

LANCET APPARATUS AND METHODS

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 This invention relates generally to lancets and more particularly to novel, self-contained, precocked and single-use lancets which, when activated, extend a tip of a lancet blade outward from a lancet housing and back into the lancet housing for safe disposal.

2. Related Art

10 In particular, U.S. Patent Number 5,514,152, entitled Multiple Segment Encapsulated Medical Lancing Device, issued to Roger E. Smith ("Smith") May 7, 1996, discloses a lancet having a cocked torsion spring wound about a centrally disposed hub frangibly connected to a lancet housing. In a plural lancet strip embodiment, the lancet housing is disclosed to be a
15 container for a plurality of lancets, each of which, after use, is frangibly separated from the rest of the strip and individually discarded. The spring is directly interconnected to a lancet blade in a cam/cam follower relationship which is taught to dispose the blade outwardly and inwardly in a substantially linear fashion. When the hub is frangibly separated from the lancet housing,
20 the cocked spring is released to drive a lancet blade tip linearly from the lancet housing and then to return it back into the lancet housing.

 Smith discloses frangible separation of the hub from the lancet housing where a base of the hub is annularly connected by sharp corners to the lancet housing. Smith also teaches that stress placed upon the base causes the hub to
25 frange from the lancet housing, permitting a lancing cycle to begin. Before each lancing cycle is initiated, a lancet housing exit is exposed to provide an orifice through which the lancet blade tip travels. It is only when the orifice is provided that the sterility of the package is compromised keeping the blade and internal contents sterile until the orifice is opened.

30 U.S. Patent Number 4,643,189, entitled Apparatus for Implementing a Standardized Skin Incision, issued to Michael Mintz February 17, 1987 ("Mintz") discloses an apparatus for implementing a skin incision which has been applied to a lancet application, particularly to a pediatric lancet,

distributed under the name Tenderfoot[®] by International Technique Corporation, 23 Nevsky Street, Edison, N.J. 08820. This skin incision apparatus comprises a pivotal arm to which a lancing blade is securely affixed and which is driven by a torsion spring. The arm communicates with a
5 surrounding lancet housing at two points, a first point at which is formed a sliding pivot disposed within the lancet housing and a second point which is within a track forming a cam follower arrangement. The arm is driven by the torsion spring to follow the track, while sliding transversely to a patient contacting surface through which the blade communicates through a slot in the
10 lancet housing. Thus, a portion of the arm and entire blade moves transversely in the direction of that portion of the arm which resides within the lancet housing between the pivot point and slot. In this manner, an elongated incision, having a controlled depth of cut, is made through the surface of the skin. It is important to note that the length of the incision at the skin surface is
15 substantially the same or longer than the length of the cut down below the skin surface. Also, the pivot is taught to be disposed more than a blade length away from a point of the blade.

In all other known safety and non-safety lancets, it is a common practice to lance the exterior (epidermis) of the skin to reach the capillary rich
20 inner dermis skin layer with an incision which is substantially the same size or greater in the epidermis layer than the subsequent incision in the dermis layer. Of particular interest, in this regard, are the well known facts that there are no blood carrying vessels disposed in the epidermis layer and that the dermis layer generally comprises a capillary rich bed which is the primary target of
25 each lancet.

SUMMARY OF THE INVENTION

In brief summary, the present invention comprises a novel apparatus and method for single use safety lancets. The invention provides a restricted
30 and relatively narrow entry through the epidermis layer coupled with a broader cut below the epidermis layer, rather than a substantially linear incision through both the epidermis and dermis layers of skin. Hence, there is less

trauma to the exterior layers of the skin, while producing a more extensive cut of controlled depth and breadth in the interiorly disposed layers. These interiorly disposed layers are generally the source of blood acquired by lancing.

5 Generally, the present invention employs an extremely narrow blade having a sharpened tip and a cutting edge disposed toward the direction of movement of the blade in the interiorly disposed layers. In this manner, the blade is directed through the epidermis (surface) skin layer, and then rotated laterally about a pivot point disposed substantially at the surface of the skin.
10 As a natural consequence, the width of penetration through the essentially blood-free epidermis is effectively the width of the thin blade, while the width of the cut in the blood-rich capillary bed of the dermis layers may be several times (e.g. four times) wider than the blade. In this manner an opening sufficient to permit blood acquisition at the skin surface is made through the
15 epidermis, while a broader incision is made in the lower dermis to provide a more abundant supply of blood from each lancing procedure.

 Though other energy storing, blade driving components may be used within the scope of the invention disclosed herein, a torsion spring is preferred for displacing a blade body, partially disposed within a lancet housing, and,
20 thereby, displacing an associated blade and blade tip angularly out from and back into a lancet housing.

 In one embodiment, a blade body comprises a slot into which an axially disposed post of a wound spring is inserted and then released to rotate as the spring unwinds. As the post rotates, the blade and associated blade tip
25 are displaced outward from the lancet housing through an exit portal. The portal comprises a side member, disposed to be in opposition to the direction of blade travel. The side member, resultingly, communicates with and acts as a fulcrum for the blade as it travels outward and then inward. Continued travel of the post maintains an edge of the blade against the side member resulting in
30 displacement of the blade tip in a direction opposite the direction of unwinding of the rotary spring and its post. In various other embodiments, the blade body may comprise a substantially circular orifice or an elongated slot through

which a torsion spring post is disposed to drive the blade as the spring unwinds. Variation of the slot shape and size provides a variety of cut width and depth patterns in the sub-epidermal tissue.

5 Generally, each device lancet housing comprises a top part and a bottom part. In one embodiment, the bottom part of a housing comprises a hub in which an elongated groove is disposed for the purpose of releasibly retaining a radially disposed arm of the spring which is extended to form the blade driving post. As the post follows a predetermined arc based upon the physical characteristics of the spring, post and hub, the blade is displaced
10 through a predetermined pattern as the spring unwinds. Generally, the pattern is significantly more narrow at entry through the epidermis layer than the resultant cut through deeper areas of the dermis layer due to rotation of the blade about the side member.

A track, disposed as a part of the housing and into which the post is
15 inserted to form a guide, provides a precision pathway is defined for the blade as the spring unwinds. In this manner, a constrained blade tip course may be predictably programmed to accomplish a desired sub-epidermal cut pattern. As an example, by arcing the guiding track medially inwardly to compensate for distal outward displacement of the post as the spring rotates, a substantially
20 constant cut depth may be accomplished.

Another embodiment comprises a torsion spring without an associated hub. A spring post is retained in a cocked state by a catch formed in a leading segment of a guide track. To actuate a lancing cycle, the post is offset and released by depressing a lancet trigger. Upon release, the post follows the
25 remainder of the guide track to steer and propagate a blade to make a predetermined cut pattern as described above.

It may be noted that in Smith (as cited above), the blade motion consists of an outwardly driven and then inwardly retracted lancet blade through a cycle which is initiated by fringing a hub, securely affixed to a
30 cocked spring, from an integrally associated housing. The blade described in Smith is constrained to follow a strictly linear in/out path. This motion produces a cut which is generally at least as large through the epidermis layer

of the skin as the resulting deeper cut below the epidermis layer. This is in marked contrast to the cut pattern of the instant invention disclosed herein.

Further, in one embodiment of the present invention, any hub in which the spring is releasibly constrained remains affixed to the housing to provide a more secure support for the spring, before it is released to unwind and drive the blade outwardly and then inwardly.

It is noteworthy that the guiding process which steers the blade action involves a guide track which directly interfaces with a post of a torsion spring and further involves a side of an exit/reentry orifice of the lancet housing. This type of interface with a biasing member is in marked contrast to Mintz, wherein an actuator acts directly upon an arm to which is affixed a long incision cutting blade and the spring slidably communicates with the arm.

Accordingly, it is an object of the present invention to provide a lancet having a lancing pattern which comprises an incision which is narrower in the epidermis layer of the skin than a resultant laceration in the dermis layer of the skin.

It is a further object of the present invention to provide a one-time-use, self-driven lancet having a narrow blade for facile insertion and narrow incision through an epidermal layer of skin, which is rotated laterally to make a nonlinear laceration through the dermal skin layer following entry through the epidermis layer to produce a broader cut in the dermis layer than the incision made in the epidermis layer.

It is another object of the present invention to provide a spring and housing combination by which a blade is driven through a predetermined pattern of travel to lance an epidermal layer of skin more narrowly than subsequent lancing of sub-epidermal skin layers.

It is an additional object of the present invention to provide a lancet activator system which securely retains the blade inside a surrounding housing before and after a lancing procedure and by which a spring is released to drive the blade through a predetermined skin lancing pattern having a relatively small entry incision through epidermal skin layers and a much larger incision pattern in sub-epidermal layers during the lancing procedure.

These and other objects and features of the present invention will be apparent from the detailed description taken with reference to accompanying drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective of a single lancet according to the invention.

Figure 2 is a perspective of a bottom part of the single lancet seen in Figure 1.

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Figure 3 is a perspective of a top part of the single lancet seen in Figure 1.

Figure 4 is an inverted perspective of the top part seen in Figure 3, wherein an inside view is seen.

Figure 5 is a perspective of an actuator button of the single lancet seen in Figure 1.

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Figure 6 is an inverted perspective of the top part seen in Figure 3 showing an internal view of the top part and a cocked spring disposed therein.

Figure 7 is a magnified perspective of the spring seen in Figure 6.

Figure 8 is a perspective of the parts seen in Figure 6 with a blade affixed to a post of the cocked spring.

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Figure 9 is a magnified top elevation view of the blade seen in Figure 8.

Figure 10 is a perspective of the parts seen in Figure 8 with the spring released from a cocked condition and the post partially rotated as the spring unwinds to deliver a sharpened point of the blade through a slot in the top part.

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Figure 11 is a perspective of the parts seen in Figure 8 with the spring further unwound than in Figure 10.

Figure 12 is a perspective of the parts seen in Figure 8 with the spring further unwound than in Figure 11.

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Figure 13 is a perspective of the parts seen in Figure 8 with the spring further unwound than in Figure 12 to begin retracting the sharpened point back into the top part.

Figure 14 is a perspective of the parts seen in Figure 8 with the sharpened point fully retracted into the top part.

5 Figure 15 is a superior elevation of the bottom part seen in Figure 2 showing the shape of a guide track which controls travel of a spring post and consequently the lancet blade to a predetermined lancing pattern.

Figure 16 is a section of a bottom part similar to the bottom part seen in Figure 15, but having a differently shaped guide track to predetermine a different guide pattern.

10 Figure 17 is a perspective of an assembly of a second embodiment of the instant invention.

Figure 18 is a perspective of a bottom part of the assembly seen in Figure 17.

Figure 19 is a perspective of the bottom part seen in Figure 18 with a torsion spring and lancet blade disposed therein.

15 Figure 20 is a perspective of the combination seen in Figure 19 with an actuator assembled therewith.

Figure 21 is a perspective of the combination of parts seen in Figure 20 wherein the actuator is displaced to initiate a lancing cycle.

20 Figure 22 is a perspective of the combination of parts seen in Figure 21 wherein an arm of the torsion spring and the lance blade are displaced to drive the lancet blade obliquely through a slot in the bottom part.

Figure 23 is a perspective of the combination of parts seen in Figure 22 wherein the arm and lancet blade are still further displaced.

25 Figure 24 is a perspective of the combination of parts seen in Figure 23 wherein the arm and lancet blade are yet further displaced.

Figure 25 is a perspective of the combination of parts seen in Figure 24 wherein the arm is further displaced and the lancet blade is fully retracted into the bottom part.

DETAILED DESCRIPTION OF THE INVENTION

In this description, the term proximal is used to indicate the segment of a device or other apparatus normally closer to a user when the device is properly used. The term distal, consequently, refers to disposition of a segment of a device which is generally disposed away from the user. Reference is now made to the embodiments illustrated in Figures 1-25 wherein like numerals are used to designate like parts throughout.

Reference is made to Figure 1-16 wherein a first embodiment is disclosed. As may be noted in Figure 1, a first single-use lancet assembly 10 comprises a top part 20, a bottom part 30 and an actuator button part 40. Although other kinds of actuators may be used within the scope of the invention, button part 40 may be simply depressed to initiate a one-time lancing cycle. Though optional, an arrow 50 is disposed in close relation to a blade exit slot 60 to permit facile determination by a user of operational orientation of assembly 10. To lance a site (not shown), a surface about the site to be lanced is disposed in close communication with a distal surface 52 of lancet assembly 10. A one-time lancing cycle is initiated by depressing button 40.

Parts 20 and 40 and other internal lancet parts (not seen in Figure 1) are removed to provide an unimpeded view of the inside portion of bottom part 30 in Figure 2. Bottom part 30 comprises a substantially planar face 62 which is placed in contact with a site to be lanced. Of course, the curvature of face 62 may be varied to conform with natural interfaces relating to specially selected lancing sites, if desired. An internally directed surface 64 is substantially planar to provide a guide plane for a lancet blade (the forced displacement of which is described in detail hereafter). An arcuate channel, disposed in surface 64 and generally numbered 70, comprises guiding edges 72 and 74, the purpose of which is fully disclosed hereafter.

Bottom part 30 comprises a plurality of guideposts 76 which afford precise positioning between parts 20 and 30 when the lancet assembly 10 is fabricated. Further, part 30 comprises an arcuate, elongated edge structure 78, which is made to match and thereby provide a sterile seal with a

complementary edge structure in part 20. Hence, assembly 10 may be formed as a self-contained part which maintains an aseptic environment for parts internal to assembly 10. Bottom part 30 (and top part 20) are preferably made from medical injection moldable plastics, such as medical grade polypropylene or polycarbonate. However, other materials may be used within the scope of the invention. Material selected for such use should be resistant to cold flow structure modification and should be relatively non-compressible. Further, if a frangible seal is imposed over exit slot 60 and is to be broken away before assembly 10 is used in a lancing procedure, a mineral filled polystyrene may be preferred.

Top part 20 is seen with parts 30 and 40 removed in Figure 3. Without button part 40, part 20 is seen to comprise an aperture 80 medially disposed in a circular button well 82. Proximally disposed from aperture 80 is a button lock slot 84. Part 20, which is proximally disposed relative to well 82, comprises a substantially planar top surface 86, which proceeds distally to integrally connect to a sloped distal side surface 88. Laterally, side surface 88 is continuous with arcuate side surfaces 90 and 92, which are further joined by a proximal surface 94. Side surfaces 90 and 92 comprise complementary indentations 96 and 98, respectively, which provide gripping surfaces used for facile digital contact during a lancing procedure.

An inverted view of part 20 is seen in Figure 4. Disposed in asymmetrical alignment with well 82 (see Figure 3), is a hollow spring holding cylinder 100. Disposed within cylinder 100, somewhat proximally from the central axis of cylinder 100, is a spring retention hub 102. Hub 102 comprises a spring arm retention slot 104 disposed across aperture 80. Slot 104 is inferiorly bounded by bottom segments, generally numbered 105, which extend radially outward on each side of aperture 80. A floor 106, from which cylinder 100 subtends, extends distally to form a top segment 108 of exit slot 60. A guide pin 110 protrudes upward from floor 106. The purpose and function of guide pin 110 is clearly disclosed hereafter. Part 20 further comprises an interior wall 112 having a complementary shape to edge structure 78 (see Figure 2), such that an aseptic seal is provided when parts 20

and 30 are securely affixed. Parts 20 and 30 may be joined by methods and materials well known in plastic adhesion art, such as by ultrasound welding, adhesives or thermal welding.

