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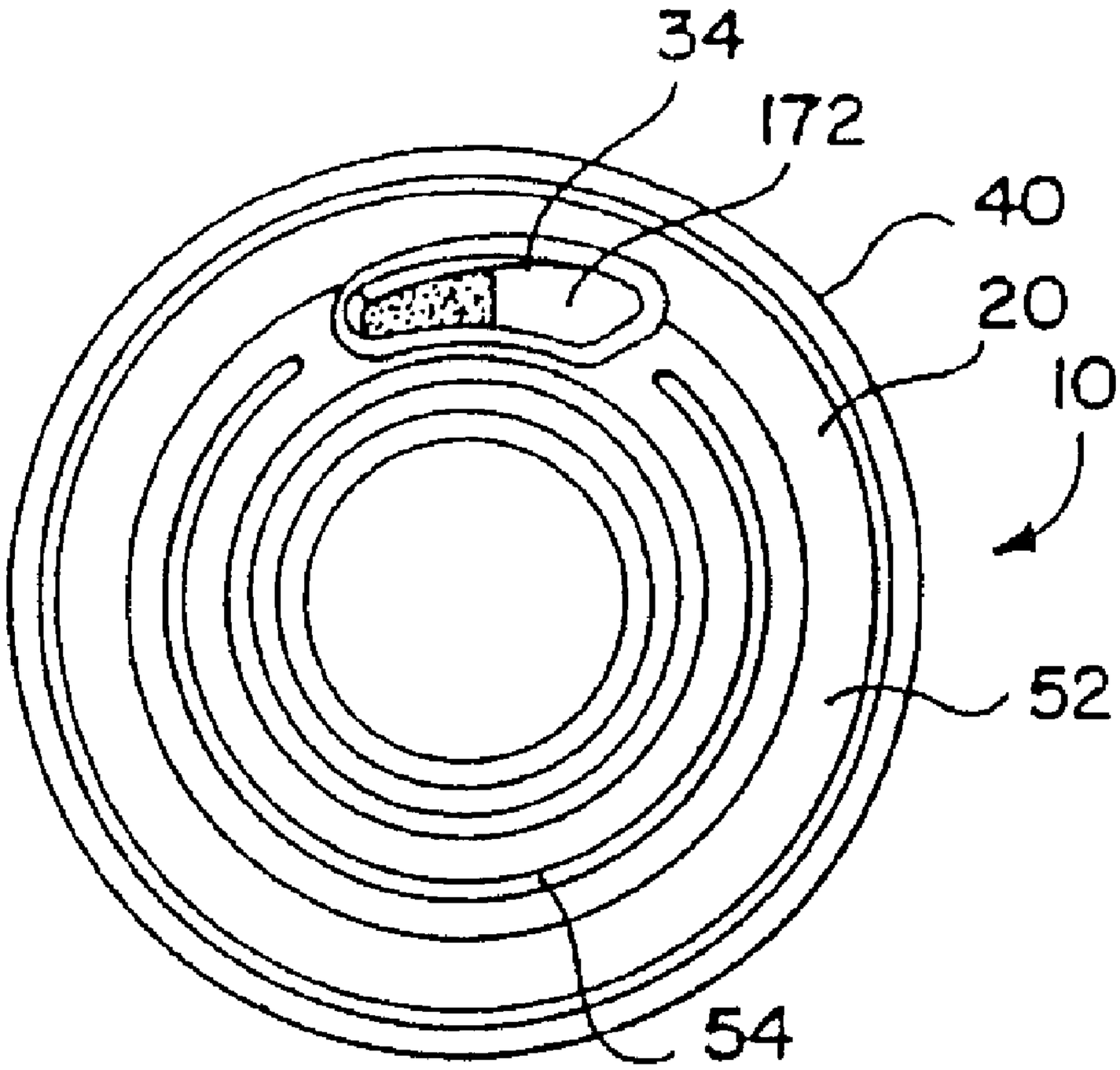
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(57) Abrégé/Abstract:
An indicating device for indicating the number of dosages of a substance that have been dispensed from or remain in a container includes a first indicator member incrementally moveable to a plurality of positions and a second indicator member operably connected to the first indicator member. The second indicator member is moveable in response to a predetermined number of movements of the first indicator member. One of the first and second indicator members includes numerical indicia and the other thereof includes color indicia.

ABSTRACT

An indicating device for indicating the number of dosages of a substance that have been dispensed from or remain in a container includes a first indicator member incrementally moveable to a plurality of positions and a second indicator member operably connected to the first indicator member. The second indicator member is moveable in response to a predetermined number of movements of the first indicator member. One of the first and second indicator members includes numerical indicia and the other thereof includes color indicia.

INDICATING DEVICE FOR AEROSOL CONTAINER

BACKGROUND OF THE INVENTION

The present invention relates generally to an indicating device for indicating the number of metered dosages that have been dispensed from, or remain in, an aerosol container, and in particular, to an indicating device adapted to be mounted to the aerosol container.

Aerosol dispensing devices have been developed that include a dose indicating device to indicate the number of metered doses that have been dispensed from the device, or to indicate the number of doses remaining therein. For example, patients have certain conditions that can be treated with medicaments dispensed in an aerosol and administered to the patient by inhalation. In one format, the aerosol with medicaments are contained in a container, and dispensed in metered, or measured, dosages with an inhalation device, or actuator boot. In such an arrangement, it can be important for the patient to be able to ascertain the number of metered doses remaining in the container, either by an indication of the number remaining therein or by knowledge of the number already dispensed therefrom, such that the patient is not caught unaware with an empty container when in need of the medicament. Thus, it may be important for the inhalation device to provide an accurate indication of either the number of doses remaining in the container, or the number of doses already dispensed therefrom.

Typically, a conventional aerosol container includes a body and a valve stem which can be depressed relative to the body so as to emit the metered dose of aerosol and medicament. The container typically is supplied with a predetermined number of metered doses, generally on the order of about 200, such that the counting of the number of valve stem depressions, and corresponding number of dispensed metered doses, can be directly correlated with the number of doses remaining in the container.

In operation, the container is typically received within a housing of the inhalation device, wherein the valve is brought into engagement with a support block in the housing. The user administers the medicament by

moving the container relative to the housing so as to depress the valve stem and internal valve and thereby release a metered dose, which is typically administered to the user through a port or mouthpiece extending from the housing. After the dose is administered, the valve stem, which is typically spring loaded, biases the container away from the support block so as to again move the container relative to the housing. In this way, a metered dose of medicament is administered by each cycle of linear reciprocal movement of the container relative to the housing.

Some actuator boots, or other devices attached to the medicament container, have indicating devices that convert the linear reciprocal movement of the container relative to the housing into a one-way, or single-cycle, movement of an indicator, wherein the indicator identifies the relative fullness of the container, the number of metered doses remaining therein or the number of doses already administered. Although these actuator boots with indicators, or separate indicator devices, have provided the advantage of generally being able to keep track of the number of dosages, there remains room for improvement. For example, indicating devices of this nature may include complex moving parts which can be difficult to assemble and expensive to manufacture. Such devices may also be susceptible to counting inaccuracies due to the configuration of the indexing or mating parts, or require excessive amounts of space within the housing to accommodate the relatively large or numerous moving parts. Others still may impede or interfere with the airflow and medicament being dispensed from the inhalation device. Alternatively, some devices use electrical circuitry to count or record the dispersements. Such devices can be relatively expensive to manufacture, however, and typically require a power source which may be susceptible to damage in various environments, such as moist conditions.

SUMMARY OF THE INVENTION

Briefly stated, the invention is directed to an indicating device for indicating the number of metered doses that have been dispensed from or remain in a container. The container has a valve stem extending

longitudinally therefrom; the valve stem being moveable between a closed position and an open position. The container dispenses a metered dosage when the valve stem is moved to the open position. The indicating device includes a base member adapted to be mounted to the container, a cap member moveably connected to the base member, an indicator member rotatably mounted to the cap member and a drive member adapted to rotate the indicator member an incremental amount upon a predetermined number of axial movements of the cap member relative to the base member.

In a preferred embodiment, the cap member is moveable relative to the base member along an axial path. The indicator member has a plurality of teeth and is rotatably mounted to the cap member about an axis substantially parallel to the axial movement of the cap member relative to the base member. A drive mechanism, including the drive member, comprises a ratchet wheel rotatably mounted to one of the base member and cap member about an axis substantially perpendicular to the axis defined by the axial movement of the cap member relative to the base member. The drive member is coaxially mounted with the ratchet wheel and a pawl is mounted to one of the cap member and base member. The pawl is selectively engaged with the ratchet wheel upon each axial movement of the cap member relative to the base member so as to rotate the ratchet wheel and drive member an incremental amount. The drive member is selectively engaged with at least one of the plurality of indicator member teeth upon a predetermined number of axial movements of the cap member relative to the base member such that the indicator member is rotated an incremental amount.

In another aspect, the indicating device comprises a first and second indicator member, with each of the first and second indicator members mounted to the cap member about an axis substantially parallel to the axial movement of the cap member relative to the base member. The first indicator member selectively engages the second indicator member as the first indicator member completes a usage cycle, representing one complete use of the indicating device and attached container, so as to rotate the second

indicator member an incremental amount. In a preferred embodiment, the first indicator member comprises dosage indicia indicating the number of doses that have been dispensed from or remain in the container, while the second indicator member comprises usage indicia indicating the number of usage cycles that have been completed for the indicating device, or the number of usage cycles remaining therefor.

In yet another aspect, the indicating device comprises a first indicator mounted to the cap member about an axis substantially parallel to the axial movement of the cap member relative to the base member and a second indicator member mounted to one of the cap member and the base member about an axis substantially perpendicular to the axial movement of the cap member relative to the base member. In a preferred embodiment, both the first and second indicator members comprise dosage indicia indicating the number of doses that have been dispensed from or remain in the container, with the second indicator member rotating an incremental amount in response to each axial movement of the cap member relative to the base member and the second indicator member rotating an incremental amount upon a predetermined number of axial movements of the cap member relative to the base member.

In another aspect, the indicating device comprises a first and second indicator member mounted to the cap member about an axis substantially parallel to the axial movement of the cap member relative to the base member and a third indicator member mounted to the cap member about an axis substantially perpendicular to the axial movement of the cap member relative to the base member. In a preferred embodiment, the first and third indicator members comprise dosage indicia, while the second indicator member preferably comprises usage indicia.

In yet another aspect, the indicating device comprises a reset member connected to one of the drive member and indicator member. The reset member can be rotated to move the indicator member relative to the cap

member independent of any axial movement of the cap member relative to the base member.

In another aspect of the invention, a method is provided for indicating the number of measured dosages dispensed from or remaining in the container. The method includes the steps of providing a housing for moveably supporting the container and providing an indicating device having a cap member, a base member and an indicator member rotatably mounted to the cap member. The method further comprises the steps of moving the cap member toward the base member so as to move the container along the longitudinal axis and thereby move the valve stem to the open position wherein a metered dosage is discharged, moving the cap member away from the base member, and moving the indicator member in response to the movement of the cap member relative to the base member.

Referring to a preferred embodiment, the method further includes the steps of engaging the ratchet wheel with the pawl upon one of the movements of the cap member toward and away from the base member and engaging the indicator member with the drive member so as to rotate the indicator member.

In yet another aspect, a method is provided for assembling a dispenser for dispensing metered dosages of medicaments from a container. The method includes the steps of providing a housing, disposing a container in the housing and mounting an indicating device to the container.

The present invention provides significant advantages over other aerosol dispensing devices and indicating devices used therewith. In particular, the indicating device can be separately manufactured and installed as needed on any number of conventional types of aerosol containers with little or no required modification to the container or housing. Moreover, the indicating device with its indicator member and drive mechanism is comprised of a relatively few, simple mechanical parts that are relatively easy to manufacture and assemble. In this way, the indicating device is made more robust and is less susceptible to damage when exposed to various adverse

user environments. In addition, the drive mechanism and indicator member provide a reliable indicating device for indicating the number of doses dispensed from or remaining in the container, and the indicating device can be made in a relatively compact configuration that does not interfere with the use of the dispensing device.

The present invention, together with further objects and advantages, will be best understood by reference to the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a top view of an indicating device having a viewing window.

FIGURE 1A is a top view of the indicating device showing an alternative embodiment of the viewing window with indicia visible therethrough.

FIGURE 1B is a top view of the indicating device showing an alternative embodiment of the indicia.

FIGURE 2 is a side view of the indicating device being mounted to the top of a container shown in cross-section.

FIGURE 3 is a top perspective view of the indicating device with the viewing window positioned in the top of the cap member.

FIGURE 3A is a top perspective view of the indicating device with the viewing window positioned along a side portion of the cap member.

FIGURE 4 is a bottom perspective view of the cap member with the indicator member mounted therein.

FIGURE 5 is an exploded perspective view of the cap member and indicator member shown in Figure 4.

FIGURE 6 is an exploded perspective view of an alternative embodiment of the indicating device, including a base member, a cap member, an indicator member, a ratchet wheel and drive member and a spring.

FIGURE 7 is a bottom perspective view of the cap member and indicator member of Figure 6, with the indicator member mounted in the cap member.

FIGURE 8 is an enlarged partial view of the indicator member and cap member of Figure 7 showing an engagement of the indicator member by the cap member.

FIGURE 9 is a bottom perspective assembly view of the cap member, indicator member, ratchet wheel, drive member and spring shown in Figure 6.

FIGURE 10 is an exploded perspective view of the base member and the cap member with the drive mechanism and indicator member mounted therein.

FIGURE 11 is a perspective assembly view of the indicating device shown in Figure 10.

FIGURE 12 is a cross-sectional view of the indicating device taken along line 12-12 of Figure 11, wherein the cap member is in a fully extended position relative to the base member prior to the application of an axial force by the user.

FIGURE 13 is a cross-sectional view of the indicating device similar to Figure 12 but with the cap member shown as moving toward the base member at an intermediate position of the stroke as indicated by the directional arrows.

FIGURE 14 is a cross-sectional view of the indicating device similar to Figure 12 but with the cap member reaching the bottom of the stroke as indicated by the directional arrows.

FIGURE 15 is a cross-sectional view of the indicating device similar to Figure 12 showing the cap member as it returns to the fully extended position relative to said base member as indicated by the directional arrows.

FIGURE 16 is a cross-sectional view of the indicating device taken through the middle of the indicating device and showing engagement members disposed in pockets formed in the base member.

FIGURE 17 is a cross-sectional view of the indicating device taken through the middle of the indicating device and showing an alternative return mechanism for the cap member.

FIGURE 18 is a bottom view of the assembly of Figure 9 (without the spring) at initial setting before a first actuation of the indicator device and container.

FIGURE 19 is a cross-sectional view taken along line 17-17 of Figure 18.

FIGURE 20 is a bottom view of the assembly of Figure 9 (without the spring) after the ratchet wheel and drive member have completed one revolution corresponding to a predetermined number of actuations.

FIGURE 21 is a cross-sectional view taken along line 19-19 of Figure 20.

FIGURE 22 is an enlarged partial bottom view of the cap member and indicator member showing the indicator member having an indexing member engaging an indentation formed on the cap member.

FIGURE 23 is a side view of an alternative embodiment of the indicating device.

FIGURE 24 is a top view of the indicating device shown in Figure 23.

FIGURE 25 is a cross-section view of the indicating device taken along line 25-25 of Figure 24.

FIGURE 26 is a cross-section view of the indicating device taken along line 26-26 of Figure 23.

FIGURE 27 is a perspective view of an indicating device with a reset device.

FIGURE 28 is a perspective view of an indicating device with an alternative embodiment of the reset device.

FIGURE 29 is an exploded view of an alternative embodiment of the indicating device with an alternative embodiment of the reset device and an adapter.

FIGURE 30 is a bottom perspective view of the indicating device and adapter shown in Figure 29.

FIGURE 31 is an exploded side view of an indicating device and adapter being applied to the bottom of a container supported in a dispenser housing shown in cross-section.

FIGURE 32 is a side view of an indicating device having an adapter applied to the bottom of a container supported in a dispenser housing shown in cross-section.

FIGURE 33 is a side view of the indicator member and a lock member in a disengaged position.

FIGURE 34 is a bottom view of the indicator member and lock member shown in Figure 33.

FIGURE 35 is a side view of the indicator member and lock member in an engaged position.

FIGURE 36 is a bottom view of the indicator member and lock member shown in Figure 35.

FIGURE 37 is a perspective view of an alternative embodiment of an indicating device having at least one indicator member with dosage indicia and an indicator member with usage indicia.

FIGURE 38 is an exploded perspective view of the indicating device shown in Figure 37.

FIGURE 39 is a bottom perspective view of the cap member shown in Figure 38.

FIGURE 40 is a bottom perspective view of a dosage indicator member shown in Figure 38.

FIGURE 41 is a top perspective view of a usage indicator member shown in Figure 38.

FIGURE 42 is a perspective view of a drive assembly and dosage indicator member shown in Figure 38.

FIGURE 43 is a perspective view of the reset member shown in the indicating device shown in Figure 38.

FIGURE 44 is an exploded perspective view of an alternative embodiment of an indicating device having indicator members with dosage indicia and an indicator member with usage indicia.

FIGURE 45 is a bottom perspective view of the cap member shown in Figure 44 with a usage indicator member installed therein and a dosage indicator member exploded out therefrom.

FIGURE 46 is a bottom perspective view of a dosage indicator member shown in Figure 44.

FIGURE 47 is a perspective view of a reset assembly shown in Figure 44.

FIGURE 48 is a perspective view of the drive member shown in Figure 44.

FIGURE 49 is a bottom perspective view of the usage indicator member shown in Figure 44.

FIGURE 50 is a top perspective view of the usage indicator member shown in Figure 44.

FIGURE 51 is a bottom perspective view of the cap member shown in Figure 44.

FIGURE 52 is a cut-away perspective view of the reset member shown in Figure 44 with the drive member in a disengaged position.

FIGURE 53 is a cut-away perspective view of the reset member shown in Figure 44 with the drive member in the engaged reset position.

FIGURE 54 is a side view of a first and second dosage indicator member with the reset member and drive member in a disengaged position.

FIGURE 55 is a side view of a first and second dosage indicator member with the reset member and drive member in an engaged reset position.

FIGURE 56 is a top perspective view of a first and second dosage indicator member, a usage indicator member and a drive assembly.

FIGURE 57 is a bottom perspective view of the base member shown in Figure 38.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

Referring to the drawings, and in particular FIGS. 31 and 32, an aerosol dispenser is shown as including a housing **200**, or actuator boot, and a container **12** disposed therein. The housing has a longitudinally extending cavity **202** shaped to receive the container. A top portion of the housing is generally open such that the container can be inserted in the housing through opening **204** and be installed therein with a bottom end **14** of the container protruding from the housing so as to be exposed to the user for actuation.

The terms "longitudinal" and "axial" as used herein are intended to indicate the direction of the reciprocal movement of the container relative to the housing, and of an indicating device cap member relative to a base member. The terms "top," "bottom," "upwardly" and "downwardly" are intended to indicate directions when viewing the inhalation devices as shown in the Figures, but with the understanding that the container is inverted such that the top surface thereof is located adjacent the bottom of the housing and vice versa. Moreover, it should be understood that a user can use the container and dispenser in any number of positions, including but not limited to the preferred upright position shown in FIGS. 31 and 32.

As shown in FIGS. 31 and 32, a cylindrical support block **212** having a well **214** is formed in a bottom portion **206** of the housing. An orifice **210** penetrates the support block to communicate with a bottom portion of the well. In one embodiment, a mouthpiece **208**, intended for insertion into the mouth of a patient, forms an exhaust port **216** that communicates with the orifice and well. The mouthpiece **208** extends laterally from the housing so as to facilitate insertion of the mouthpiece into the mouth of the patient.

The container **12** is cylindrical and has a hub **16** disposed on a top surface **17** thereof. A valve stem **18** extends longitudinally from the hub. The valve stem extends coaxially from the container and is biased outwardly therefrom by a spring (not shown) mounted within the valve stem of the

container. The container 12 is mounted in the housing by press fitting the valve stem 18 in the well 214 of the support block.

In a preferred embodiment, the container 12 is filled with a pressurized aerosol and medicament which is dispensed therefrom in specific metered doses by depressing or moving the valve stem 18 from an extended closed position to a depressed open position. A single metered dose is dispensed from the container by each reciprocal, longitudinal movement of the valve stem.

In operation, the opening of the valve stem is effected by moving the container 12 reciprocally within the housing 200 along a longitudinal axis, defined by the valve stem and the reciprocal movement of the container, by depressing the bottom end 14 of the container relative to the housing so as to move the valve stem 18 to the open position as it is supported within the well by the support block. As the valve stem is moved to the open position, the container dispenses a metered dose of aerosol and medicament through the well 214 and orifice 210. The aerosol and medicament are then transmitted to the patient through the exhaust port 216 of the mouthpiece by way of either a self-generated or assisted airflow.

In other delivery systems, the housing and holder for the container are attached to a component having a chamber with an output end. Examples of these kinds of delivery systems are shown for example in U.S. Patent 5,012,803, issued May 7, 1991, and U.S. Patent 4,460,412, issued September 11, 1984, both of which may be referred to.

In these kinds of delivery systems, the component having the chamber can be adapted to receive the mouthpiece of the housing, or it can be integrally connected with a holder supporting the container. In either embodiment, the metered dose of medicament in aerosol is first dispensed from the container into the chamber, and thereafter inhaled by the patient.

In a preferred embodiment, the container **12** is intended to dispense a predetermined number of metered doses of medicament. For example, conventional inhaler containers typically hold on the order of 100 to 200 metered doses. It should be understood, however, that the range of available doses could potentially vary from as few as one dose to as many as 500, or even more, depending, for example, on the capacity of the container, and/or the size of the metering dose valve. In operation, it can be important for the patient to be aware of the number of metered doses remaining in the container such that the patient is not caught unaware with an empty container when in need of the medicament.

Now generally referring to the Figures, a dose indicating device is shown. The indicating device **10** indicates the number of metered doses that have been dispensed from or remain in the container. As shown in the embodiments of FIGS. 1-3A and 10-11, respectively, the indicating device **10**, **200, 500** includes an indicating device housing comprised of a cap member **20, 220, 520** disposed in a base member **40, 540**. The base member **40** is configured such that it can be mounted to the bottom of the container **12**. In a first embodiment, shown in FIGS. 2, 6 and 12-17, the base member includes a convex, or curved bottom portion **50**, or floor, which is shaped to be received in and to mate with the bottom end **14** of the container, which has a concave or inwardly curved contour (see FIG. 2). The base member **40** is preferably bonded to the bottom of the container with adhesive, double sided tape, or similar bonding agent. As shown in FIGS. 6 and 10-15, a circumferential skirt member **94** extends upwardly from the base portion to form a cavity **96**.

Alternatively, as shown in FIG. 25, the base member **140** includes a bottom portion **150**, a downwardly depending circumferential skirt **152** and an upwardly depending circumferential skirt **156**. Depending skirt **152** forms a recess or cavity **154** which is shaped to receive the bottom end of the container. The base member is mounted on the container either by bonding one or more of the bottom portion or skirt to the container, or by press fitting

the container in the cavity **154** so as to provide an interference fit between the container and the depending skirt. The upwardly depending skirt **156** and bottom portion form an upper cavity **158** overlying the lower cavity **154**.

In yet another embodiment, shown in FIGS. 29-32, an adapter member **90** is attached to one of the above-mentioned base members by way of bonding, an interference fit, a snap fit, or a threadable engagement. The adapter member **90** preferably has a cylindrical configuration and comprises a circumferential skirt **92** that is shaped to receive the bottom end of the container. Again, the adapter can be mounted to the container by way of bonding, an interference fit, or both. Adapters having different internal diameters can be provided such that a single indicating device having a modular base member can be mounted on various aerosol containers having a variety of outer diameters.

Alternatively, as shown in FIG. 57, the base member **1040** includes a downwardly depending circumferential skirt **1152** forming a recess **1154**. The skirt **1152** includes one or more steps **1155** or shoulders, which form various inner diameters in the base member **1040**. In this way, a single base member **1040** can be used with containers having different diameters. It should be understood that although only one step is shown, so as to thereby form two inner diameters on the skirt **1152**, the base member could be configured with additional steps so as to provide a plurality of various inner diameters dimensioned to receive various containers by way of a friction fit. The skirt **1152** is also configured with a plurality of cut-outs, or slits **1153**, which permit enhanced air flow around the base member in embodiments where the base member may be in close proximity to the area where the medicament or aerosol is being dispensed.

Although the disclosed container and indicating device, and in particular, the cap member and base member, are shown as preferably having a circular cross section, those skilled in the art should understand that the container and indicating device, including any adapter, can be configured

in other shapes, including for example, but not limited to, a rectangular or triangular cross-section.

As best shown in FIGS. 1, 1A and 1B, the cap member **20** has a top portion **52** with a viewing window **34**, **59** formed therein. Preferably, the cap member **20** is circular and the viewing window is formed in the top portion adjacent the outer periphery of the cap member so as to overlie indicia applied to the top of an indicator member supported beneath the cap member. The viewing window can be configured in a number of various shapes. For example, the viewing window **34** can be tapered as shown in FIG. 1, or it can be an arcuate shaped window **59** bounded by coaxial inner and outer curved borders **57**, **58** and radial side borders **56** as shown in FIGS. 1A and 1B. The top of the cap member preferably has a plurality of raised portions **54** forming a grippable pattern for the user's thumb, or finger. In this way, the user can firmly press down on the cap member without slippage. One of skill in the art should recognize that other patterns or grippable surfaces, such as a knurled pattern, can be applied to the cap member to facilitate the use of the indicating device.

Referring to FIGS. 4, 6, 38 and 44 the cap member **20**, **220, 1020, 2020** comprises a circumferential skirt **92**, **292, 1092, 2092** depending downwardly from the top portion **52**, **252, 1052, 2052**. The skirt preferably has a smaller diameter than the upwardly depending skirt of the base member, such that the cap member skirt nests within the upwardly extending skirt of the base member. Alternatively, the cap member can be configured with a skirt having a larger diameter than the skirt of the base member such that the base member skirt nests in the cap member skirt. The cap member **20**, **220, 1020, 2020** is moveably mounted to the base member **40, 1040, 2040** by way of a snap fit.

