figs 1A, 1B, and 1C. An opening 2002 for receiving the removable needle housing 114 is also seen. A portion of the needle drive 810 is also shown. The needle driver 810 is able to enter the slot 115 of the removable needle housing 114 to actuate the needle by pressing on the mechanism attachment point 1704.

[0087] Fig. 23 shows a cross sectional view of the inserter 200 that is mounted on a cradle 112. The box labeled 2300 shows a region which is enlarged in Fig. 24. Fig 24 shows how the cradle 112 is mounted to the bottom of the inserter 200.

[0088] Fig. 25 illustrates how the removable needle 114 assembly interfaces with the inserter 200. In this Fig. the cradle 112 is shown as being mounted in the inserter 200. The removable needle assembly is moved away from both the cradle 112 and the inserter 200 for clarity. The needle drivers 810 would pass through the slots 115 and be used for driving the insertion needle 1700 of Fig. 17. As the inserter 200 is slid onto the cradle two gripping elements 2500 would grip a gripping location 2502 of the removable needle assembly 114.

[0089] Fig. 26 and Fig. 27 shown an assembly comprising the cradle 112 and an insulin pump 2602. In Fig. 26 the insulin pump is mounted on the cradle 112. In. Fig. 27 the insulin pump

has been removed from the cradle. In Fig. 27, the cannula 1702 is shown as being inserted into a subject. The insulin pump 2602 is able to attach to the cannula 1702 to pump insulin into the subject.

List of reference numerals

[0090]

100 cartridge
102 opening
103 housing
104 interior volume
105 sealing surface
106 first guiding structure
107 first side wall
108 supplementary guiding structure
109 second side wall
110 guiding path
112 cradle
114 removable needle housing
115 slot
116 backing material
118 attachment point
200 inserter
201 medical system
202

cover

202'

top cover

202"

bottom cover

203

portion of inserter

204

button

206

second guiding structure

208

sliding element

400

surface of subject

400'

adhesive layer

700

move at least a portion of the inserter into the interior volume of the housing along the guiding path

702

remove the inserter and the cradle from the interior volume

704

attach the cradle to the exterior surface of the subject

706

operate the insertion mechanism to actuate the insertion needle to insert the subcutaneous element into the subject

708

remove the inserter from the cradle

800

insertion mechanism

802

priming spring

804

retraction spring

806

drive spring or stored energy component

808

drive arm

810

needle driver

812

safety element

814

sloped surface
816
end point
818
connection point
820
release element
1000
sensing point
1001
mounting surface
1002
zoomed region
1004
release pin
1100
notched region
1400
curved surface
1500
zoomed region
1700
insertion needle
1702
cannula
1704
mechanism attachment point
1800
retracted position
1900
extended position
2000
additional guiding structure
2002
opening
2300
zoomed region
2500
gripping element
2502
gripping location
2600
assembly
2602

insulin pump

REFERENCES CITED IN THE DESCRIPTION

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- US7879010B **[0008]**
- US7815607B **[0009]**
- EP1475113A1 **[0010]**
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- US20040133164A1 **[0012]**
- WO2012108959A1 **[0013]**

PATENTKRAV

1. Patron (100), hvilken patron omfatter:

- et hus (103) med en indre volumen (104), hvor huset omfatter en første styremekanisme (106) inden i den indre volumen til styring af en anden styremekanisme (206) på en indføringsenhed (200) langs en styrebane, hvor huset og fortrinsvis den første styremekanisme omfatter et stift element (106) til at gå i indgreb med en lagret energikomponent (806, 208) i en indføringsmekanisme (208) på indføringsenheden; og
- en holder (112) til montering af et medicinsk udstyr, hvor holderen omfatter et subkutant element, hvor holderen befinder sig inden i den indre volumen, hvor holderen endvidere omfatter en indføringsnål, hvor indføringsnålen er udformet til at blive aktiveret til indføring af det subkutane element i subjektet, hvor holderen omfatter et klæbelag til fastgørelse på en ydre overflade på et subjekt, hvor holderen omfatter et bagbeklædningslag (116), der dækker klæbelaget for at forhindre klæbelaget i at klæbe til den indre volumen, hvor huset har en åbning (102), hvor en del (118) af bagbeklædningen er fastgjort til huset.

2. Patron ifølge krav 1, hvor fastgørelsen af bagbeklædningen til huset er udformet til at trække bagbeklædningen af klæbelaget, når holderen udtages fra huset.

3. Patron ifølge krav 1 eller 2, hvor delen af bagbeklædningen, der er fastgjort til huset, er udformet til at forblive fastgjort til huset, når holderen udtages fra huset langs styrebanen.

4. Patron ifølge et hvilket som helst af kravene 1 til 3, hvor huset har en åbning (102) til den indre volumen, hvor åbningen er plan, hvor den indre volumen har et rektangulært profil vinkelret på styrebanen, hvor åbningen hælder i forhold til det rektangulære profil, således at huset har en tærteagtig form.

5. Patron ifølge krav 4, hvor åbningen hælder mellem 20 grader og 60 grader i forhold til det rektangulære profil.

6. Patron ifølge et hvilket som helst af kravene 1 til 5, hvor den første styremekanisme er dannet i en første sidevæg (107) i den indre volumen, og hvor det stive element er dannet af en del af den første sidevæg.

7. Patron ifølge krav 6, hvor den indre volumen har en anden sidevæg (109) modsat den første sidevæg, hvor den anden sidevæg omfatter en supplerende styremekanisme.

8. Indføringsenhed (200),

hvilken indføringsenhed omfatter:

- en anden styremekanisme (206) til parring med et hus til en patron (100), hvor den anden styremekanisme er udformet til at føre indføringsenheden ind i den indre volumen langs en styrebane, der er defineret af den første styremekanisme, hvor patronen omfatter en holder (112), hvor delen af indføringsenheden er udformet til aftagelig fastgørelse til holderen, når den føres ind i den indre volumen, hvor holderen omfatter en indføringsnål; og

- en indføringsmekanisme (208) til aktivering af indføringsnålen til indføring af det subkutane element i subjektet, hvor indføringsmekanismen omfatter en energilagringskomponent (208, 806) til indføring af indføringsnålen ind i subjektet og ud af subjektet, hvor huset omfatter et stift element (106) til at gå i indgreb med energilagringskomponenten, hvor energilagringskomponenten er udformet til at blive klargjort, når den presses mod det stive element, når indføringsenheden bevæges ind i den indre volumen af huset langs styrebanen.

9. Indføringsenhed ifølge krav 8, hvor indføringsenhed omfatter et låg, hvor den anden styremekanisme er en første rille i låget, hvor indføringsmekanismen omfatter et glideelement (806) til at glide inden i den første rille, og hvor glideelementet er udformet til at klargøre energilagringskomponenten ved bevægelse langs den første rille.

10. Indføringsenhed ifølge krav 9, hvor indføringsenheden endvidere omfatter en yderligere styremekanisme (2000), hvor den yderligere styremekanisme er en anden rille i låget, hvor den yderligere styremekanisme flugter med styrebanen.

11. Indføringsenhed ifølge et hvilket som helst af kravene 8 til 10, hvor indføringsmekanismen omfatter en knap (204) til aktivering af indføringsmekanismen, når den lagrede energikomponent er klargjort.

12. Indføringsenhed ifølge et hvilket som helst af kravene 8 til 11, hvor indføringsmekanismen omfatter et sikkerhedselement (812), hvor indføringsenheden har en monteringsoverflade (1001), hvor sikkerhedselementet strækker sig gennem monteringsoverfladen, når den lagrede energikomponent er klargjort, hvor sikkerhedselementet er udformet til at blive trykket ned i niveau med monteringsfladen, når den lagrede energikomponent er klargjort, hvor indføringsmekanismen er låst, medmindre sikkerhedselementet er trykket ned i niveau med monteringsoverfladen.

13. Indføringsenhed ifølge et hvilket som helst af kravene 8 til 12, hvor mindst en del af indføringsenheden er parret med den indre volumen af patronen.

14. Medicinsk system, hvilket medicinsk system omfatter en patron (100) ifølge et hvilket som helst af kravene 1 til 7, hvor det medicinske system endvidere omfatter en indføringsenhed (200) ifølge et hvilket som helst af kravene 8 til 13.