5 One embodiment of button part 40 is seen in Figure 5. It is preferred that button part 40 have a button 120, which provides a large area to reduce digitary pressure required to initiate a lancing procedure. Extending from a bottom face 122 of button 120 is an elongated stem 130, which is abruptly truncated at surface 132. Surface 132 is disposed at a level which is even with bottom segments 105 (see Figure 4) at the bottom of spring retention slot 104
10 until assembly 10 is used in a lancing procedure. Of course, sufficient clearance must be maintained within well 82 for button stem surface 132 to be displaced from the level of bottom segment 105 to essentially clear slot 104 of a spring arm residing therein. It should be noted that button 120 is preferably made from an essentially incompressible, yet somewhat flexible synthetic
15 resinous material, such as polypropylene.

It is critical that button part 40 be securely affixed to assembly 10. For this purpose, a locking leg 134 is provided. Leg 134 comprises a latch 136, which is inserted through lock slot 84 (see Figures 3 and 4) to form a secure catch. Leg 134 may be replaced by a bulbous section (not shown), molded
20 about stem 130 and a complementary ledge in aperture 80 (also not shown), which permits stem 130 to be forced into aperture 80 relatively easily, but not easily removed therefrom. Such latching and catching connections are known in the plastics molding art.

Attention is now directed to Figure 6 wherein button part 40 stem 130 is inserted into aperture 80, and a torsion spring 140 is disposed in cylinder 100. As better seen in Figure 7, spring 140 comprises an elongated base extension 142, a coil 144 and a cross-arm 146. Cross-arm 146 further
25 comprises an upwardly distending post 148. Spring 140 is preferably made from 0.023 inch in diameter stainless steel or silicone lubricated piano wire.

30 Referring once more to Figure 6, spring 140 is seen disposed in cylinder 100 in a wound state with cross-arm 146 located in a position ready

for insertion into slot 104. Post 148 is superiorly directed relative to floor 106. Latch leg 134 is disposed through slot 84 to catch latch 136 thereat.

In Figure 8, cross-arm 146 of spring 140 is disposed and thereby cocked in slot 104. Further, a lancet blade 150 is hingeably affixed to spring 140 via insertion of post 148 through an elongated slot 152.

In Figure 9, lancet blade 150 is seen to comprise an arcuately shaped body portion 154 and a blade segment 156. Blade segment 156 comprises a sharpened point 160 and a sharpened edge 162. Body portion 154 is integrally connected to blade segment 156. In addition to slot 152, lancet blade 150 communicates with a rotating cross-arm 146 through post 148 as spring 140 unwinds, on one side. Body portion 154 comprises a guide hook 164 which is releasibly affixed to guide pin 110 (see Figure 8) to direct the sharpened point 160 of blade segment 156 through exit slot 60 (also see Figure 8) at the beginning of a lancing procedure. Sharpened point 160 should have a sufficient degree of sharpness to facilitate entry into a site to be lanced. Also, sharpened edge 162 should be sufficiently sharp to incise an extended length of tissue as blade segment 156 is rotated in the direction of edge 162.

Lancet blade 150 is preferably made from medical grade stainless steel having a thickness of .006 to .012 inches, although different blade thicknesses may be used within the scope of the instant invention disclosed herein. Blade 150 may be made by a number of processes including machining and laser cutting. However, to make a blade at reduced cost, it is preferable to make the blade by coining. A coined blade has a sufficiently sharp point and cutting edge to provide a substantially painless high velocity incision, such as an incision driven by spring 140.

Care must be taken to consider a number of variables concerning various blade designs. First, the cutting blade segment 156 should have as small a width as possible, thereby precluding blades which are too small in width and might result in blade bending or knurling during a lancing procedure. The selection of material which defines the blade thickness is also important. A material which is too thin may result in reduced blood flow due to a restricted blood acquisition path and more rapid clotting than is desired.

As is evident in Figure 8, lancet blade 150 is secured in place prior to release and activation of torsion spring 140 by interaction between guide pin 110 and guide hook 164, post 148 and slot 152, and interior wall 112 of top part 20 and an edge 166 of blade body portion 154 (see Figure 9). Rotation of lancet blade 150 is restricted until post 148 is freed to travel. So disposed, blade 150 is held immobile until arm 146 is ejected from retention slot 104 which, of course, is accomplished by pressing button 40 inwardly into part 20 and forcing stem surface 132 against arm 146.

An important feature of device 10 is seen at that portion of exit 60 which is formed by part 20. At exit 60, part 20 comprises an abutment 170 which opposes direction of travel of post 148 and blade segment 156 as spring 140 unwinds. Abutment 170 is preferably relatively sharp and knifelike, being formed by a pair of intersecting sides 172 and 174 which are disposed to be free of conflict with an anterior edge 176 of blade segment 156 during a lancing procedure. Further, sharpened point 160 of blade segment 156 is steered by action of arm 146 through post 148 in slot 152 and guide pin 110 in guide hook 164, obliquely through slot 60. Consequent to the direction of rotation of post 148, anterior edge 176 is forced against abutment 170 which acts as a fulcrum about which blade segment 156 rotates until sharpened point 160 is withdrawn from slot 60 at the end of a lancing cycle.

It should be noted that, when a tissue site (not shown) to be lanced is disposed against surface 52 (see Figure 1), it can reasonably be expected that a portion of tissue surrounding the tissue site will conform to and at least partially bulge into slot 60 providing ready access for an extending sharpened point and associated blade segment 156. Lancet blade 150 is arcuately driven by the travel of post 148, and sharpened point 160 is steered through slot 60 by interactive guidance provided by guide pin 110 and steering hook 164. In this manner, sharpened point 160 is driven past abutment 170 and a portion of blade segment 156 is discharged obliquely (relative to the tissue site and surface 52) to commence a lancing cycle as seen in Figure 10.

An ever broadening subsurface incision is made by blade segment 156, as sharpened edge 162 is displaced through tissue at the lance site as noted in

Figures 11, 12 and 13. It is noteworthy that the direction of lancing opposes the direction of angular travel of blade body portion 154. This rotation about abutment 170 produces an epidermal incision which is substantially the width of blade segment 156 at a maximum insertion point, while the breadth of cut made along a line of traverse of sharpened point 160 is much broader than the blade width. For this reason, the blade segment should have as small a width as possible to reduce trauma to epidermal skin layers. However, it may be necessary to make anterior edge 176 somewhat thicker to displace tissue sufficiently for adequate blood flow.

Figures 12 and 13 illustrate that slot 152 is elongated to permit blade segment 156 to remain distally extended as post 148 begins to be proximally displaced. Other slot configurations may be used within the scope of the invention to produce a variety of predetermined lancing patterns.

Finally, post 148 is displaced to be in contact with a proximal portion of slot 152, and lancet blade 150 is fully retracted, as seen in Figure 14, for safe disposal. It may be desired to constrain blade 150 to a different lancing pattern than that disclosed in Figures 10-14. As mentioned above, channel 70, as seen in Figures 2 and 15, is formed to guide post 148 through a natural arc which corresponds to angulation of arm 146 as torsion spring 140 unwinds. Edges 72 and 74 form a track which limits extension of blade segment 156 and thereby controls with precision the pattern of each lancing incision.

Other patterns than those which follow a path of natural displacement of arm 146 may also be implemented within the scope of the instant invention, as is exemplified by a guide track (also numbered 70 per the general connotation indicated earlier) seen in Figure 16. Guide track 70 in Figure 16 comprises arcuate sides 180 and 182. Medially sides 180 and 182 are proximally displaced relative to sides 72 and 74 seen in Figure 15. Such displacement causes post 148 to follow an abnormal pattern, which might cause binding unless a portion of torsion spring 140 is displaced proximally as well. Such a displacement is possible since coil 144 may be readily deformed to accommodate the displacement as post 148 travels along track 70.

A second embodiment of the instant invention is illustrated in Figures 17-25. An assembly 210 of the second embodiment is seen in Figure 17. Assembly 210 comprises a top cover 220, a bottom part 230 and an actuator 240. Generally cover 220 is formed to accomplish a tight aseptic seal when affixed to bottom part 230, and provides a generally planar exterior surface 242 for one side of assembly 210. An elongated wing 244 rises transversely from surface 242 to provide a first handle for facilely gripping assembly 210. A complementary second handle is disposed on a side of bottom part 230 that is opposite surface 242 (not shown). By placing an index finger against one handle and a forefinger against the other handle, for example, assembly 210 may be disposed against a site to be lanced and actuator 240 depressed with a thumb of the same hand, thereby permitting facile one-handed operation.

A perspective inside view of bottom part 230 is seen in Figure 18. Part 230 comprises a pair of elongated upright sides 250 and 252, which are interconnected by a front face 254 to form a tray-like container 255 having an open, proximally disposed entry site 256 for an actuator button (described hereafter) and a planar floor 258. Distally disposed within container 255 are a spring arm anchor 260 and a spring lock and guide assembly 270. Anchor 260 comprises a raised outer ring 271 and a centrally disposed aperture 272, wherein a post of a locking arm of a spring is rotatably disposed. Details related to the spring are addressed in detail hereafter.

Guide assembly 270 comprises an arcuate, closed wall structure 274 forming a track 276, wherein a post of another arm of the spring is guided. The purpose and result of guiding the post of the other spring arm is disclosed in detail hereafter. Structure 274 comprises a substantially planar superior surface 278, which is interrupted by a proximally disposed channel 280. Channel 280 is proximal to a portion 282 of track 276, which is displaced proximally from a larger more transversely disposed segment 284. Proximally disposed within portion 282 is a medially inclined indentation 286 in wall structure 274, which acts as a catch for the post of the other arm of the spring. Structure 288 rises substantially above surface 278 and is laterally disposed to track 276.

Front face 254 comprises a pair of aligned walls 290 and 292. In combination, walls 290 and 292 comprise juxtaposed frame members 294 and 296, respectively, which form an opening 300 for exit and reentry of a lancet blade. For reasons more fully clarified hereafter in the disclosure related to patterns of travel of lancet blades, it is preferred that frame 296 be formed with as sharp an edge as is reasonably moldable, while maintaining sufficient structural strength to prevent undesirable deformation.

Reference is now made to Figure 19, wherein a lancet blade 310 and a torsion spring 320 are disposed in bottom part 230. Torsion spring 320 comprises a first arm 322, a second arm 324 and a spring coil 326. Lancet blade 310 comprises a blade body portion 328 and a blade segment 330, wherein blade segment 330 is similar in form and function to blade segment 156. Similar to blade segment 156, blade segment 330 comprises a sharpened point 332, a sharpened edge 334 and an anterior edge 336. Rather than a slot, as found in blade body portion 154, blade body portion 328 comprises a substantially round orifice 340.

The second arm 324 of spring 320 comprises a substantially transverse bend at a free end 342, which is disposed in aperture 272 to securely anchor arm 324 thereat. A post 344, formed by a transverse bend in first arm 322 of spring 320, is disposed through orifice 340 and securely, but releasibly anchored by disposition in indentation 286 in wall structure 274 (Figure 18).

Further, blade body portion 328 comprises a substantially straight edge 346 (as seen in Figure 22), which affords a flat surface against which a substantially planar surface 348 of structure 288 acts to retard rotation of lancet blade 310. As will be evident hereafter, surface 348 not only retards rotation while arm post 344 is anchored in indentation 286, but also acts as a guide urging sharpened point 332 into and through opening 300 as post 344 is displaced into segment 284 of track 276.

Reference is now made to Figure 20, wherein actuator 240 is seen to comprise a depressible button 350, a hollow section 352 (in which spring coil 326 partially resides while the spring is cocked) and an elongated leg 354 which extends from hollow section 352 to close juxtaposition with post 344 of

arm 322. Leg 354 is sized to be stabilized and guided by channel 280 (see Figure 18 and 21). Spring coil 326 and, therefore, torsion spring 320 are restrained from undue twisting while disposed in hollow section 352.

Depressing actuator 240 distally forces post 344 from its anchored position at indentation 286 toward and into segment 284 of track 276, as seen in Figure 21. Sharpened point 332 is forced into juxtaposition relative to opening 300. As post 344 is displaced into segment 284, arm 322 reactively follows track 276 toward arm 324.

As seen in Figure 22, blade segment 330 exits through opening 300 at an oblique angle relative to front face 254. The direction of travel of lancet blade 310 and post 344 disposes anterior edge 336 of blade segment 330 into sliding contact with frame member 296, such that lancet blade 310 is angularly displaced relative to front face 254 and opening 300 along a line from orifice 340 to frame member 296. This displacement defines an arc of travel of the sharpened point which is substantially longer than the width of blade segment 330 at its greatest extension from surface 254. Also, should a skin surface of a patient be disposed to protrude or bulge into opening 300, the length of an epidermal layer cut is substantially less than the length of the associated cut through the dermal layer as determined by travel of sharpened point 332. In this manner, there is less trauma at the skin surface than the concurrent length of cut in the subsurface (capillary rich) tissue in sub-epidermal layers.

Reference is now made to Figures 23 and 24 wherein lancet blade 310 rotates to drive a sharpened point acutely toward wall 290 for broadening the path of deep incision. The depth of the cut is determined by the angulation of segment 284 of track 276. An incision of nearly constant depth may be achieved by changing the substantially concave shape of track 276 to a planar or convex shape. Post 344 and arm 322 are free to follow such a track 276 shape as coil 326 floats freely. Coil 326 of spring 320 is permitted to be displaced by the action of arms 322 and 324 as spring 320 unwinds. In this manner, the travel of lancet blade 310 is entirely determined by the disposition of post 344 in track 276 and the action of anterior edge 336 against frame member 296.

As seen in Figure 25, lancet blade 310 is completely retracted into container 255 when post 344 reaches the end of track 276. For this purpose, spring 320 should retain a bias when post 344 reaches the end of track 276. At this point, lancet blade 310 is totally protected and thereby made safe for disposal.

Parts 220, 230 and 240 may be made from the same materials as those indicated previously for parts 20, 30 and 40, respectively. Injection molding of these parts is preferred. However, 0.040 inch stainless steel or treated (e.g. with silicone) piano wire is preferred for torsion spring 320.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed and desired to be secured by Letters Patent is:

THE CLAIMS

1. A one-time-use, self-powered lancet apparatus comprising:
a housing comprising a hollow space for fully containing a
5 lancet blade member, and an open frame forming a slot through which a blade
portion of the lancet blade member is extended and retracted;
the lancet blade member which comprises a proximally
disposed planar portion having an aperture for communicating with an energy-
storing memory element and a distally disposed elongated thin blade section
10 having a sharpened tip and at least one sharpened edge;
the energy storing memory element comprising a latching
member by which the element is retained in an energy storing state and a part
which is displaced as stored energy is released, said part being disposed to
communicate with the aperture;
15 a lancet actuation mechanism comprising a releasible catch
which is disposed within the housing to releasibly restrain the latching
member and an element is displaced to release the latching member to free the
energy storing member to initiate a lancing procedure; and
in combination, said frame comprising a side abutment, said
20 energy storing memory element comprising an energy release vector and said
blade section comprising a blade edge such that, when the energy storing
memory element is freed and displaces the proximal portion in a given
direction, the blade edge communicates with the side abutment to displace the
blade section disposed within the frame in an arcuate direction opposite to the
25 given direction such that a resulting lancing incision has a characteristic
pattern having a smaller cut at the surface of the incision than in the subsurface
thereof.
2. A lancet apparatus according to Claim 1, wherein the energy
30 storing memory element comprises a spring.