In particular, as shown in FIGS. 5, 6, 7, 9, 10, 16, 29, and 44 the cap member includes a plurality of engagement members **28**, **228, 428** extending from an outer circumferential surface of the skirt. The cap member **20, 220, 420** is inserted axially within the recess or cavity **96** of the base member such

that the engagement members **28**, **228, 428** which have a tapered surface, slide past the rim **42** of the base member skirt until the engagement members are disposed in a plurality of pockets **43** formed along the inner circumferential surface of the base member skirt to form a snap-lock fit. In particular, the upper surface of the engagement member engages an engagement surface **45** defining the top of the pocket. In this way, the cap member is moveable with respect to the base member along an axial, or longitudinal, path. Alternatively, the rim of the base member can be curved slightly inward such that the engagement members engage the inwardly curved rim portion so as to prevent the cap member from being separated from the base member.

The axial movement of the cap member **20**, **220, 1020**, **2020** relative to the base member **40** is bounded or constrained by the engagement of the engagement members with the top of the base member pockets (or the base member rim) at a fully extended position and by engagement of a bottom rim **21**, **221, 1021, 2021** of the cap member skirt with the upper surface of the bottom portion at the bottom of the stroke as shown for example in FIGS. 12-15. One of skill in the art should understand that the engagement members can alternatively be formed on the base member skirt so as to engage pockets or openings, or a rim (or like protrusion), formed on the cap member skirt.

As shown in FIGS. 6, 9, 16 and 17, a spring **100** is disposed between the cap member and the base member. The spring is preferably disposed in a downwardly extending hub portion **30, 230** of the cap member (shown in FIGS. 4 and 6) and an upwardly extending hub portion **44** (shown in FIGS. 10, 16 and 17) of the base member, which are received one in the other. Alternatively, as shown in FIG. 25, a spring **300** is disposed between the cap member and base member and is of such a size that the coils are positioned adjacent the inner circumferential surface of the cap member skirt **392**. The spring **100, 300** functions as a return mechanism and biases the cap member **20, 220, 1020, 2020** upwardly in the base member such that the engagement

members **28**, **228** of the cap member engage the upper portion of the pockets of the base member. Although a compression spring is shown in the Figures, it should be understood that a belleville washer, cantilever, torsion, leaf and/or tension springs would also work to bias the cap member upwardly into engagement with the base member. The springs can be made of metal or plastic.

As shown in FIGS. 4, 5, 16, 17 and 45, the return mechanism acting between the cap member and base member includes a plurality of resilient arm members **400, 2400** extending downwardly from the cap member. As the cap member is moved toward the base member, one or more of the arm members engages a ramped biasing surface **402** formed along an outer portion of the hub portion **44**. The ramped biasing surface biases one or more of the resilient arm members outwardly as the cap member moves toward the base member. As shown in the embodiment of FIGS. 4 and 5, six arm members **400** are arranged circumferentially around the hub portion **30**. Alternatively, as shown in the embodiment of FIG. 39, six arm members **1400** are arranged in an "X" pattern around the hub **1030** so as to conserve space and provide additional room under the cap member **1020**. Corresponding ramps, or ramped biasing surfaces are similarly arranged in the base member **1140**.

The resilient arm member(s) act as cantilever springs to bias the cap member away from the base member when the cap member is released by the user. One of skill in the art should understand that the resilient arm members can also be formed on the base member so as to engage a ramped surface formed on the cap member. One of skill in the art should also understand that the spring and resilient arm members can be used together, as shown in FIGS. 16 and 17, or separately. In addition, it should be understood that one or more arm members and/or ramps may be used, with the size and shape of the arm member and/or ramp members being modified to provide more space between the cap member and base member.

As shown in FIGS. 4, 6, and 44 a key member **32**, **232**, or alignment rib, extends radially from the cap member hub portion **30**, **230**. As shown in FIG. 10, a key hole **47**, or slot, is formed in a radially extending portion of the hub portion **44** of the base member. The slot extends radially from the opening in the hub portion. During assembly, the key member of the cap member is received in the key hole of the base member so as to prevent rotation therebetween.

The dosage indicator member may be moveably mounted to one of the base member or the cap member. Referring to the various embodiments of FIGS. 4-9, 12-15, 38, 40, and 44-46, a dosage indicator member **60, 260, 1060, 2060** is rotatably mounted in the cap member **20**, **220**, **1020**, **2020** about an axis substantially parallel to the axial movement of the cap member relative to the base member. The indicator member is generally open in the middle and includes a top portion **76**, **276**, **1076**, **2076** having an upper surface **62**, **262** that rotatably slides along a bottom surface of the top portion of the cap member. Alternatively, the indicator member can be mounted on the outside of the cap member with a viewing window formed in the indicator member for viewing indicia applied to the top of the cap member.

As shown in the embodiments of FIGS. 5, 6, 38 and **44**, the indicator member **60**, **260**, **1060**, **2060** includes a circumferential skirt **74**, **274**, **1074**, **2074** depending downwardly from the top portion. Referring to FIGS. 5 and 8, a plurality of protrusions **26**, **226**, or engagement tab members, extend from an inner circumferential surface of the cap member skirt and engage a rim **64**, **264** formed on the bottom of the indicator member skirt. Alternatively, the indicator member can include an engagement member, or rim, that engages a groove or similar opening in the cap member. In this way, the indicator member is secured to the cap member so as to prevent axial movement therebetween but where the indicator member is permitted to rotate relative to the cap member. The indicator member is installed by snap-fitting the indicator member within the cap member. One of skill in the art should understand that the indicator member could alternatively be rotatably

mounted on the cap member hub portion (having a portion of the key member cut away), or on a similar axle secured to the cap member.

In yet another alternative embodiment, shown in FIGS. 25 and 26, a plate member **380** holds the indicator member **360** against the inner surface of the top portion of the cap member **320**, wherein the spring **300** engages a bottom surface of the plate member **380** to bias a top portion **398** of the plate member against the cap member **320** and the cap member **320** away from the base member. The indicator member **360** is nested in the recess formed between an outer flat portion of the plate member and the bottom surface of the cap member. Referring to FIG. 26, the drive assembly is mounted to the plate member **380** by inserting axle **384** through openings in downwardly extending walls **388** of the plate member. An enlarged portion **396** on the end of the axle engages one of the walls, while the ratchet wheel **382** and drive member **386** are mounted to the other end of the axle to complete the assembly. A top portion of the plate member abuts the cap member.

As shown in the embodiments of FIGS. 4-9, 40 and 46 the indicator member **60**, **260**, **1060**, **2060** has a plurality of inwardly facing teeth **66**, **266**, **1066**, **2066** formed around the inner circumference of the skirt. As shown in FIGS. 5, 6, and 40, the teeth are preferably formed about only a portion of the circumference, such that a gap **1061** is formed therebetween.

Alternatively, as shown in the embodiment of FIGS. 25 and 26, the indicator member **360** has a plurality of teeth **366** formed radially inwardly about an inner rim of an opening formed in the indicator member, which is configured as a relatively flat ring that does not include a skirt. In yet another embodiment, shown in FIG. 29, the plurality of teeth **466** extend axially downwardly from a ring-like indicator member **460**.

As shown in the embodiments of FIGS. 5 and 44-46, the indicator member **60**, **2060** includes a plurality of indentations **68**, **2068** formed about the outer circumferential surface of the skirt **74**, **2074**. The cap member includes a pair of upwardly extending resilient indexing members **22**, **2022** each having an end portion that engages one of the indentations so as to

releasably engage the indicator member and prevent rotation therebetween. The angular distance between the indentations **68**, **2068** is substantially the same as the angular distance between the plurality of indicator member teeth **66**; **2066**. In this way, the indexing member selectively engages the next indentation upon each incremental advancement of the indicator member defined by the distance between adjacent teeth. In the embodiment shown in FIG. 46, the indentations are preferably formed as ratchet teeth which only permit one-way rotation of the indicator member **2060** relative to the cap member.

Alternatively, as shown in the embodiments of FIGS. 6 and **38**-39, the indentations and indexing member are reversed, *i.e.*, the indentations **224**, **1224** are formed about an inner circumferential surface of the cap member skirt and, and shown in FIG 6, an indexing member **270** depends downwardly from the indicator member in a void formed in the skirt of the indicator member, or, as shown in FIG. 38, a pair of index members **1270** are configured as flexible arms formed along a rim portion **1078** along the bottom edge of the skirt **1074**. In the embodiment shown in FIGS. 38, 39 and 40, the interaction between the index members **1270** and the indentations **1224**, which are preferably shaped as ratchet teeth, function to index the indicator member by holding it in place between actuations of the cap member and also to prevent the backward rotation of the indicator member **1060**. It should be understood that one or more index members can be engaged with a plurality of indentations, preferably formed as ratchet teeth, to control the rotational movement of the indicator member, regardless of whether the index members or indentations are formed on the cap member or the indicator member.

In yet another alternative, shown in FIG. 26, the plate member **380** includes a resilient indexing member **370** that engages one of the plurality of teeth **366** to selectively engage the indicator member so as to prevent the inadvertent rotation thereof. Alternatively, the indexing member can extend from the cap member.

As shown in FIGS. 1A and 1B, dosage indicia **72**, **172** in the form of numbers or color codings are provided on the top surface of the indicator member and are visible to the user through the viewing window **34**, **59** provided in the top of the cap member. Alternatively, as shown in the embodiment of FIGS. 24 and 26, a zero is positioned adjacent a rectangular viewing window **394**, preferably by permanent etching, to indicate a multiplication by ten of the indicia visible in the viewing window. One and two digit indicia **372** are formed on the top of the indicator member **360** such that a three digit number is indicated to the user.

In yet another alternative embodiment shown in FIG. 3A, the viewing window **534** is formed in an upper portion of the downwardly depending circumferential skirt **592** of the cap member. The indicia are applied to the outer circumferential surface of the indicator member skirt **574** so as to be visible through the window. In this embodiment, a rim **542** of the base member is preferably scalloped in alignment with the viewing window **534** to provide an unobstructed view of the indicia and to inform the user as to the location of the viewing window.

One of the skill in the art should understand that other indicia indicating the number of doses remaining in or dispensed from the container would include, but not be limited to, various alpha-numerical characters, words, terms or phrases (such as "full" and "empty"), scales, grids, arrows, raised portions, indentations, color coding and segmentation, shading and like markings, or any combination thereof. For example, a segmented color grid **172** displayed in the viewing window (as shown, e.g., in FIG. 1B) could turn from green, indicating a full container, to yellow, indicating an intermediate capacity, and finally to red, indicating an empty container. It should also be understood that the indicia can be formed integrally with the counter member, or applied thereto by means of paint, dye, etching, pad printing, hot stamping or adhesive labels. When using numerical indicia, the numbers can be arranged to go from 0 (or some beginning number) to the predetermined number of available doses such that a display of that number

to the user indicates that the container is empty, or, conversely, to go from the starting predetermined number to 0 (or some ending number), which again indicates to the user that the container is empty.

In a preferred embodiment, the indicator member is made of acrylonitrile butadiene styrene ("ABS"), which is receptive to certain alternative processes of printing or applying the indicia, including pad printing and hot stamping. The cap member and base member are preferably made of a hard plastic material such as Acetel.

Referring to FIGS. 5-9 and 12-18, a drive mechanism is shown as including a drive assembly **80**. The drive assembly **80** includes a ratchet wheel **82** coaxially mounted to a drive member **86** on an axle **84**. The ratchet wheel, drive member and axle can be made separately, with the ratchet wheel and drive member then mounted on the axle, or all three parts can be integrally molded as a one-piece component. The drive assembly is preferably made of hard plastic material such as Acetel.

In an alternative embodiment, shown in FIGS. 38 and 42, the drive assembly further includes a second dosage indicator member **1800** coaxially mounted with and between the drive member **86** and ratchet wheel **82**. The indicator member **1800** is configured as a wheel and preferably includes dosage indicia positioned around the peripheral surface **1802** thereof. Preferably, the indicia are comprised of consecutive numerals running from 0 to 9.

In yet another alternative embodiment, shown in FIG. 44, the drive assembly includes a ratchet wheel **82** coaxially mounted with an indicator member **1800**. The drive member **86** is formed separately from the ratchet wheel and indicator member and includes a single tooth **81** that is dimensioned to be received in a groove **1801** formed in a collar **1082** extending axially from the indicator member **1800**. The tooth **81** of the drive member **86** is received in the groove **1801** of the collar and can be moved axially with respect to the collar, ratchet wheel and indicator member.

The ratchet wheel **82** includes a plurality of teeth **88** (preferably ten) formed around its periphery. Each of the teeth includes an engagement surface **89** and a tapered surface **87**. As noted above, the drive member **86**, whether integrally formed with the ratchet wheel or separately connected thereto, includes a single tooth **81** extending radially from the axle **84**, or drive member collar.

In the embodiments shown in FIGS. 5, 6 and 45, the drive assembly is mounted to the cap member by engaging opposite ends of the axle **84** with downwardly extending hub portions **36**, **236**, **2236** such that the axle, ratchet wheel and drive member rotate about an axis substantially perpendicular to the axial movement of the cap member relative to the base member and to the axis of rotation of the indicator member. Alternatively, the drive assembly can be mounted to the base member in a similar manner.

Alternatively, as shown in the embodiment of FIGS. 38-39, the axle **84** is received in a single hub **1036**, or flexible snap enclosure rib. In this embodiment, the drive assembly further includes a ramp **1083**, which ramps up to a plurality of radially extending teeth **1085** formed around the rotational axis of the drive assembly. A larger diameter axle **1084** extends outwardly from the teeth. A reset member **1106** includes a grippable wheel portion **1107** and a collar **1109** that is dimensioned to be received in an laterally facing opening **1302** formed in the skirt of the cap member. A bearing support **1300** is formed around the periphery of the opening so as to provide support for the collar. The reset member **1106** further includes four flexible, resilient fingers **1304** extending axially from the collar **1109**. Each finger **1304** includes a engagement portion **1306** extending radially inward from the end of the finger. The engagement portion is shaped to engage one of the teeth **1085** formed on the drive assembly. A protrusion **1308**, or rib, is formed on one of the fingers so as to extend radially outward therefrom. The protrusion **1308** acts as a drive portion and engages a downwardly depending protrusion **1310** formed on the bottom of the indicator member adjacent the gap **1061** formed between the teeth on the indicator member, as

shown in FIG. 40. Preferably, the protrusion **1310** is positioned so as to be at the angular midpoint between the two teeth spanning the gap.

As shown in FIGS. 12-15, the drive mechanism further includes a pawl member **48**, shown as a flexible rod or finger, which extends upwardly from the bottom portion of the base member and selectively engages one of the teeth of the ratchet wheel. Alternatively, the pawl member can be moveably secured to the cap member and extend through the base member to engage the top of the container, such that the axial movement of the cap member toward the container causes the pawl to move toward the ratchet wheel and engage one of the teeth thereon as described below. A non-return member **238**, also shown as a flexible rod or finger, extends downwardly from the top portion of the cap member and selectively engages another of the teeth **88** of the ratchet wheel. It should be understood that the pawl member could alternatively extend from the cap member (and the non-return member from the base member) when the drive assembly is mounted to the base member, as described above.

In operation, as shown in FIGS. 12-21, the user depresses the cap **220** member from a fully extended position (see FIG. 12) toward the base member such that the cap member bottoms out in the base member at the bottom of the stroke (FIG. 14) and such that the base member imparts an axial load on the container until a metered dosage is dispensed therefrom. In a preferred embodiment, the biasing force of the spring **100** (shown in FIG. 6), or alternative return mechanism such as the resilient arm members which act as springs, is less than the biasing force of the spring located in the metering valve of the container, such that the cap member first bottoms out in the base member with the container then being moved downwardly in the housing until a metered dose is dispensed.

Referring to FIGS. 12, 13 and 14, as the cap member **220** is depressed toward the base member **40**, the pawl **48** selectively engages the engagement surface **89** of one of the ratchet wheel teeth and rotates the ratchet wheel. The tapered surface **87** of one of the teeth formed on the

ratchet wheel simultaneously biases the non-return member **238** outwardly until it selectively engages the next tooth near the bottom of the stroke. The user then releases the cap member whereinafter the spring **100** (shown in FIG. 6), or similar return mechanism, biases the cap member **220** away from the base member **40** until the engagement member engages the base portion at the top of the stroke as shown in FIG. 15. When the cap member is released by the user, the container is biased upwardly within the housing along the longitudinal axis such that the valve stem is moved to the closed position within the container. Simultaneously, as the cap member is released and allowed to move away from the base member, the pawl **48** is biased outwardly by the tapered surface **87** of one of the teeth on the ratchet wheel as the non-return member **238** prevents a backwards rotation thereof so as to maintain a unidirectional rotation of the ratchet wheel. At the top of the stroke (shown in FIG. 15), the pawl **48** is again placed in position for selective engagement with one of the teeth of the ratchet wheel. In this way, the ratchet wheel **82**, and connected drive member **86** (shown in FIGS. 18-21), are advanced an incremental amount for every actuation of the container and the attendant release of medicament. The incremental amount is defined by and dependent on the number of teeth formed about the periphery of the ratchet wheel. When formed with ten teeth, as shown in the preferred embodiment, the ratchet wheel will make one full revolution for every ten actuations of the indicator device and container, or a tenth of a revolution for each actuation. One skilled in the art will appreciate that the ratchet wheel can be provided with various numbers of teeth formed about its periphery such that the more or less axial movements or actuations of the container are required to make one full rotation of the ratchet wheel.

Alternatively, the operation of the ratchet wheel can be reversed. In this embodiment, the pawl is biased outwardly by the tapered surface of one of the ratchet wheel teeth on the downstroke. At the bottom of the stroke, the pawl is biased into engagement with one of the teeth. When the cap member is released by the patient, the spring, or equivalent return mechanism, biases

the cap member upwardly within the base member along the longitudinal axis such that the pawl member engages one of the teeth and thereby rotates the ratchet wheel an incremental amount. In this embodiment, the non-return member maintains the rotational position of the ratchet wheel on the downstroke.

As shown in FIGS. 18-20, 38 and 44 the drive member **86** is shown as preferably having a single tooth **81** or segment. Therefore, upon every tenth actuation, the drive member **86** is rotated such that the tooth selectively engages one of the teeth **266** formed on the indicator member so as to rotate the indicator member an incremental amount. The incremental amount of rotation is defined by the distance between adjacent teeth, otherwise defined as the circular pitch of the teeth. In this way, the drive member is selectively engaged with at least one of the teeth of the indicator member after and upon a predetermined number of axial movements of the cap member relative to the base member so as to rotate the indicator member the incremental amount. The predetermined of number axial movements required to cause the indicator member to rotate is defined by and dependent upon the reduction ratio of the ratchet wheel and drive member, which, in turn, is defined by dividing the number of teeth formed on the ratchet wheel by the number of teeth formed on the drive member. For example, as shown in the preferred embodiment, a ratchet wheel having ten teeth and a drive member having one tooth will result in an incremental movement of the indicator member, otherwise defined as the advancement of one tooth of the indicator member, upon every ten axial movements. Similarly, if the drive member had four teeth, and the ratchet wheel twenty, the predetermined number would equate to five axial movements, and so on. A one-to-one gear ratio would result in a predetermined number of one axial movement, wherein the indicator member would be moved upon every axial movement.

Referring to FIG. 19, the indicator member **260** and drive member **86** are shown prior to an initial actuation or use by the user. In particular, the drive member tooth is positioned adjacent the first tooth **266** on the indicator

member. In this embodiment, wherein the ratchet wheel comprises ten teeth, ten actuations are required before the tooth **81** engages the first tooth **266** on the indicator member as shown in FIG. 21. At this point, the indicator has completed a single cycle equal to the number of predetermined number of axial movements, which results or culminates in the incremental movement of the indicator member. The cycle is then repeated (by again making the predetermined number of axial movements) so as to again culminate in the incremental movement of the indicator member. Preferably, as shown in FIGS. 1A, 3A, 24 and 26, numerical indicia (including numbers and dots) are applied in increments of ten to correlate to the preferred embodiment requiring ten axial movements for one incremental advancement of the indicator wheel.

The ratchet wheel and drive member with their reduction ratio provide a simple but reliable mechanism for advancing the indicator member. In particular, the indicator member can be made with fewer teeth than if it were required to advance upon every actuation of the indicator member and container. For ease of manufacturing, it is desirable to provide as coarse a pitch on each of the indicator member and ratchet wheel as possible, although the gears are still defined as fine-toothed gears. However, it is also intended that the indicator member make only a single revolution (single-cycle) corresponding to a complete evacuation of medicament from the container. Thus, when a large number of doses (on the order of 200 or more) are contained within the container, it is important for the ratchet wheel and drive member to provide a relatively high reduction ratio, such that 200 linear reciprocal movements of the cap member and container correspond to one or less revolutions of the indicator member. As such, the indicator member can be made with coarser teeth at less cost. In addition, larger coarser teeth interacting with a relatively large drive member tooth helps to improve the accuracy of the device as those parts mesh. In addition, the mechanism, and its attendant reduction ratio, permits the indicator member to make only a single revolution during the life of the container, i.e., until it is

emptied, even when the container contains a relatively large number of metered doses (on the order of 200 or more doses). This single revolution corresponds to a usage cycle, which is defined as the movement of the dosage indicator from an initial reading, which indicates that the container is full, to a final reading, which indicates that the container is empty. Of course, the indicator member, if initially set to a smaller number of dosages, may make less than a complete revolution in completing a usage cycle.

In the alternative embodiments shown in FIGS. 38 and 44, the viewing window **1034, 2034** is large enough such that the first and second dosage indicator members **1060, 2060, 1800** with their indicia are visible therein. In the operation of these embodiments, the indicator member **1800** rotates with each actuation of the cap member **1020, 2020** relative to the base member **1040, 2040** as the ratchet wheel **82** is driven by the pawl member. The indicator member **1800** rotates about an axis substantially perpendicular to the axial movement of the cap member relative to the base member and to the rotational axis of the indicator member **1060, 2060**. In the preferred embodiment, with the indicator member **1800** having "ones" indicia and the ratchet wheel **82** having ten teeth, the indicator member **1800** is advanced upon each actuation and provides indicia visible to the user to notify them of such advancement. As the indicator member **1800** completes a cycle, or rotation, the indicator member **1060, 2060** is advanced one increment by the drive member **86** and the indicator member **1800** begins another cycle. In this way, the user is advised as to each actuation of the indicating device and the attendant dispensment of a dosage from the attached container.

Where, as shown in FIGS. 5 and 40, the teeth **66, 1066** extend only partially around the periphery of the indicator member, the indicator member **60 1060** is not advanced after the drive member engages the last tooth, even when the cap member is repeatedly moved to actuate the container. This ensures that the indicator member cannot be advanced past the last indicia indicating that the container is empty to a first indicia indicating that the container is full, so as to confuse the user.

Alternatively, as shown in FIGS. 33-36, the indicating device includes a lock device. In particular, the base member includes a first lock member **702**, configured as a post member extending upwardly from the bottom of the base member. The indicator member **760** includes a second lock member **704**, shown in FIG. 35 as an extension of one of the plurality of teeth **766** formed around the circumference of the indicator member. In operation, the cap member is moved towards and away from the base member as described above so as to rotate the indicator member. During this operation, as shown in FIGS. 33 and 34, the first lock member **702** is positioned inside the inner diametrical surface of the plurality of teeth so as to not interfere therewith as it is moved into the recess formed by the indicator member as shown in FIG. 33. After the indicator member has made one complete rotation, which preferably correlates to an emptying of the container, the second lock member **704** is rotated over the first lock member **702** as shown in FIGS. 35 and 36. In this position, the cap member cannot be moved toward the base member and the user is thereby prevented from further discharging, or attempting to discharge, an empty container. The immobility of the cap member also provides a secondary indicia that the container is empty. One of skill in the art should understand that the size and shape of the first and second lock members can be varied. For example, a post member may extend from the cap member so as to engage a stepped surface in the base member.

As shown in FIGS. 29 and 30, a reset wheel **106** is coaxially mounted with the ratchet wheel **82** and drive member **86**. The outer periphery **108** of the wheel, which includes a plurality of teeth for gripping by the user's thumb, is exposed as it extends through the bottom surface **50** of the base member. One of skill in the art should understand that the reset wheel can be exposed by extending from other portions of the indicator device for access by the user. The user rotates the reset wheel **106** to manually rotate the indicator member to its original starting position, or any other desired setting, without having to move the cap member relative to the base member. In this way, the

indicator member can be recycled for use on a new container, or can be moved to the proper setting prior to installing the indicating device on the container. In this way, the same indicating device can be used with various containers containing varying numbers of metered dosages of medicament. During the movement of the indicator wheel relative to the cap member, the force of the indexing member against the indentations in one of the cap member and indicator member is overcome such that the indexing member repeatedly moves into and out of engagement with the indentations as the indicator member is rotated by the user to the desired setting. This movement is similar to the movement of the indexing member occurring upon each incremental advancement of the indicator member relative to the cap member.

Preferably, the reset wheel of FIGS. 29 and 30 is used with an indicator member having teeth formed about its entire periphery, such that the indicator wheel need only be moved a few teeth (one or more) to return it to the zero (or full, e.g., 200) position. The reset wheel can be used with or without the lock device described above, since the wheel can be used to move or rotate the indicator wheel independent of any axial movement between the cap member and base member.

In an alternative embodiment shown in FIG. 28, a reset selector member **602** is mounted to the end of the axle and is exposed in an opening **604** in the side or skirt **694** of the base member. The reset selector member **602** is mounted on the axle. The selector member **602** is provided with a slot adapted to receive the head of a screw driver or like tool, which can be actuated by the user to rotate the axle, coaxially mounted drive member and indicator member until the desired indicia are visible in the viewing window. This feature can be valuable for resetting an indicating device for use on a new container, or for initially setting the device for the proper number of doses contained in the container. One of skill in the art should understand that recesses and/or protrusions other than the disclosed slot can be exposed on the selector member to allow the user to grip or otherwise operably

engage the selector member and to thereafter rotate the indicator member. One of skill in the art should also understand that the opening in the base member could be positioned anywhere along the longitudinal path of the axle as the cap member moves relative to the base member so as to expose the selector member when aligned with the opening.