DRAWINGS

FIG. 1A

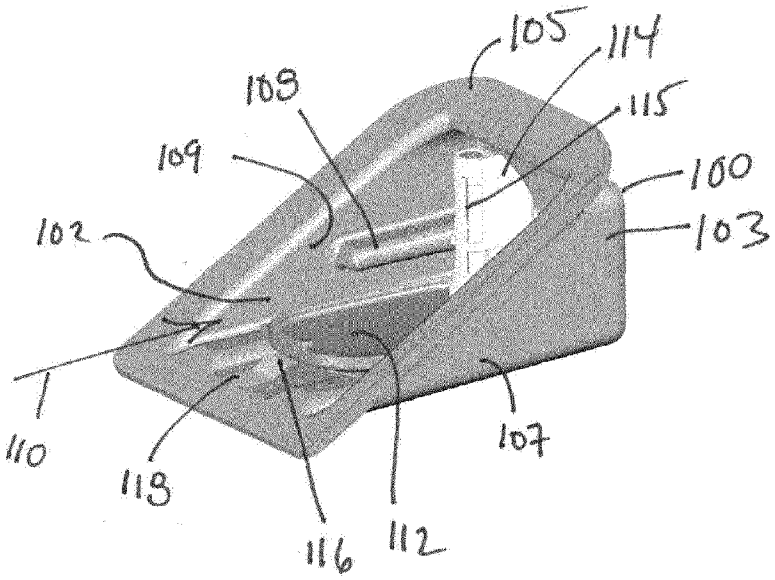
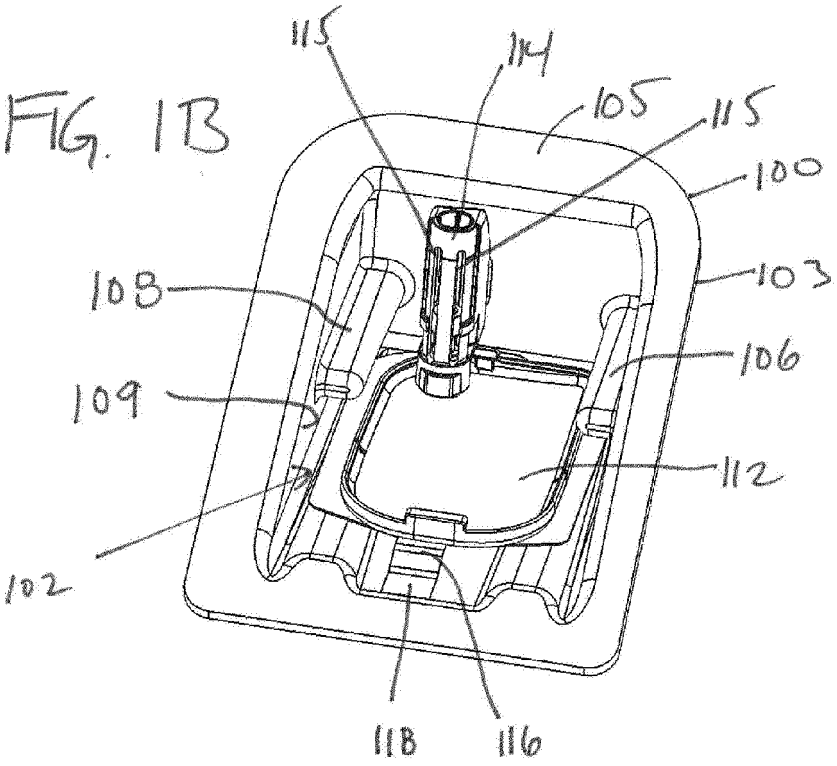


FIG. 1B


115
114
105
115
100
103
108
106
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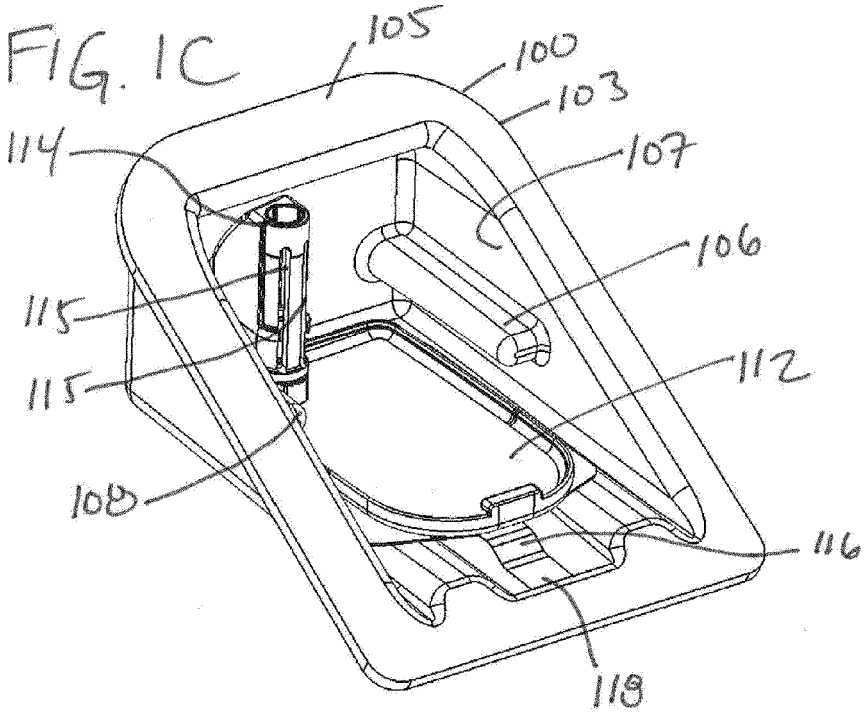
112
102
118
116

FIG. 1C


105
100
103
114
107
106
115
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112
108
116
118