3. A lancet apparatus according to Claim 2, wherein the spring comprises a torsion spring.

4. A lancet apparatus according to Claim 3, wherein said torsion spring comprises a post which communicates with the aperture.

5. A lancet apparatus according to Claim 1, wherein said housing comprises a hub which comprises a groove which is the catch.

6. A lancet apparatus according to Claim 1, wherein said latching member and displaced part are the same part.

7. A lancet apparatus according to Claim 1, wherein said lancet actuation mechanism comprises a button disposed to be displaced transversely relative to the plane of the blade member.

8. A lancet apparatus according to Claim 1, wherein said lancet actuation mechanism comprises a slider which is displaced parallel to the plane of the blade member.

9. A lancet actuating apparatus according to Claim 1, wherein said housing comprises a guide track which communicates with said displaced part to restrictively control breadth and depth of the pattern.

10. A method of lancing comprising the steps of:
providing a lancet actuating apparatus comprising:

a housing having a side which is disposed against a site to be lanced during a lancing procedure, said side comprising a blade exit and reentry slot;

a lancet blade component safely disposed within said housing prior to use in the lancing operation, said component comprising a proximally disposed portion which remains in the



housing during the lancing procedure and a blade, having a sharpened tip and at least one cutting edge, at least a segment of which exits the housing to perform a lancing procedure and returns to the housing for safe disposal;

5 an energy storing memory element which, when actuated, communicates with said proximally disposed portion to urge the blade through a predetermined lancing pattern outwardly and then inwardly through the blade exit and reentry slot; and

10 a lancet actuating mechanism comprising a release trigger which activates the energy storing memory element; placing the apparatus against a site to be lanced; triggering release of the energy storing memory element which

subsequently communicates with the proximally disposed portion to accomplish the following steps:

15 forcibly steering the proximally disposed portion to guide the blade obliquely outward through the slot;

rotating the blade laterally about an edge of the slot under influence of the memory element and, thereby, displacing the proximally disposed portion in a first direction relative to said slot while at the same time displacing the blade in a direction opposite the first direction; and

20 returning the blade into the housing.

11. A method according to Claim 10, wherein said housing comprises a guide track and said energy storing memory element comprises a track follower and which act in combination during the rotating step.

12. A method according to Claim 10, wherein said forcibly steering and rotating steps comprise partially unwinding a torsion spring.



13. Apparatus for extending a lancet from and retracting the lancet back into a safety housing, said apparatus comprising:

the housing comprising a frame about an opening through which the lancet is extended and retracted;

5 the lancet comprising an elongated, thin knife-like blade and a sharpened point;

an energy storing memory element which, when actuated, communicates with the lancet to urge the blade through a predetermined lancing pattern outwardly and then inwardly through the opening;

10 an mechanism comprising a trigger used to actuate the energy storing memory element; and

a segment of said frame which acts as a fulcrum against said blade to constrain entry of the blade into the entry site to a breadth of cut which is substantially the same as the maximum width of the portion of blade
15 inserted into the site.



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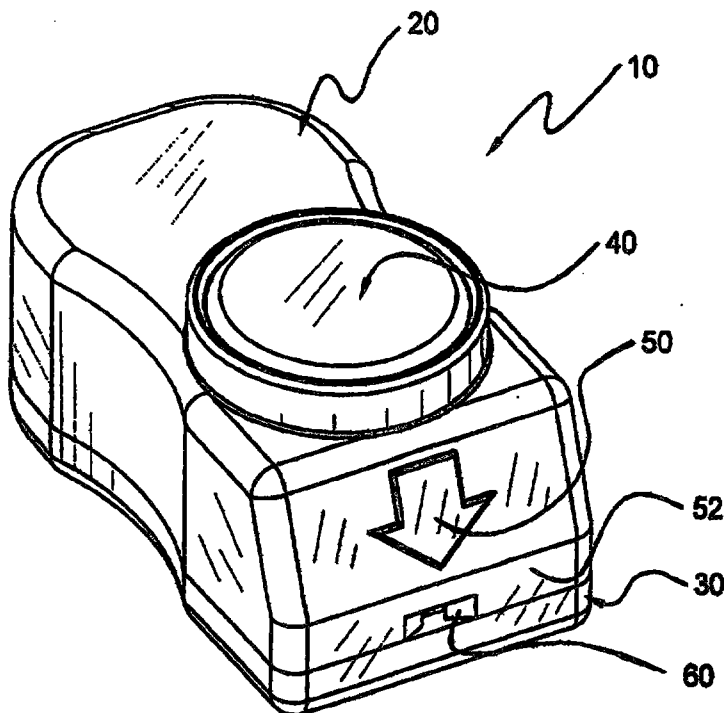
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(54) Title: LANCET APPARATUS AND METHODS

(57) Abstract

A one-time-use, self-powered, restricted entry lancet apparatus (10, 210) which provides a smaller incision in a surface or epidermal layers of a lancing site then in subsurface or dermal layers. Two embodiments (10, 210) of the invention are disclosed. Generally, each embodiment comprises a housing (20, 30, 220, 230), a blade component (150, 310), a rotary spring (140, 320) and an actuator (40, 240). The blade (150, 310) generally comprises a proximal portion (156, 330) and a distal section (154, 328). The proximal portion (156, 330) is disposed within the housing (20, 30, 220, 230) and is displaced laterally in a first direction during a lancing procedure. During the lancing procedure, the distal section (154, 328) is extended from the housing (20, 30, 220, 230) through an open exit slot (60, 300) and is rotated about an abutment member (170, 294, 296) of the exit slot (60, 300) to be laterally displaced in a direction opposite the first direction. This rotation about the abutment (170, 294, 296) results in an incision pattern which has a smaller cut in the epidermis than in the dermis. Thus, surface trauma is reduced, while a broad cut is made in capillary rich regions of the dermal layers.



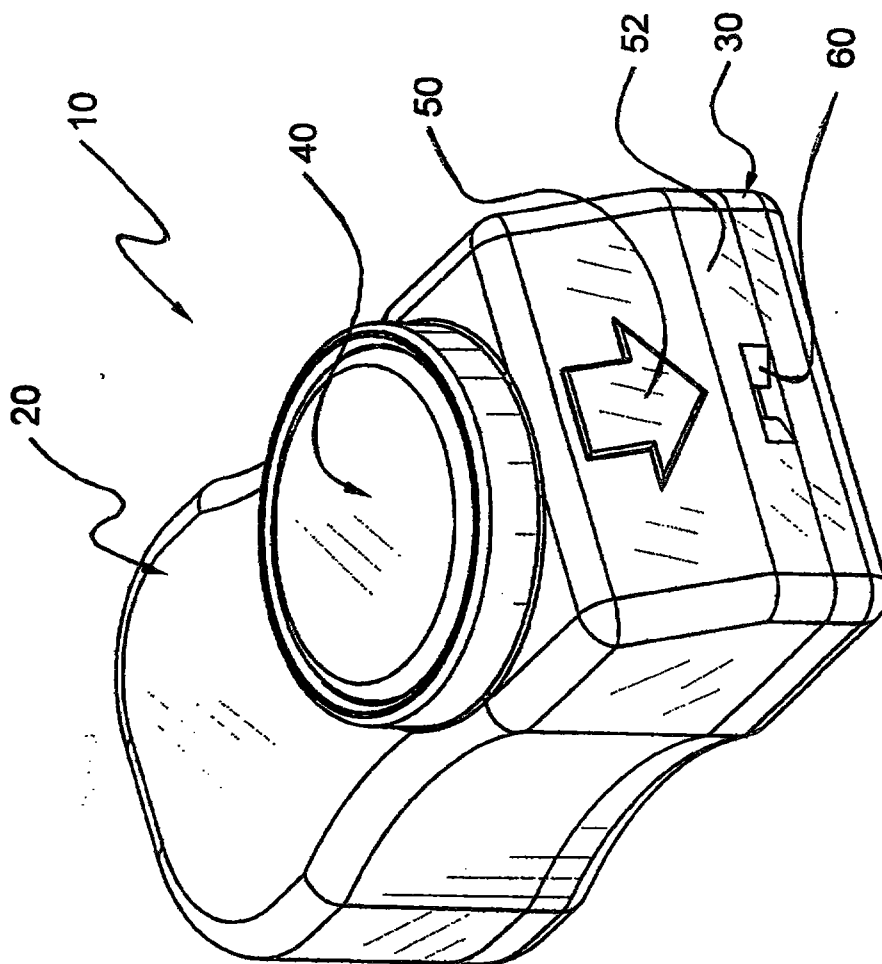


FIGURE 1

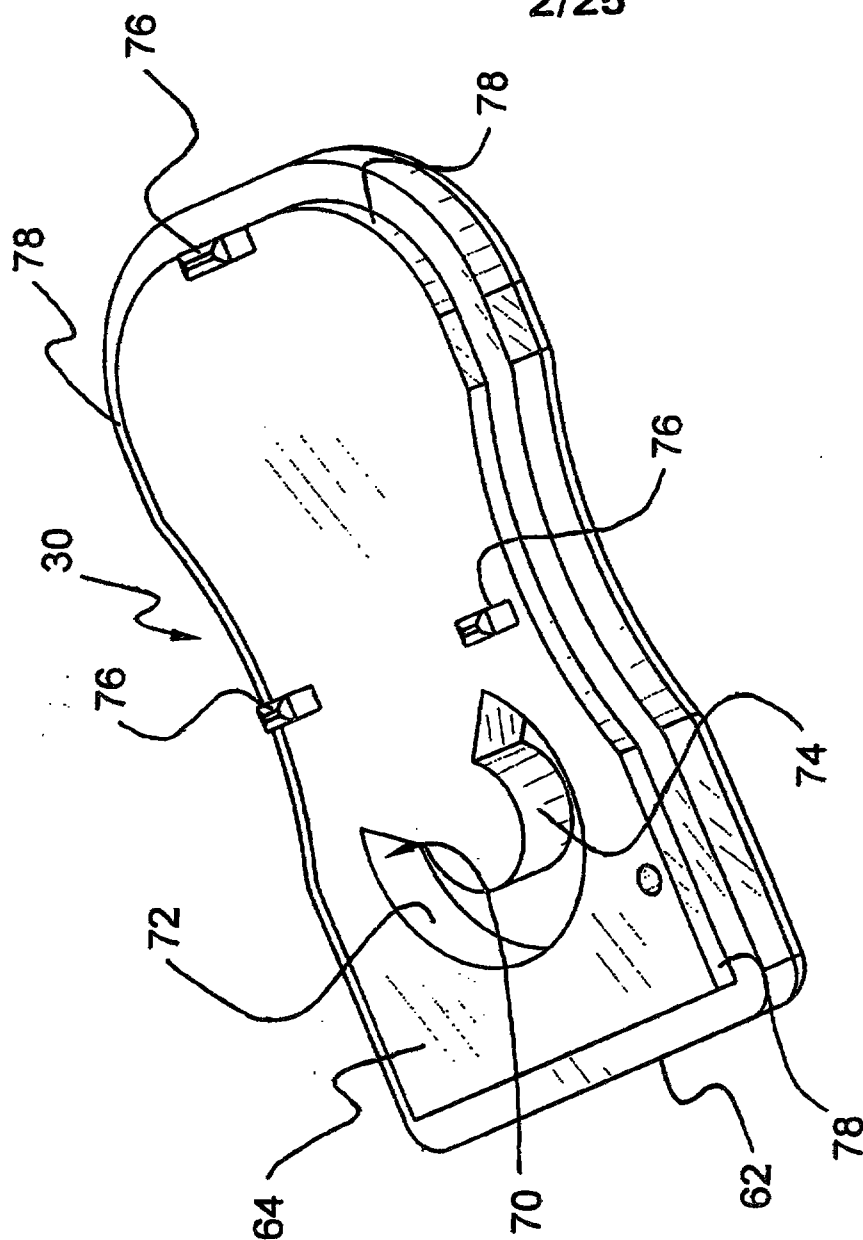


FIGURE 2

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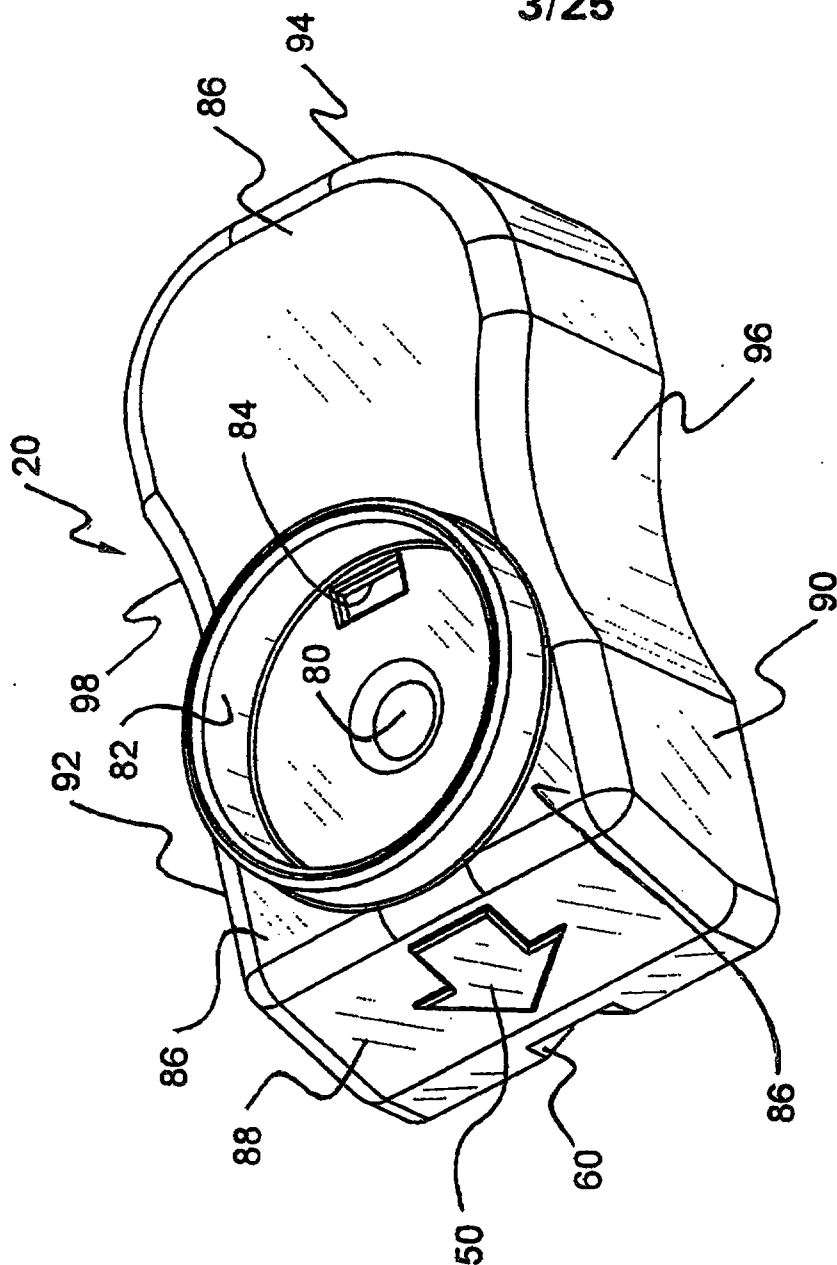