In yet another alternative embodiment, shown in FIG. 27, a selector window **806** is formed in the top of the cap member. A reset selector member **802**, configured as a protrusion or like grippable member, is exposed in the window as the indicator member is rotated to the empty position. In one embodiment, as described above, the plurality of teeth are formed only around a portion of the periphery of the indicator member so as to leave a gap between the first and last tooth. In such an embodiment, the selector window **806** is preferably of such length that the user can move the reset selector member **802** within the window until the first tooth is again in position for engagement with the drive member. It should be understood, however, that the reset selector member can also be used with an indicator member having teeth formed around the entire periphery of the member.

In an alternative embodiment, a plurality of reset members, or a similar grippable surface, configured for example as a plurality of notches or teeth, can be formed around the entire periphery of the indicator member and exposed in a selector window, or alternatively, in the viewing window. In such an embodiment, the indicator wheel can be rotated to expose different indicia at any time simply by engaging the reset selector members on the indicator member with the user's thumb or like member.

In yet another embodiment, shown in FIG. 24, an opening, or selector window **906**, is provided in the top of the cap member. A thin tool, such as a paper clip, is inserted through the opening to bias the resilient indexing member **370** out of engagement with the indicator member. The user can then operably engage the indicator member with their finger or the like, either through the viewing window or a selector window, to move the indicator member to the desired setting.

In yet another alternative embodiment, shown in FIG. 43, the reset member, with the collar **1109** disposed on the axle **1084** of the drive assembly, is pulled axially outward with respect thereto from a disengaged position, where the engagement portions **1306** of the flexible fingers **1304** are positioned circumferentially around the axle **84**, to an engaged reset position, such that the engagement portions **1306** of the flexible fingers are biased outwardly as they ride up the ramp **1083** and are thereafter moved into engagement with the teeth **1085** formed around the axle of the drive assembly. The user then rotates the reset member **1106** about a rotation axis, which is substantially perpendicular to the axial movement of the cap member relative to the base member. As the reset member is rotated, the protrusion **1308** on the flexible fingers is brought into engagement with the protrusion **1310** on the indicator member **1060** so as to rotate the indicator member an incremental amount and thereby bring the first tooth on the other side of the gap **1061** into position for engagement by the drive member, thus bridging the gap **1061** between the teeth of the indicator member. As the reset member **1106** is further rotated, the drive member tooth **89** engages the teeth **1066** of the indicator member, and the reset member can be rotated to manually drive the indicator member, or indicator members, to the desired preset condition. For example, the indicator members can be reset to indicate 200 dosages for use with a container having 200 dosages.

In a preferred embodiment, the engagement portions **1306** and/or teeth **1085** formed on the axle of the drive assembly are configured to allow rotation of the drive member in only one direction. Therefore, rotation of the reset wheel in an opposite direction will not effect a rotation of the drive member in that same direction as the flexible fingers, with their engagement portions, will simply slide over the teeth formed about the axle. This one-way rotation prevents the drive member from engaging and rotating the indicator member in an opposite direction, which direction is opposed both by the non-return member engaging the ratchet wheel, and the one-way indexing interface between the cap member and indicator member.

To install the reset member and drive assembly, the drive assembly is installed in a vertical manner such that the axle **84** is received in the flexible snap enclosure **1036**. Once the drive assembly is snapped in place, the reset member **1106** is inserted through the opening in the cap member and over the axle **1084** until the fingers eventually are disposed around the axle **1084** in the disengaged position. In this way, the reset member, which is supported by the bearing surface **1300** of the cap member, further supports the drive assembly.

In yet another embodiment, best shown in FIGS. 52-55, the indicator member **2060** has a plurality of teeth extending around the entire circumference thereof. At least one of the teeth **2067** has a cut-away portion **2069** aligned with the tooth **81** of the drive member. Accordingly, at the end of a cycle, the drive member is positioned in a disengaged position where even repetitive actuations of the indicating device do not lead to the advancement of the indicator member as the drive member, with its one or more teeth **81**, merely passes through the cut-away portion **2069** of the tooth, with which it is aligned. In this embodiment, however, the drive member **86** is axially moveable with respect to the indicator member **1800** and ratchet wheel **82**.

As best shown in FIGS. 44, 47 and 52-56, a reset member **2106** includes a grippable wheel **2107** connected to a drive shaft **2109**. As shown in the preferred embodiment of FIG. 47, the end of the drive shaft includes a plurality of teeth **2306**, that engage slots **2308** or openings dimensioned to receive the teeth formed in one end of the drive member **86**. The drive member is installed on the shaft of the reset wheel such that the teeth **2306** formed on the end thereof engage the slots **2308** formed in the drive member. The drive member is then inserted into the groove **1801** of the collar **1082** extending from the indicator member.

In operation, the user pulls the reset member **2106** axially outward so as to move axially the drive member **86** from a disengaged position, where the drive member tooth **81**, or teeth, is aligned with the cut-away portion **2069**

of the tooth on the indicator member, to an engaged or reset position, where the drive member tooth is brought into engagement with the portion **2067** of the tooth that is not cut-away. In the reset position, the user rotates the reset wheel **2107** and connected drive member **86** so as to advance the indicator member **2060**, or indicator members, to the desired setting independent of the axial movement of the cap member relative to the base member. In the disengaged position, the reset wheel is recessed between a pair of tapered flanges formed around the circumference of the base member.

As shown in FIGS. 44 and 52-56, the indicator member **2060** includes a cover portion **2087** that extends radially inward from the top portion of the indicator member. The cover portion is brought into alignment with the viewing window at the end of the usage cycle such that the indicator **1800**, which can continue to be spun beneath the cover portion is not visible. Indicia, such as the number "0" or the words “end” or “empty” can be applied to the cover portion to inform the user that the container is empty.

As shown in FIG. 38, the indicating device also includes a usage indicator member **1500**. The indicator member **1500** is configured as a ring and is disposed around the skirt **1074** of the dosage indicator member **1060** where it is trapped between the rim flange **1078** of the indicator member and the bottom surface of the top of the cap member. In this way, the usage indicator member **1500** is supported by and is moveable about the dosage indicator member **1060**. The indicator member **1500** also is thereby rotatably mounted about an axis substantially parallel to the axial movement of the cap member relative to the base member. The indicator member **1500**, which is configured as a ring, has a plurality of teeth **1502** formed around the outwardly facing radial periphery thereof. As the indicator member **1500** is advanced as explained above, a flexible finger **1273** formed along the circumferential rim **1078** of the indicator member **1060** is biased radially inward by a ramp **1277** formed on the inside of the cap member so as to engage at least one of the plurality of teeth **1502** formed on the indicator member and thereby advance the indicator member an incremental amount,

defined by the distance between adjacent teeth. The number of teeth formed around the indicator member corresponds to the number of intended usage cycles of the indicating device.

In the preferred embodiment, which has only a single ramp **1277**, the usage indicator member **1500** is advanced one tooth upon each complete rotation of the dosage indicator member **1060**, which corresponds to one complete usage cycle for the indicating device. For example, the indicating device can be initially set to reveal an initial count of 200 dosages. As the indicating device is successively actuated to dispense the dosages, the indicator members **1060**, **1800**, with indicia, are actuated to count down until they reveal a final count of 0 dosages available for use. At that time, the drive assembly is positioned in the disengaged position, as explained above.

As the reset member **1106** is used to actuate the drive assembly to reset the device for another usage cycle, the indicator member **1060** with its resilient finger **1273** is biased into engagement by the ramp **1277** such that the usage indicator member is rotated. In this way, the usage indicator member **1500** is rotated, or advanced, upon the completion of each successive usage cycle. The number of teeth **1502** on the indicator member **1500** corresponds to the number of intended uses for the indicator. For example, in the embodiment shown in FIGS. 38 and 41, the indicator member **1500** has twelve teeth corresponding to an intended twelve uses of the indicating device with twelve different containers. As noted above, the reset member can be used to reset the indicia at any desired reading, such that one indicating device can be used with successive containers having different numbers of dosages contained therein. The indicator member **1500** also includes a stop member **1506** formed as a protrusion that extends radially inward from the top of the indicator member. The stop member **1506** engages a stop member **1508** extending downwardly from the top portion of the cap member upon completion of the final usage cycle. This engagement prevents the user from attempting to advance the dosage indicator member **1060** by way of the reset member and drive assembly, because the finger

1273 is biased into engagement with at least one of the teeth on the usage indicator member, which is immobilized. In this way, the entire device is immobilized. It should be understood that although the preferred embodiment is configured for twelve usage cycles, the usage indicator member could be provided with more or less teeth corresponding to more or less total available usage cycles.

Referring to FIG. 41, the usage indicator member **1500** further includes a indexing member **1510** configured as a protrusion extending radially outward from the outer circumferential surface of the indicator member. The indexing member **1510** selectively engages a plurality of teeth **1512** formed around the inner circumferential surface of the skirt of the cap member. The indexing member **1510** and teeth **1512** are configured as a ratchet to allow one-way rotation of the indicator member **1500** relative to the cap member **1020**. In a preferred embodiment, the indexing member and teeth are tapered to interact and provide for the one-way action.

As shown in FIGS. 37 and 38, a plurality of viewing windows **1600** are arranged around the outer periphery of the top of the cap member. A plurality of indicia **1602**, shown as successive numbers, are affixed to the top of the cap member adjacent the viewing windows. The upper edge **1514** of the usage indicator member is provided with indicia that is visible through the viewing windows **1600**, such that the user can ascertain which usage cycle the indicating device is currently functioning in. For example, in the embodiment shown in FIGS. 37 and 38, twelve viewing windows **1600** are provided with the numbers 1 to 12 arranged adjacent thereto, which correspond to the 12 usage cycles defining the life of the indicating device. The numbers, or other indicia such as various colors, can be applied to the cap member by printing, molding or any other of the techniques described above. Alternatively, a single viewing window can be provided to expose the indicator member, whereupon indicia can be applied to the top surface or upper edge **1514** thereof, or, if the window is provided in the side of the cap member, along the outer circumferential surface thereof.

In the embodiment shown in FIGS. 44-45 and 49-51, the usage indicator member **2500** includes a hub **2520** having an opening **2521** that is rotatably mounted on a post **2522** extending downwardly from the inner surface of the top portion of the cap member **2020**. In this way, the usage indicator member **2500** is rotatably mounted to the cap member **2020** about an axis substantially parallel to and spaced from the rotational axis of the dosage indicator member **2060**. The axis of rotation for the dosage usage indicator member is also substantially parallel to the axial movement of the cap member relative to the base member.

The indicator member **2500** includes a ring **2524** formed about the hub **2520** which is connected thereto with a rib **2526** and a bottom surface **2528**. The indicator member **2500** has a plurality of inwardly, radially extending teeth **2514** formed about the inner periphery of the ring, and a plurality of outwardly, radially extending teeth **2502** formed on the bottom surface of the indicator member around the outer periphery thereof. Both pluralities of teeth are configured as ratchet teeth to allow only for one-way rotation of the indicator member **2500**.

Referring to FIG. 46, an engagement member **2573** extends from the indicator member **2060** and engages an engagement surface of one of the ratchet teeth **2502** as the dosage indicator member **2060** completes one full cycle. As the engagement member **2573** engages the engagement surface of one of the teeth **2502**, the indicator member is rotated an incremental amount.

Referring to FIG. 51, an indexing member **2577** extends downwardly from the cap member **2020** in a parallel and spaced apart relationship with the post **2522**. The indexing member **2577** is disposed in the space between the hub **2520** and the ring **2524** and selectively engages the inner teeth **2514** formed around the inner periphery of the ring. Again, the indexing member **2577** and teeth **2514** are preferably configured to allow for only one-way rotation of the usage indicator member **2500** relative to the cap member **2020**. The number and angular spacing between the inner and outer teeth

2514, **2502** correspond such that the advancement of the indicator member **2500** by way of engagement of the engagement member **2573** with one of the outer **2502** teeth further advances the indexing member **2577** one tooth **2514** along the inner periphery of the ring. The predetermined number of usages for the indicating device corresponds to the number of teeth formed around the inner periphery of the ring. After the completion of the final usage cycle, the indexing member **2577** is brought into engagement with the rib **2526**, which functions as a stop member and does not permit the indicator member to be further rotated or advanced. At the same time, the engagement member **2573** is brought into engagement with one of the teeth **2502** formed about the outer periphery of the ring such that the indicator member also cannot be advanced. In this way, the device is immobilized. Again, the indicating device can be provided with a predetermined number of inner and outer teeth, which corresponds to the number of predetermined usage cycles for the indicating device.

The upper surface **2528** of the indicator member ring, which is preferably domed, is provided with usage indicia to indicate the number of usage cycles completed or remaining for the indicating device. The usage indicia is visible to the user through a viewing window **2600** provided in the cap member, as shown in FIG. 44. Again, the usage indicia can take the form of various alphanumeric characters, colors or any of the other varieties described above.

Although the present invention has been described with reference to preferred embodiments, those skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. As such, it is intended that the foregoing detailed description be regarded as illustrative rather than limiting and that it is the appended claims, including all equivalents thereof, which are intended to define the scope of the invention.

What is claimed is:

1. An indicating device for indicating the number of metered doses dispensed from or remaining in a container, said indicating device comprising:

a first housing member adapted to be mounted to the container, said first housing member moveable relative to a second housing member along a longitudinal axis;

an indicator member rotatably mounted to at least one of said first and second housing members about said longitudinal axis, wherein said indicator member comprises dosage indicia; and

a drive member moveable in response to each of said movements of said second housing member relative to said first housing member along said longitudinal axis, wherein said drive member is successively engaged with said indicator member upon a predetermined number of said movements of said second housing member relative to said first housing member, wherein said predetermined number of axial movements is greater than one, and wherein said drive member is disengaged from said indicator member for the remainder of said predetermined number of axial movements, wherein said indicator member is immobile when said drive member is disengaged from said indicator member.

2. The indicating device of claim 1 wherein said indicator member is rotatably mounted to said second housing member.

3. The indicating device of claim 1 or 2 wherein said drive member is rotatable about a rotation axis substantially perpendicular to said longitudinal axis.

4. The indicating device of claim 3 wherein said drive member comprises at least one tooth, and said indicator member comprises a plurality of teeth, wherein said at least one tooth is engaged with at least one of said plurality of teeth upon said predetermined number of said movements of said second housing member relative to said first housing member.

5. The indicating device of claim 4 further comprising a ratchet wheel coupled to and rotatable with said drive member, said ratchet wheel comprising a plurality of ratchet teeth, wherein the number of plurality of ratchet teeth on said ratchet wheel is greater than the number of said at least one tooth on the drive member.

6. The indicating device of claim 5 further comprising a pawl engageable with said ratchet wheel upon each axial movement of said second housing member relative to said first housing.

7. The indicating device of claim 5 wherein said predetermined number of movements is determined by dividing the number of said plurality of teeth on said ratchet wheel by the number of said at least one tooth on said drive member.

8. The indicating device of any one of claims 1-7 wherein at least one of said first and second housing members comprises a viewing window, wherein said indicia of said indicator member is visible through said viewing window.

9. The indicating device of any one of claims 1-8 wherein one of said indicator member and said first or second housing members comprises a plurality of indentations and the other of said indicator member and said first or second housing members comprises an indexing member, said indexing member engaging at least one of said plurality of said indentations.

10. The indicating device of any one of claims 1-9 wherein said indicator member is a first indicator member comprising first dosage indicia, and further comprising a second indicator member rotatable about a transverse axis extending substantially perpendicular to said longitudinal axis, wherein said second indicator member comprises second dosage indicia, and wherein said second indicator member is the only indicator member comprising dosage indicia rotatable about said transverse axis.

11. The indicating device of claim 10 wherein said first and second dosage indicia comprise at least first indicia corresponding to a full container and second indicia corresponding to an empty container.

12. The indicating device of any one of claims 1-11 further comprising a container of medicament connected to said first housing member.

13. The indicating device of claim 12 wherein said indicator member is the only indicator member comprising dosage indicia rotatable about said longitudinal axis.