FIG. 2

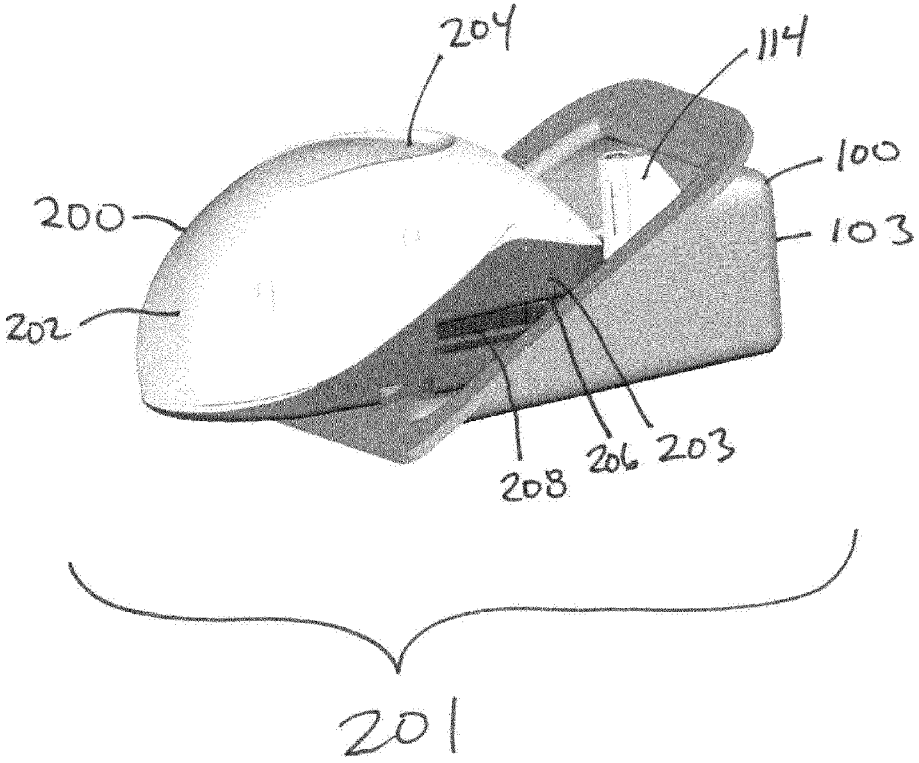


FIG. 3

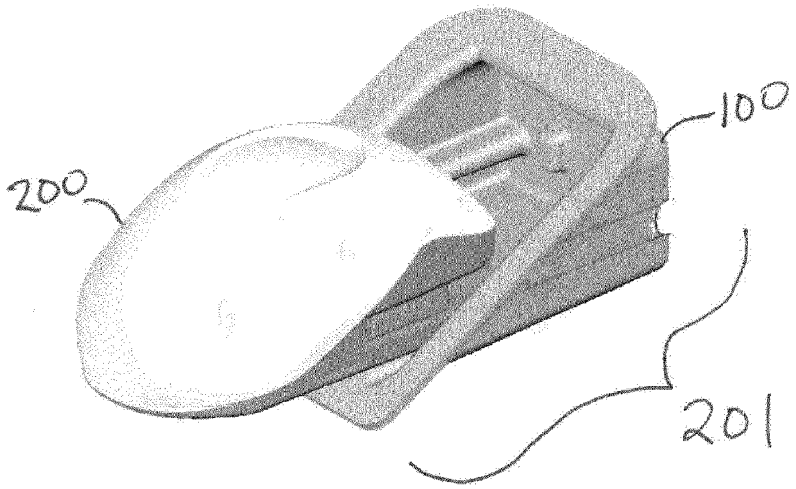


FIG. 4

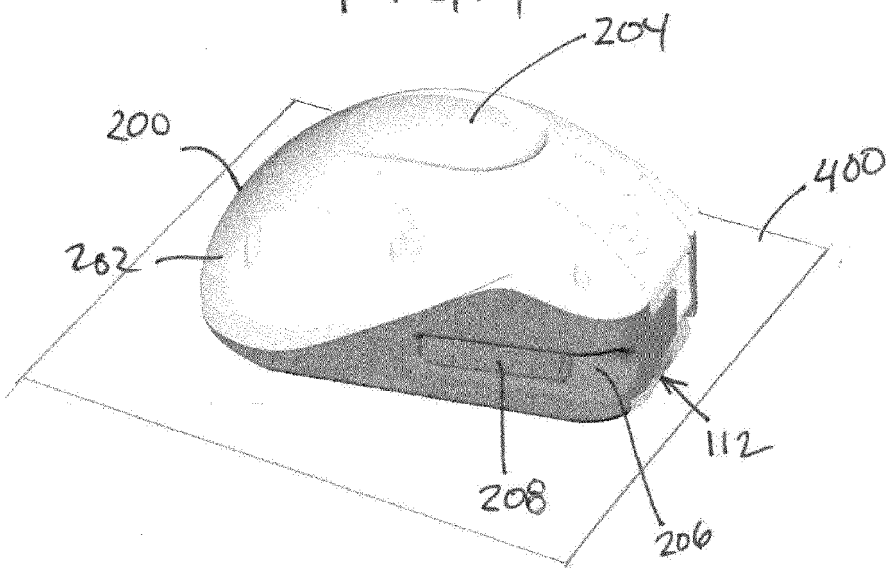


FIG. 5

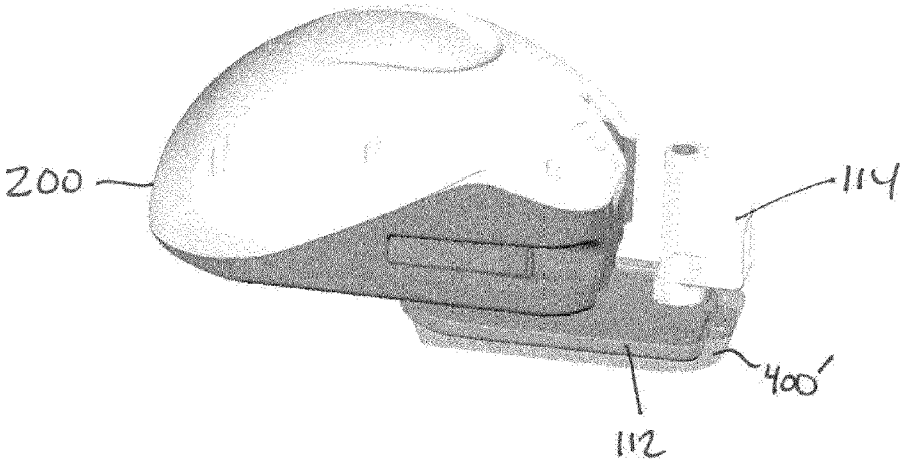


FIG. 6

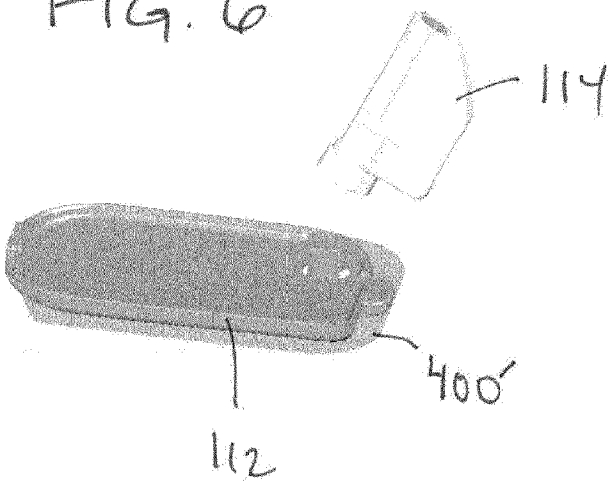


FIG. 7

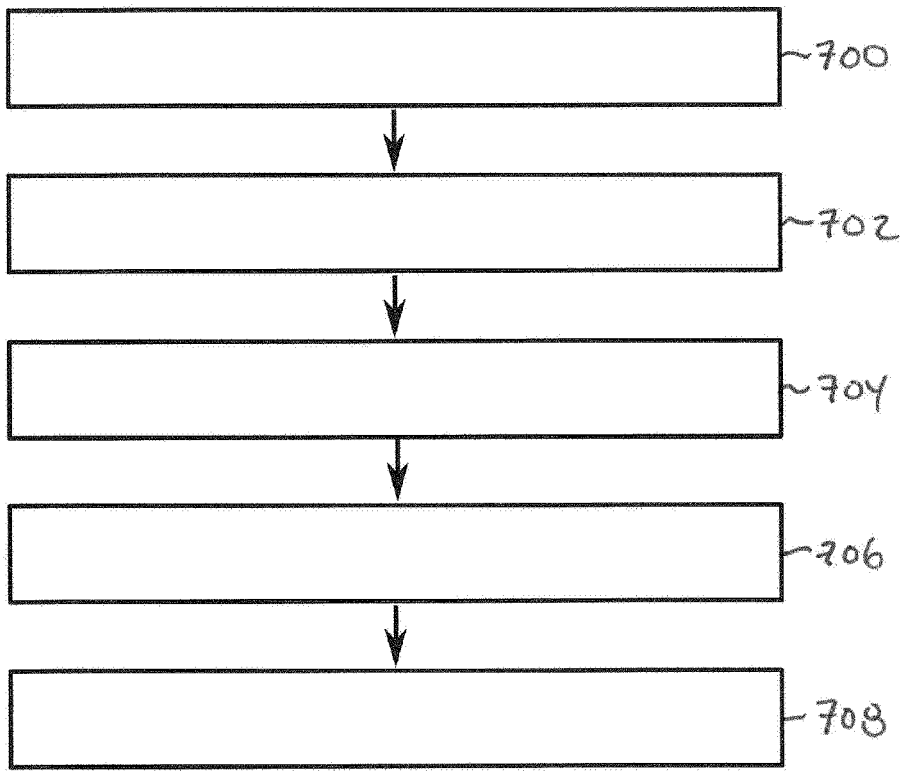