FIGURE 3

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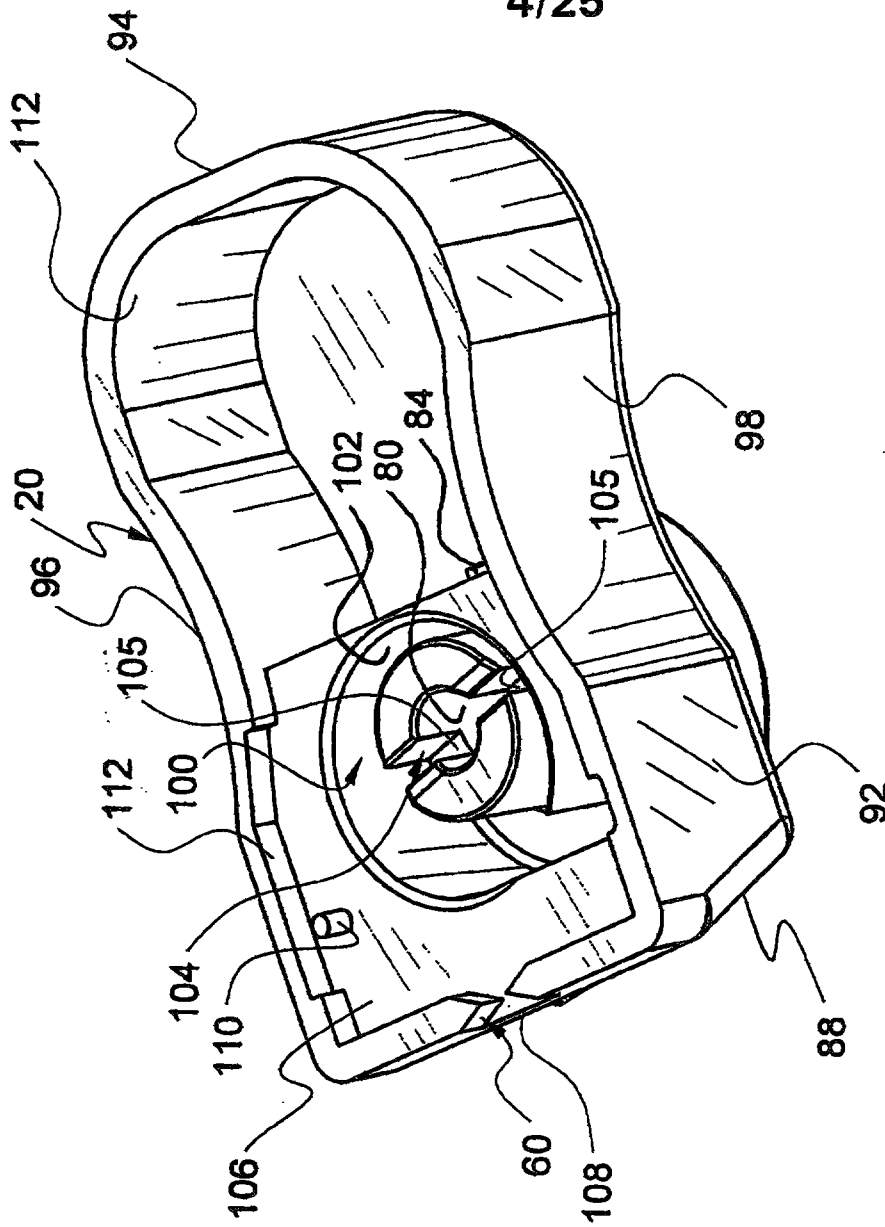


FIGURE 4

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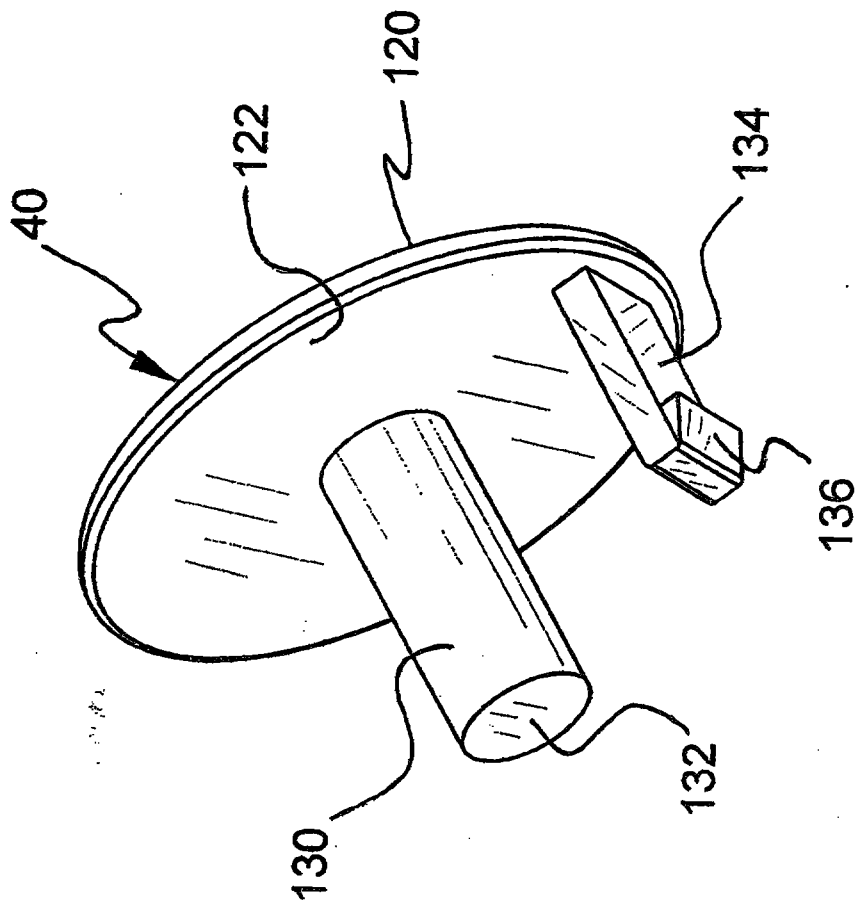


FIGURE 5

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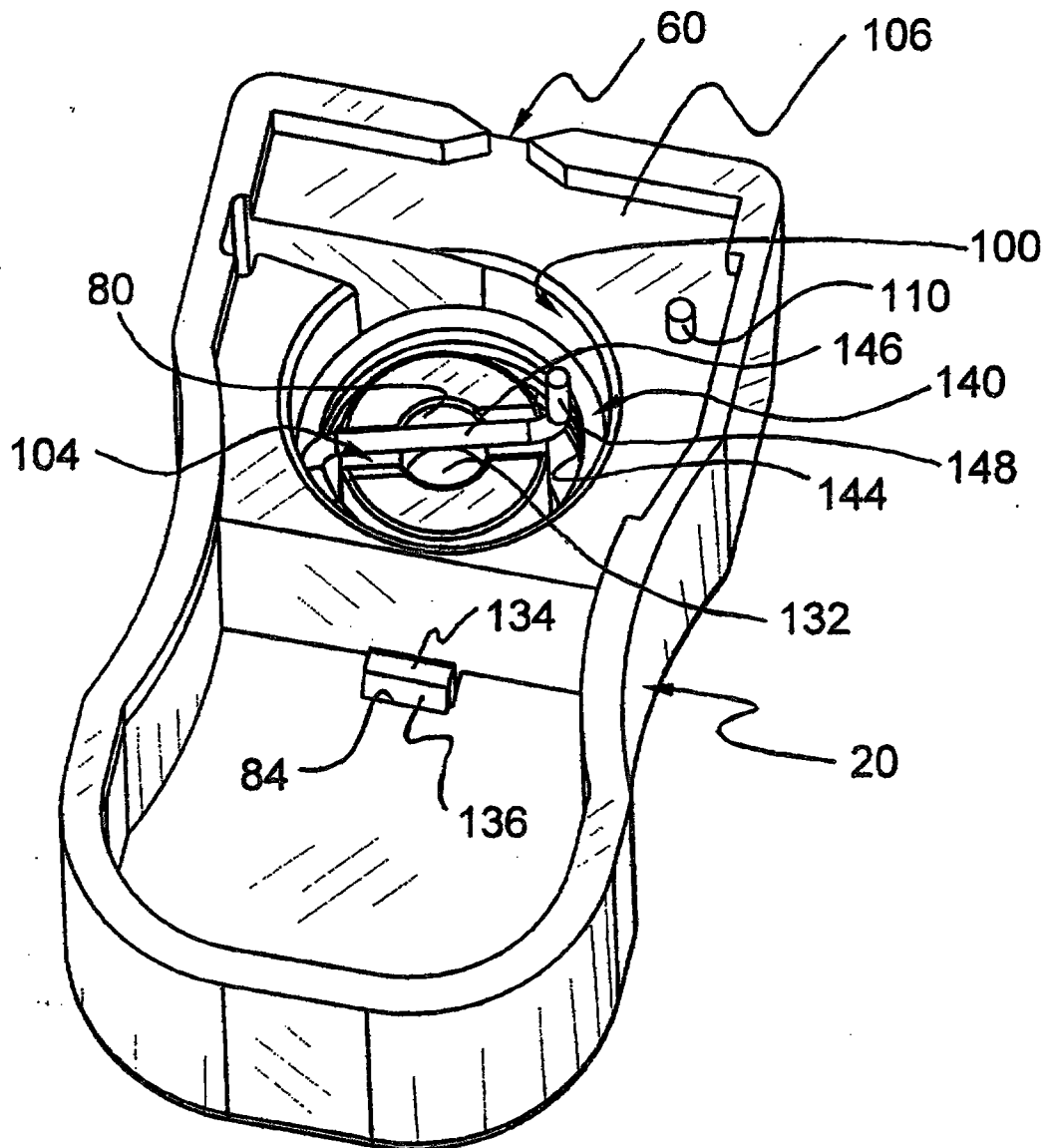