FIG. 1

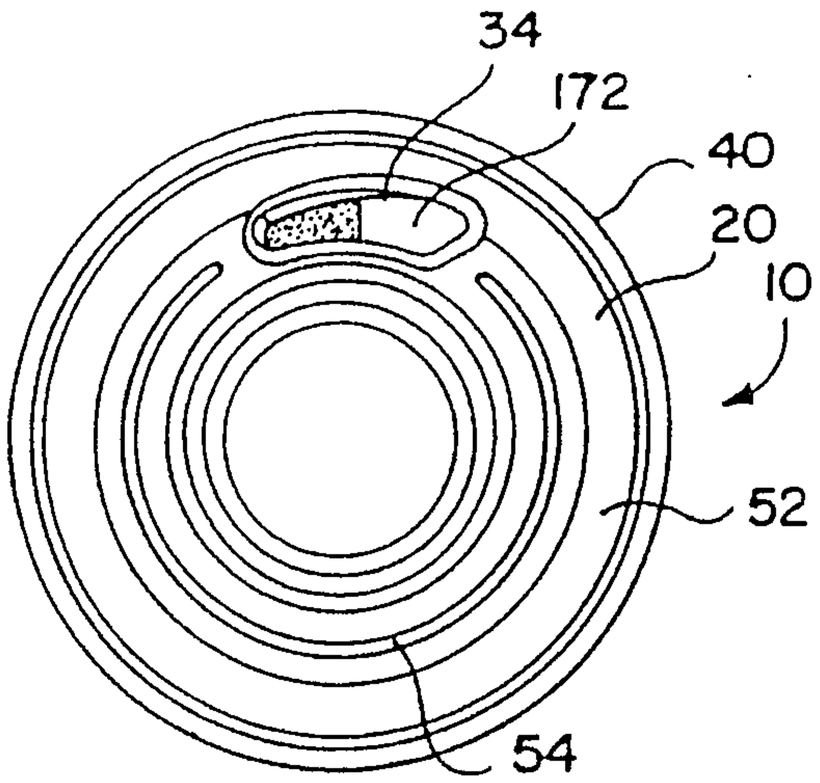


FIG. 1A

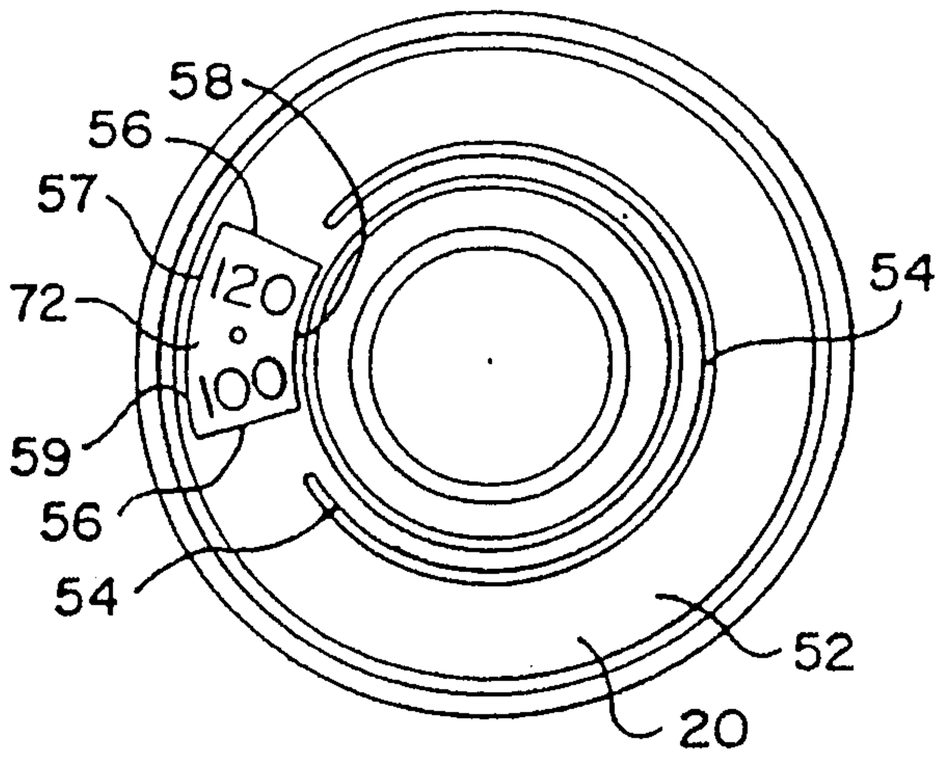


FIG. 1B

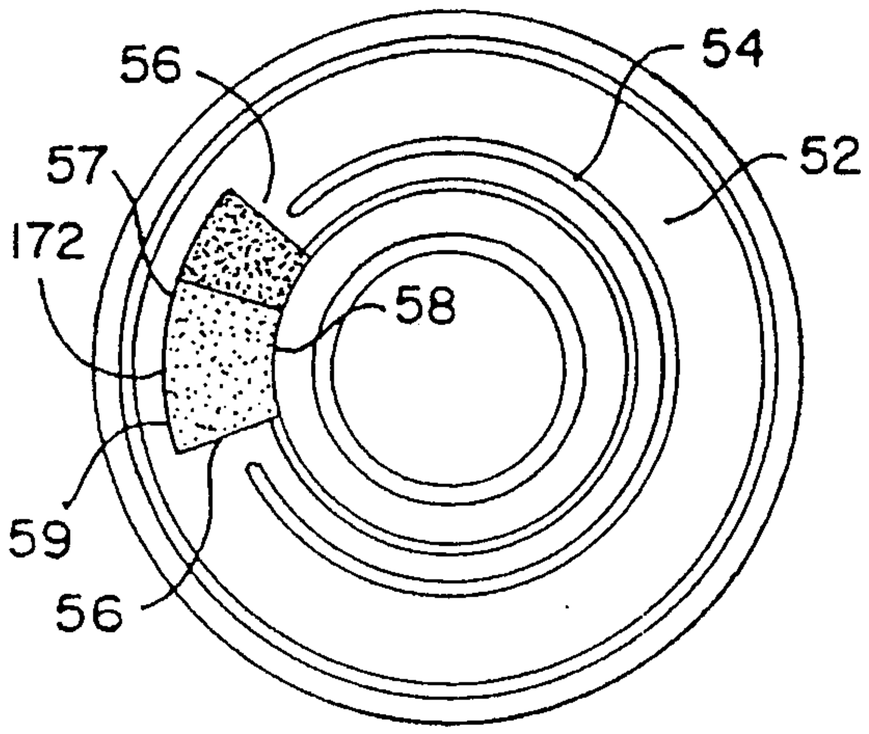


FIG. 2

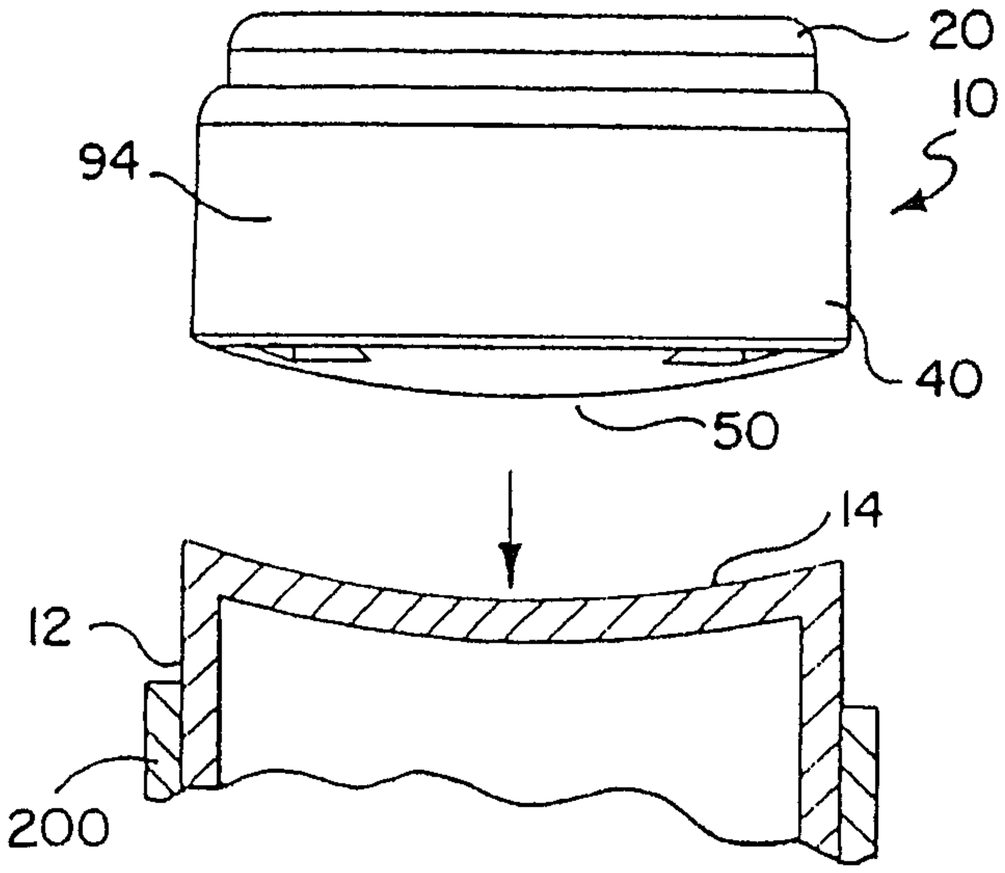


FIG. 3

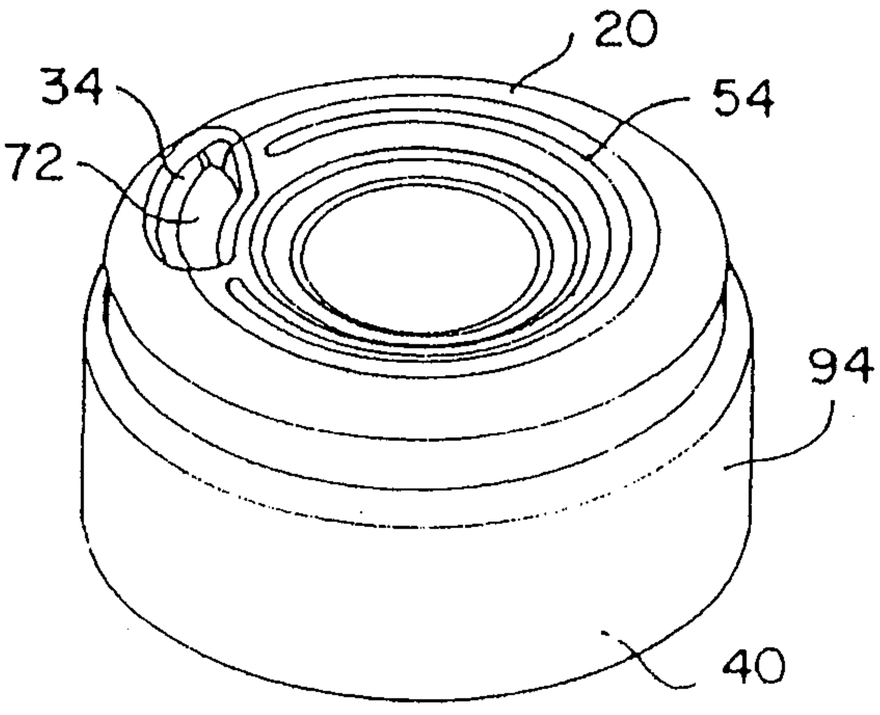


FIG. 3A

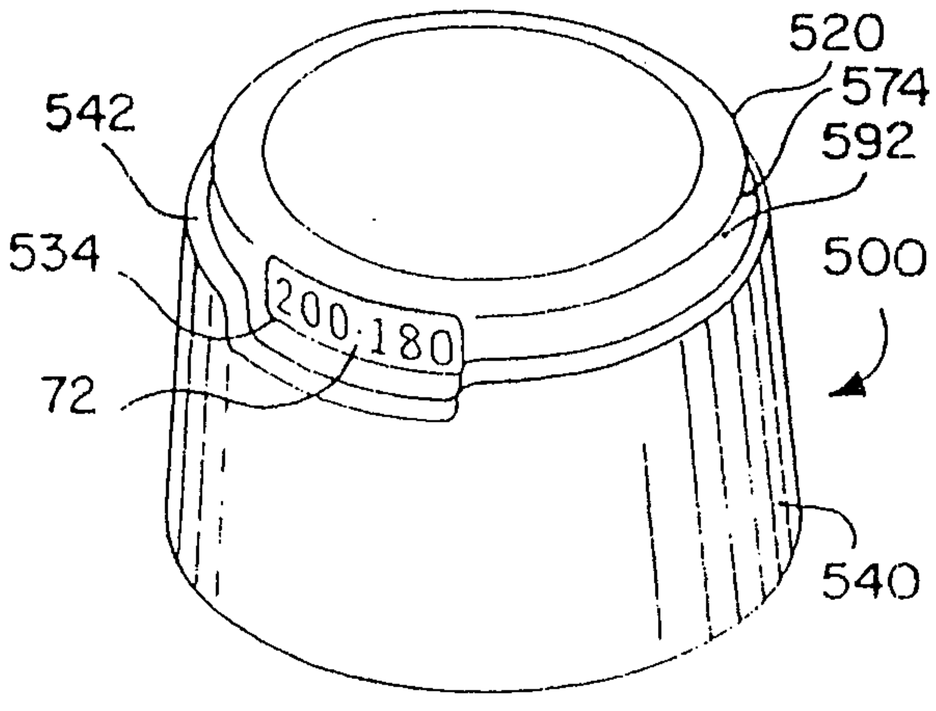


FIG. 4

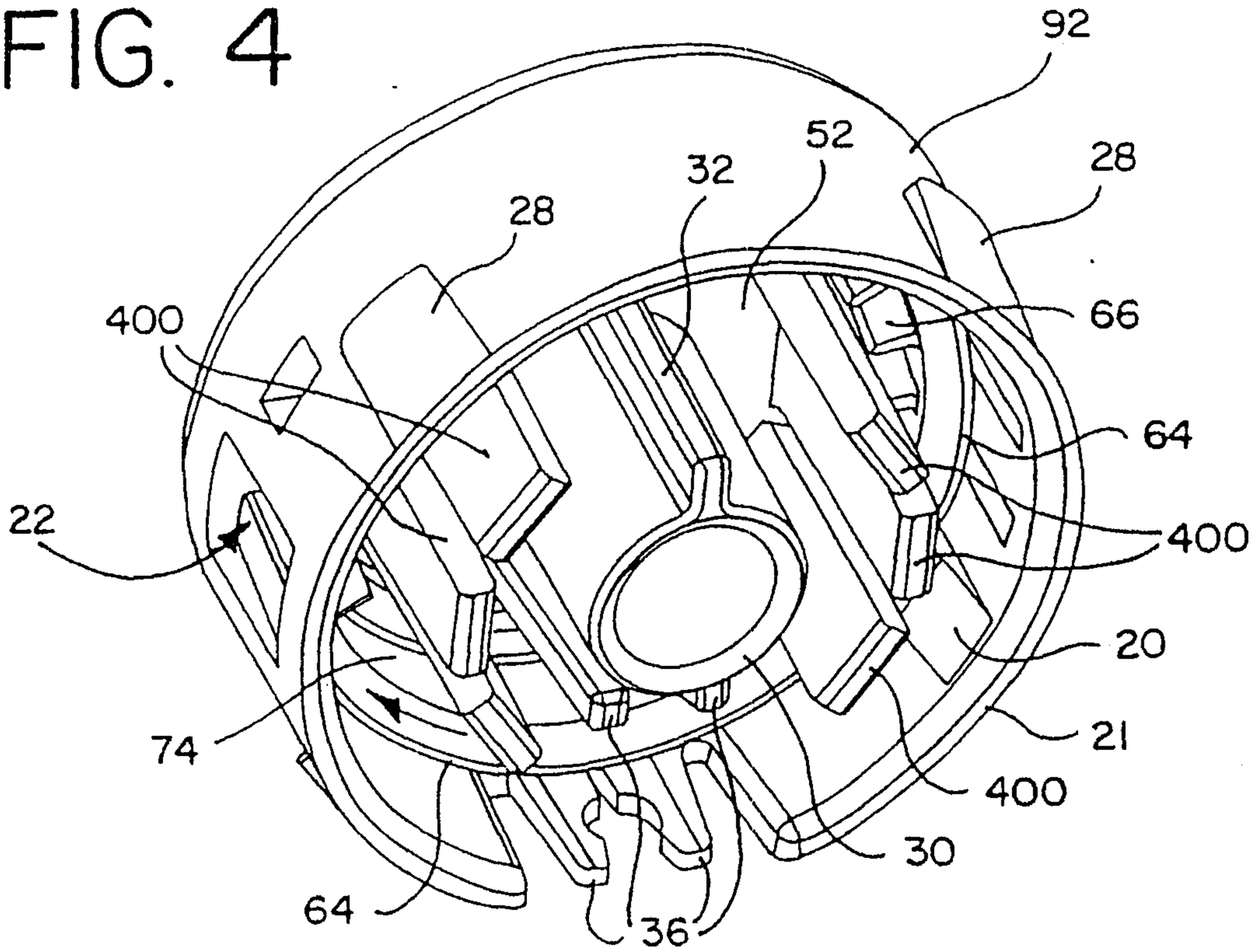

92
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FIG. 5

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FIG. 6

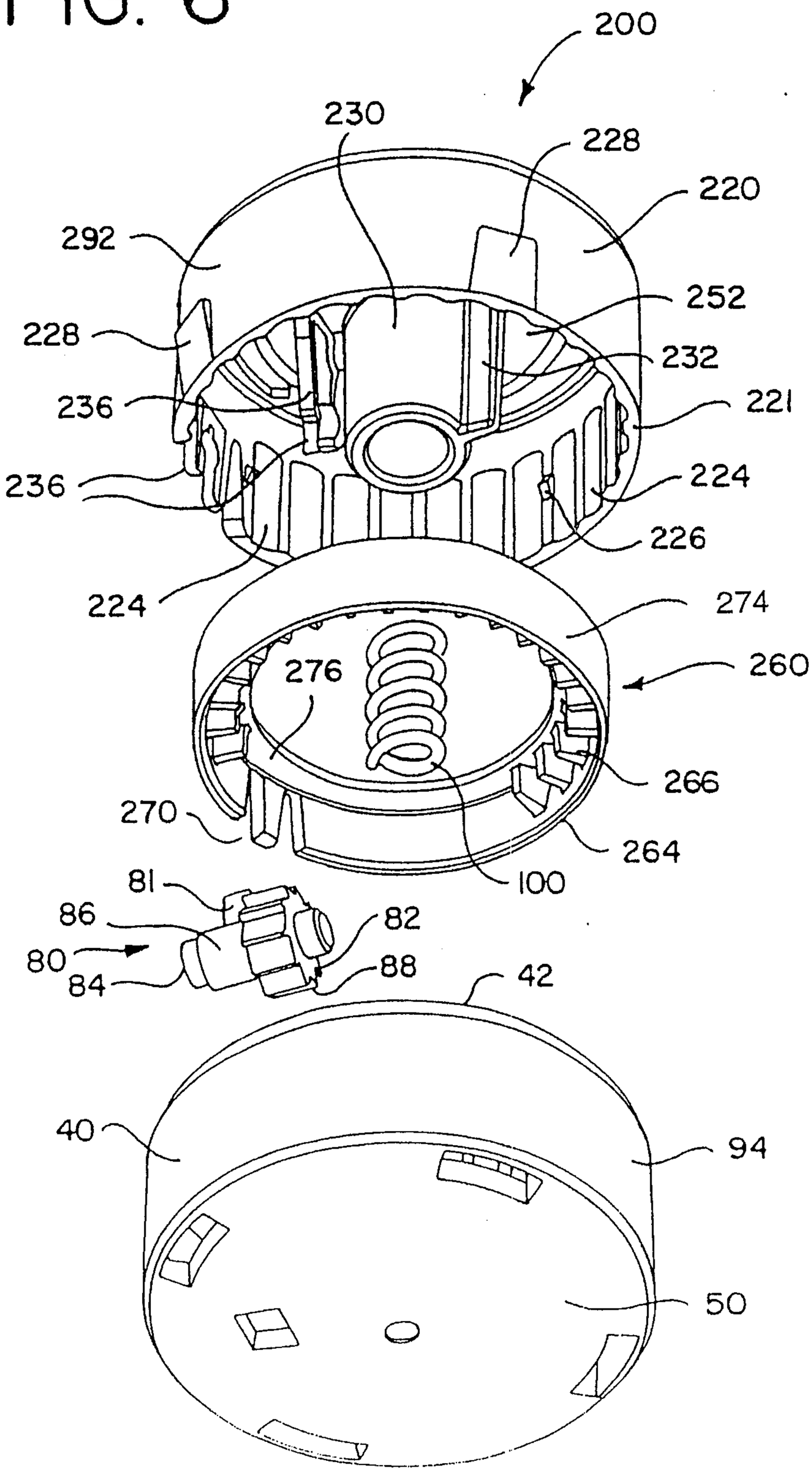

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FIG. 7

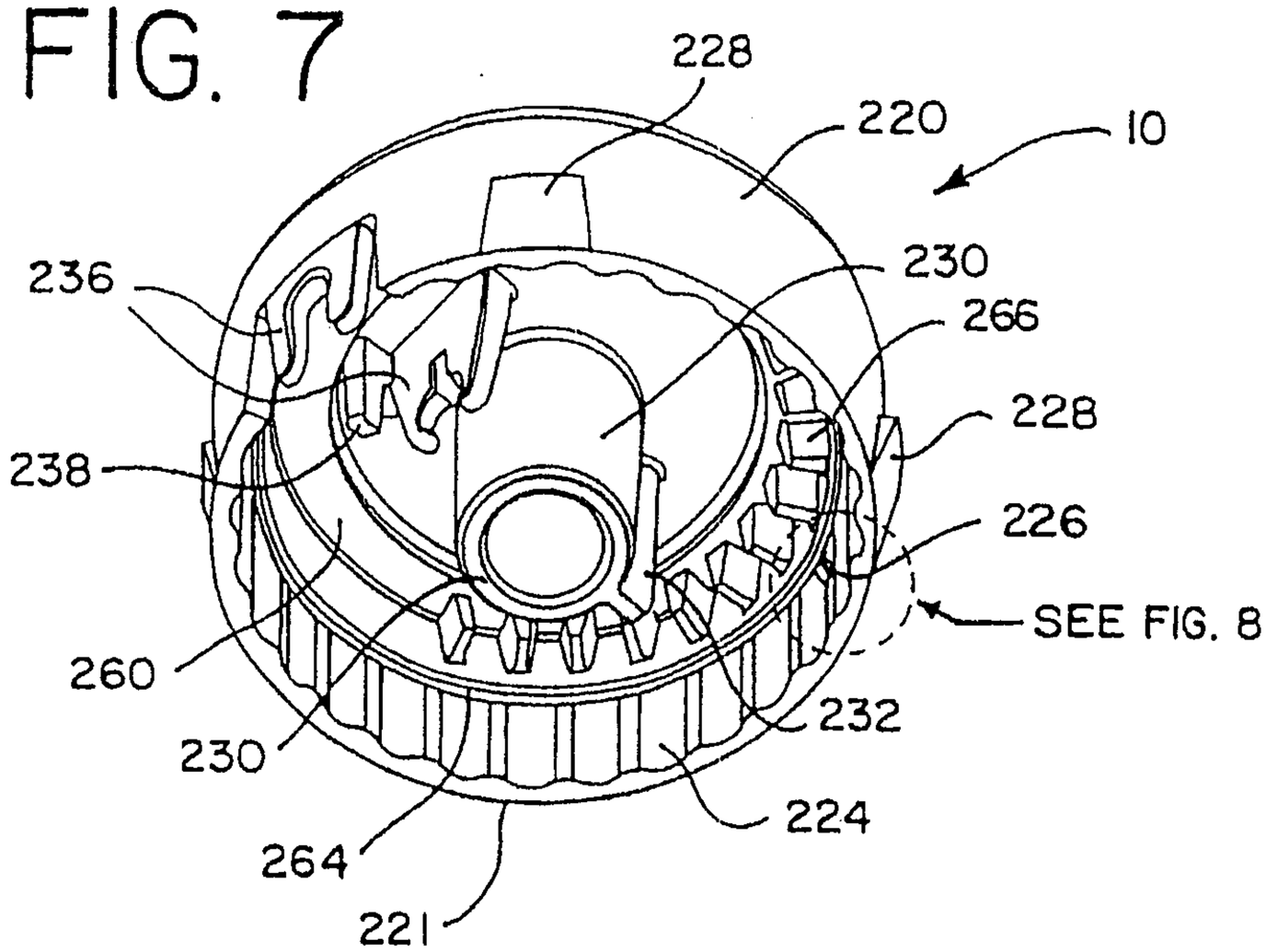


FIG. 8

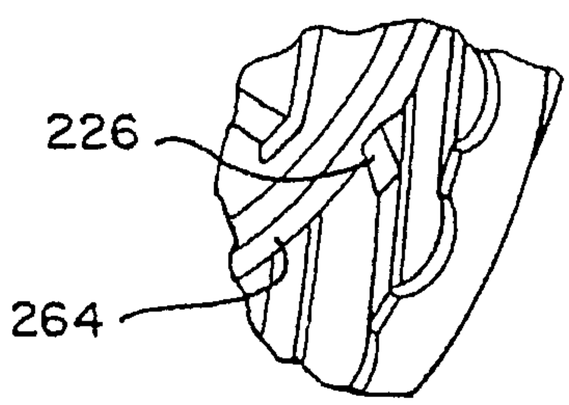


FIG. 9

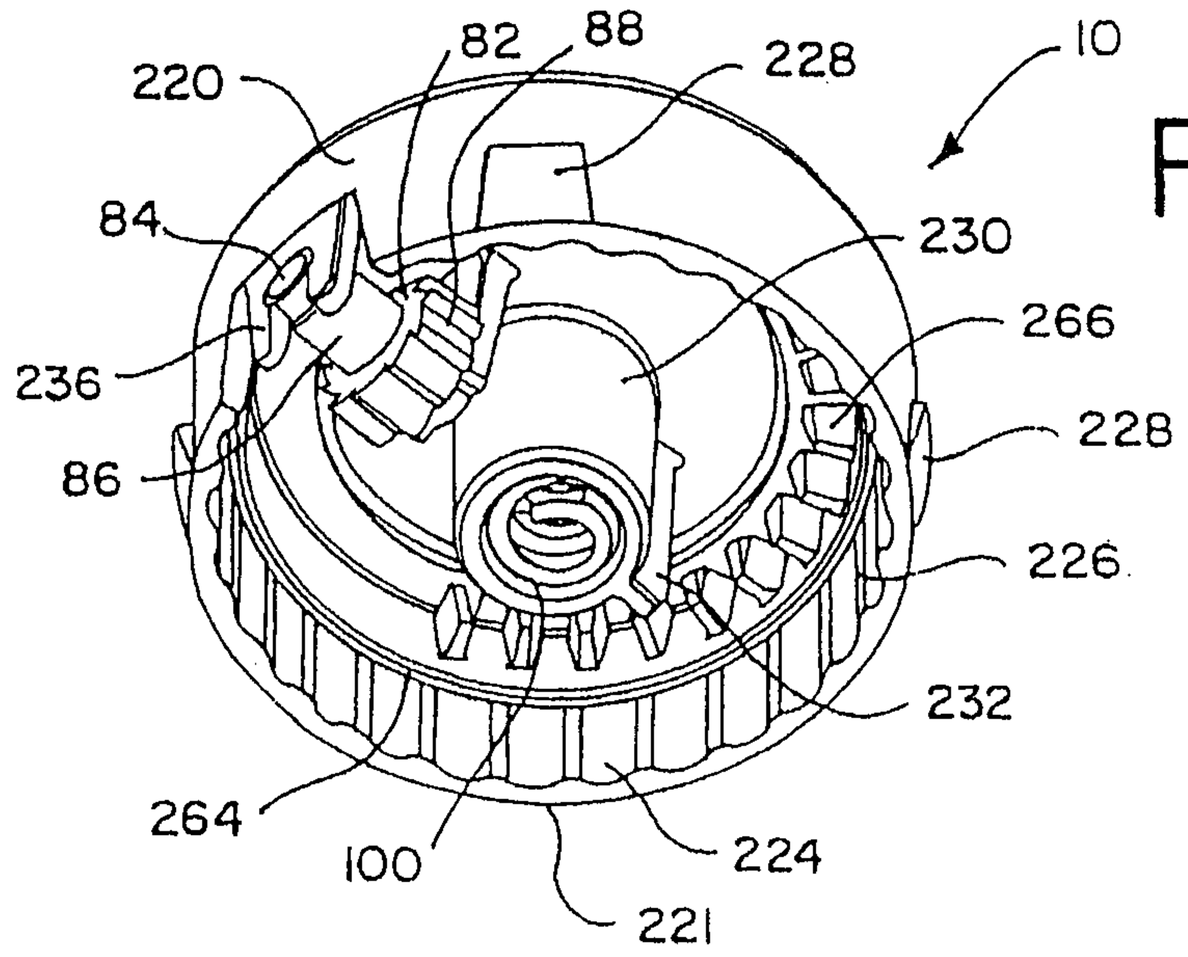


FIG. 10

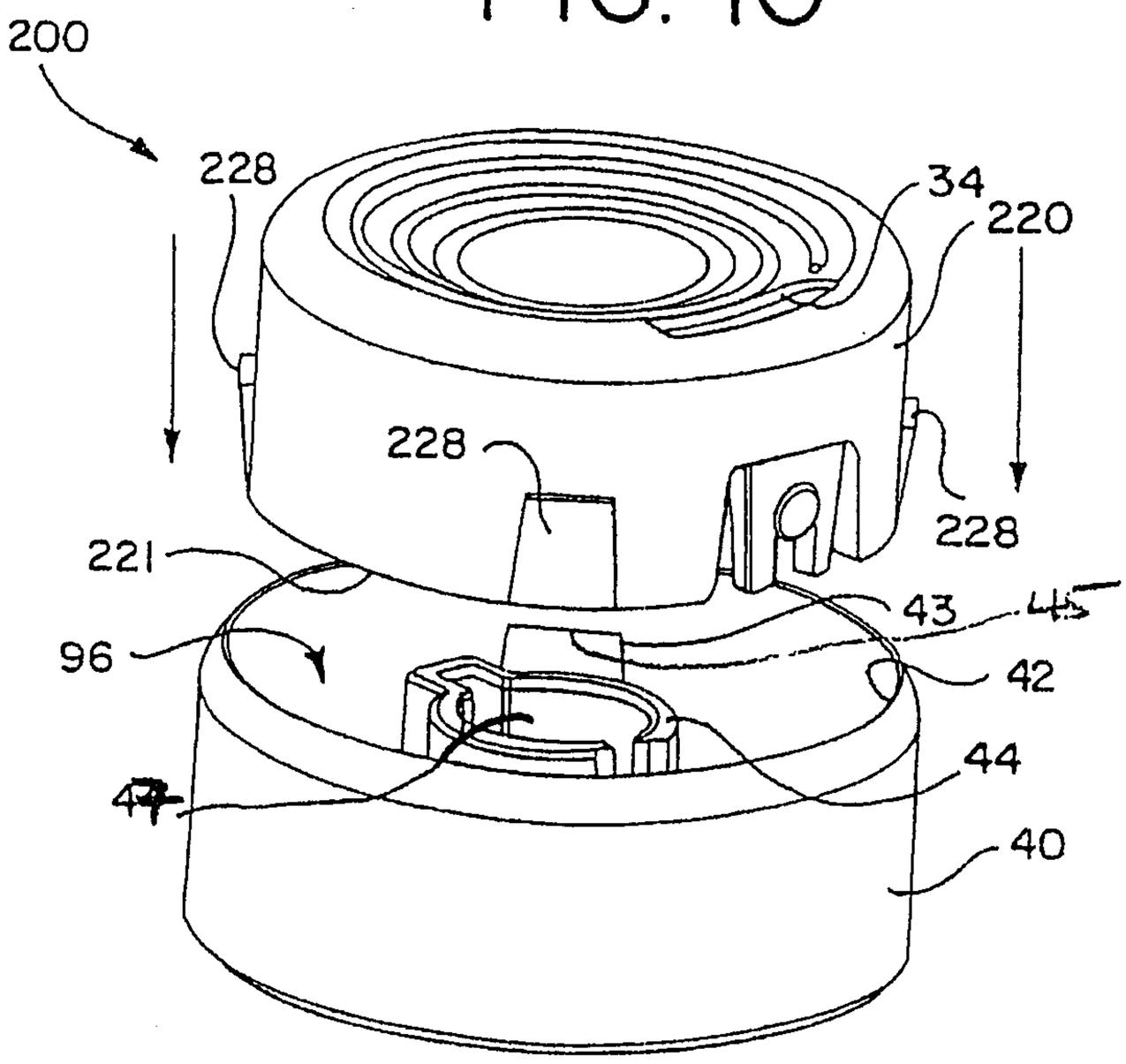

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FIG. 11

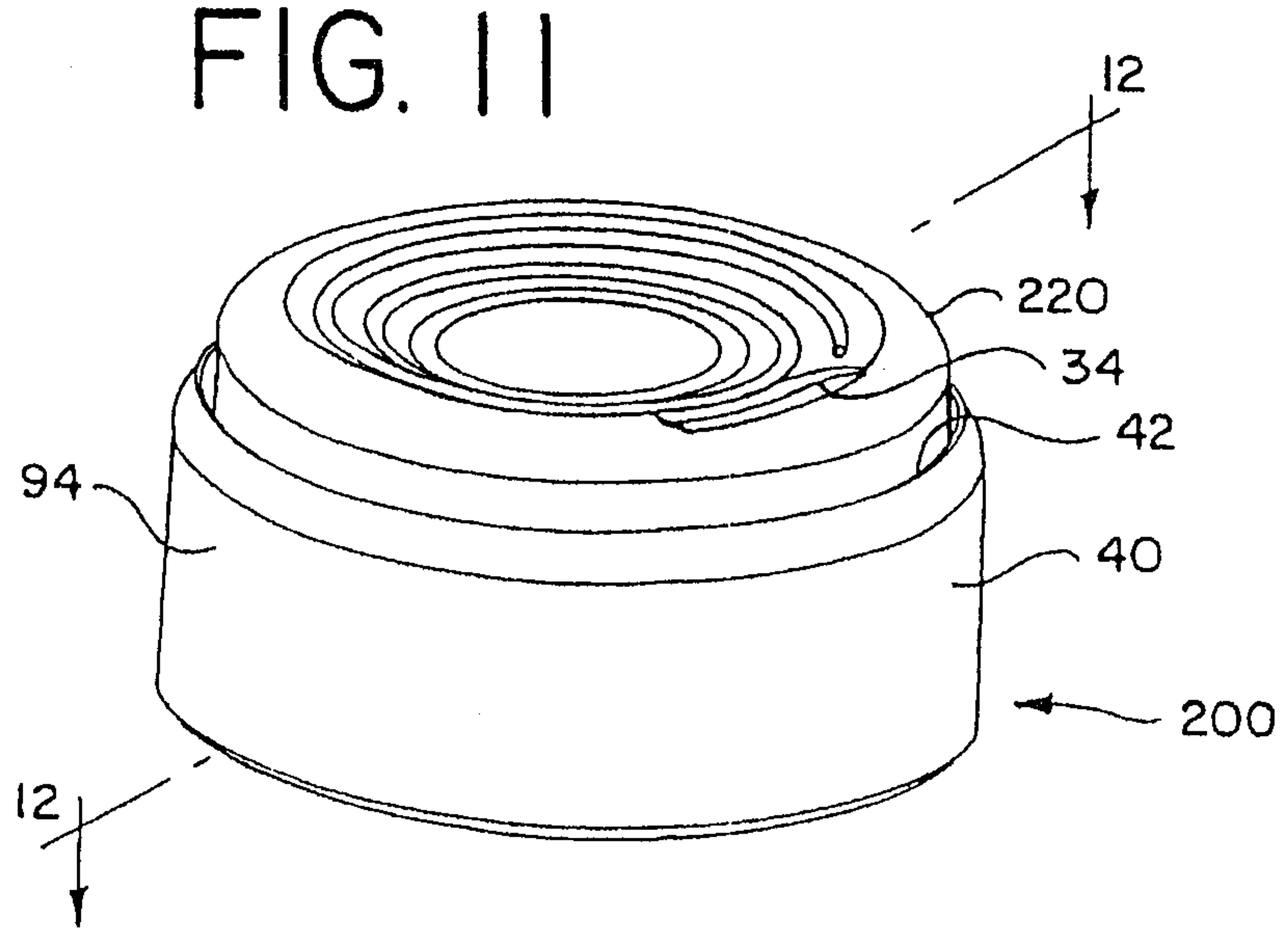

12
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94
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200
12