FIG. 8

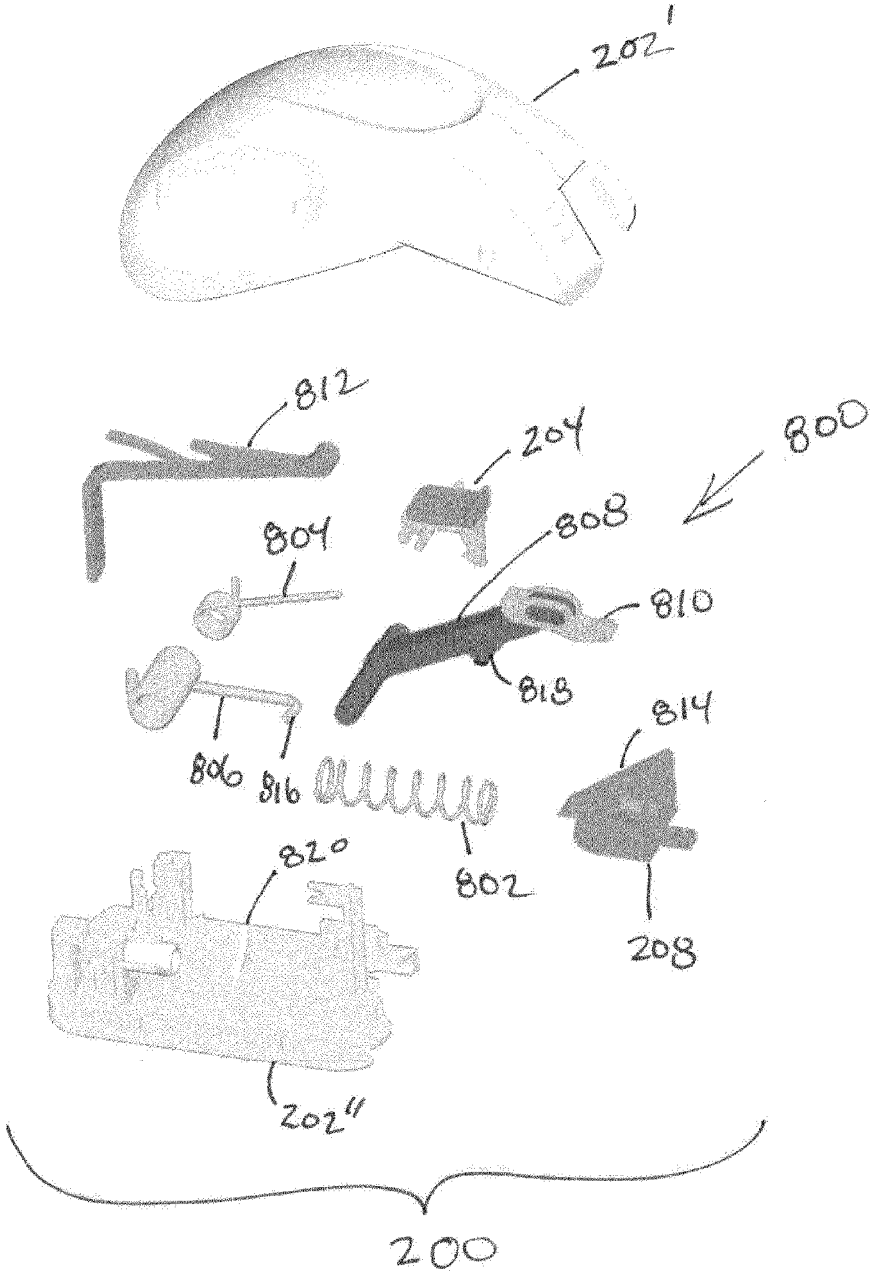


Fig. 9

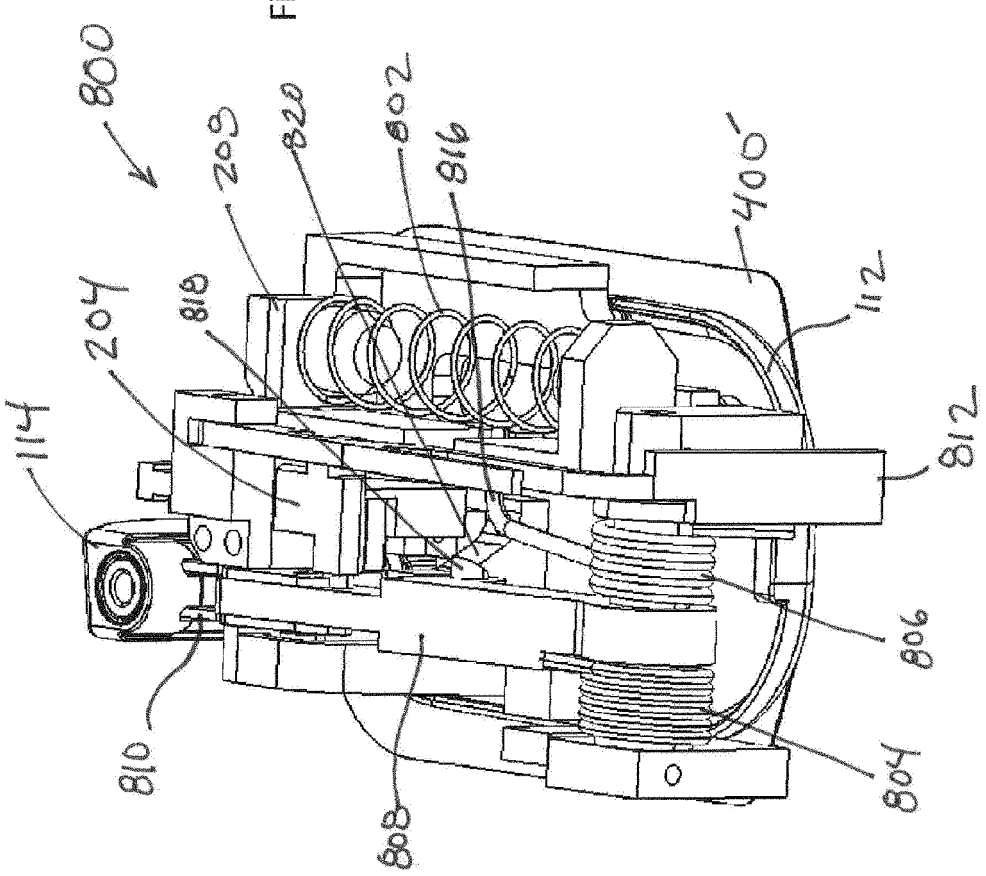
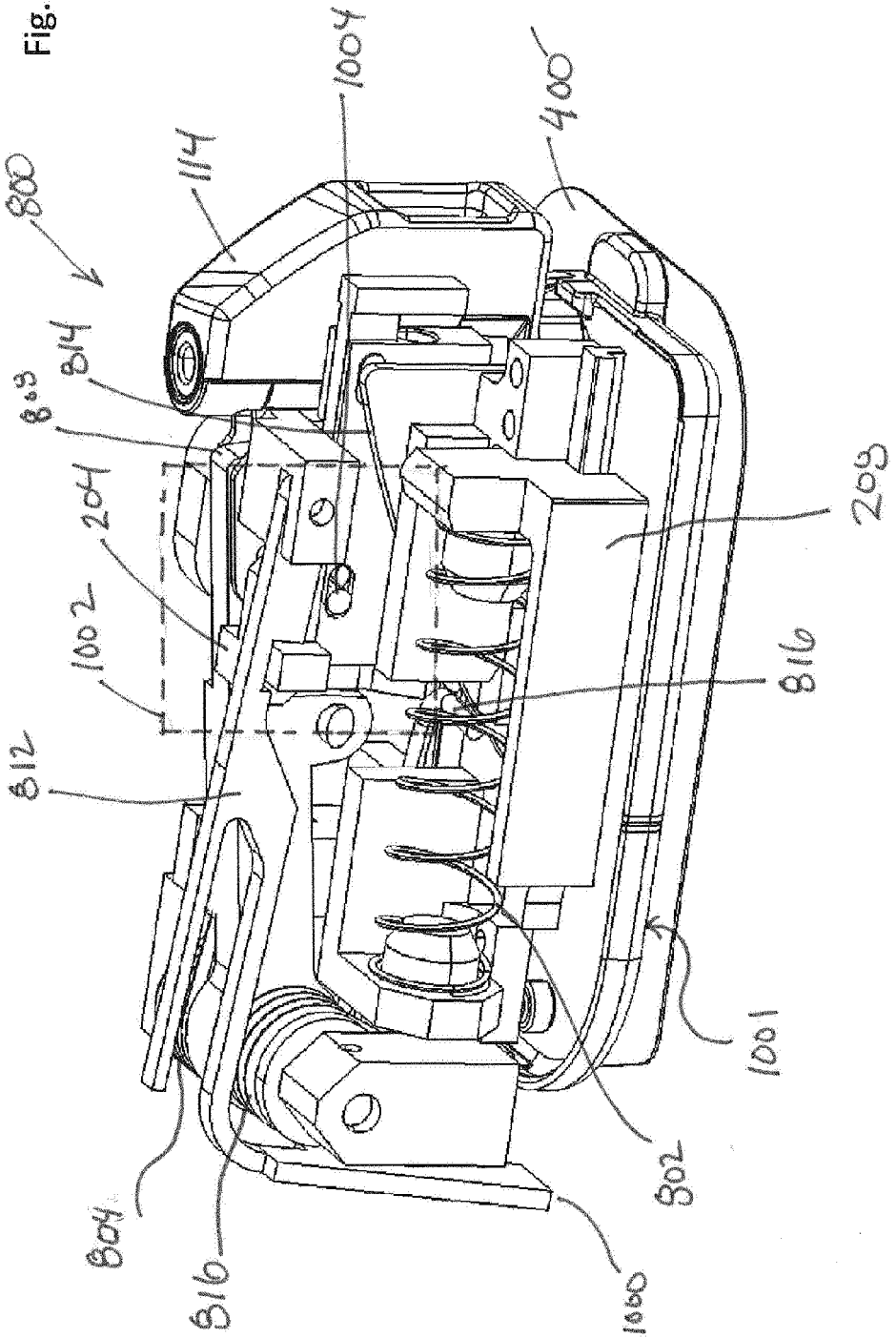


Fig. 10


800
114
1004
400
814
803
204
1002
203
816
812
1001
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802
810
1000