FIGURE 6

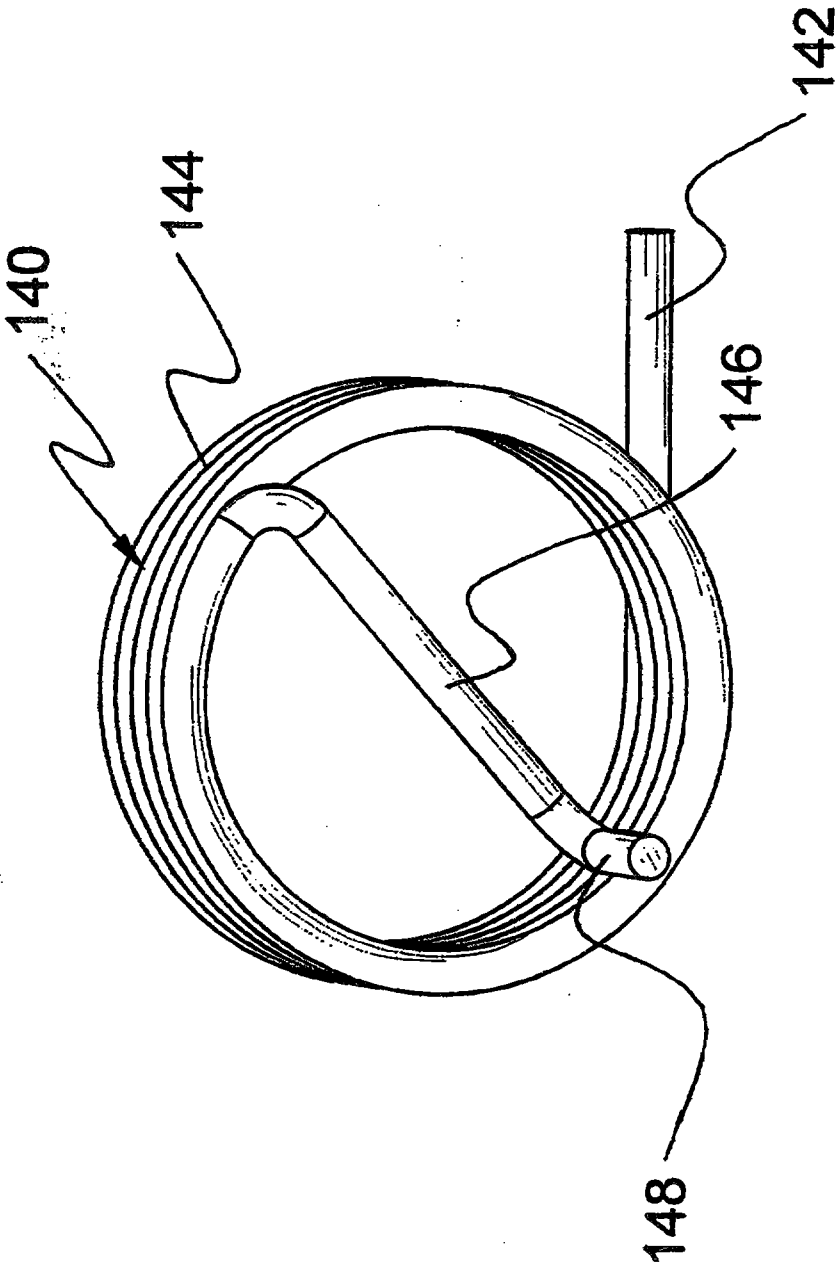


FIGURE 7

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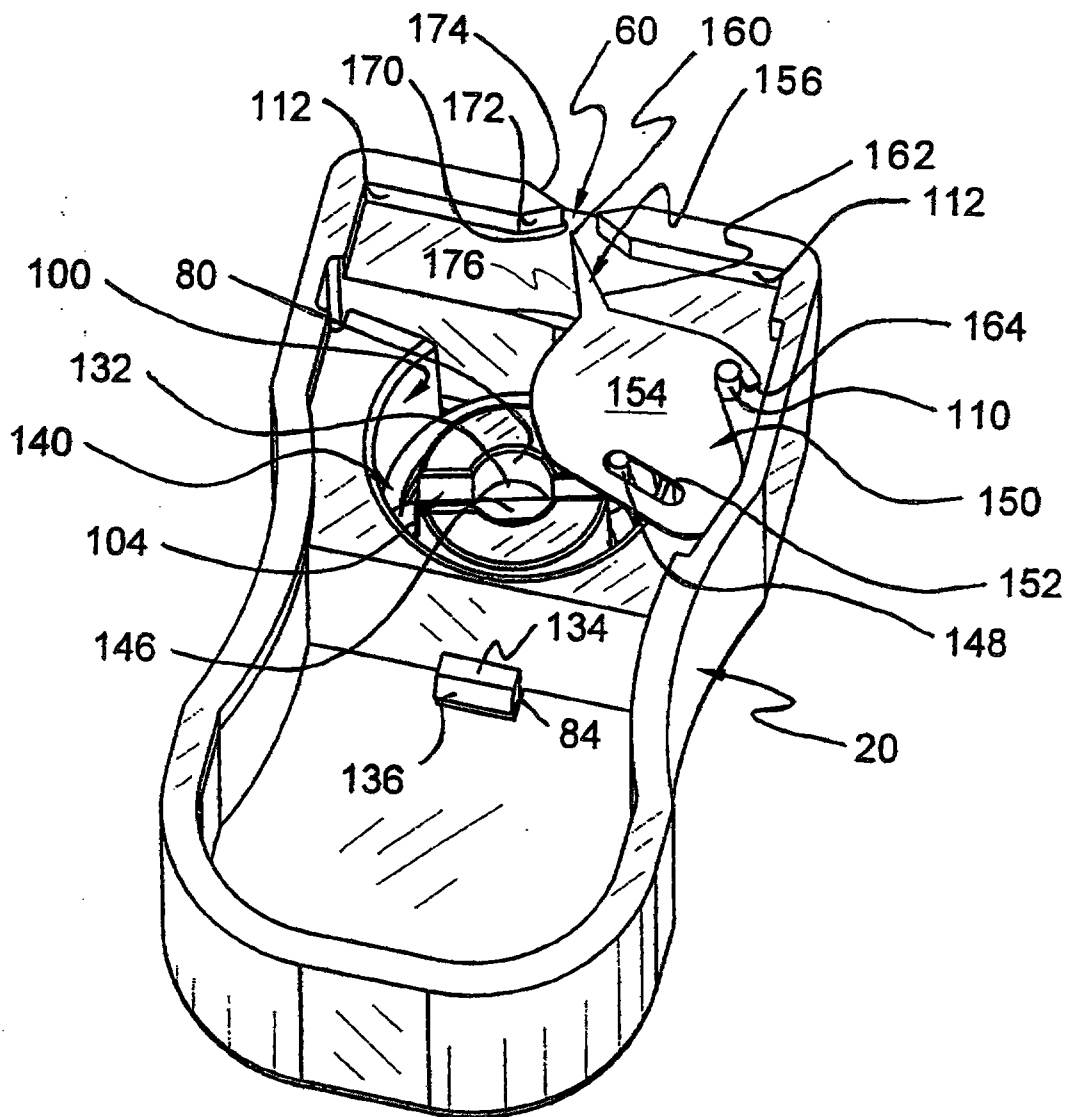


FIGURE 8

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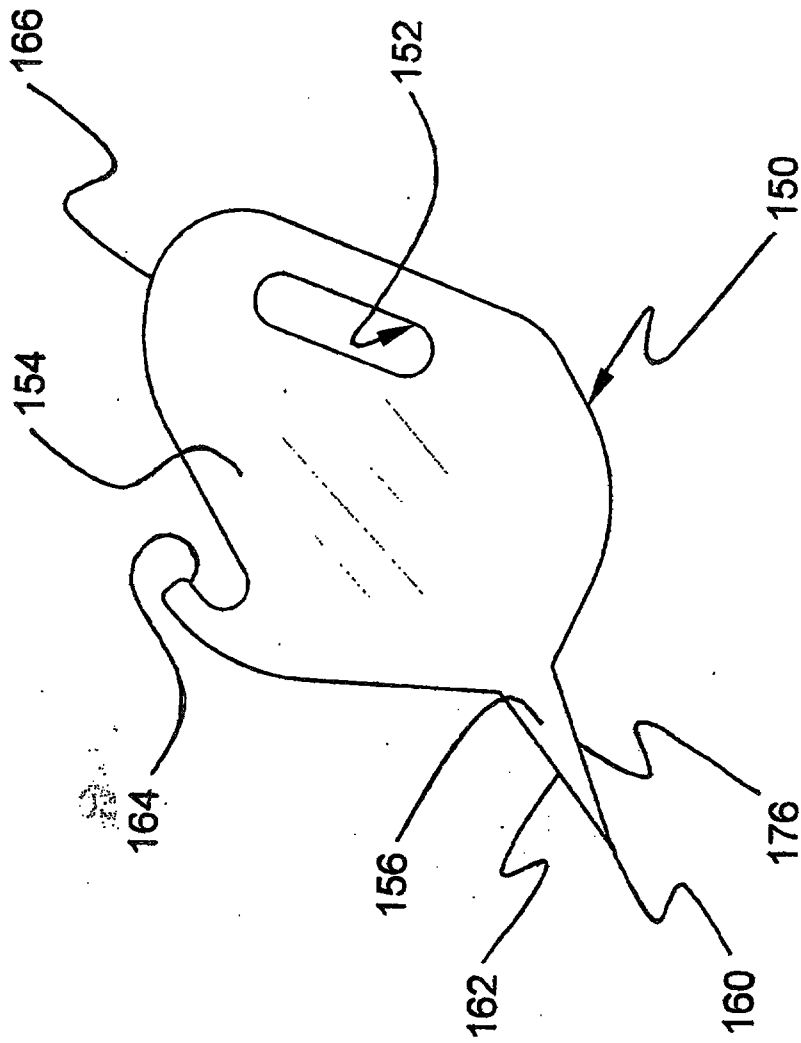


FIGURE 9

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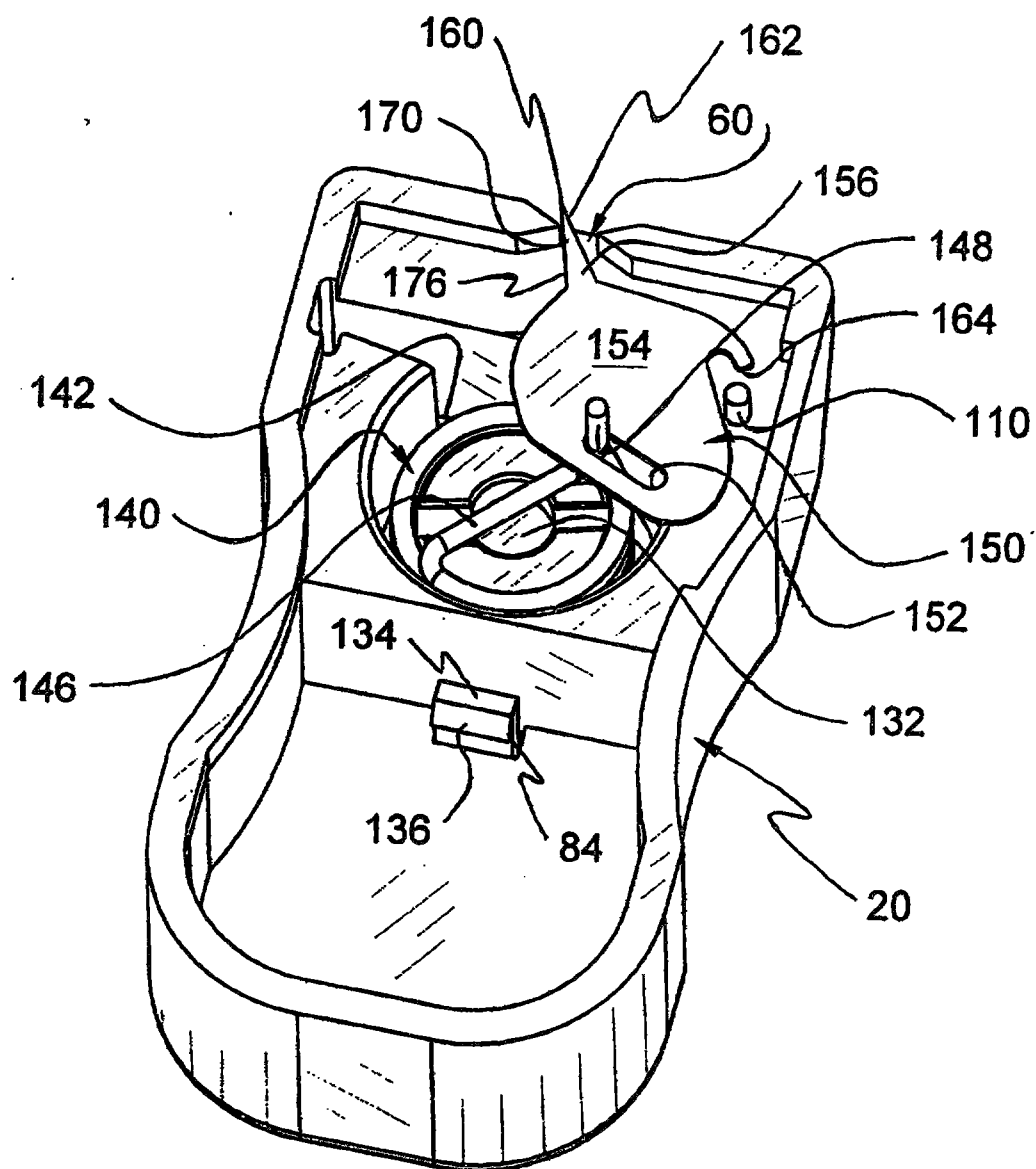


FIGURE 10

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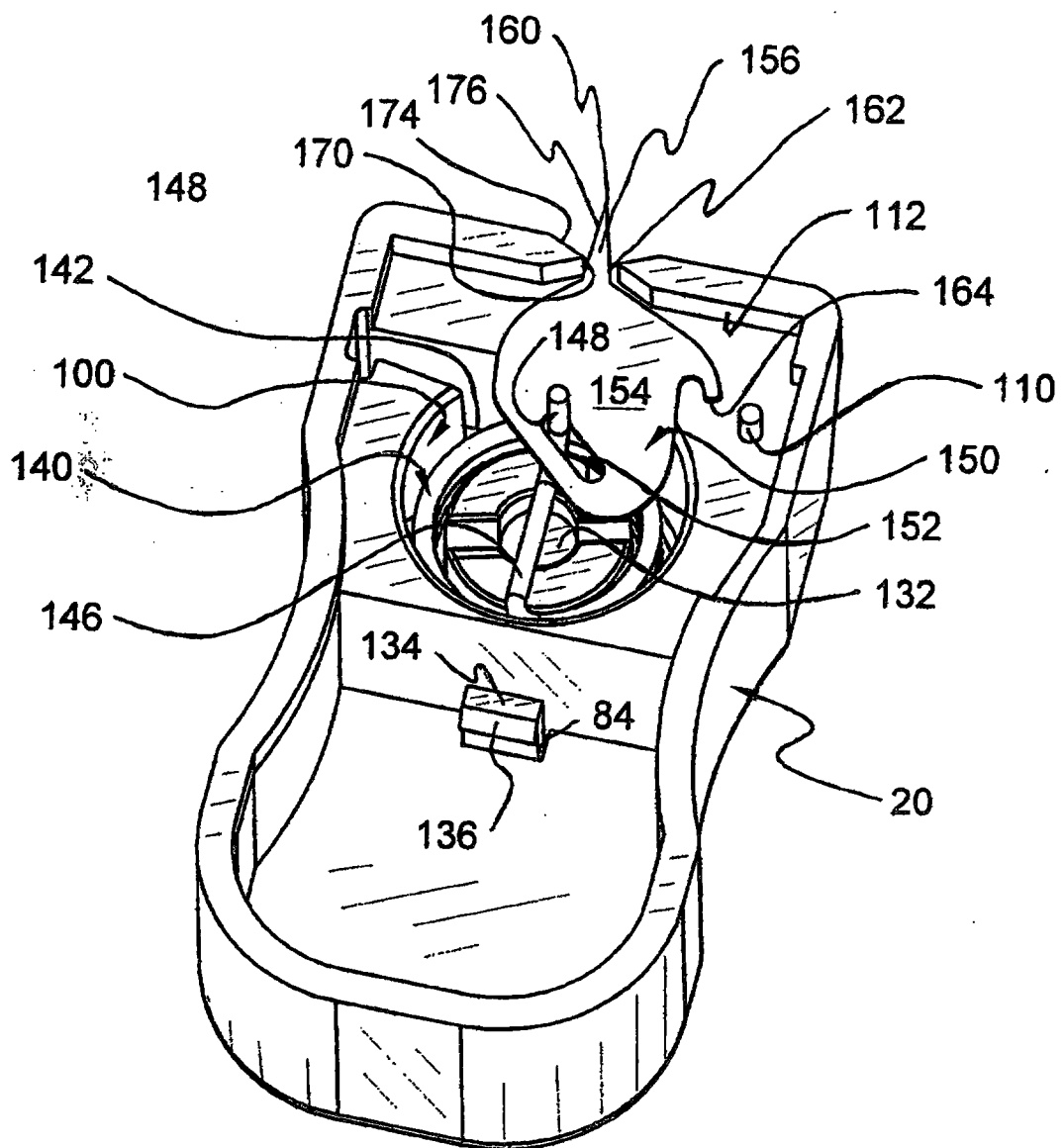


FIGURE 11

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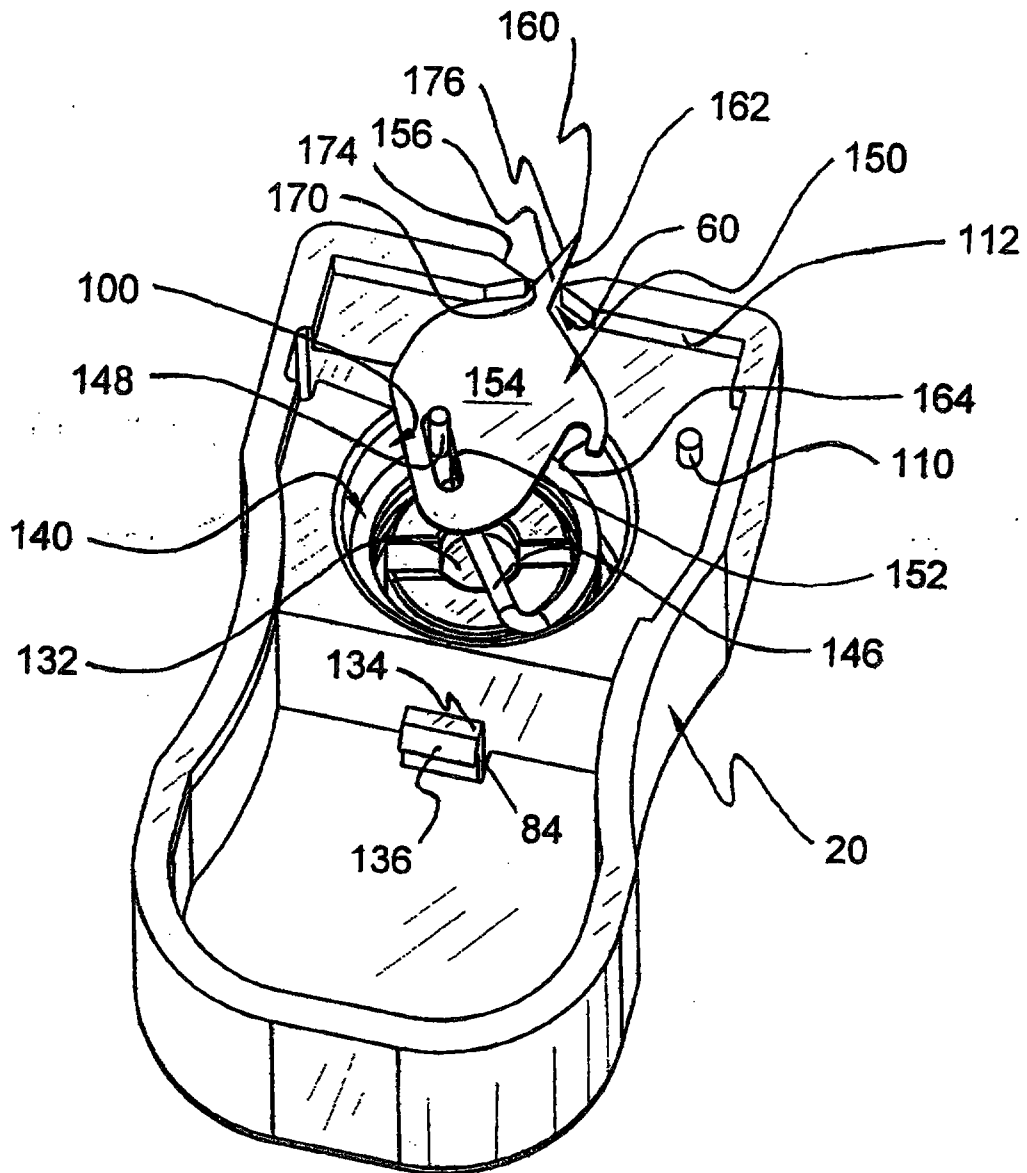