FIG. 12

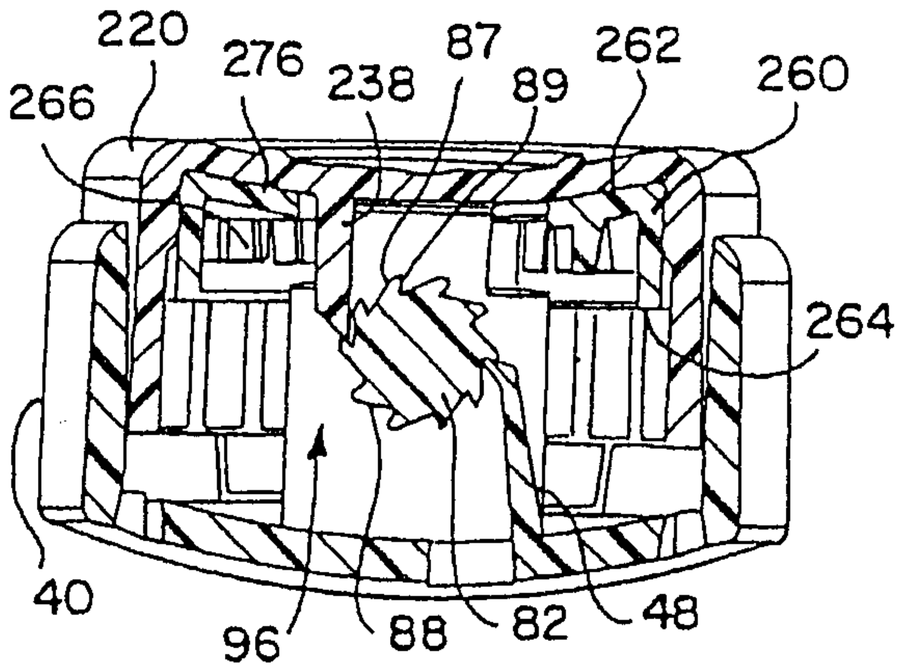


FIG. 13

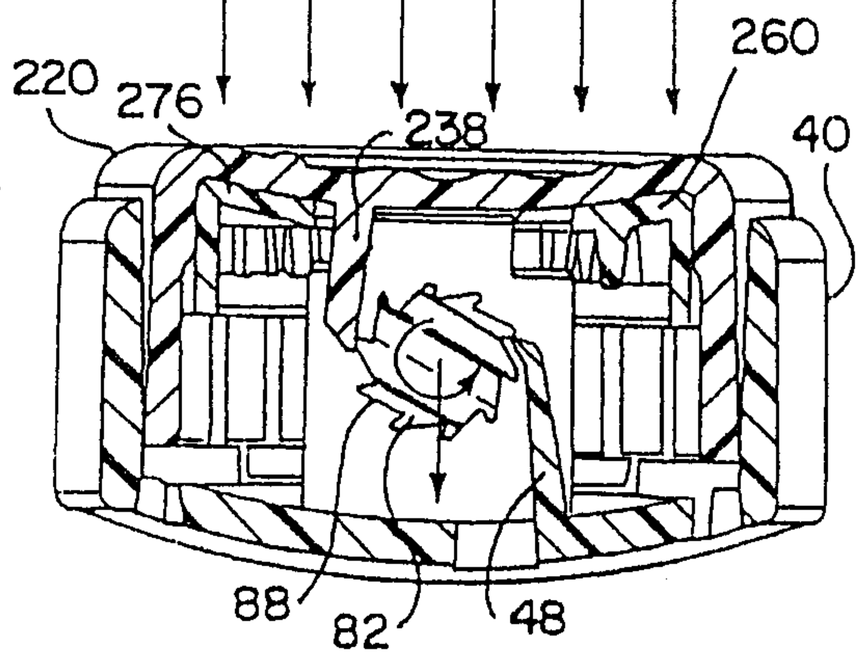


FIG. 14

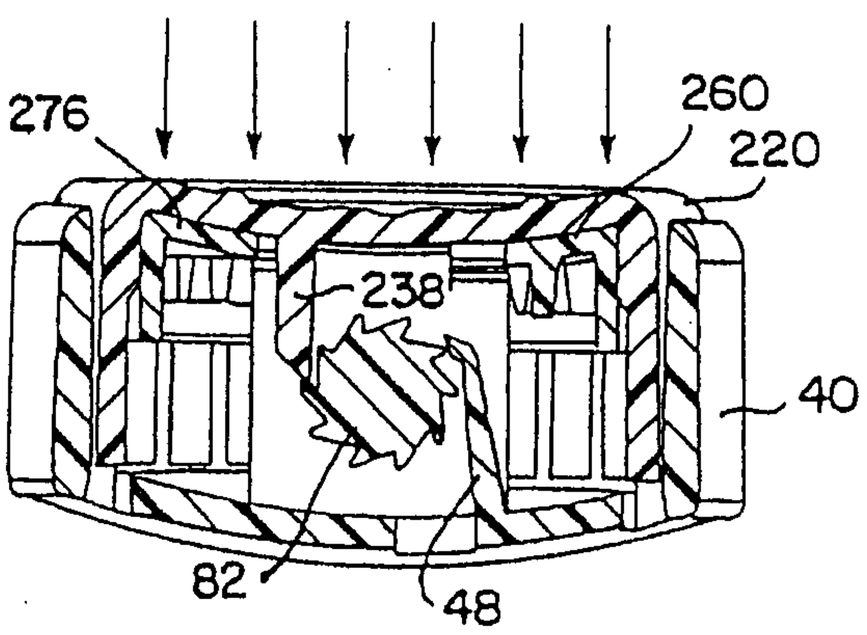


FIG. 15

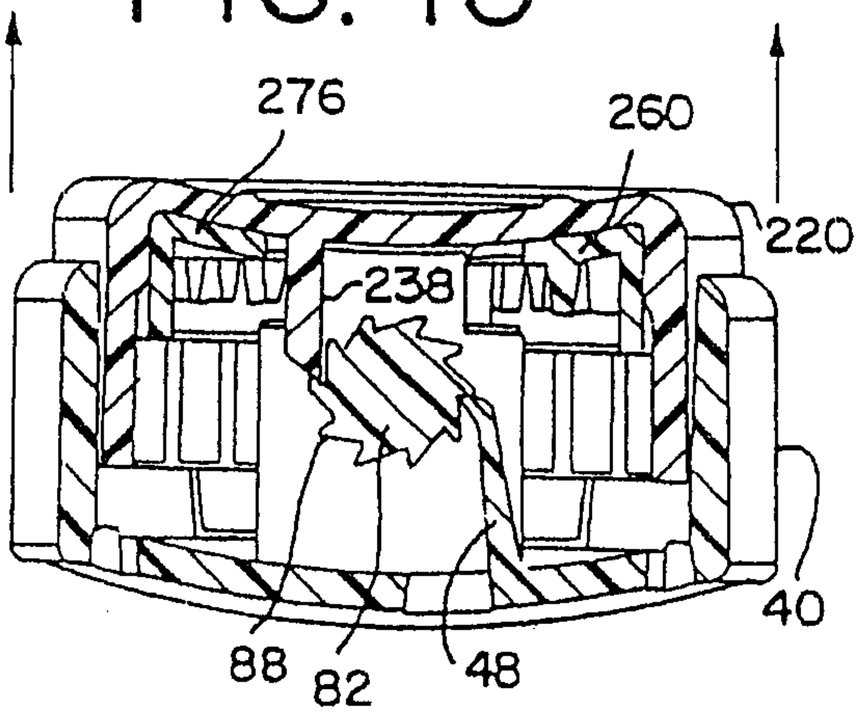


FIG. 16

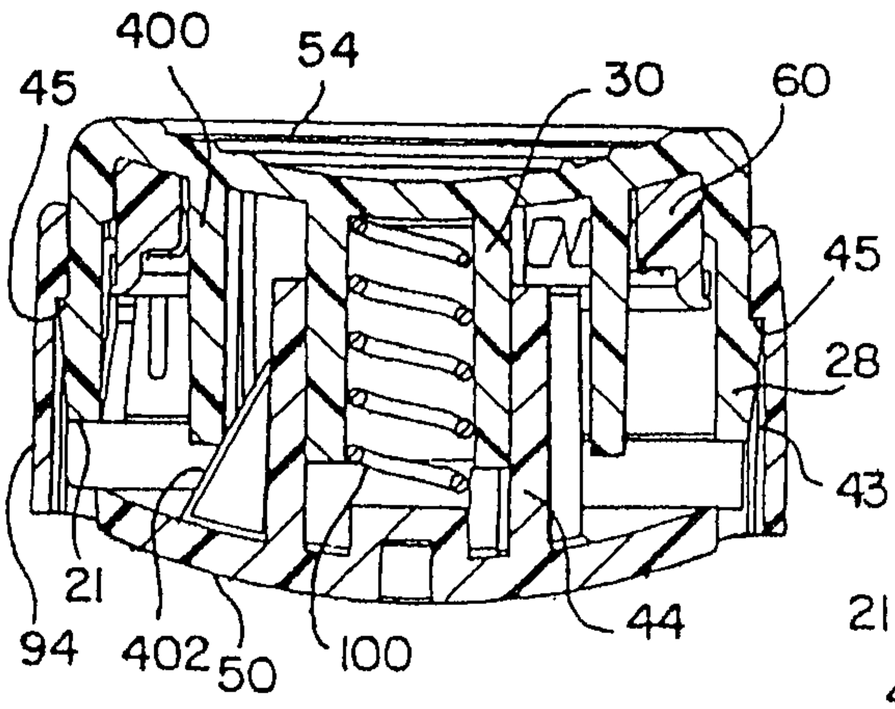


FIG. 17

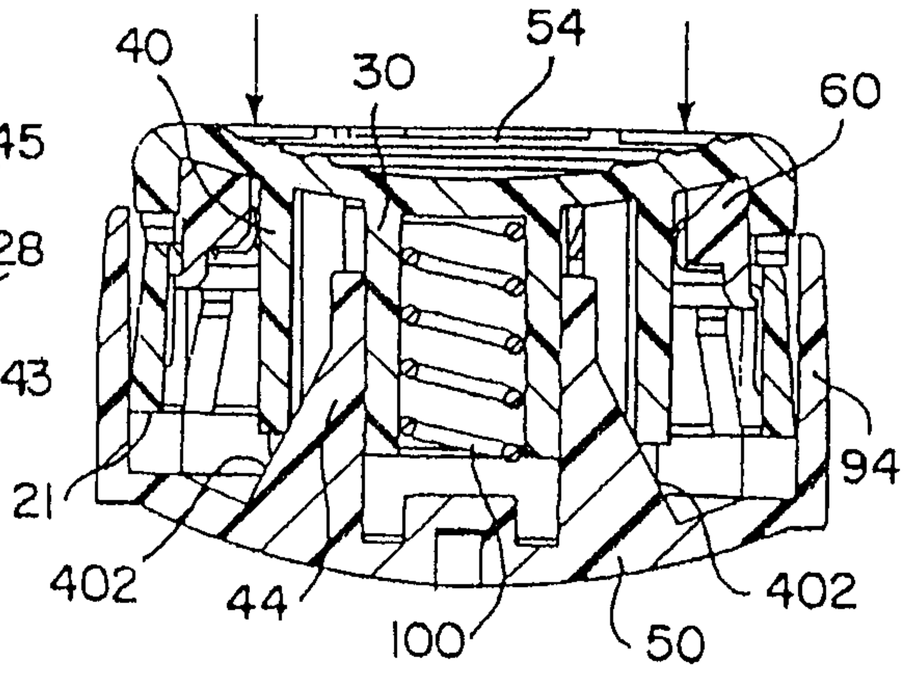


FIG. 18

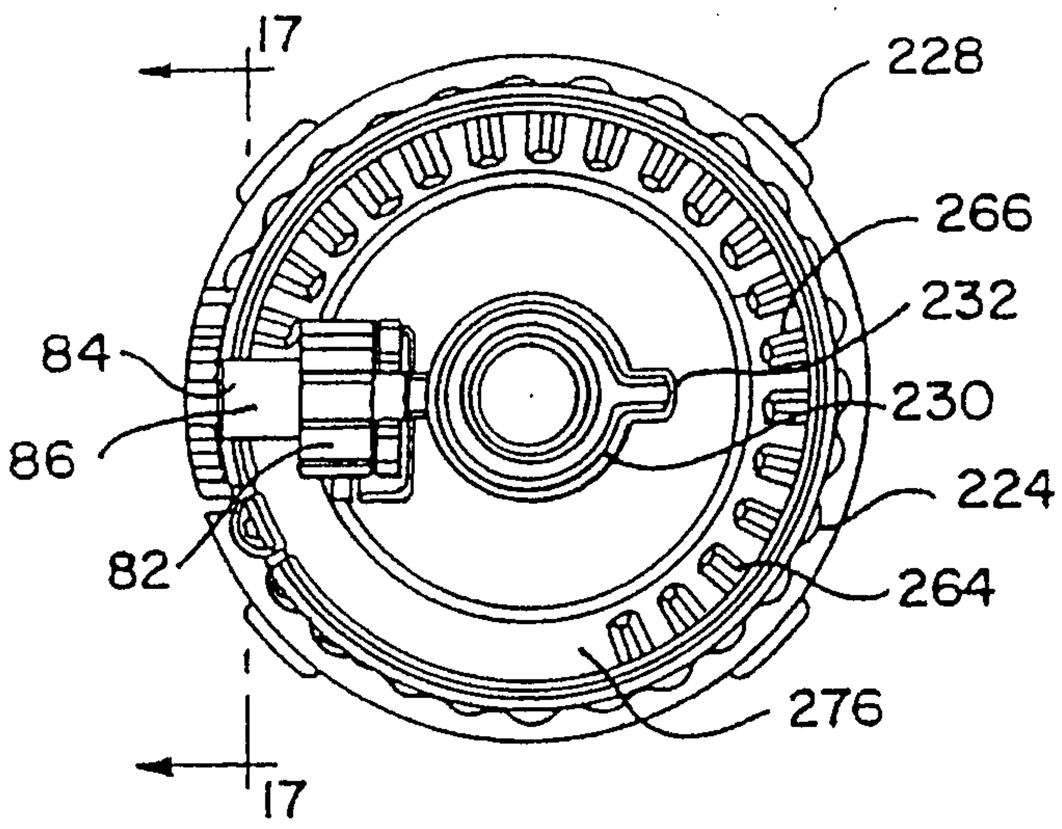


FIG. 19

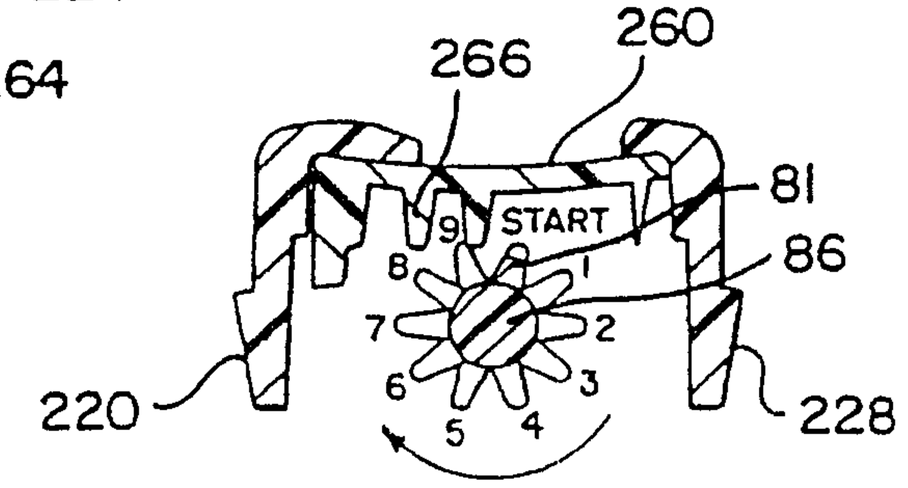


FIG. 20

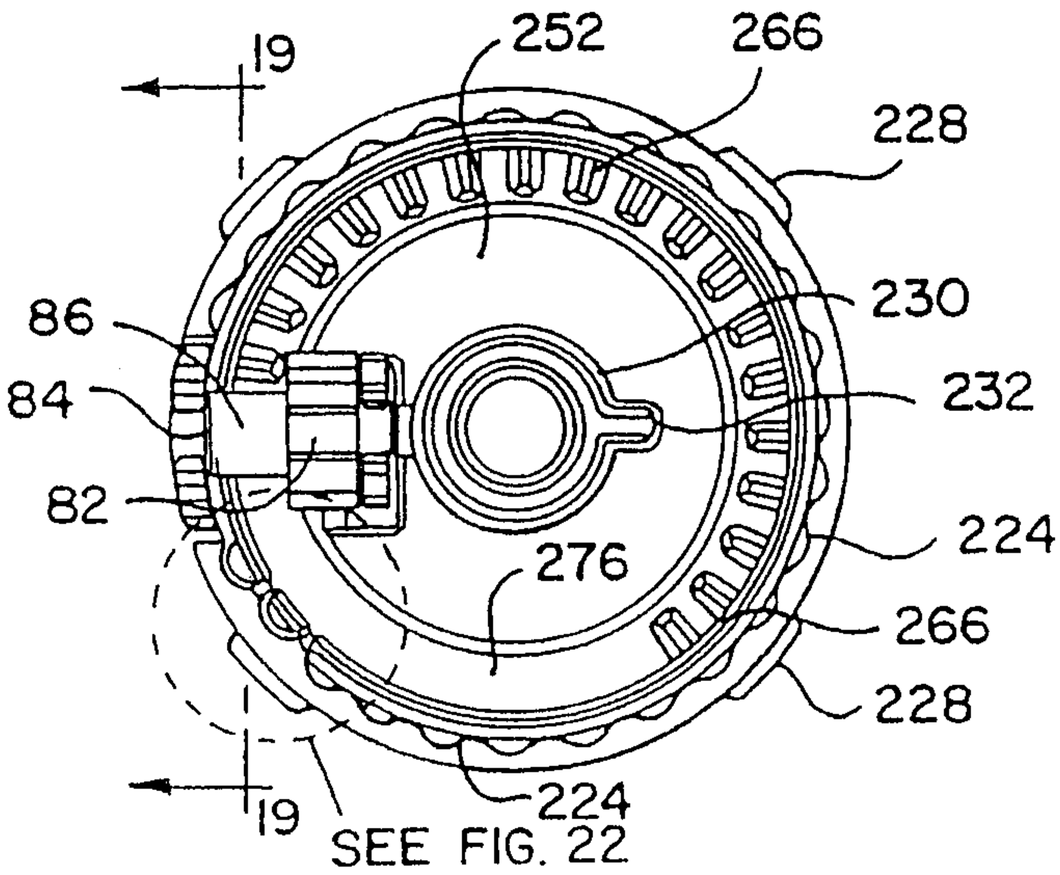
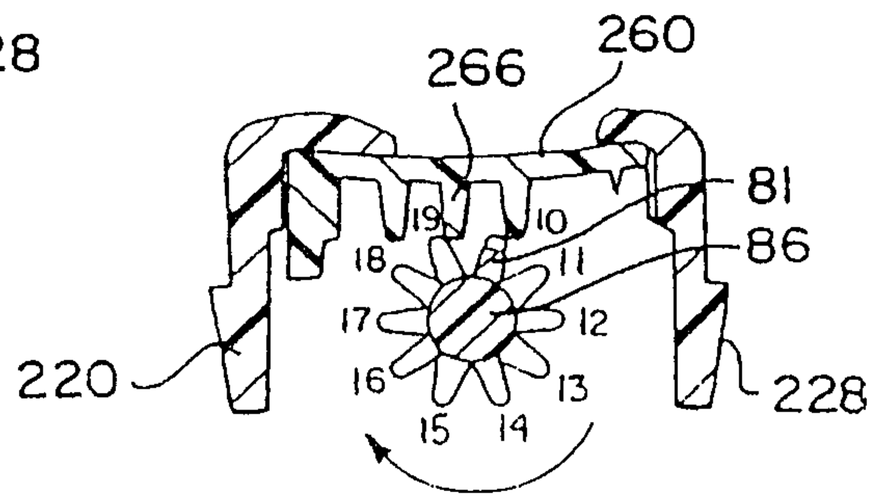