Fig. 11

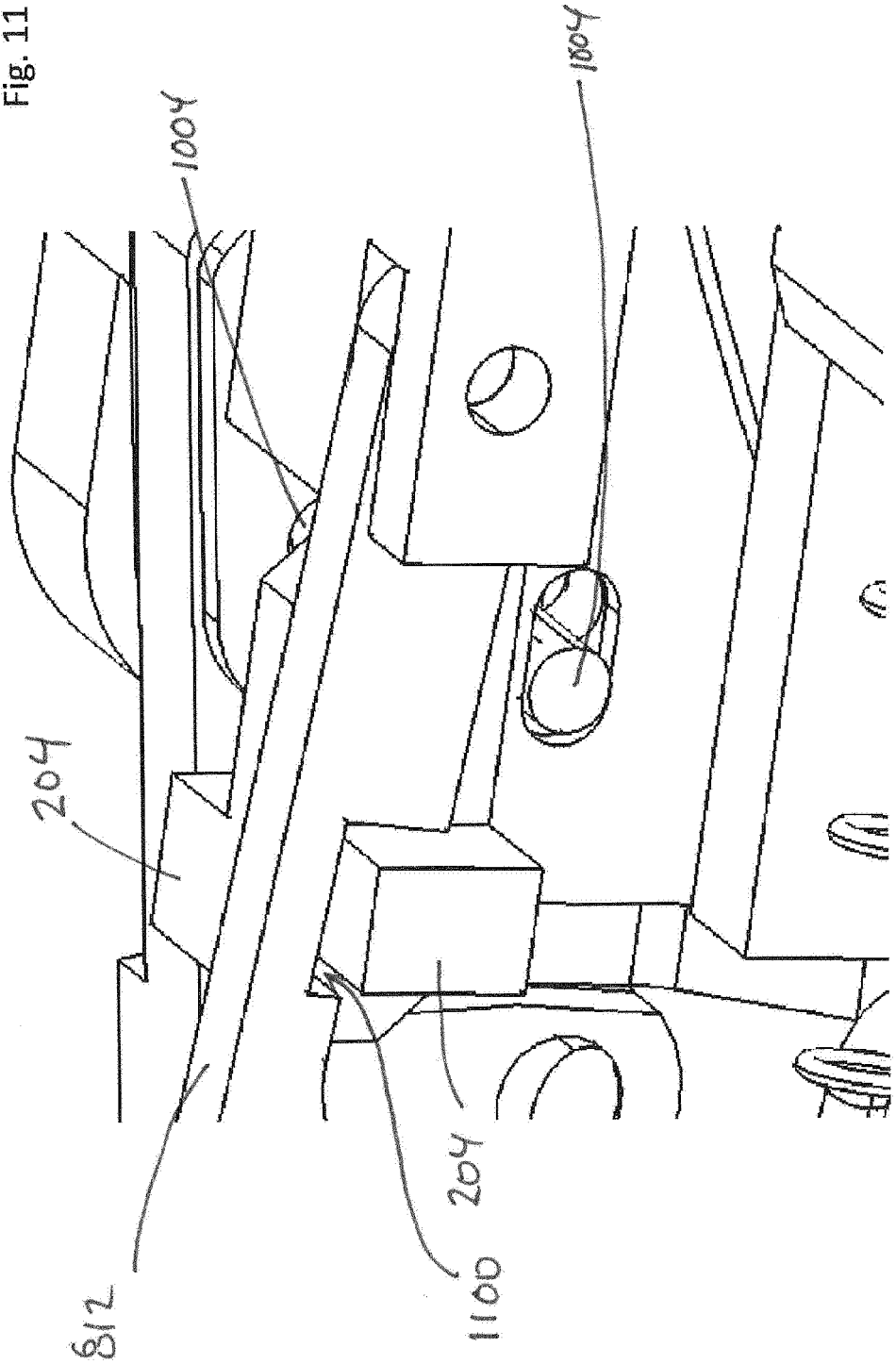

Fig. 12

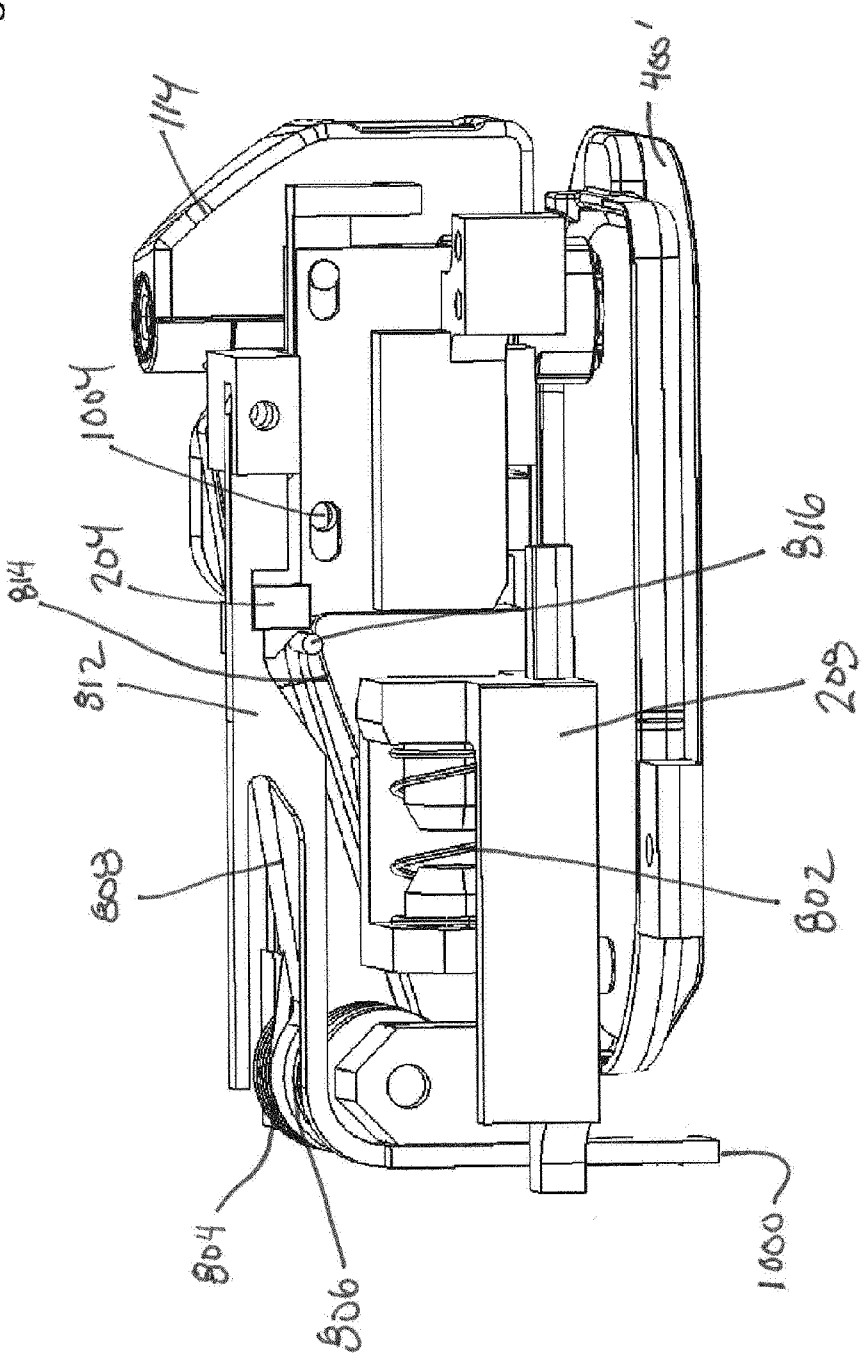

Fig. 13

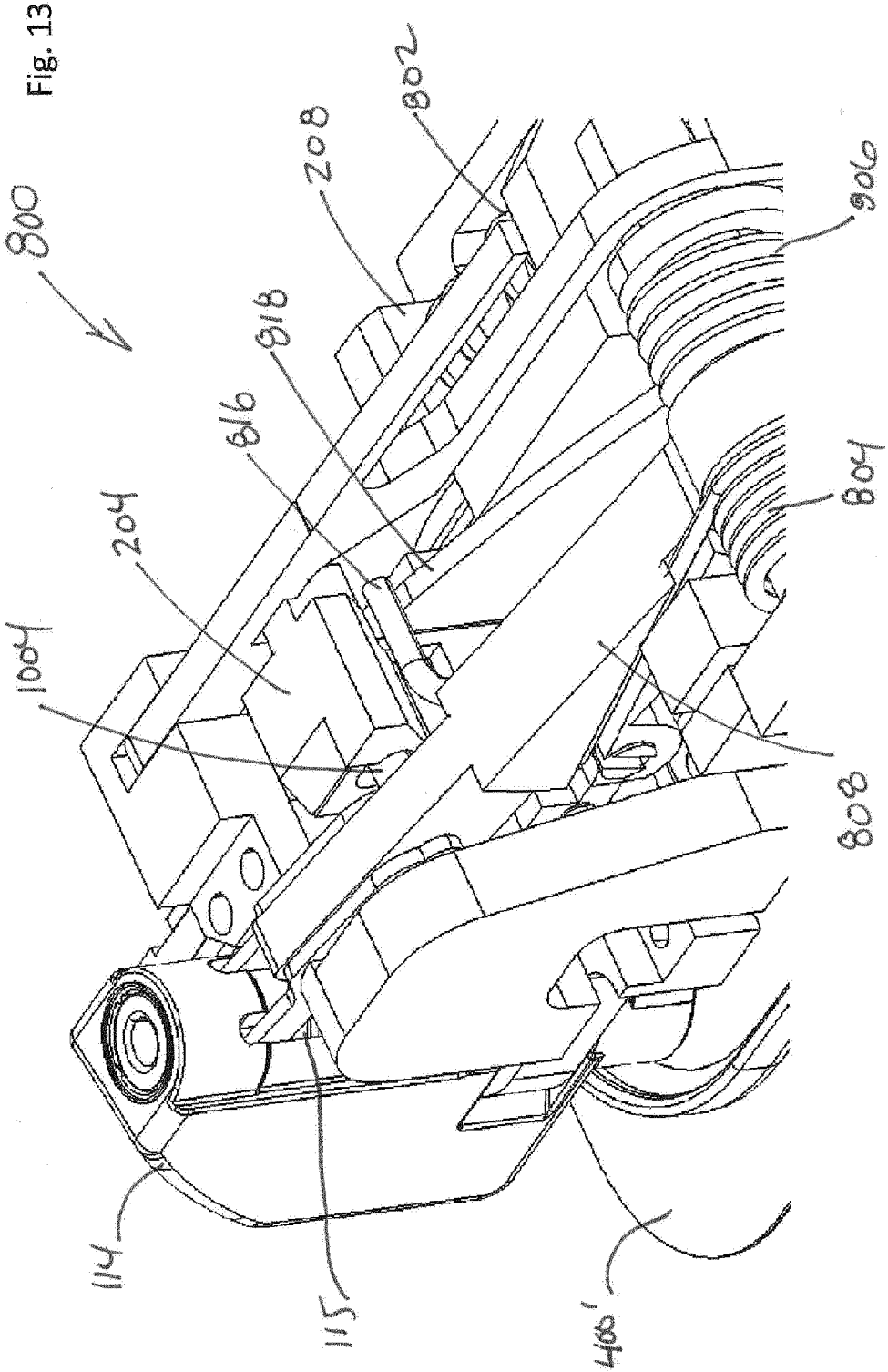

Fig. 14

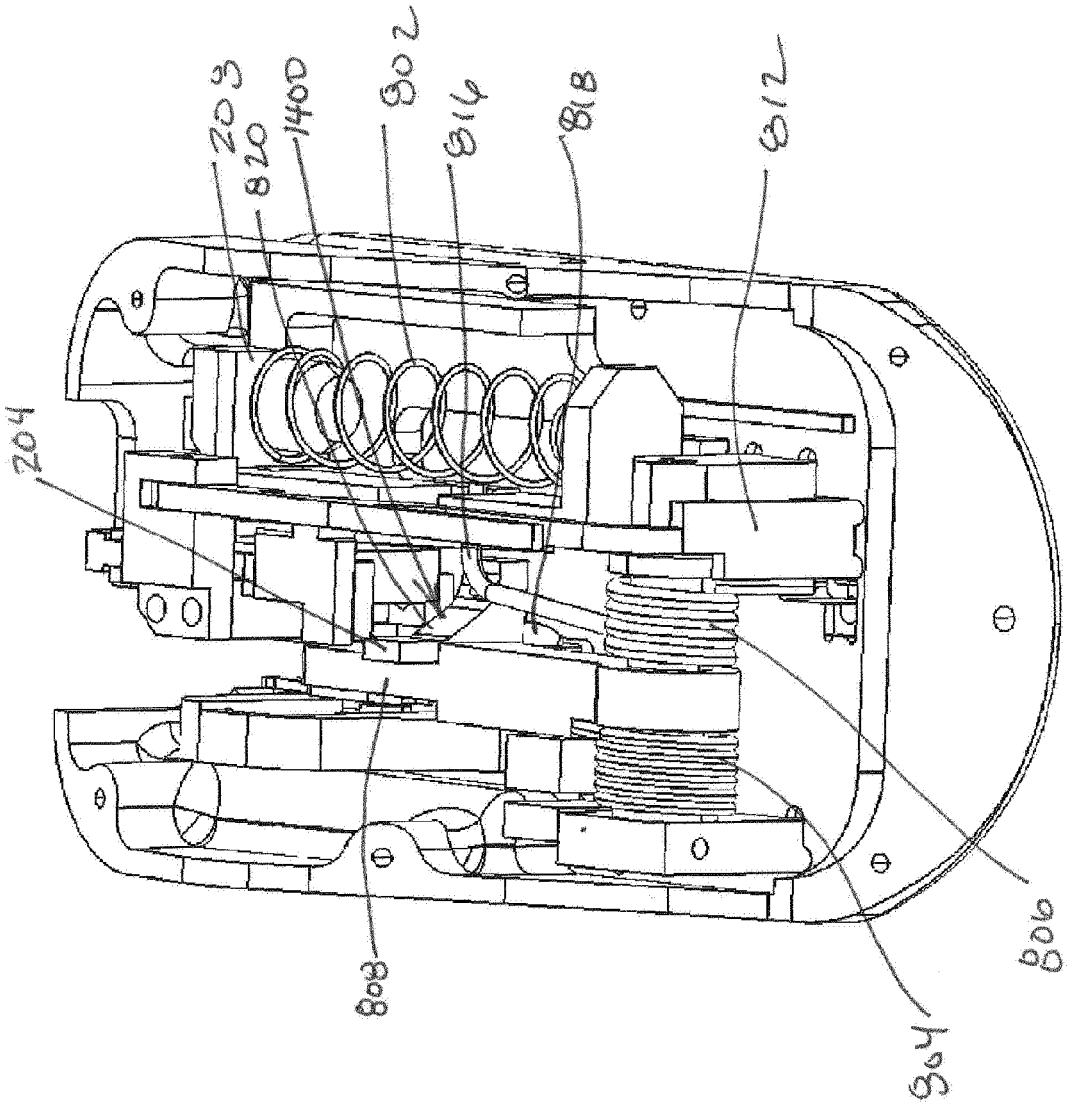