FIGURE 12

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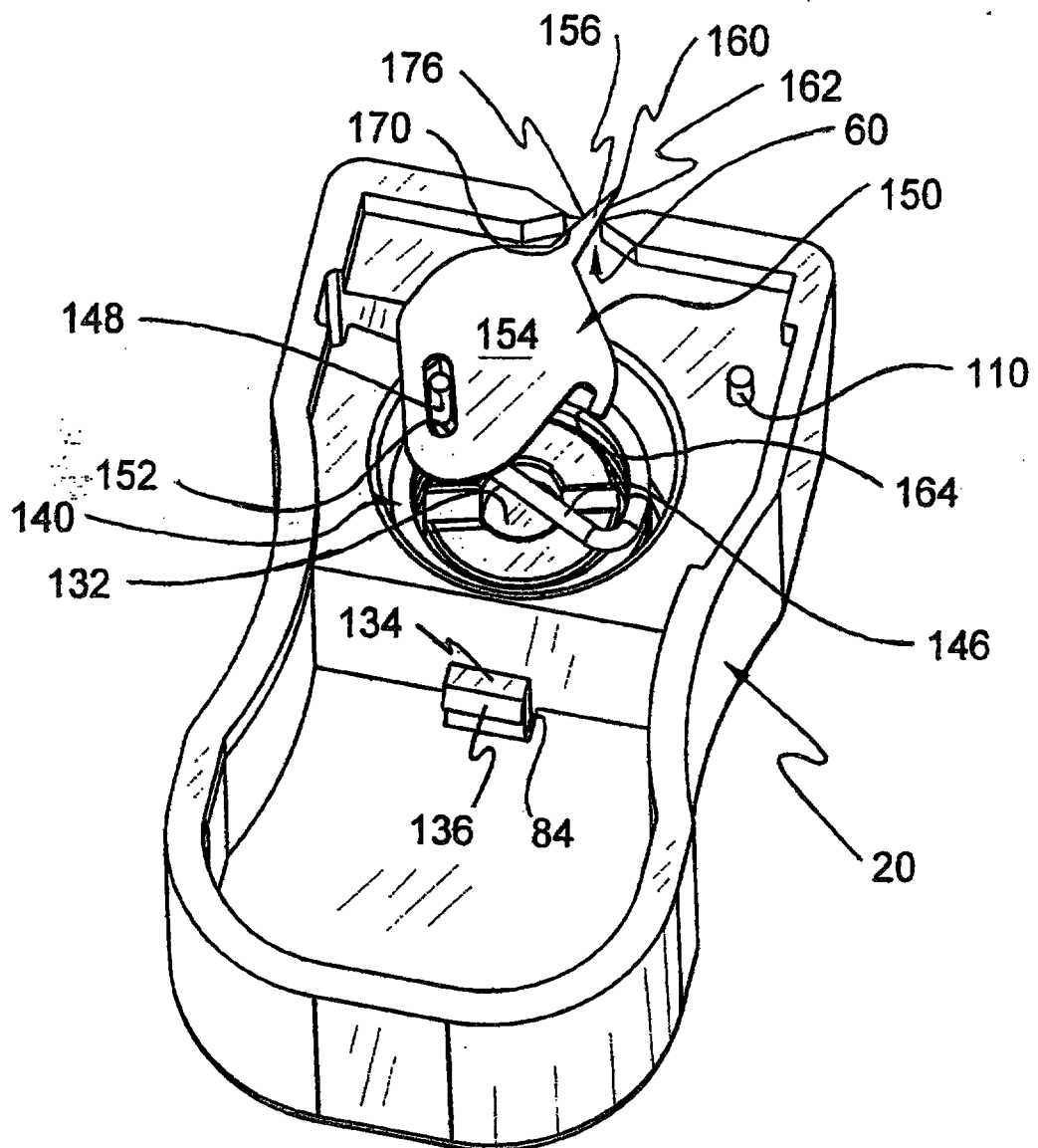


FIGURE 13

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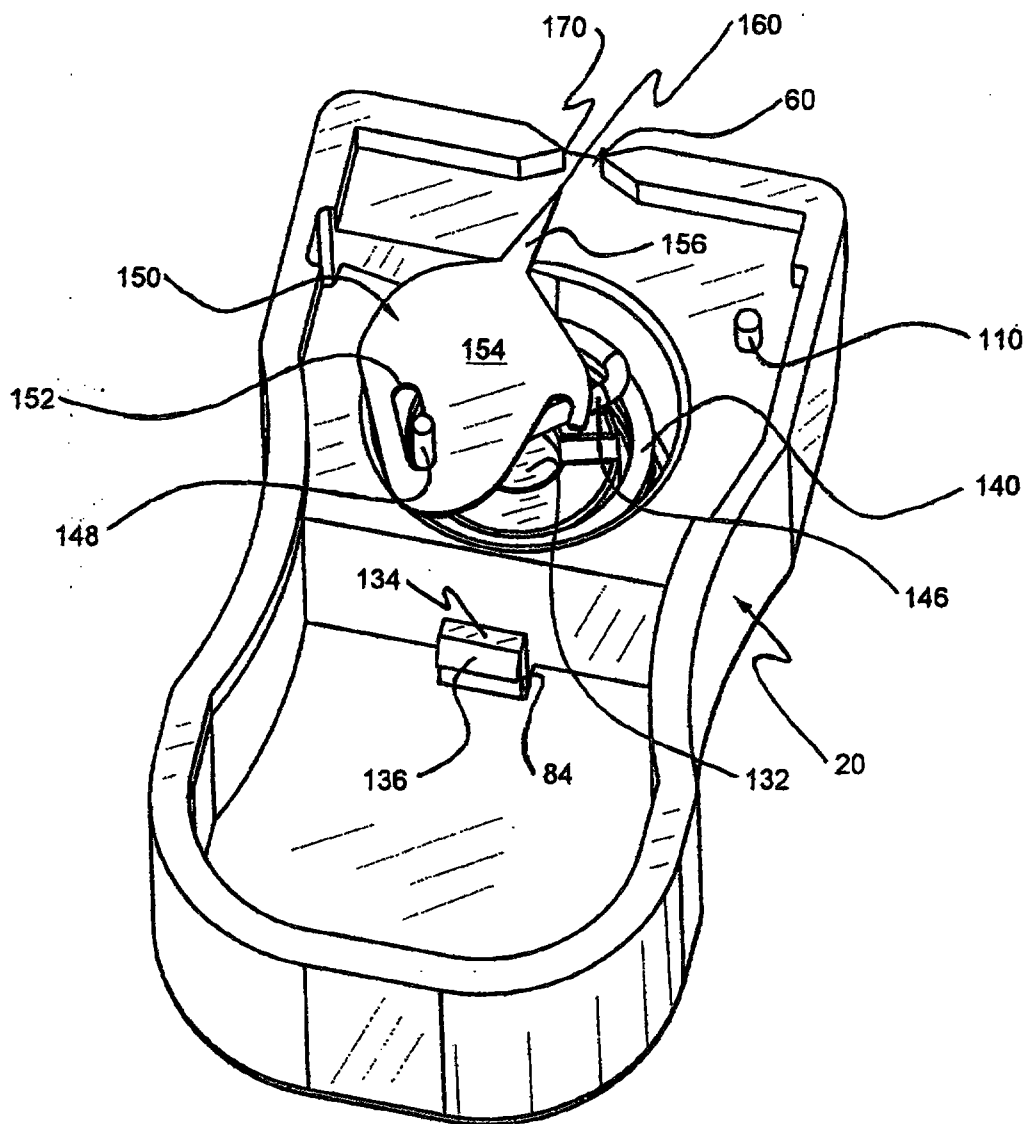


FIGURE 14

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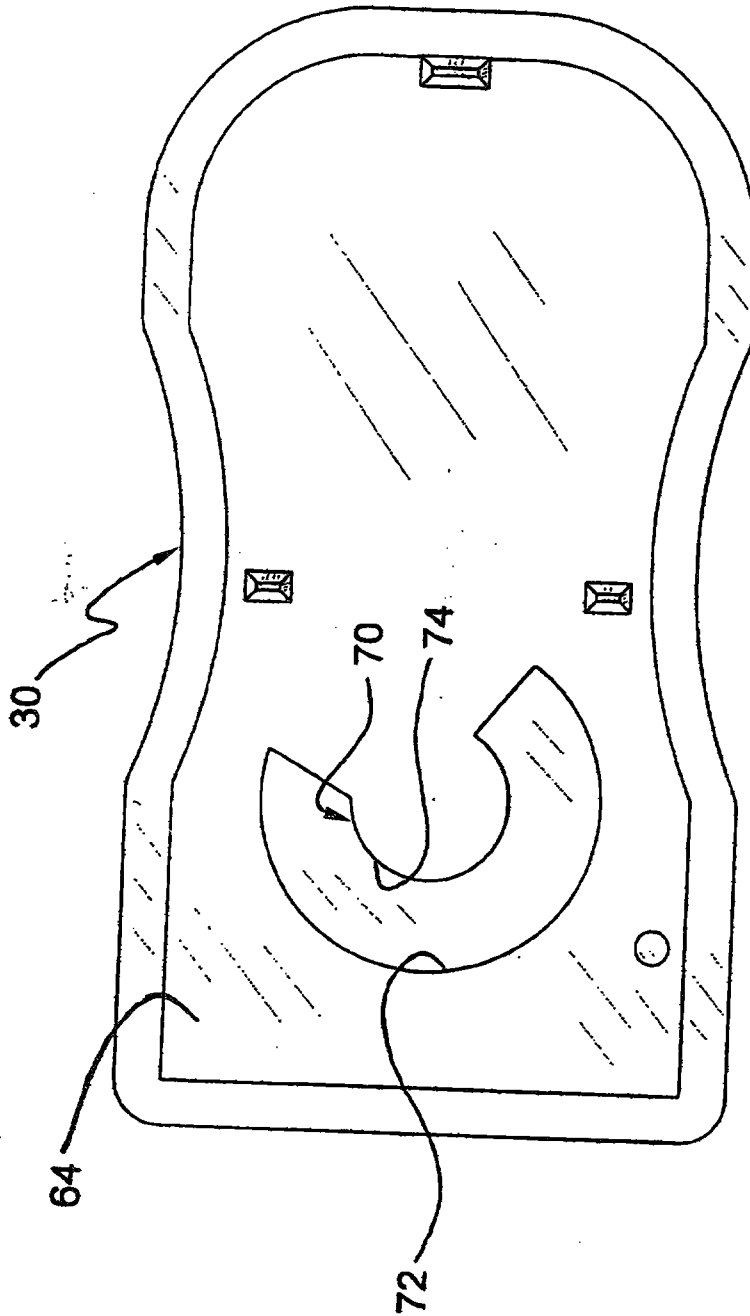


FIGURE 15

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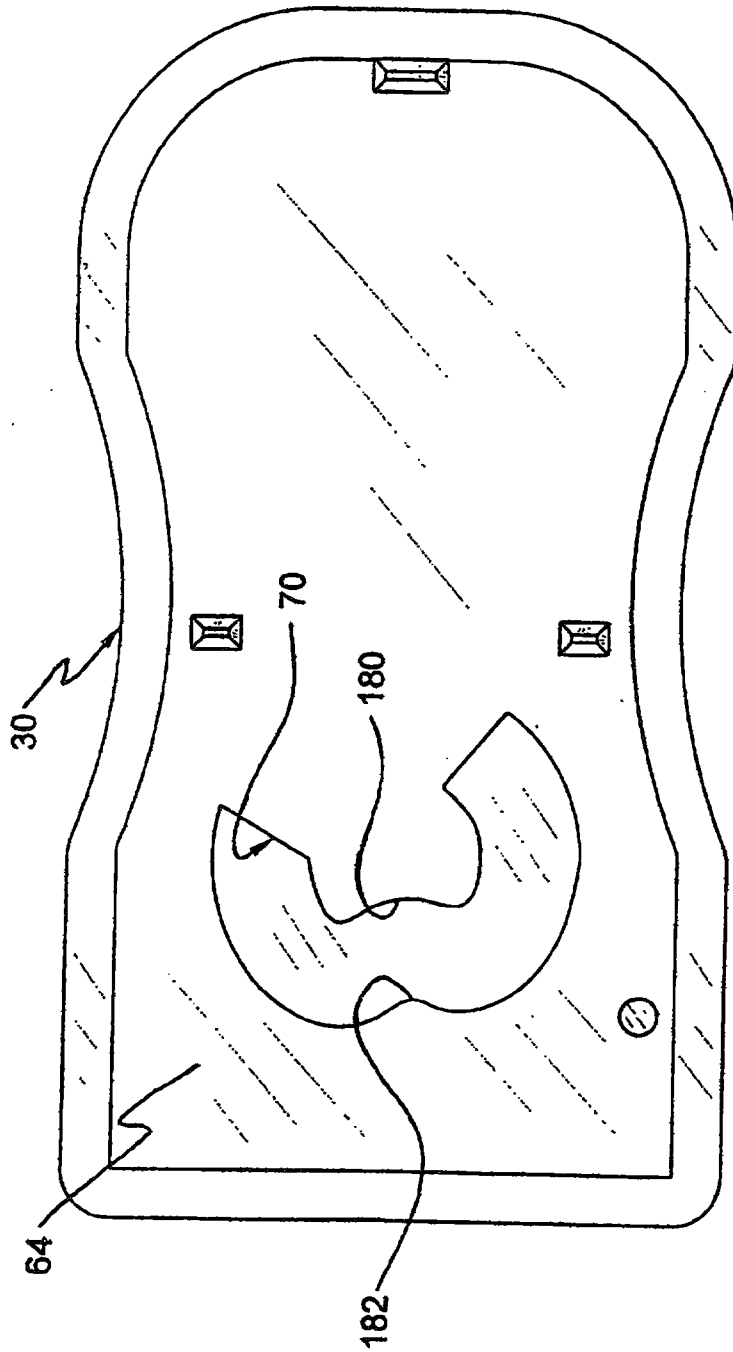