FIG. 21



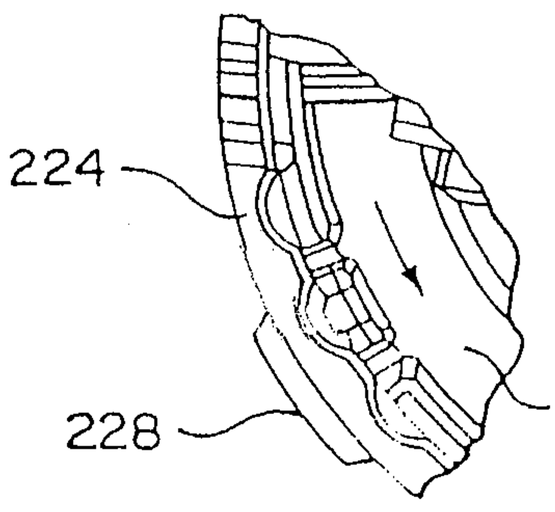


FIG. 22

FIG. 23

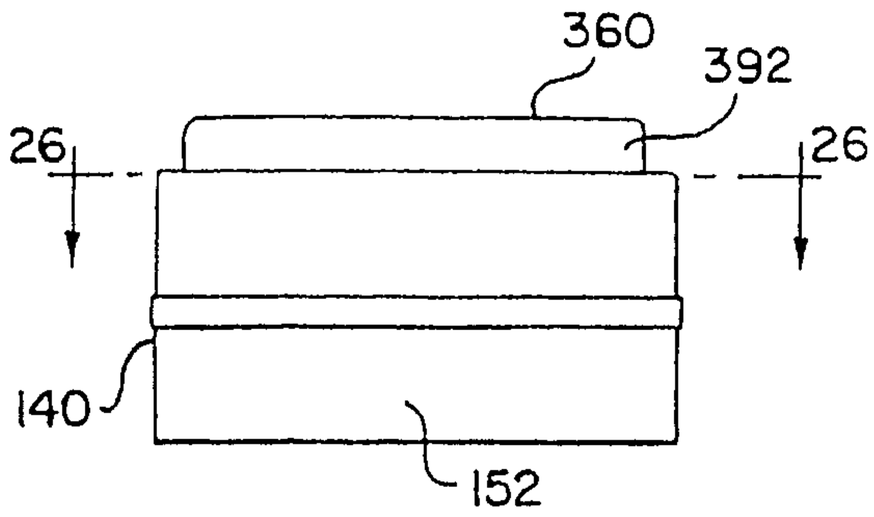


FIG. 24

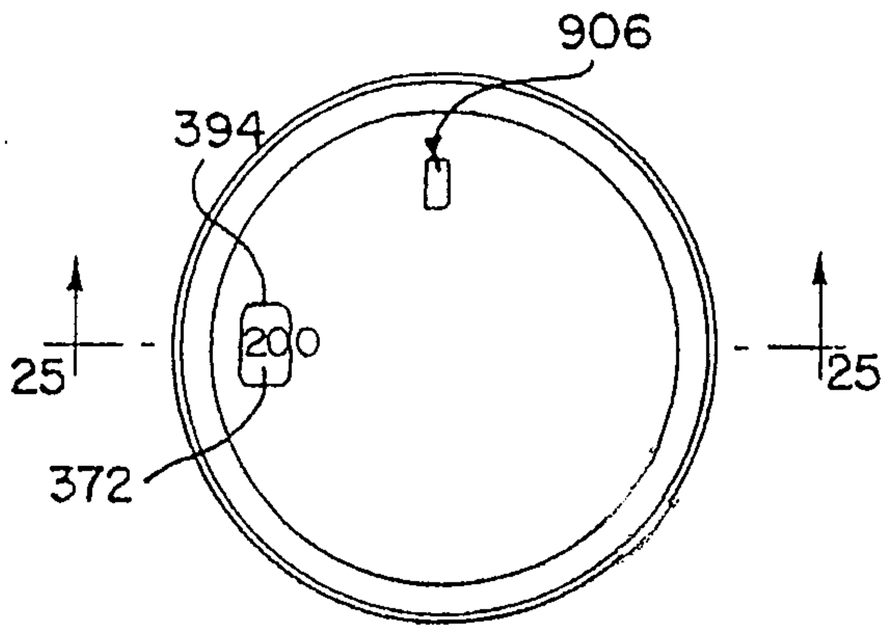


FIG. 25

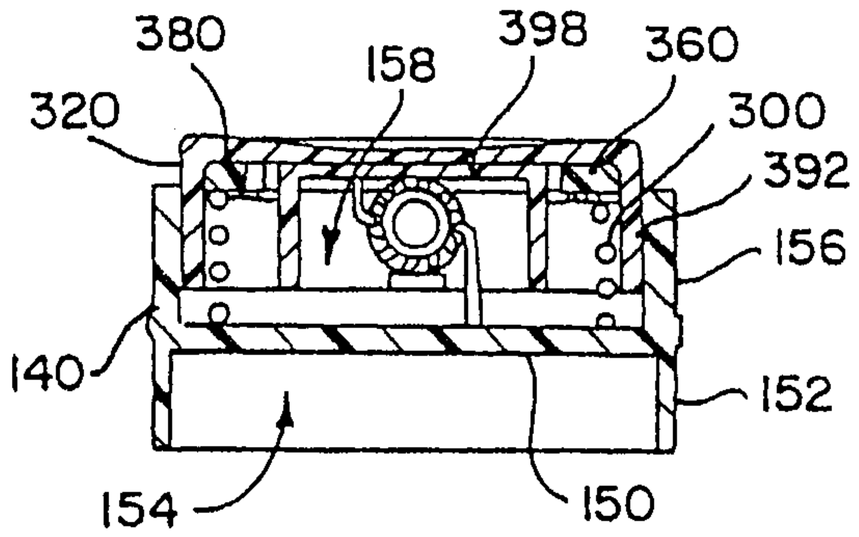


FIG. 26

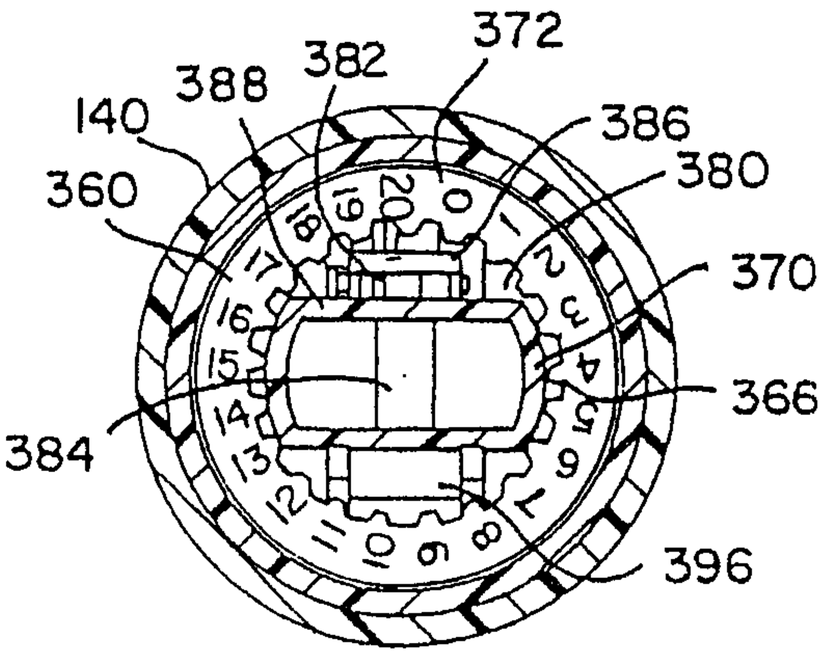


FIG. 27

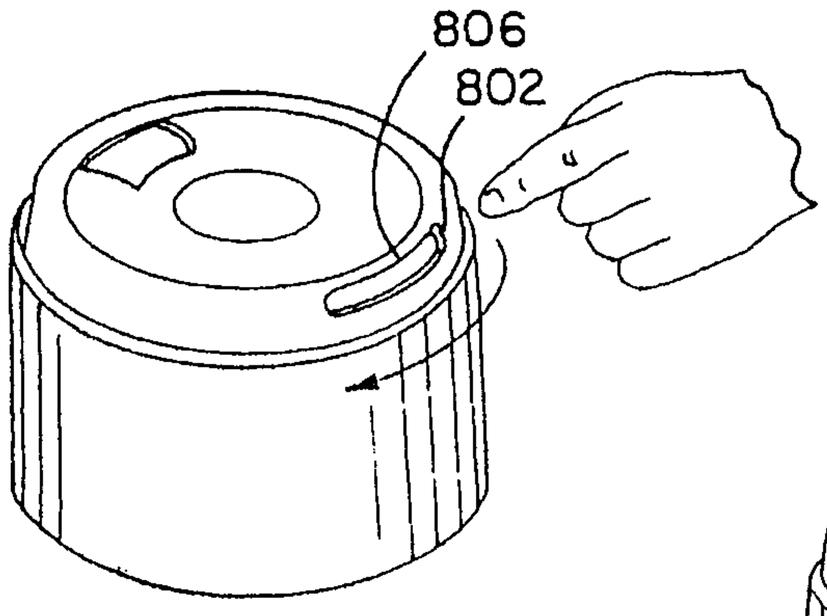
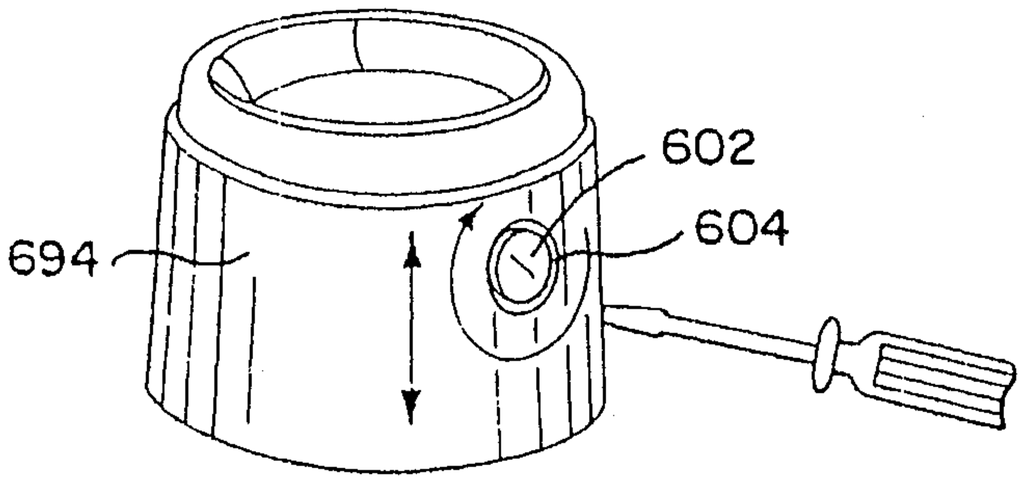


FIG. 28



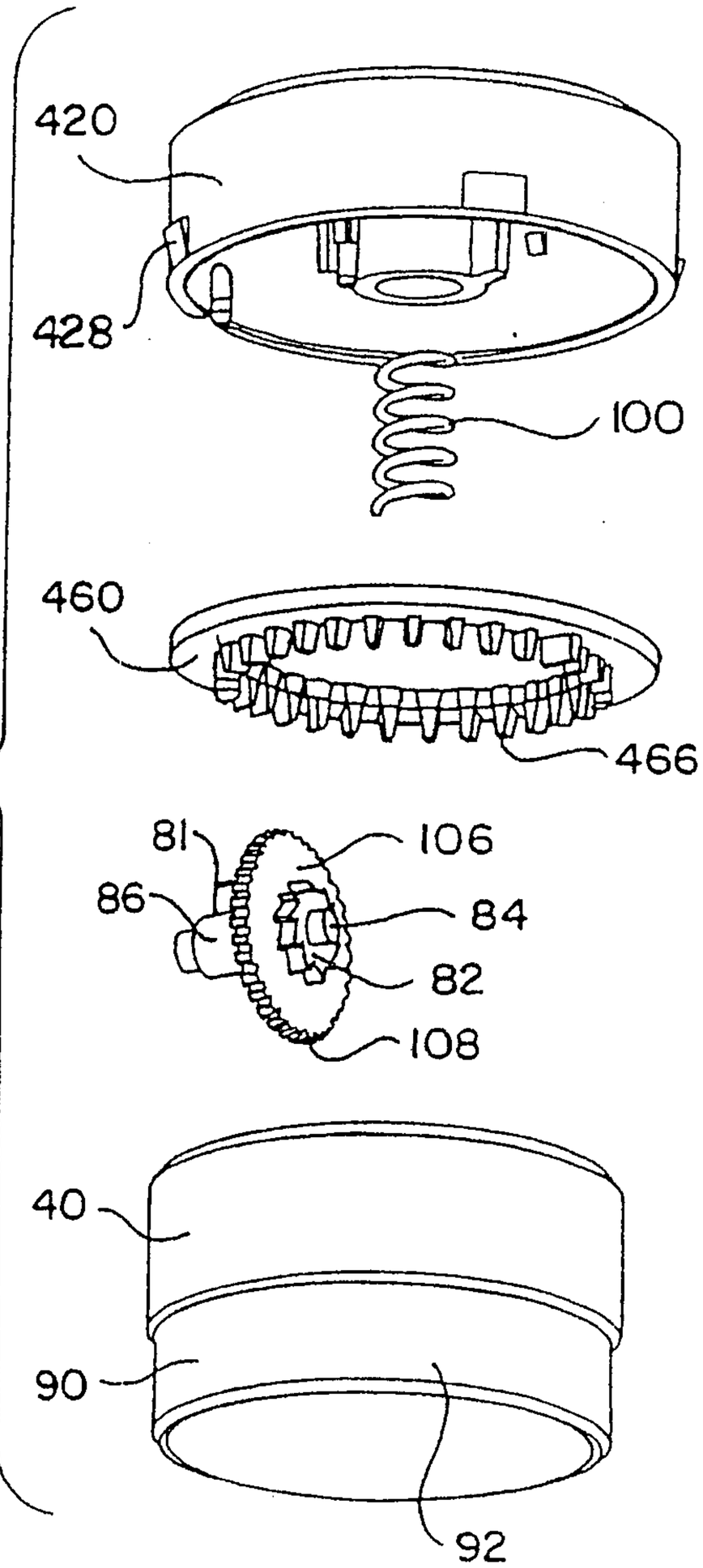


FIG. 29

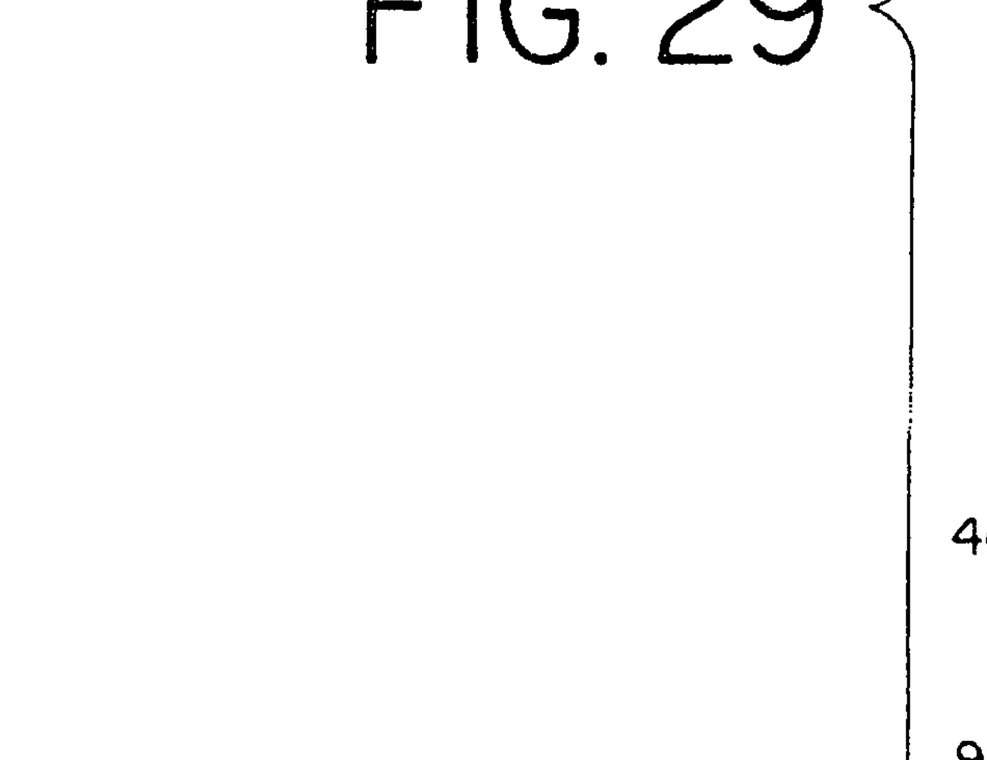


FIG. 30

FIG. 31

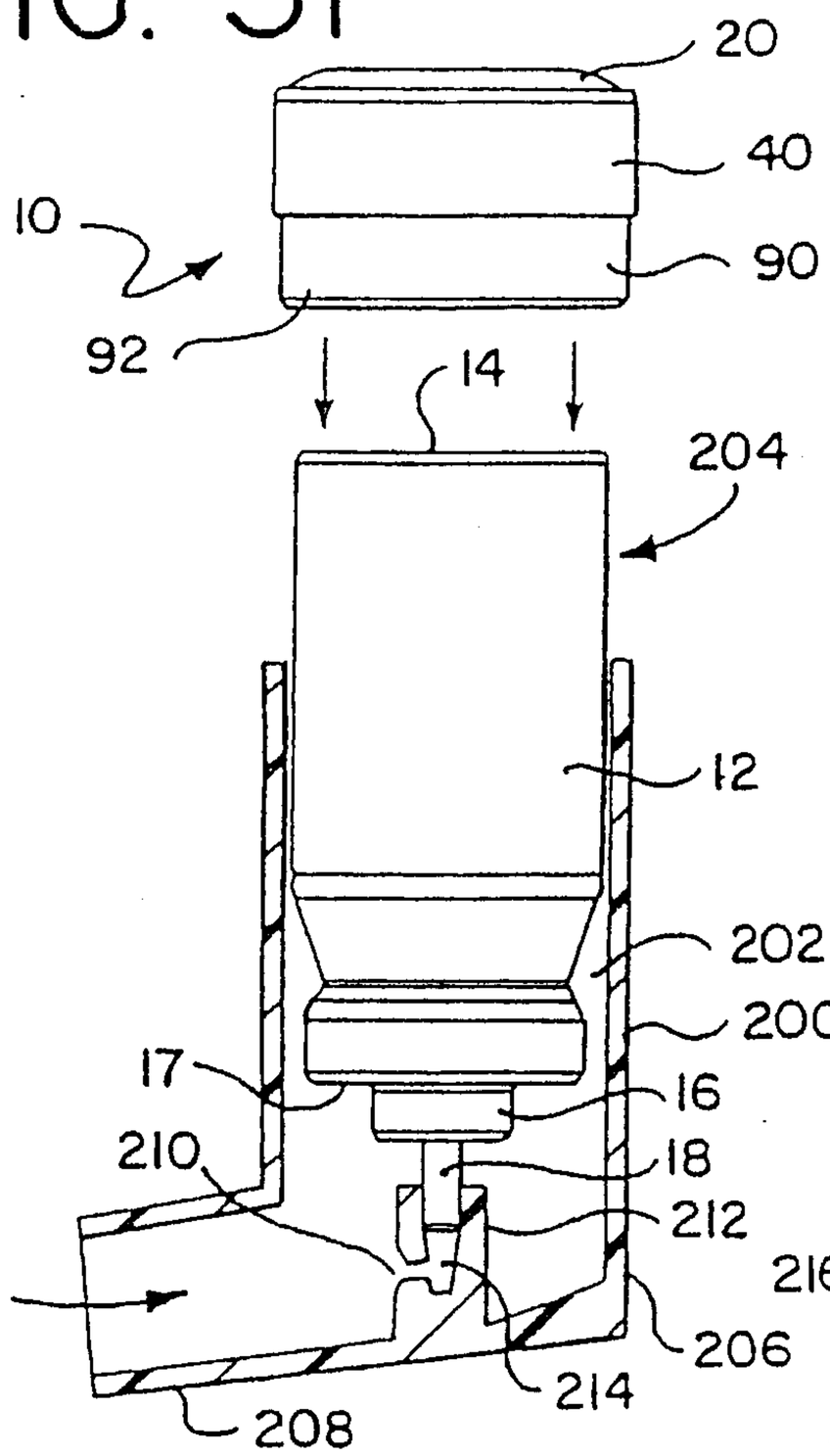


FIG. 32

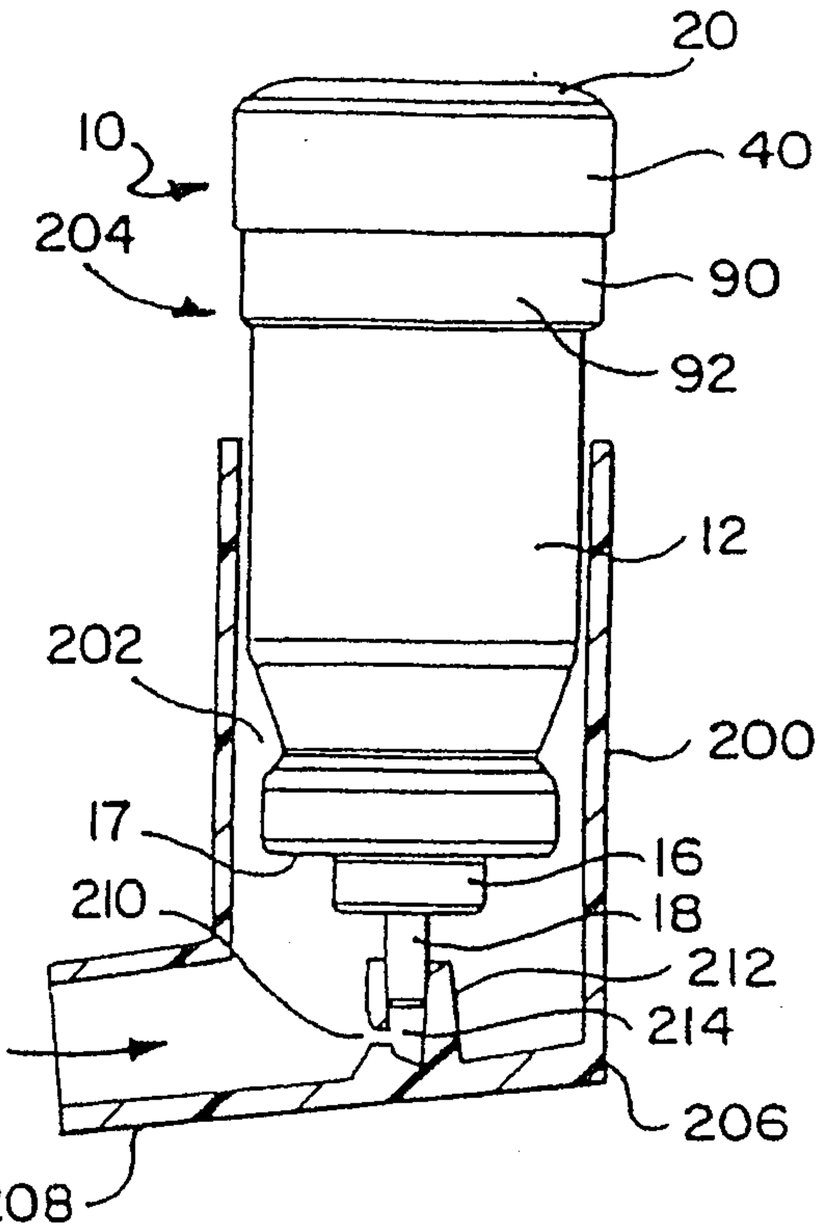


FIG. 33

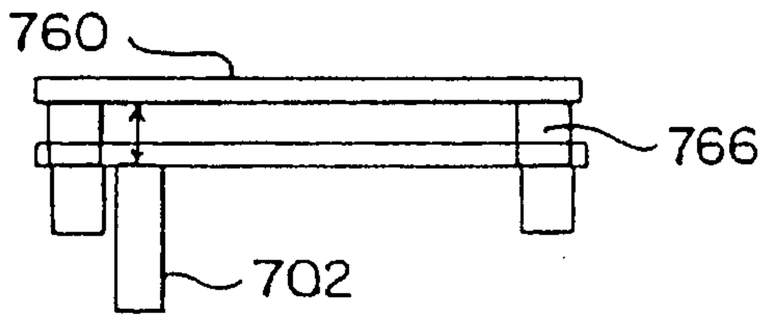


FIG. 35

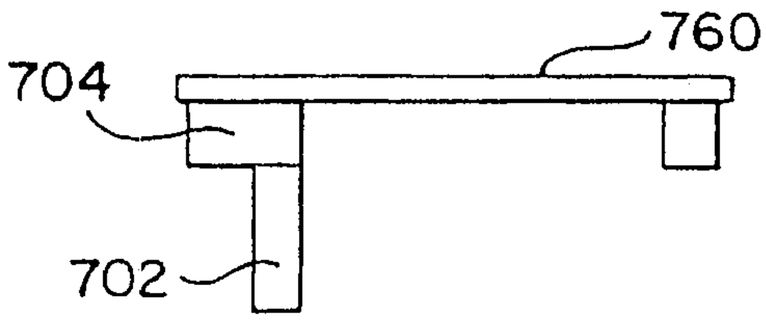


FIG. 34

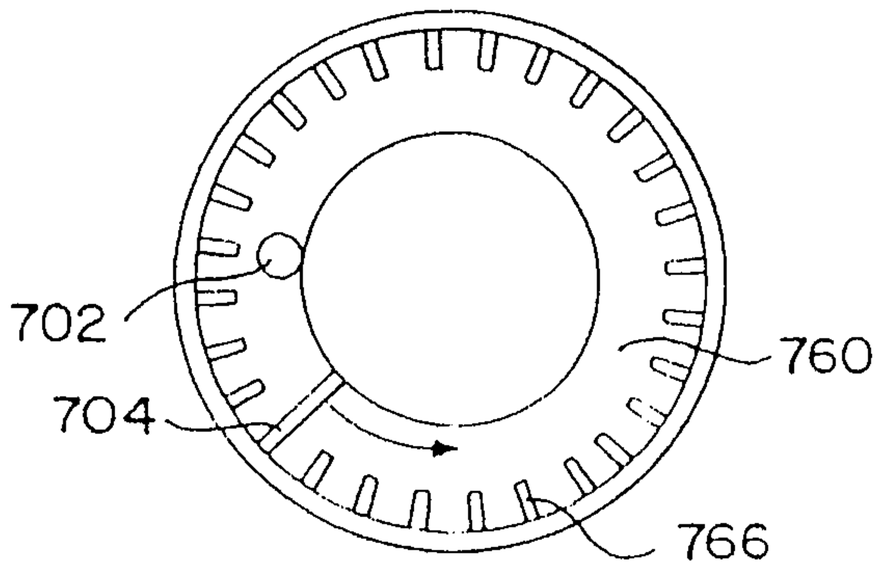
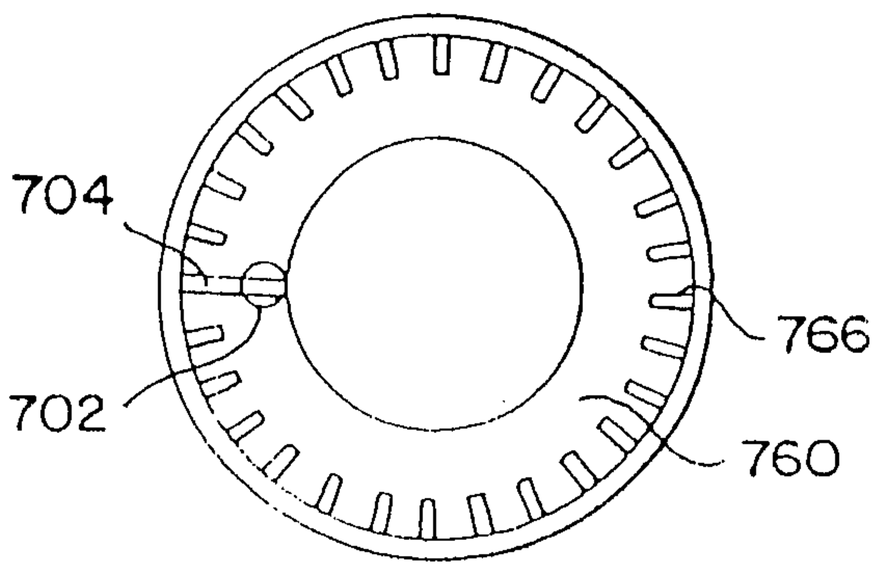