FIG. 15

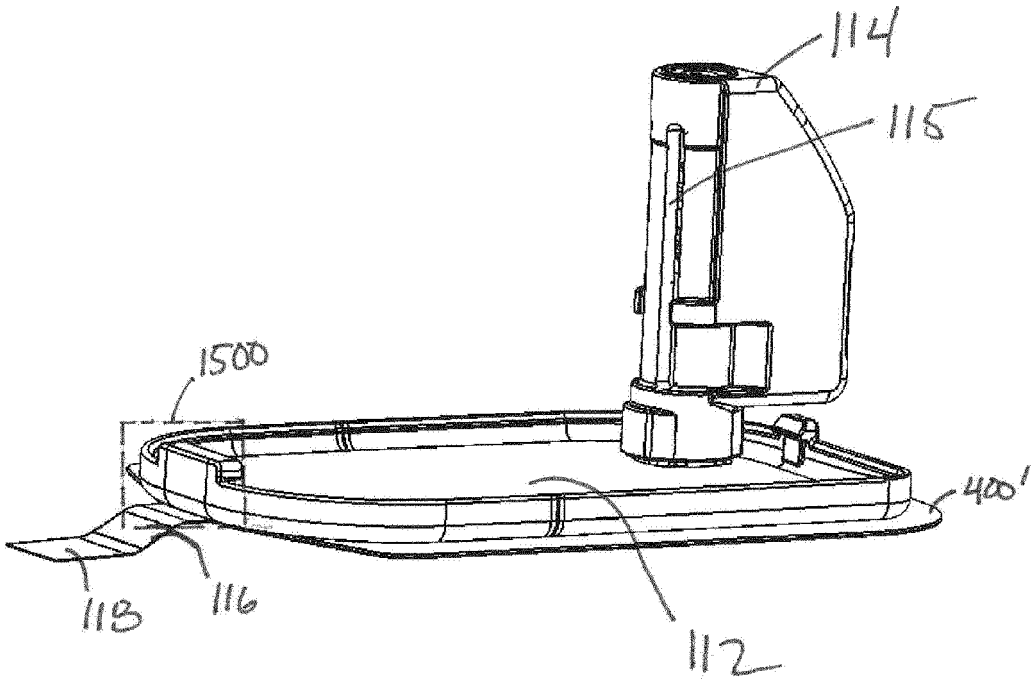

FIG. 16

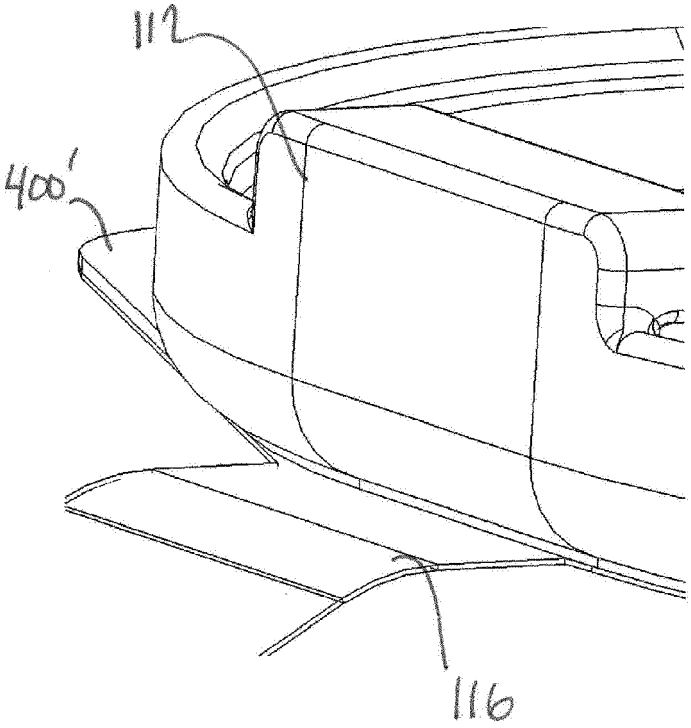

FIG. 17

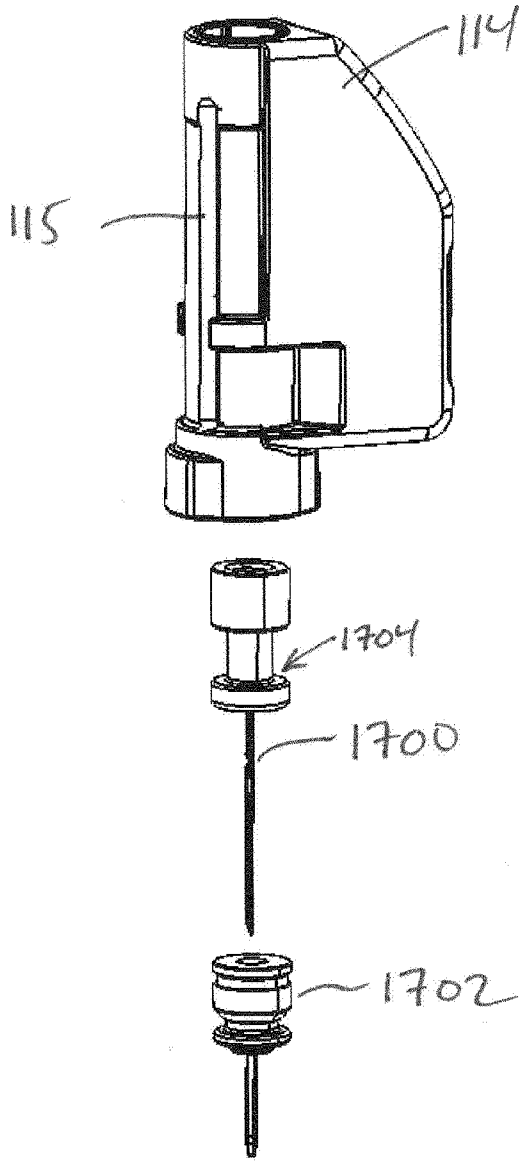

FIG. 18

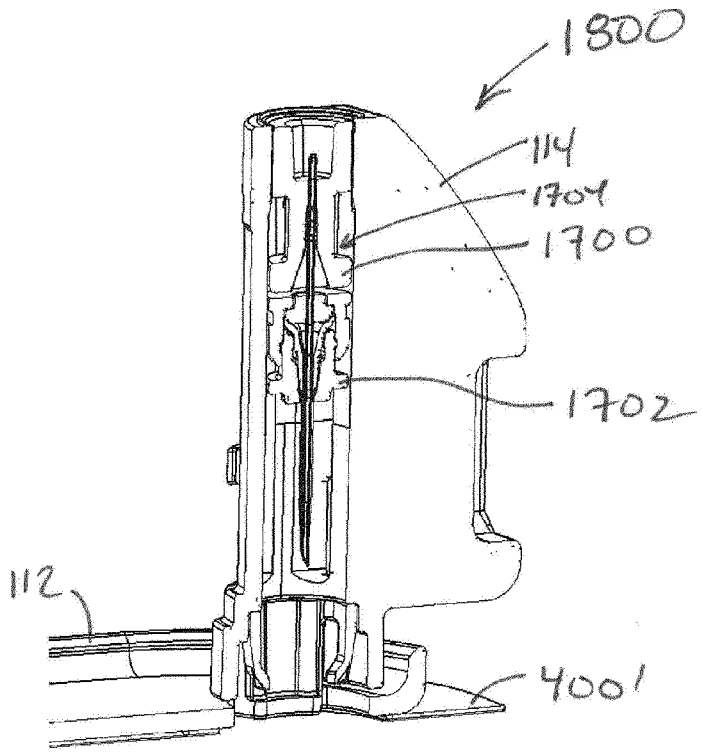