FIGURE 16

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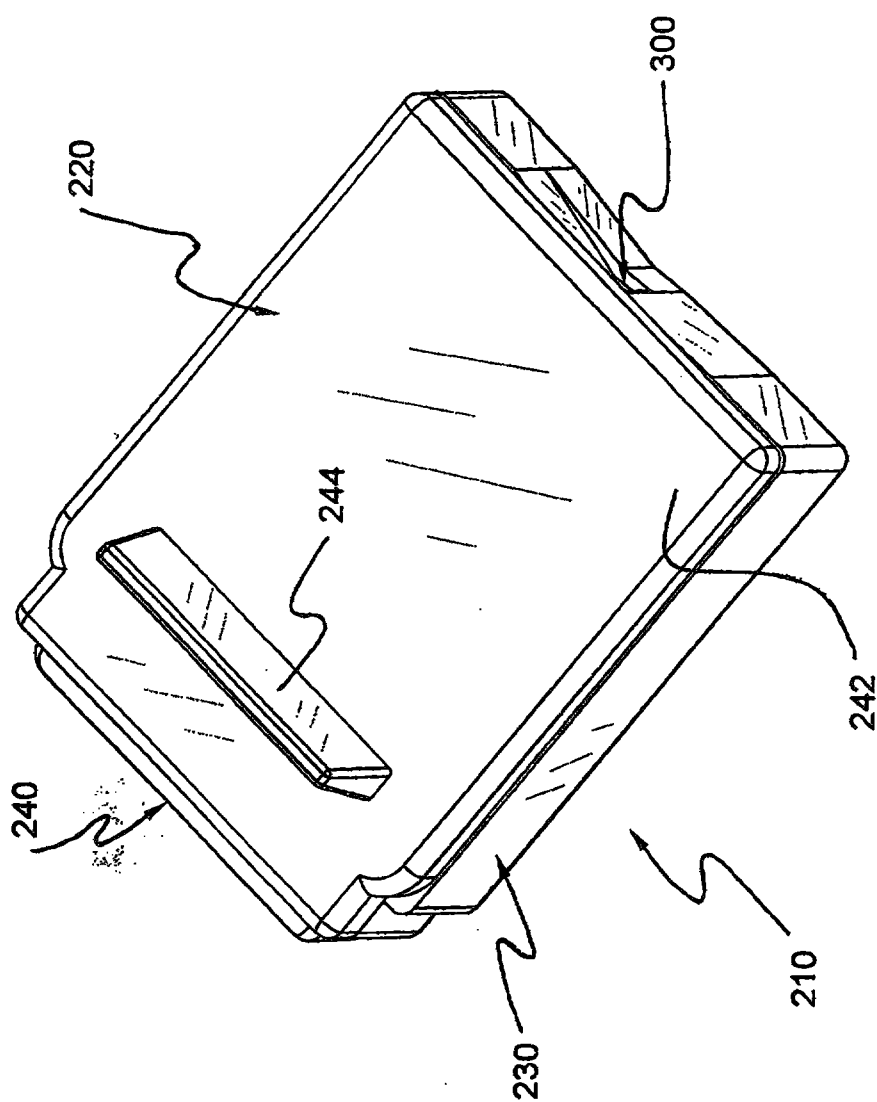


FIGURE 17

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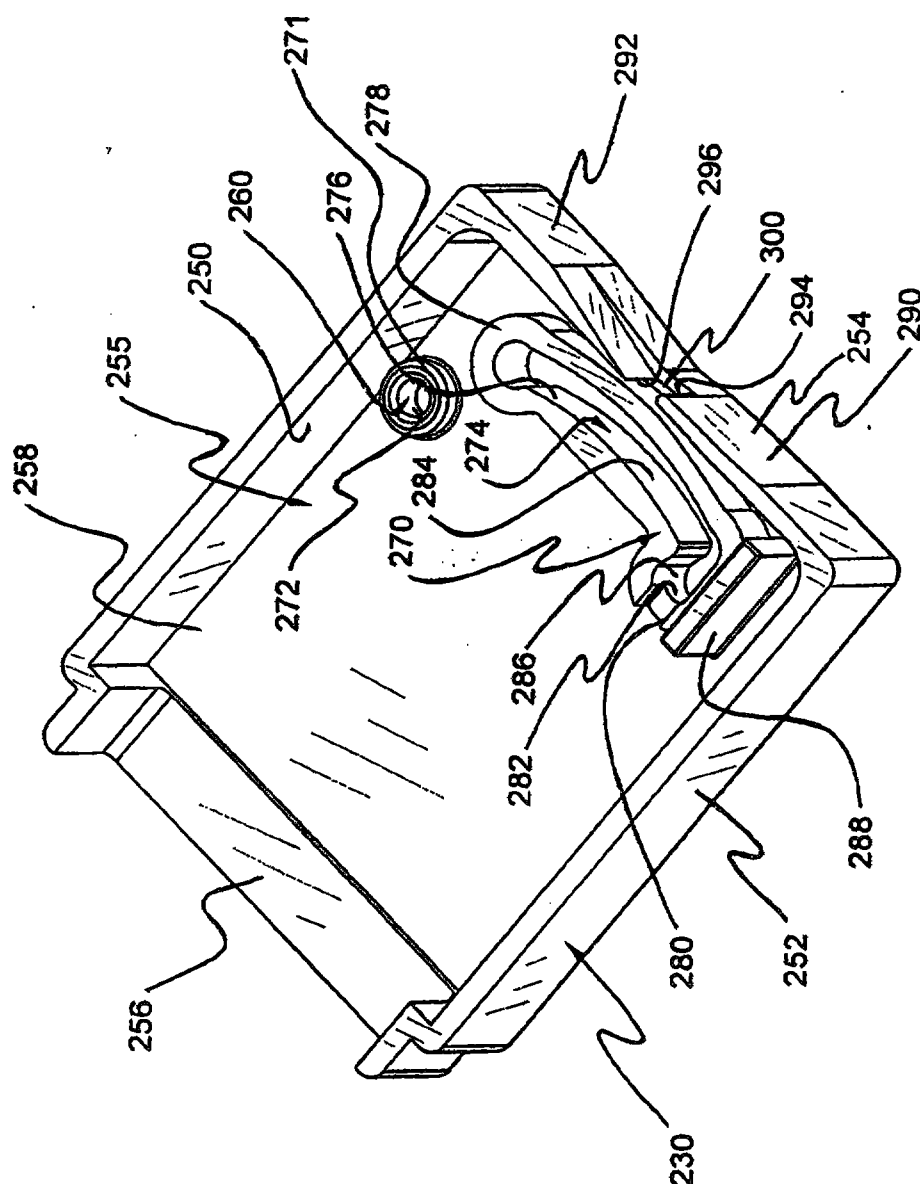


FIGURE 18

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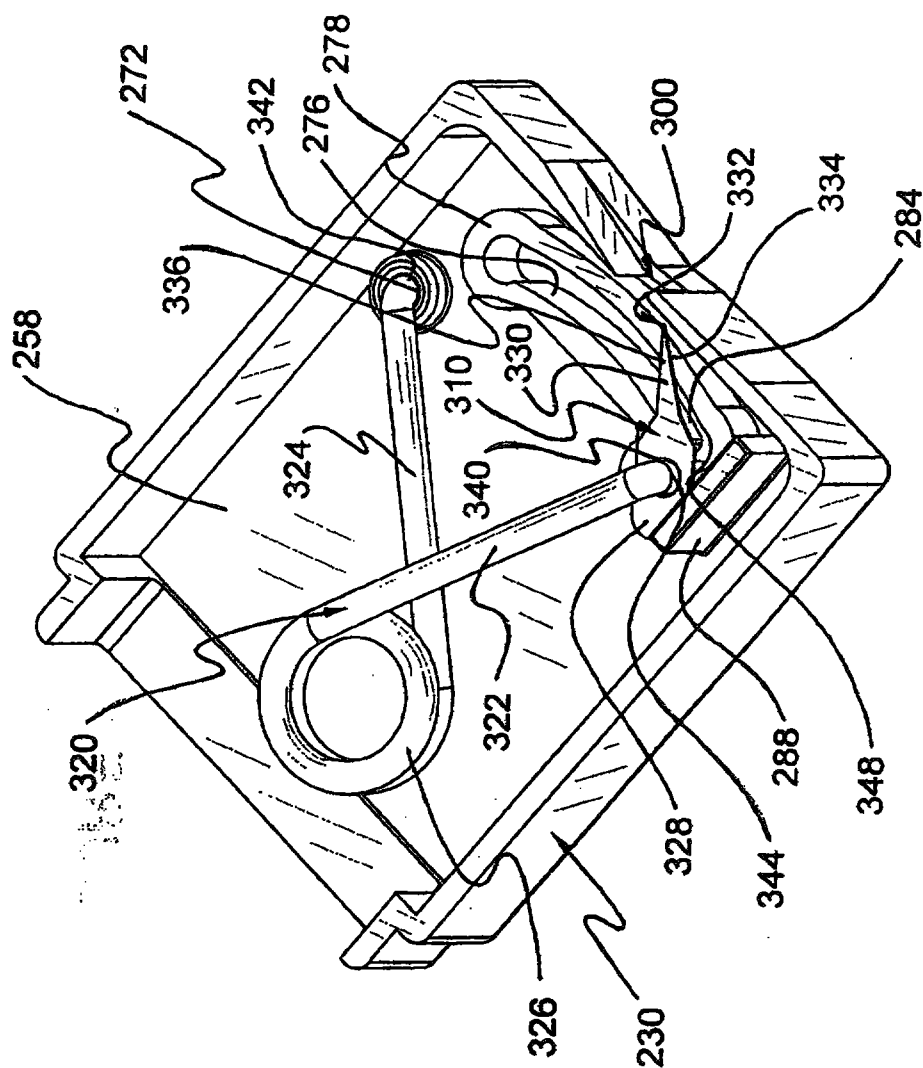


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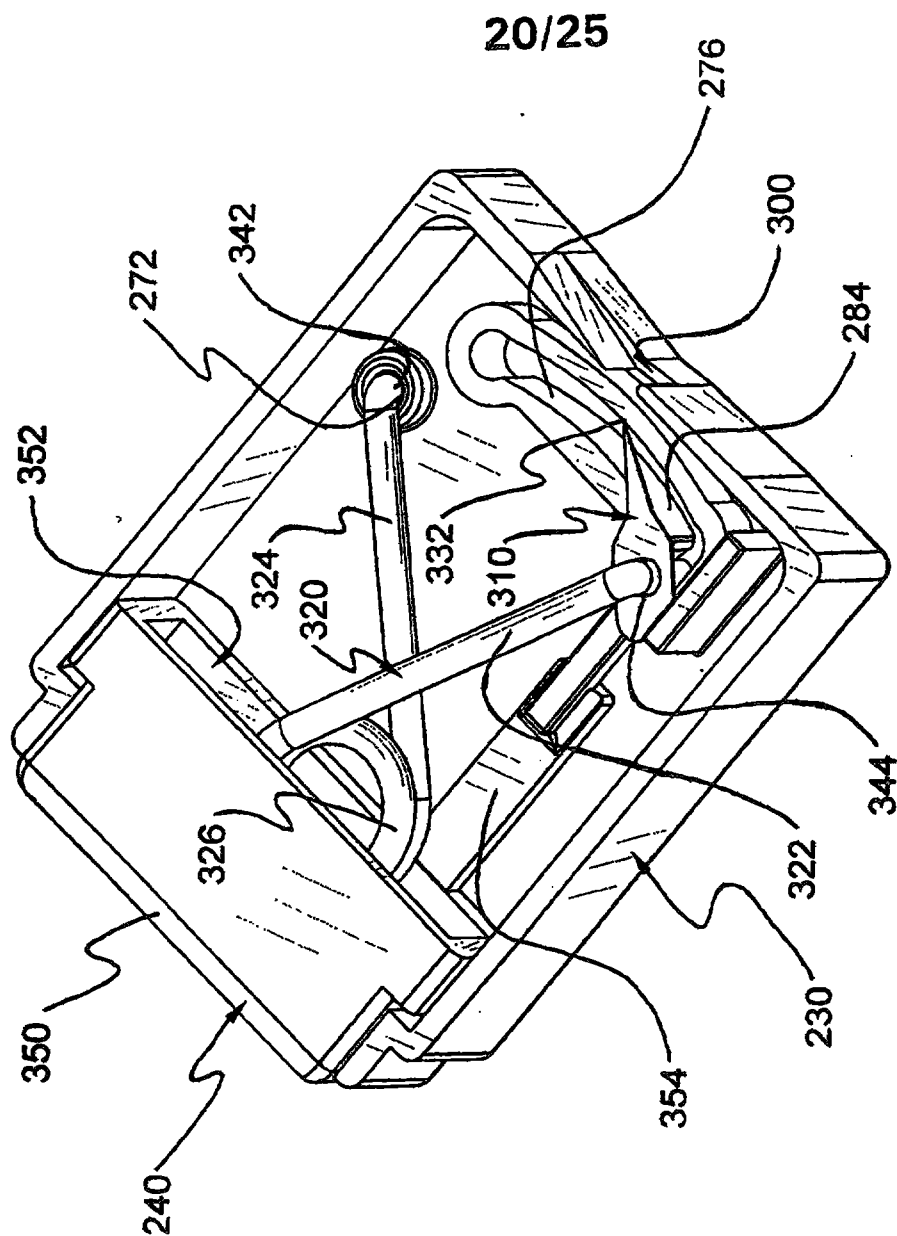