FIG. 36



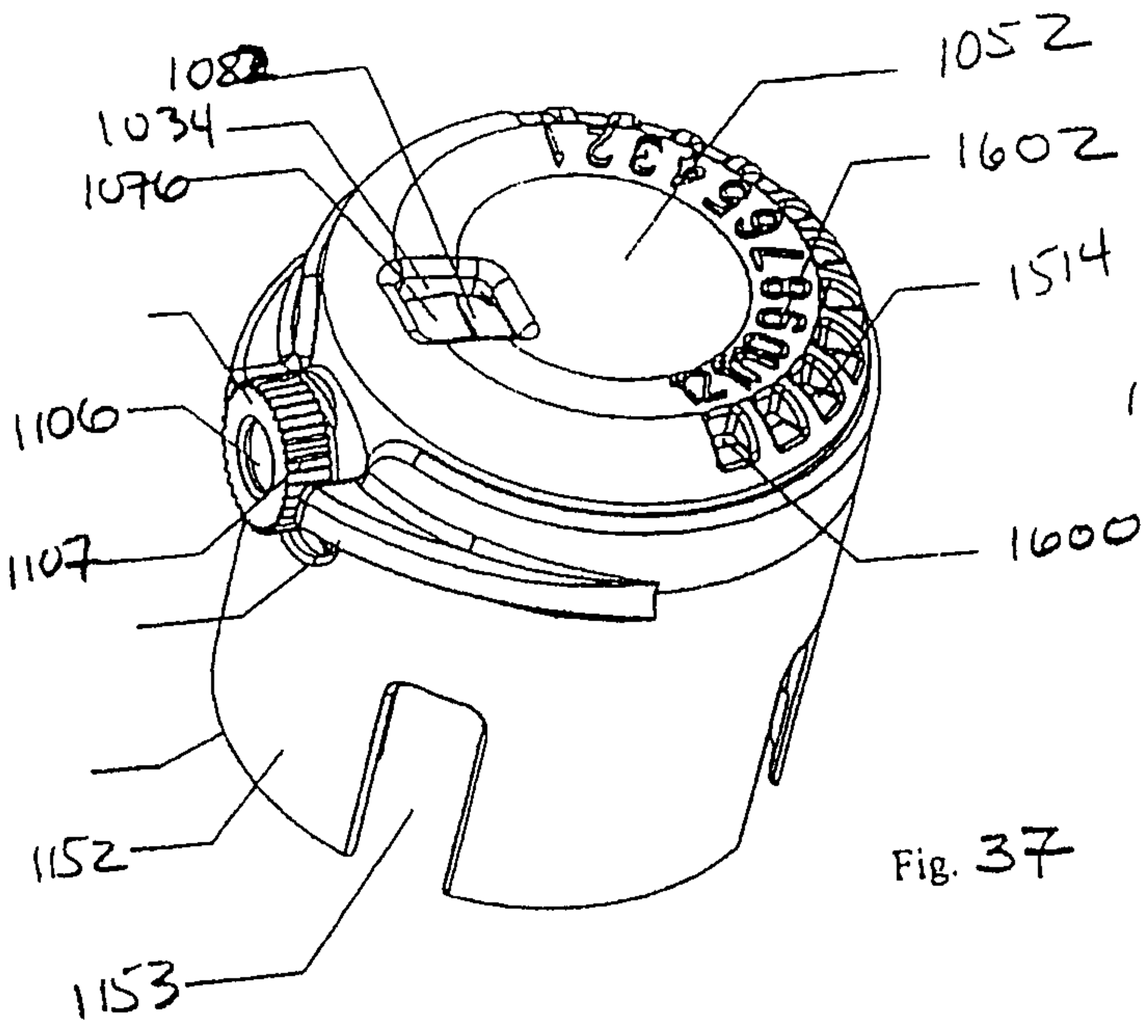


Fig. 37

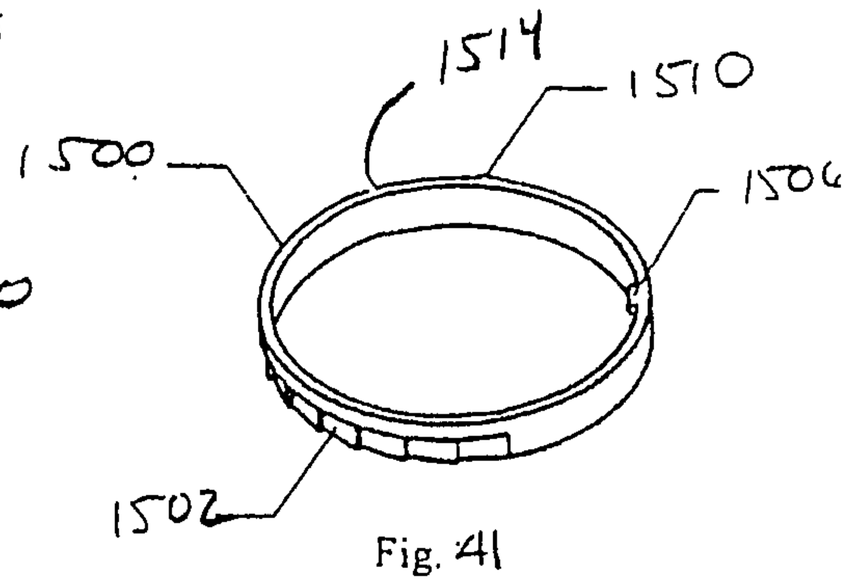


Fig. 41

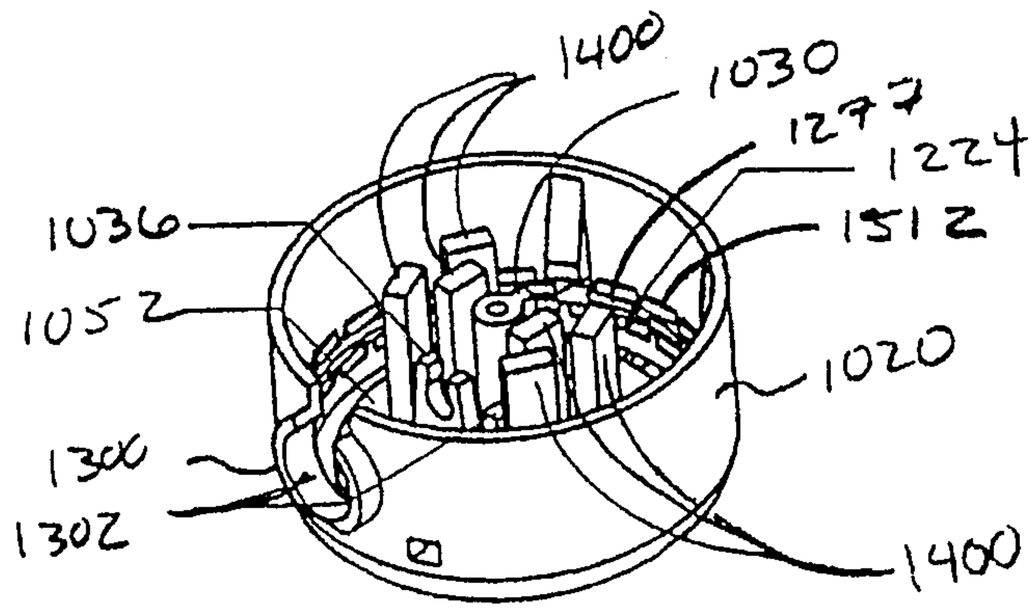


Fig. 39

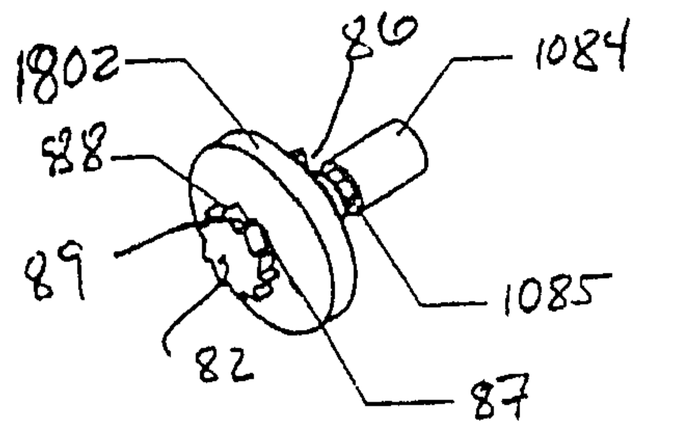


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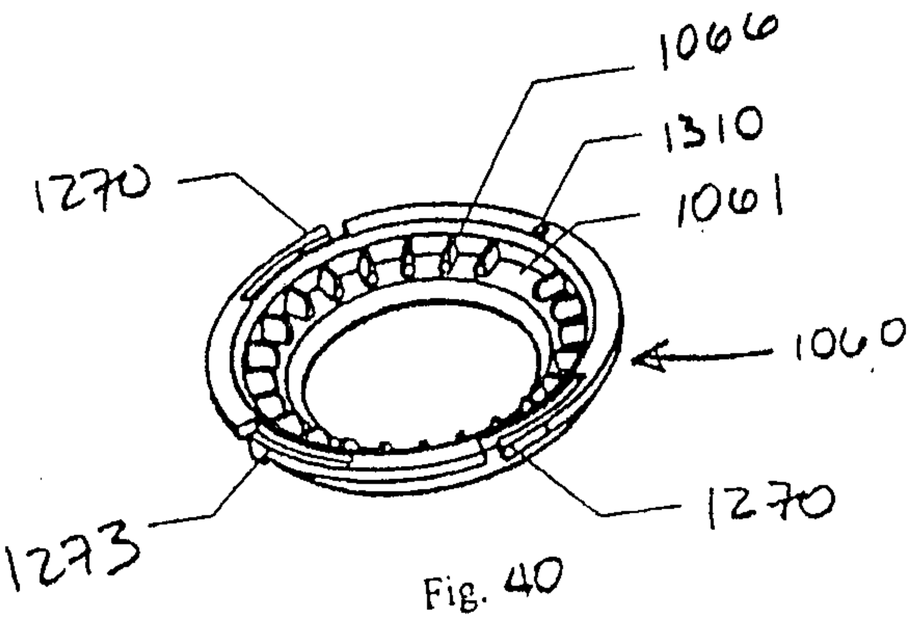


Fig. 40

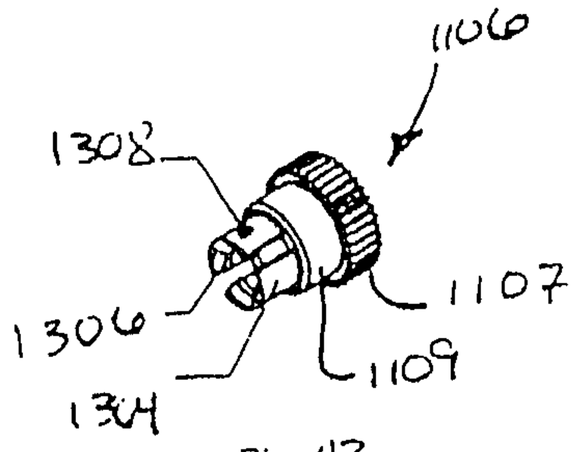


Fig. 43

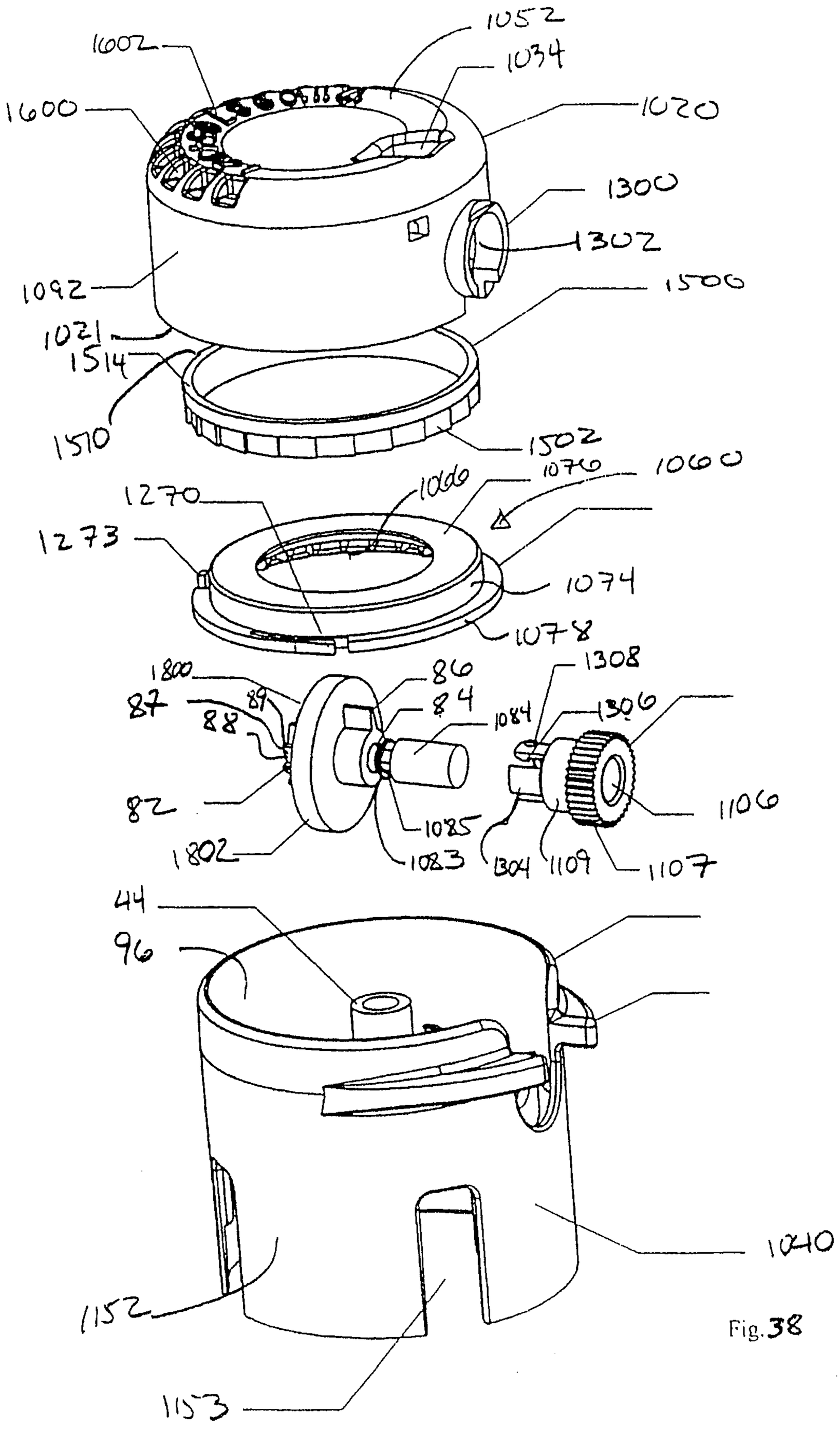

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Fig.38

FIG. 45

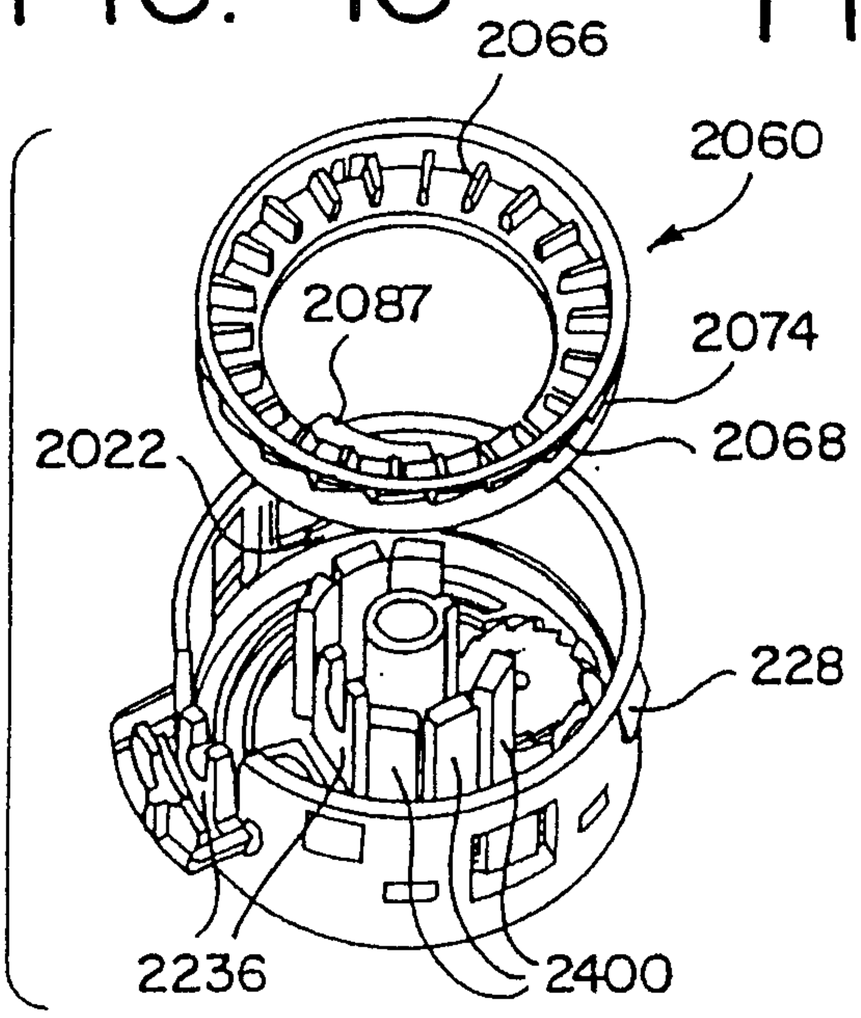


FIG. 44

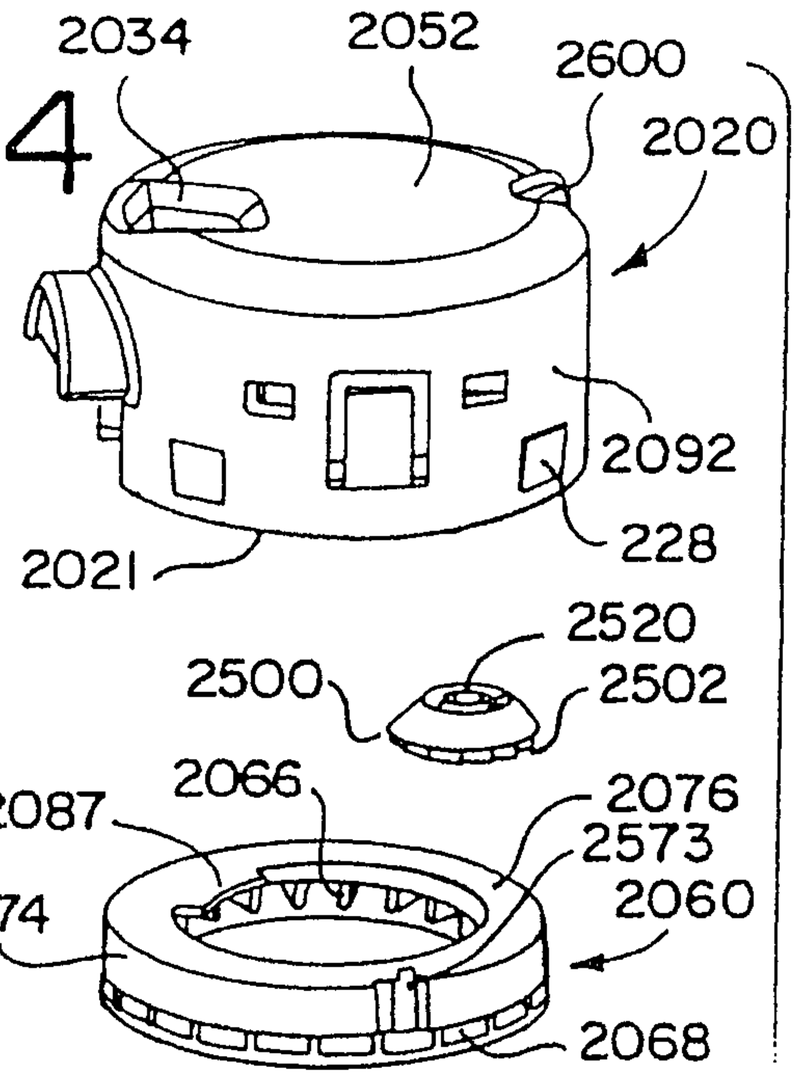
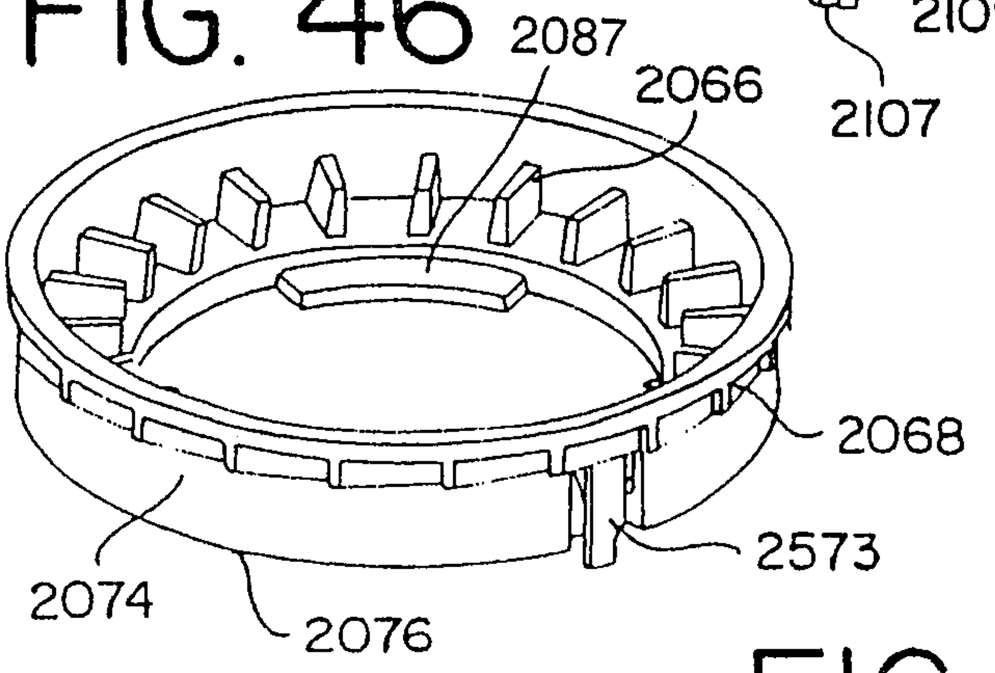