FIG. 19

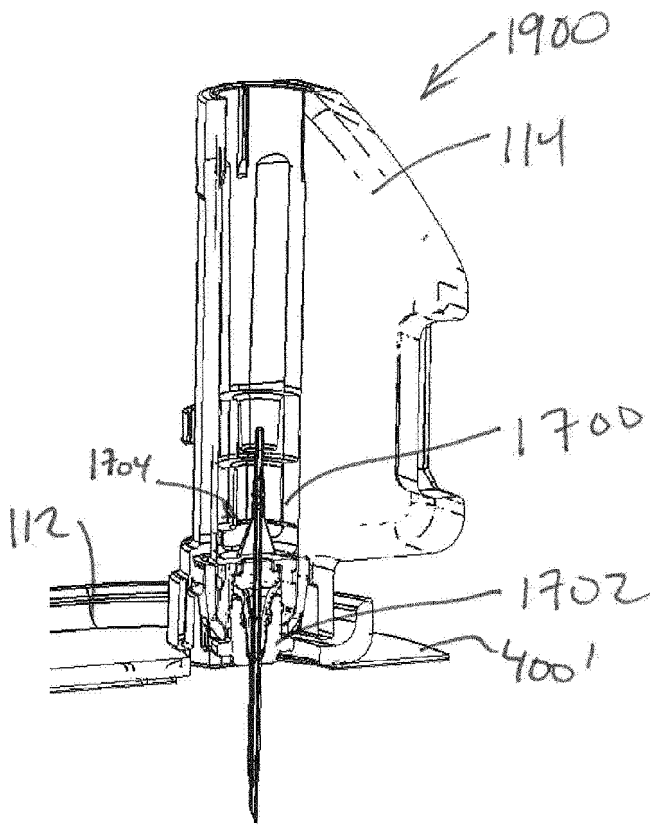

FIG. 20

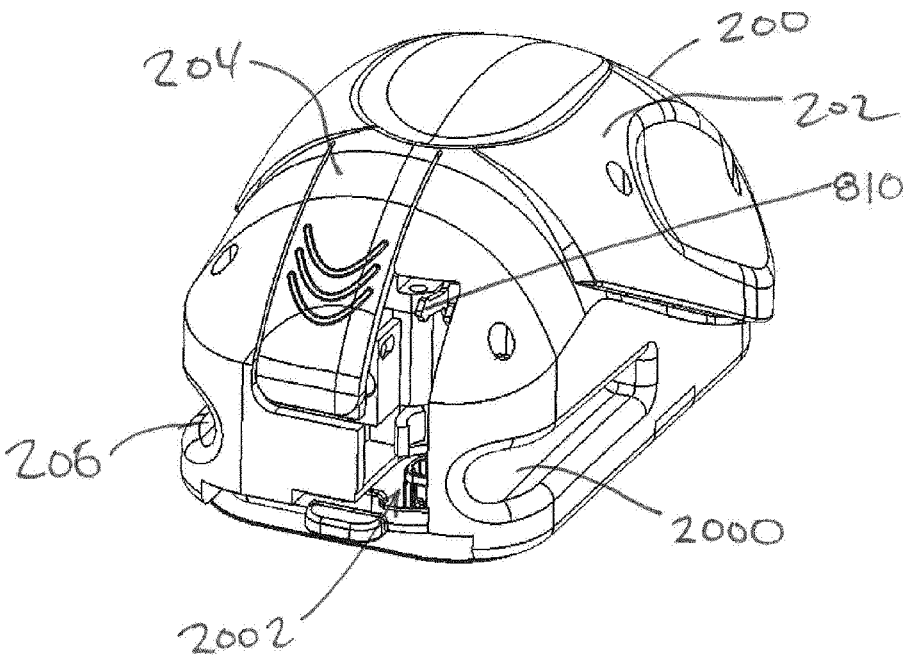

FIG. 21

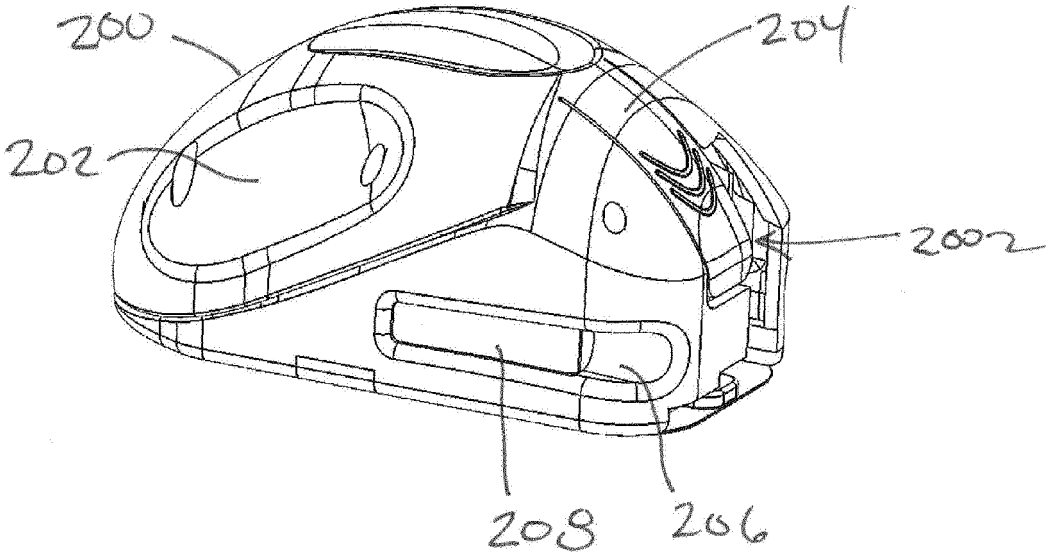

FIG. 22

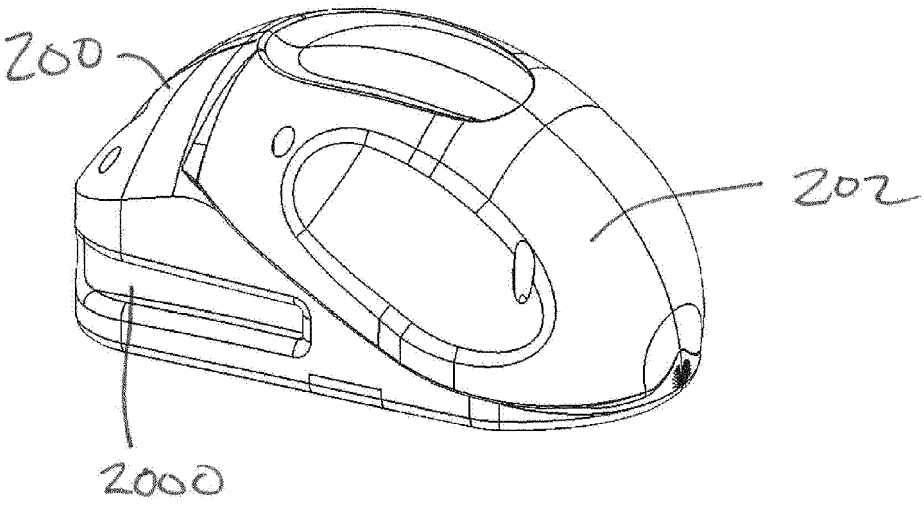

FIG. 23