FIGURE 20

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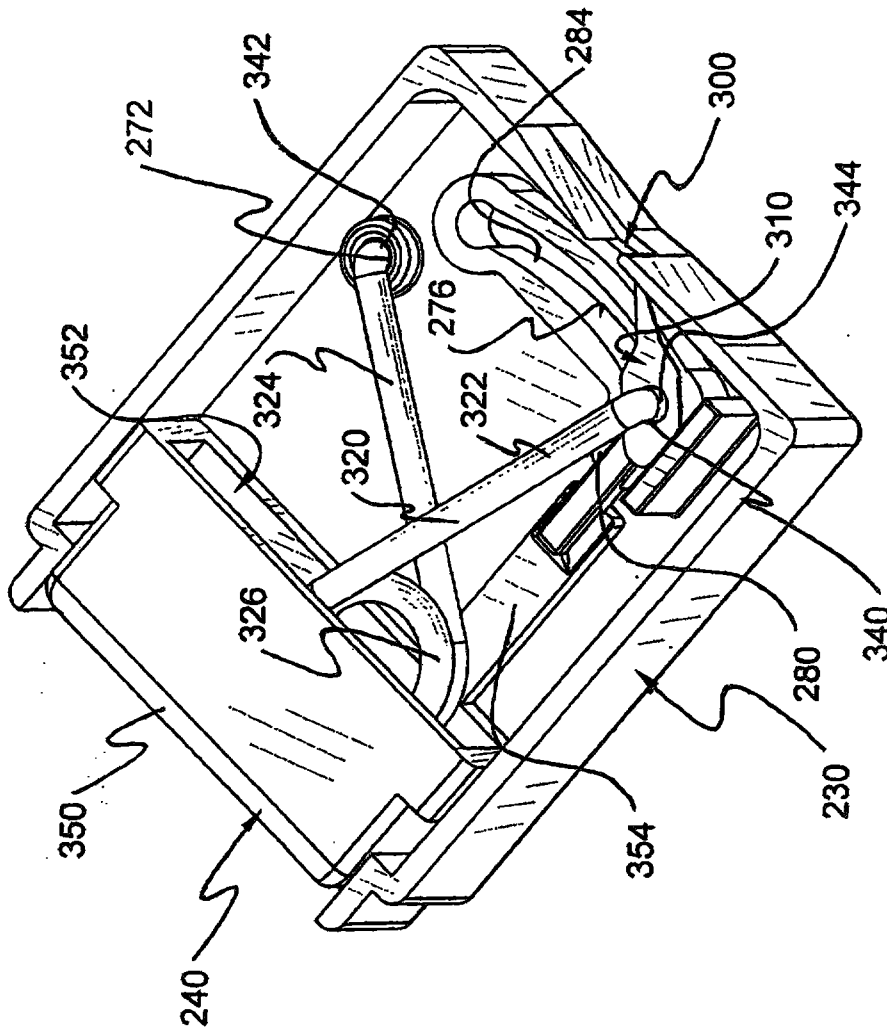


FIGURE 21

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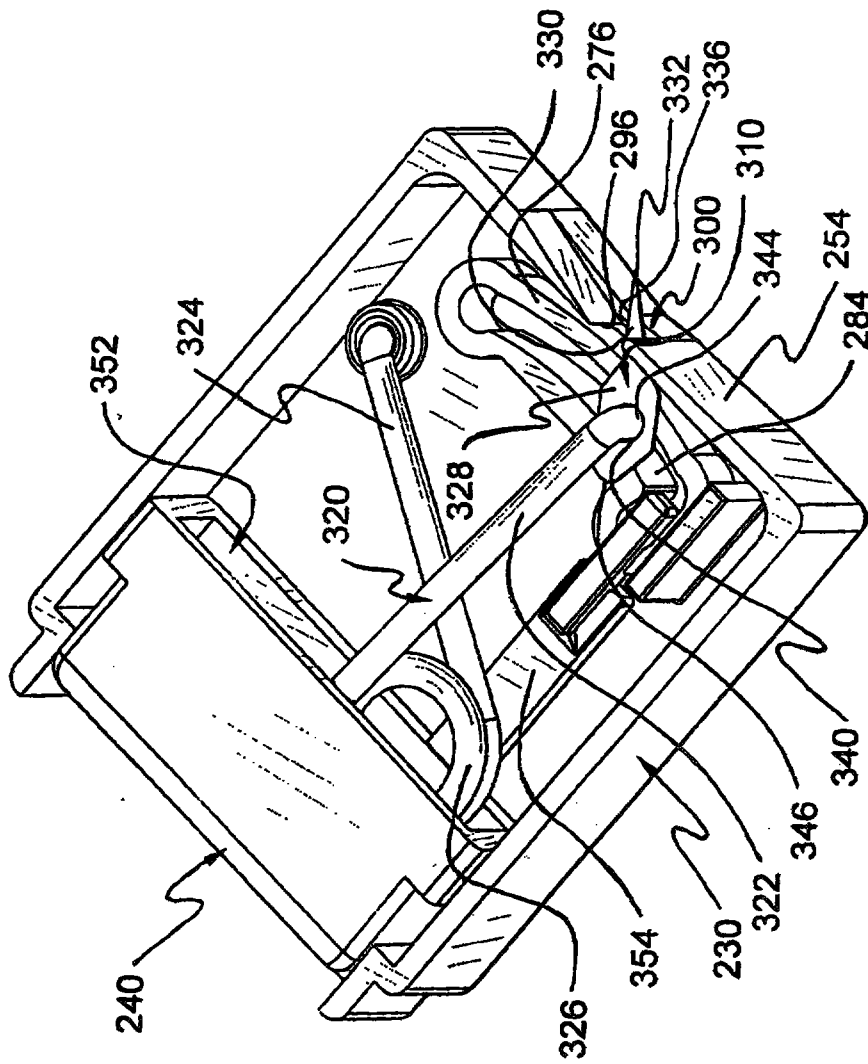


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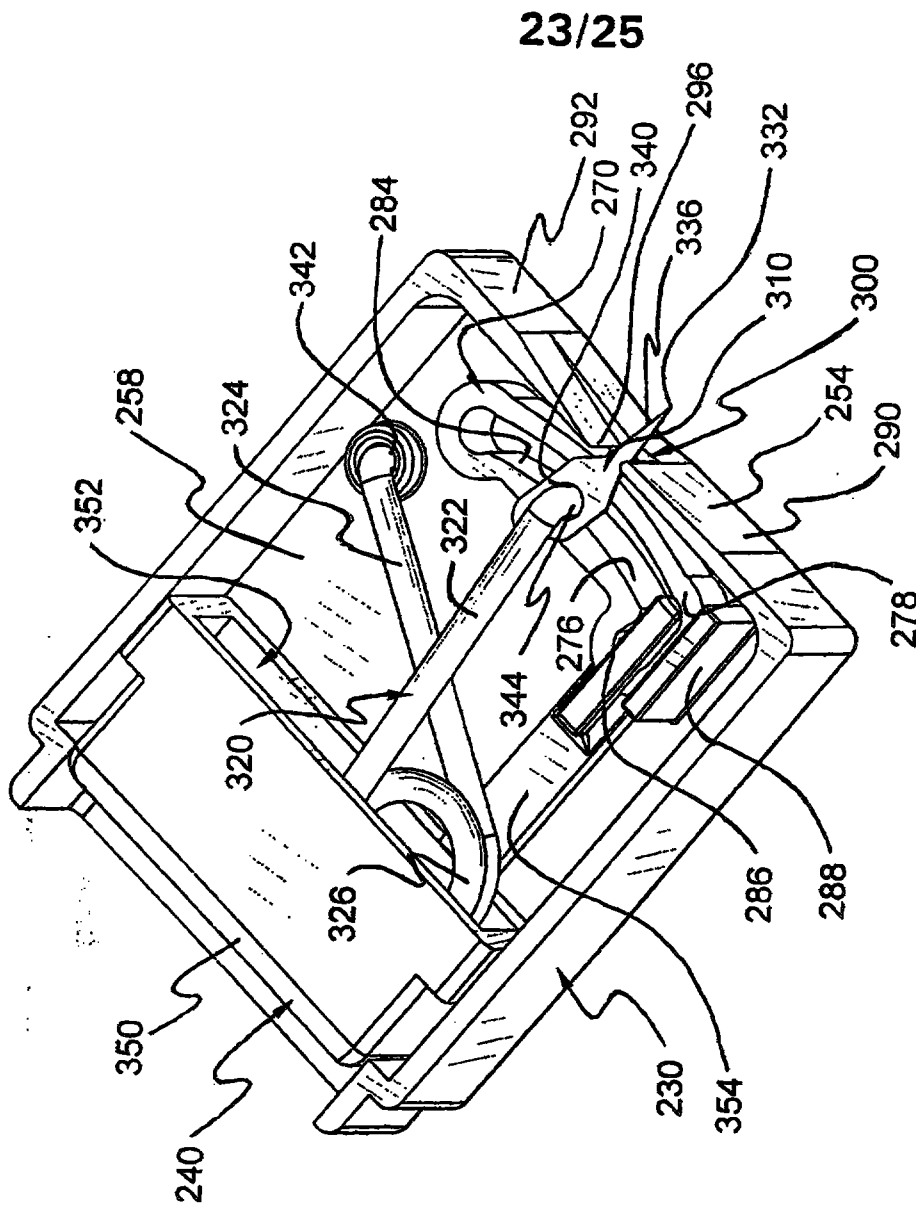


FIGURE 23

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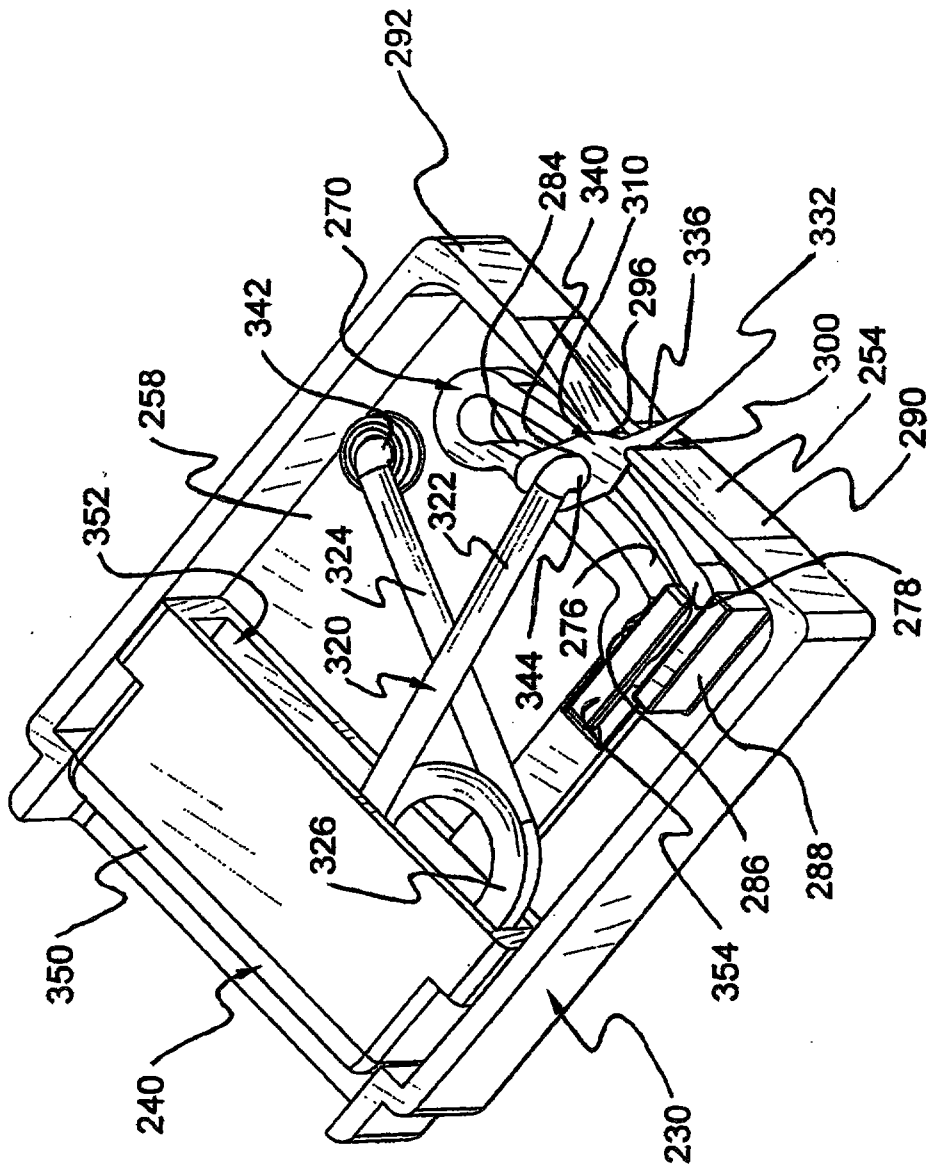


FIGURE 24

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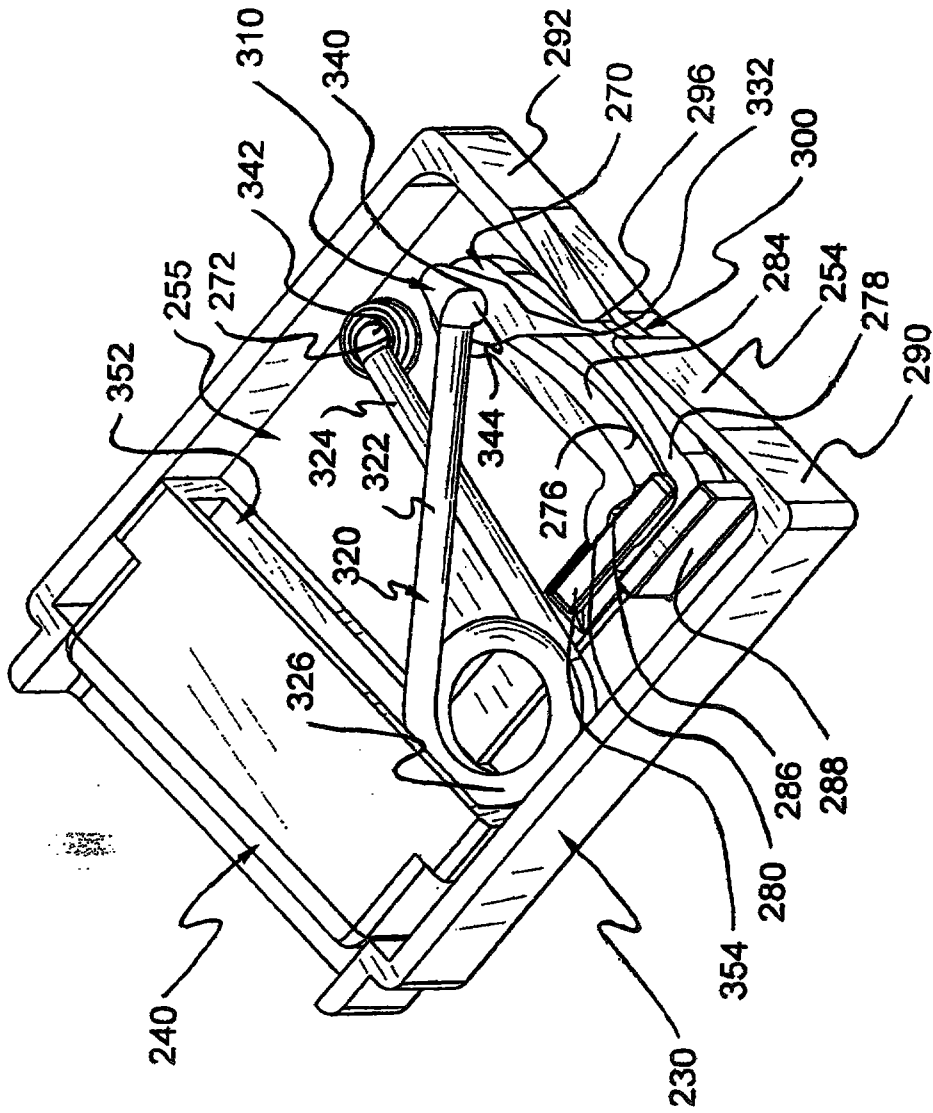


FIGURE 25