FIG. 46



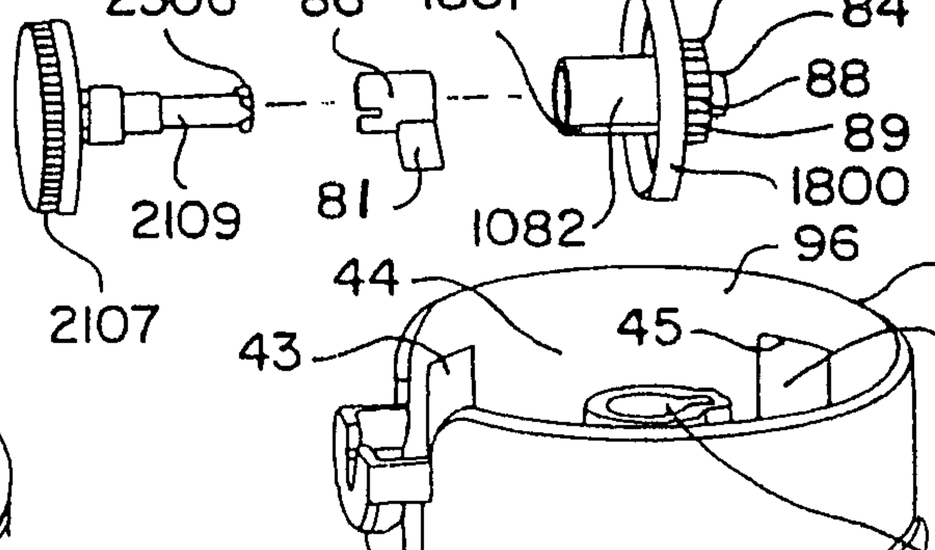


FIG. 49

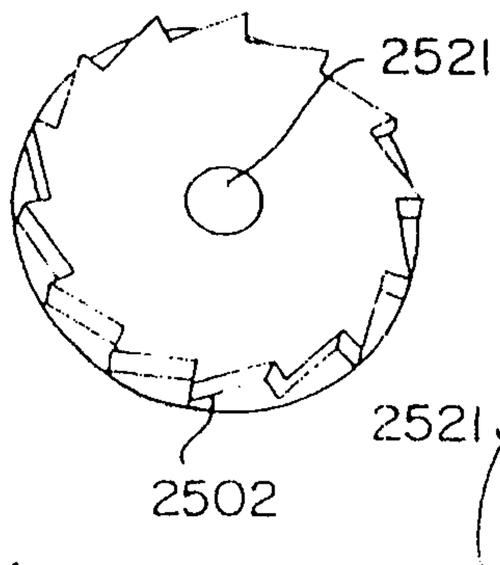


FIG. 47

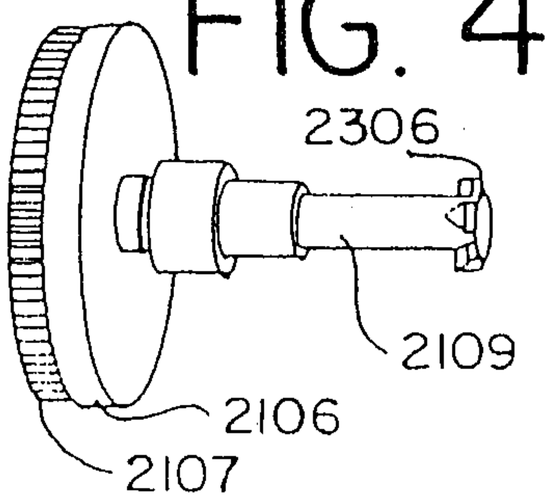


FIG. 50

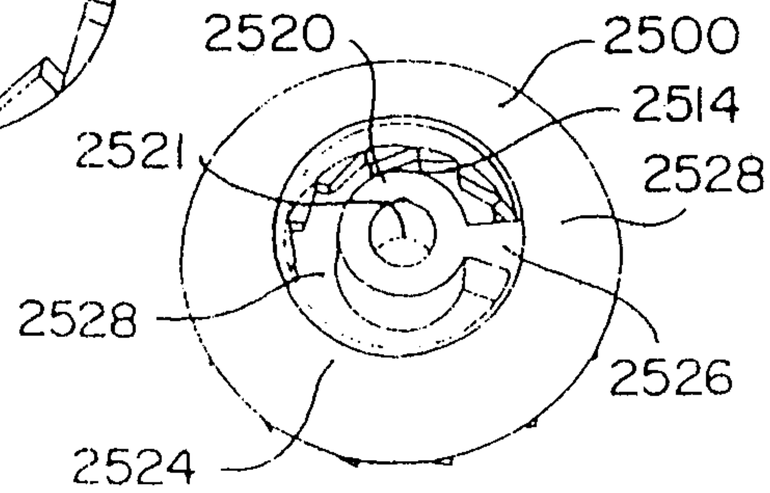


FIG. 48

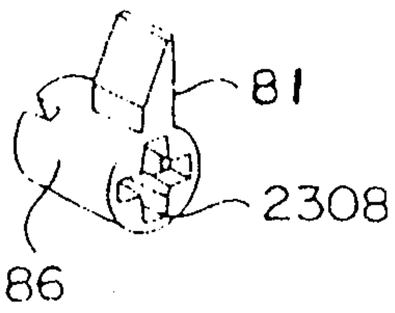


FIG. 51

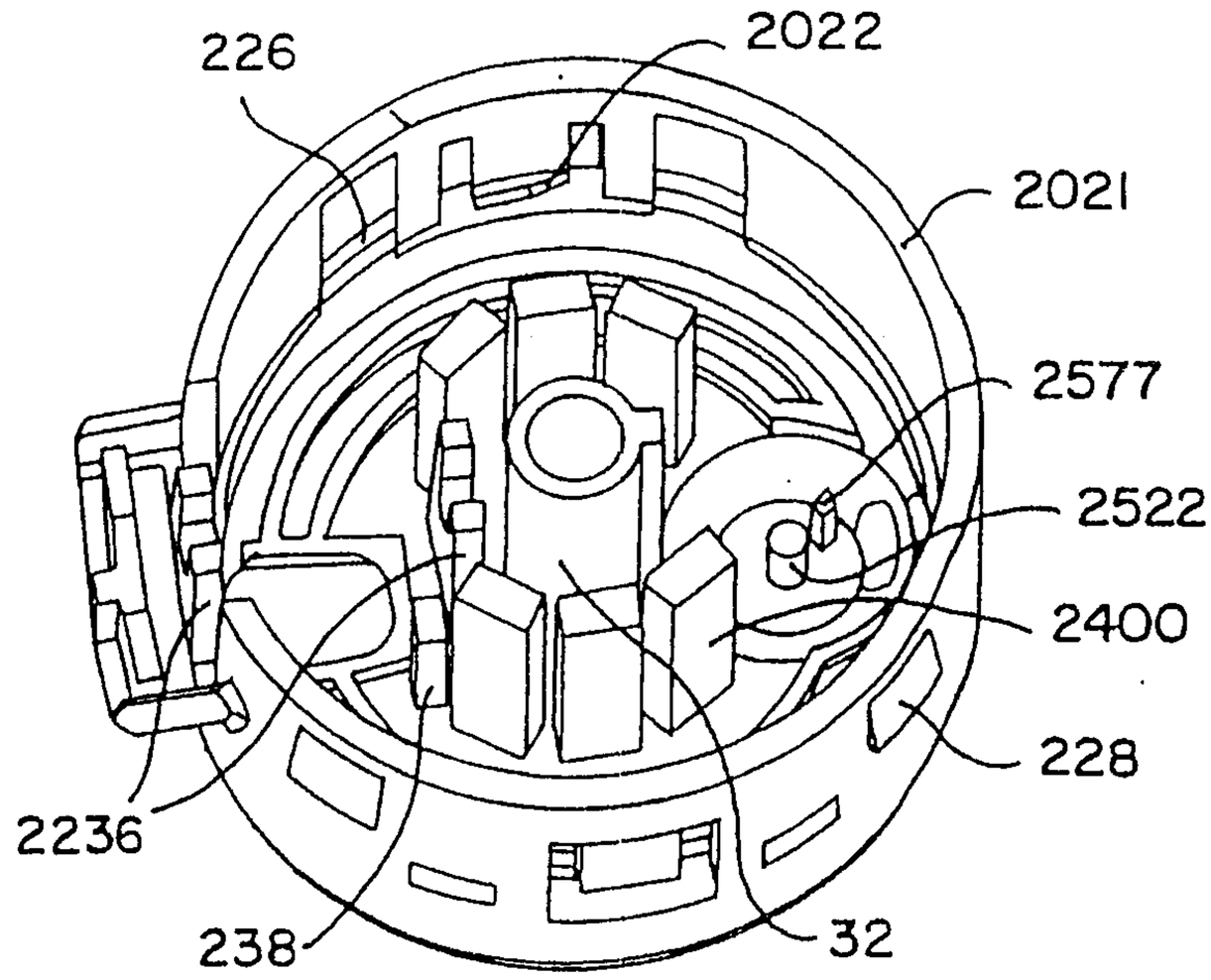


FIG. 52

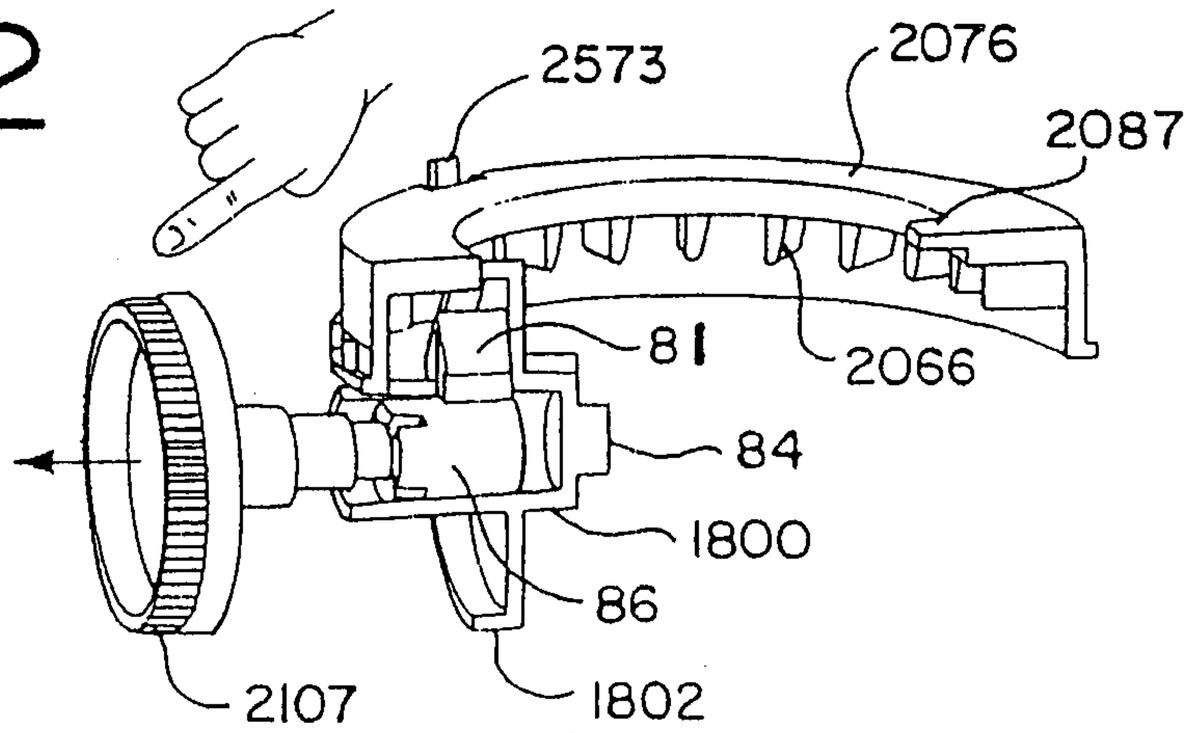


FIG. 53

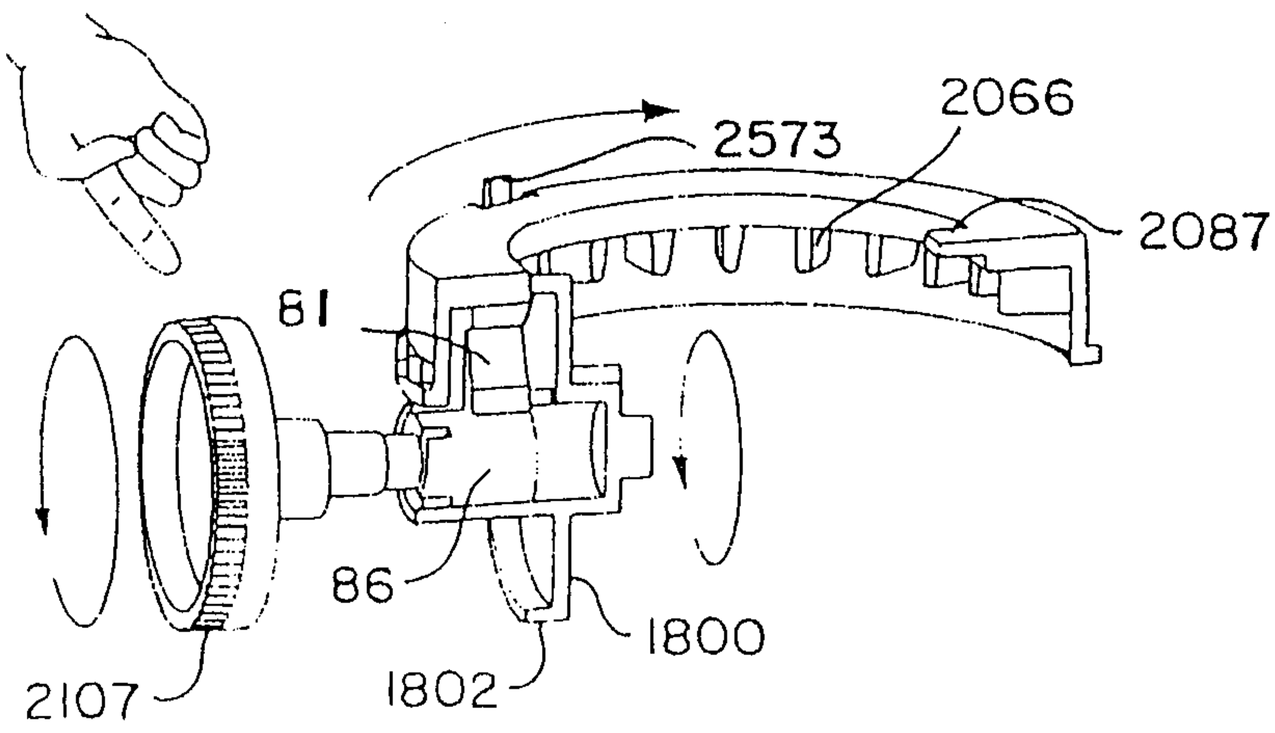


FIG. 54

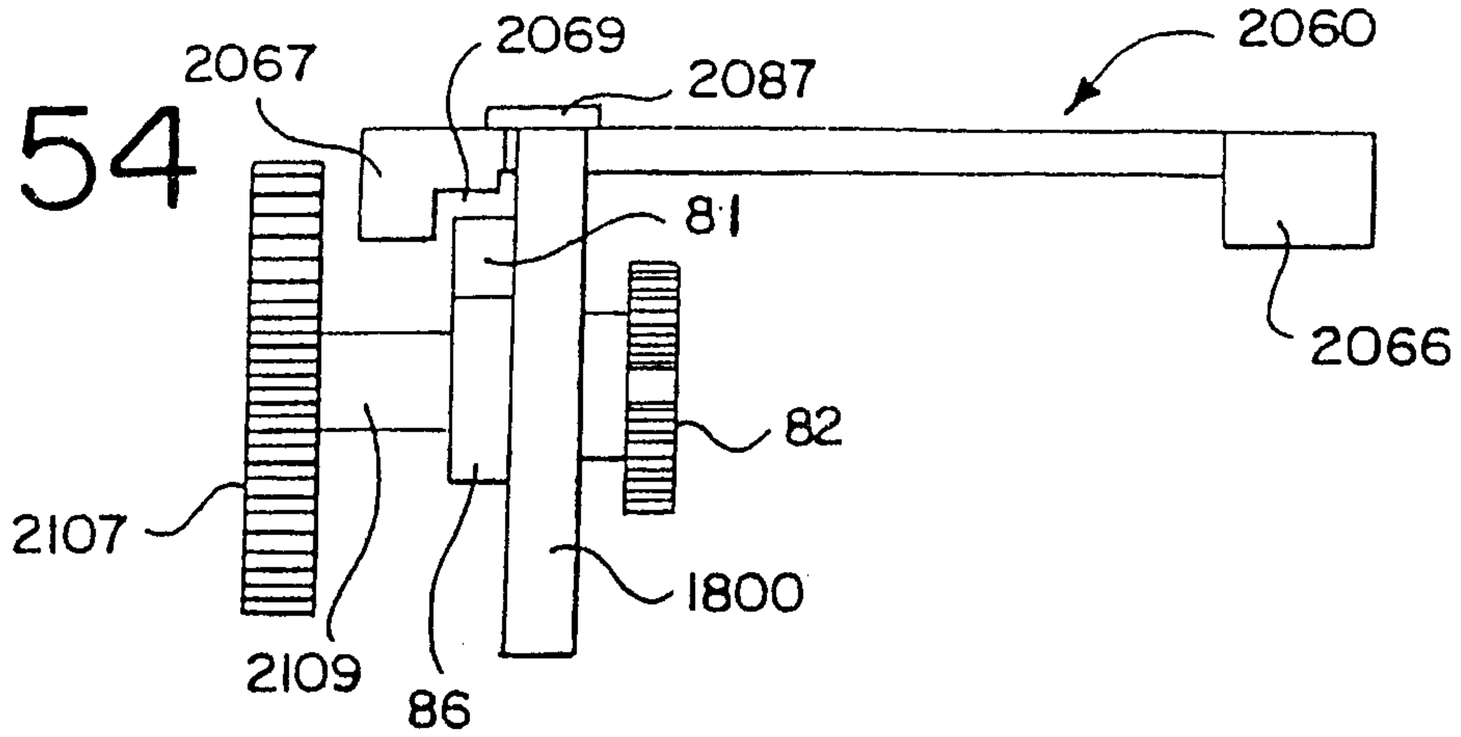


FIG. 55

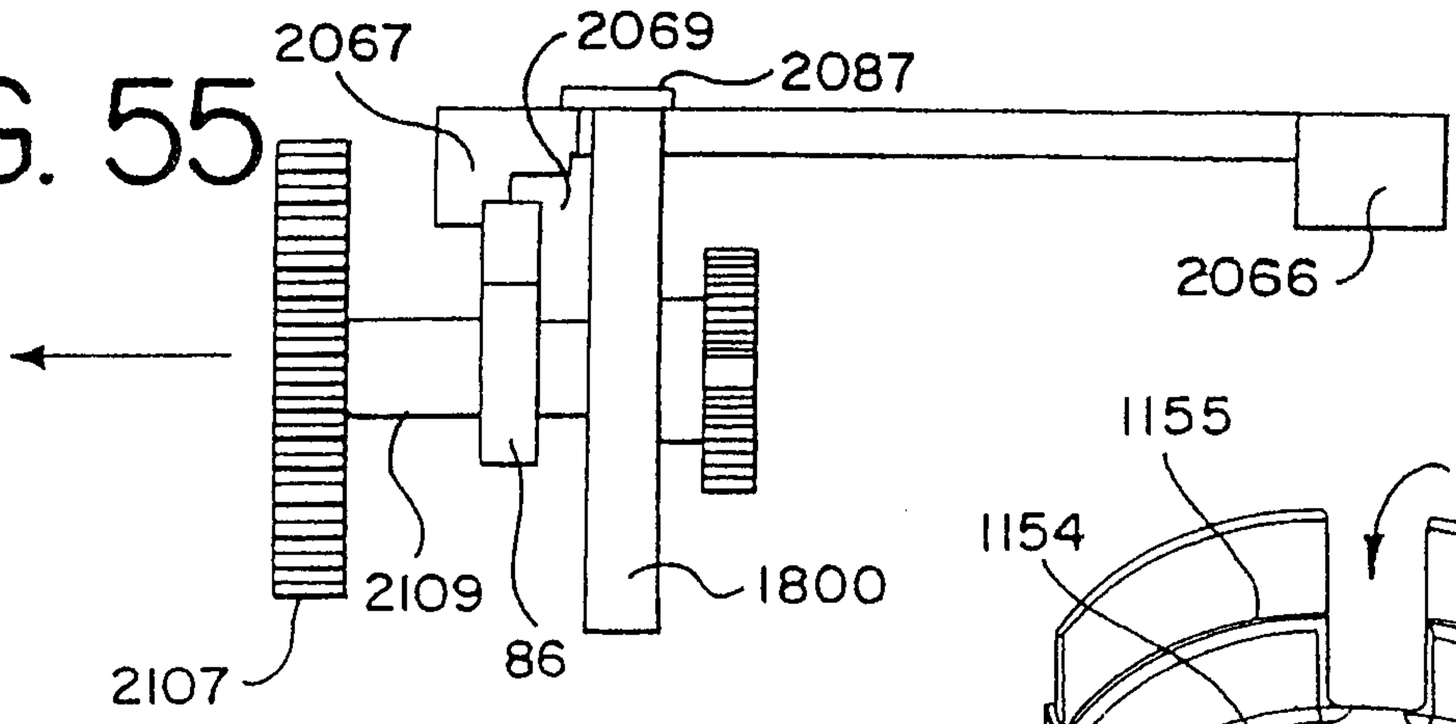


FIG. 57

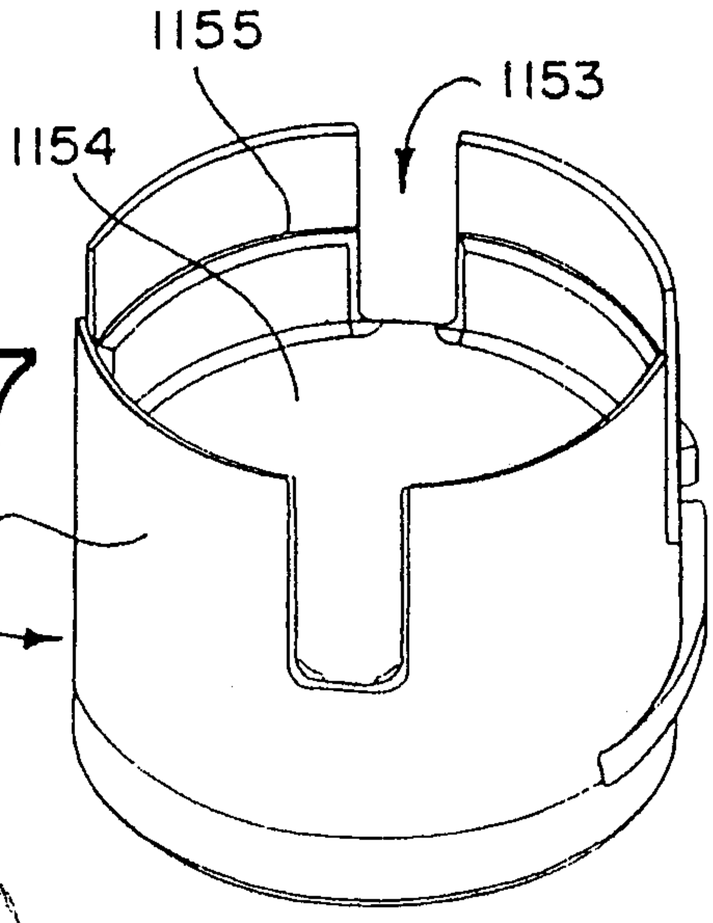
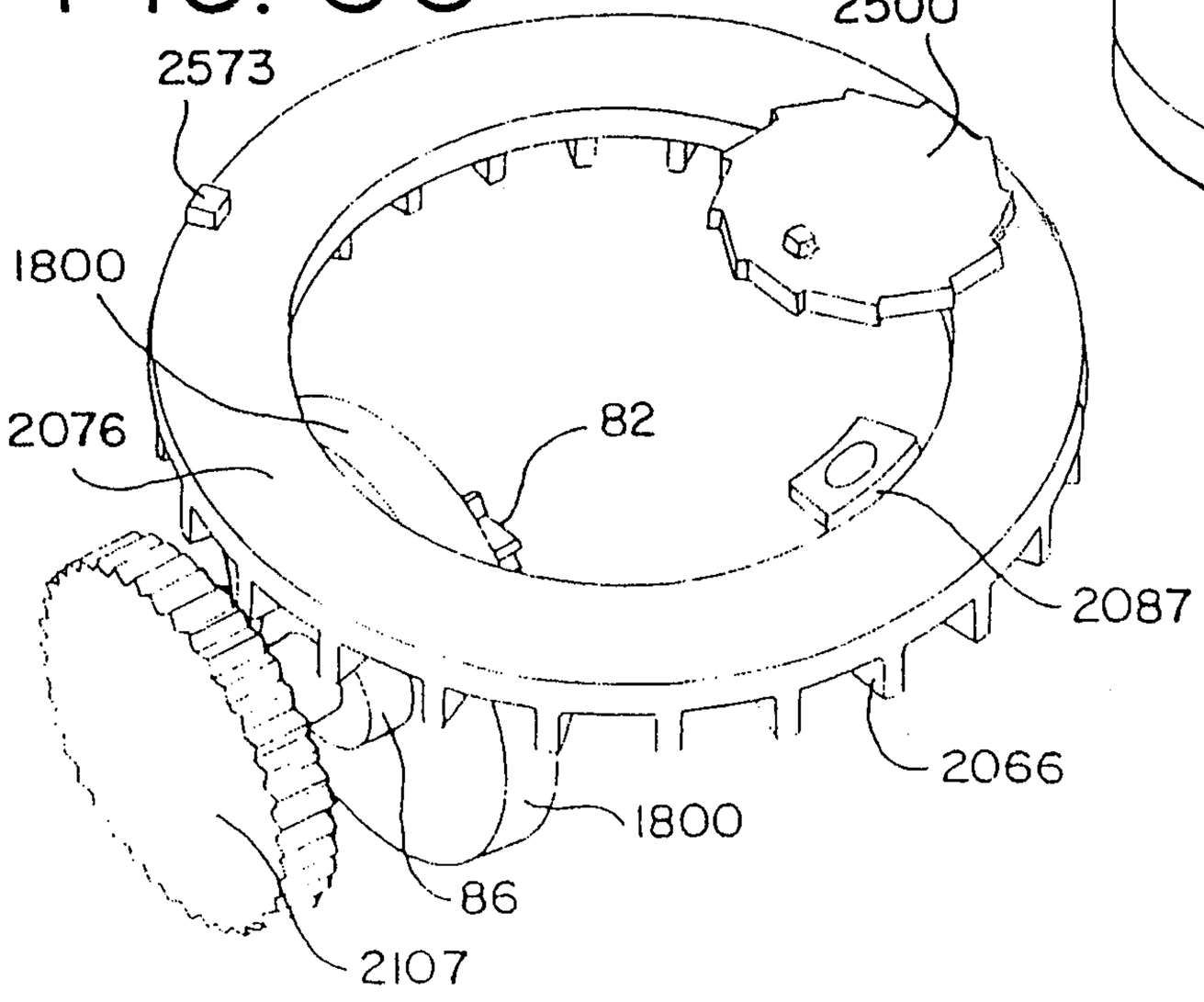
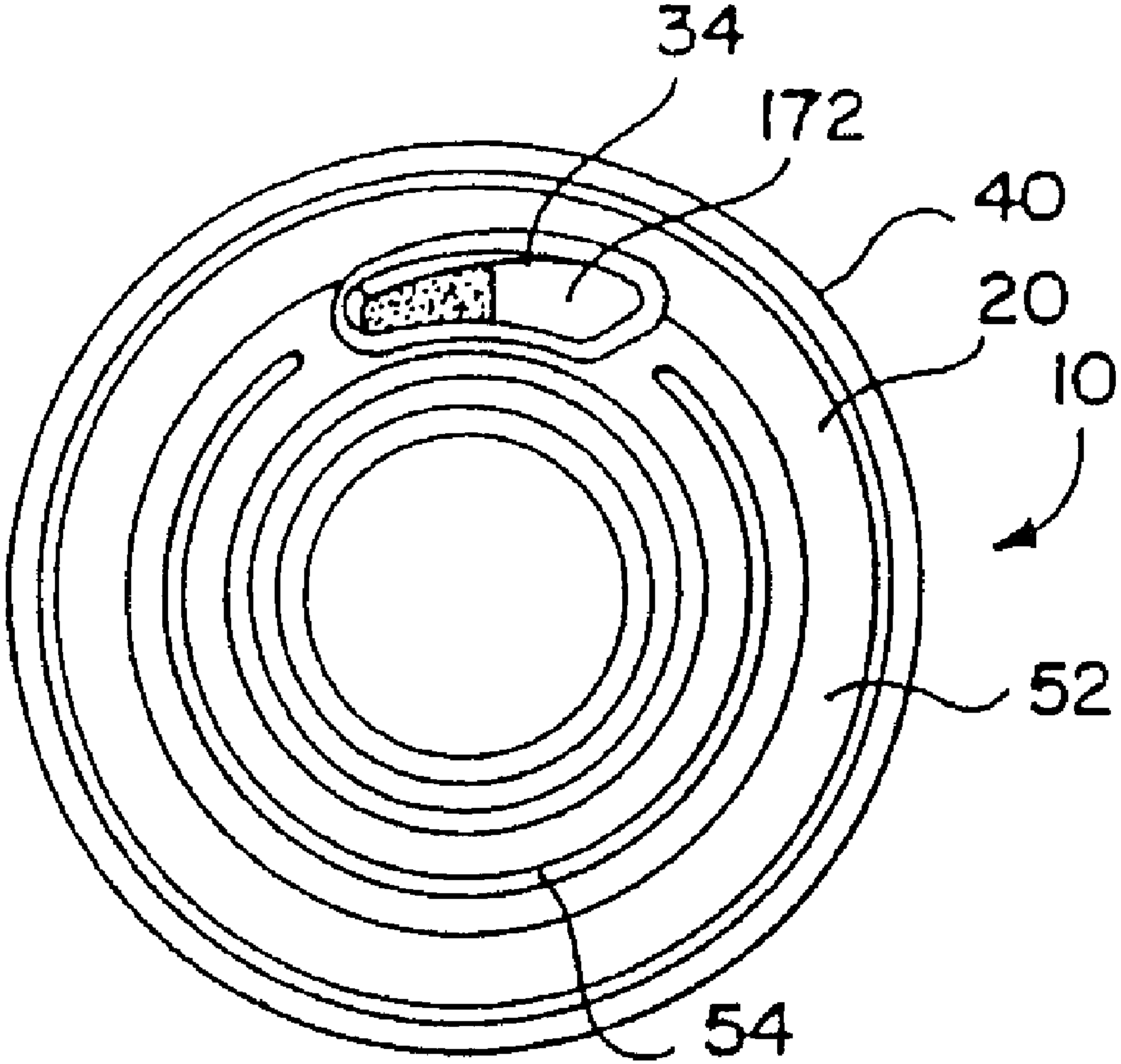


FIG. 56




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