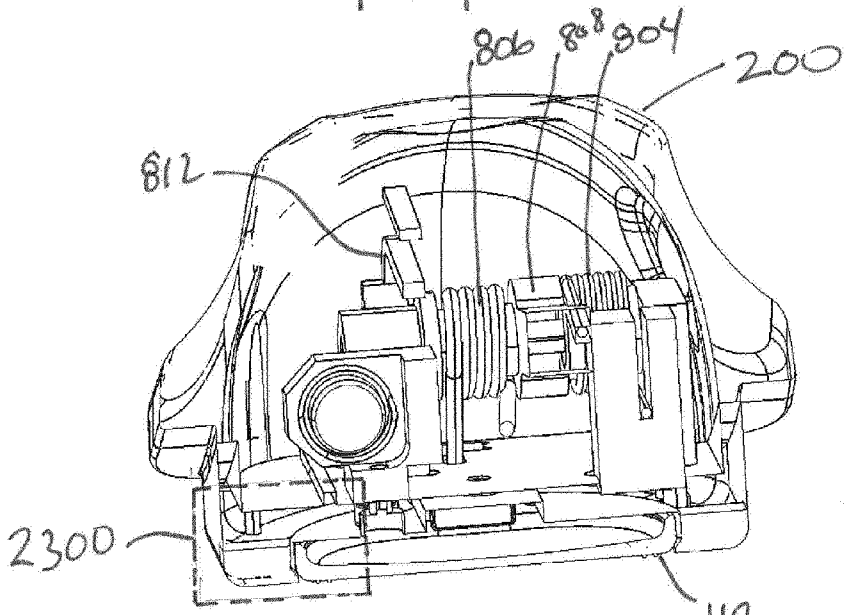

FIG. 24

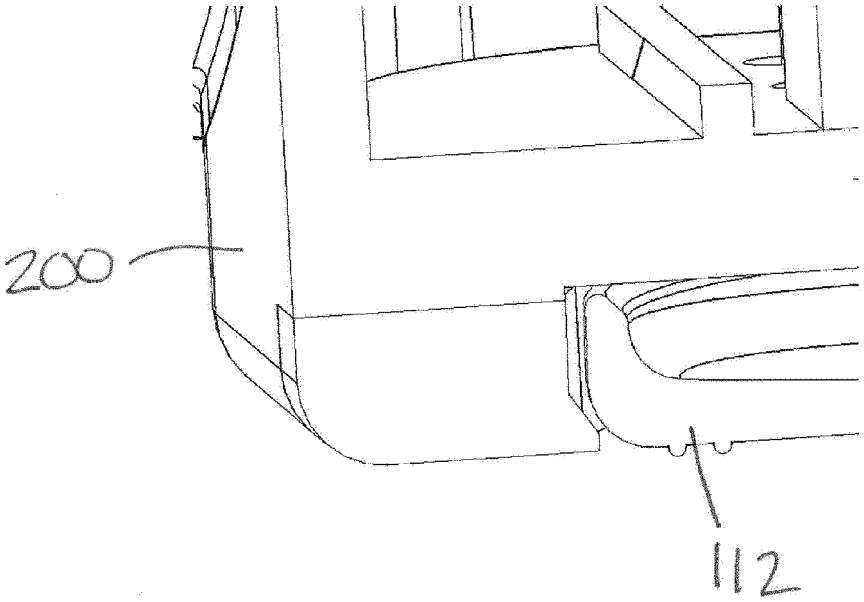

FIG. 25

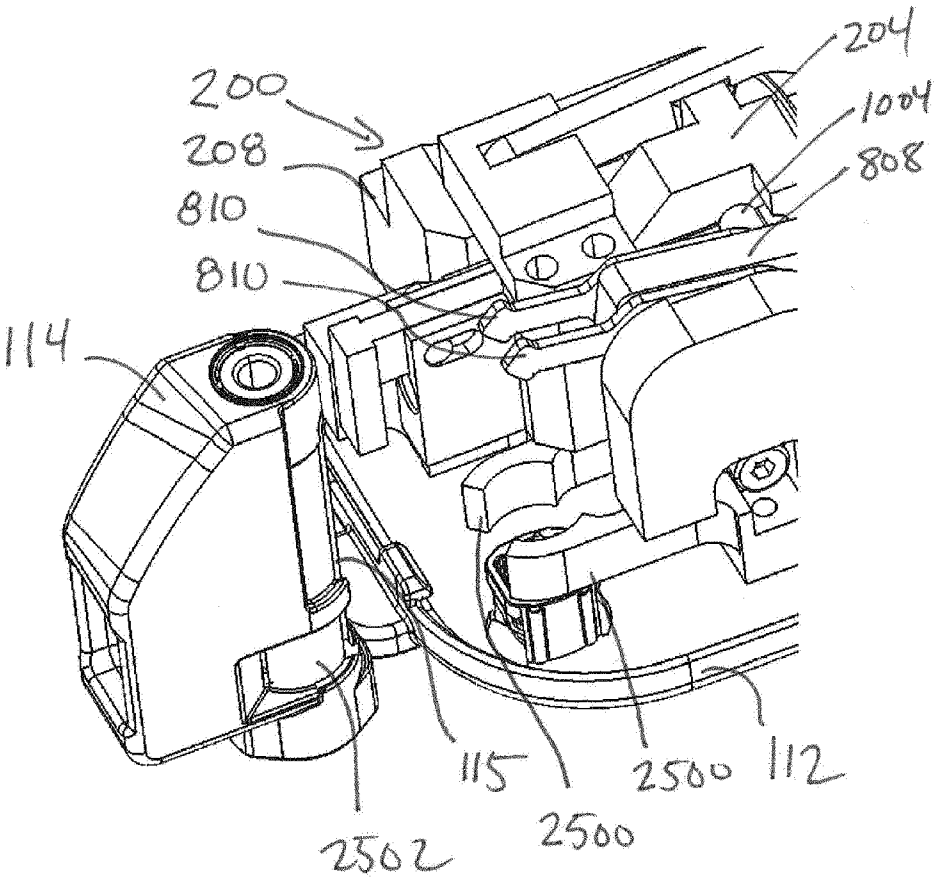

FIG. 26

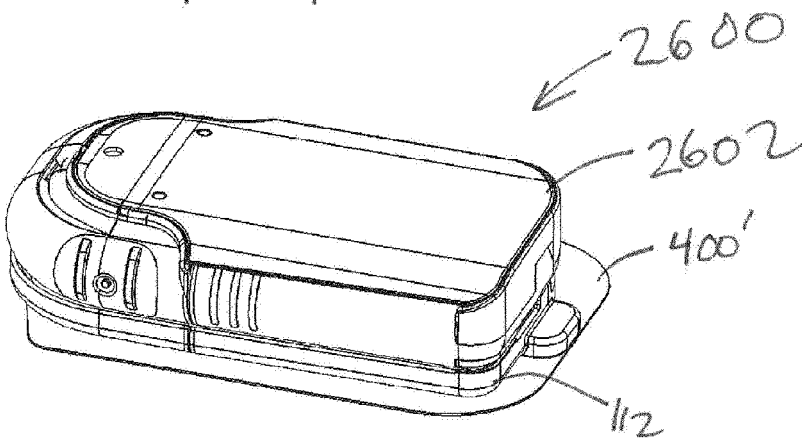

FIG. 27