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(54) Benævnelse: **Nålemonteringsorgan og anvendelse af nålemonteringsorganet til montering af en nålekonstruktion**

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Description

THE TECHNICAL FIELD OF THE INVENTION

The present invention relates generally to injection devices and, in particular, provides needle mounts for mounting a needle to an injection device or to an ampoule that my be mounted in the injection device.

DESCRIPTION OF RELATED ART

Injection devices, also referred to as dosers, have greatly improved the lives of patients who must self-adminster drugs and biological agents. Dosers may take many forms, including simple disposable devices that are little more than an ampoule with an injection means or they may be highly sophisticated instruments with numerous functions. Regardless of their form, they have proven to be great aids in assisting patients to self-adminster injectable drugs and biological agents. They also greatly assist care givers in administering injectable medicines to those incapable of performing self-injections.

In particular, pen-style injection devices, have proven to be an accurate, convenient, and often discrete, way to administer drugs and biological agents, such as insulin. Modern devices have become more sophisticated and often include diverse and robust functions, such as memories for remembering time and amount of last dose, as well as, in the case of insulin devices, blood glucose monitors. While pen-style dosers are typically cylindrically shaped with needles protruding from the most distal portion of one end of the device, some of the more modern and /or sophisticated dosers have other shapes with the needle no longer protruding from the most distal part of an end of the device. (See e.g., Innovo® and InnoLet® from Novo Nordisk A/S Bagsvaerd Denmark).

Typically, injection devices use a pre-filled cartridge containing the medication of interest. The cartridge may be an integral part of the doser or it may comprise an ampoule having a membrane at one. See U.S. Patent No. 6,312,413 to Jensen et. al, which is hereby incorporated by reference. Often the end of the ampoule having the membrane is fitted with a needle mount. The needle mount usually comprises a threaded mounting surface to allow a needle assembly, such as a needle and hub assembly, to be screwed on. The needle mount may be an integral part of the ampoule or may be a separate adapter top (see U.S. Patent Nos. 5,693,027 and 6,126,646, which are hereby incorporated by reference) that is mounted to the ampoule. Of course, some dosers have needle mounts that are integral parts of the doser.

The prior art document CH 332.340 discloses a needle mounting system for mounting a needle assembly onto a needle mount of an injection device. The needle assembly comprises a needle attached to a hub, which hub has an interior threaded wall part. The needle mount shows the combination of features of the preamble of claim 1. It comprises a cylindrical outer wall having a top end and threads disposed on the cylindrical outer wall. Further two grooves are disposed in the cylindrical outer wall beginning at the top end of the cylindrical wall and defining a passageway that is generally parallel to a cylindrical axis of the cylindrical outer wall. The interior threaded wall parts of the hub travel in these two grooves during mounting of the needle assembly on the needle mount.

A further prior art document US 5.019.045 discloses a needle assembly comprising a hub and a needle attached to the distal end of the hub.

In the typical injection device where the needle mount is not part of the doser, the end of the ampoule having the needle mount protrudes from the injection device. Where the needle mount is part of the doser, the needle mount is usually disposed on an outer end of the doser. In either embodiment, the needle hub is then screwed onto the needle mount. One disadvantage of the prior art needle mounting systems is that they require the patient to screw the needle hub onto the end of the ampoule, or the doser, by turning the needle relative to the device several times. For patients with dexterity problems, this is inconvenient. Moreover, it is often desirable to store needles for the injection devices in a magazine. Often many newer generation injection devices are not cylindrical and in many new devices, other parts of the device extend past the needle mount making it impossible to mount the needle on the injection device without first removing it from the magazine.

SUMMARY OF THE INVENTION

The present invention provides a needle mount as defined in claim 1. The present invention allows a needle and hub assembly to be mounted on an ampoule and/or injection device without having to rotate completely the needle hub assembly relative to the injection device. The needle assembly also includes a means for mounting the hub to a needle mount with only a partial rotation of the needle hub relative to the mount.

At least one embodiment of the present invention includes the use of a needle assembly in combination with a needle mount according to claim 1. In this embodiment, a plurality of protrusions extends radially inward from the wall of the hub. Typically, the hub wall is cylindrical. The needle mount according to the present invention, includes a structure

having a cylindrical outer wall. A plurality of grooves is disposed on the outer wall. The grooves begin at the top of the wall and contain at least two portions: a first portion that defines a passageway that is substantially parallel to the cylindrical axis of the outer wall, and a second portion that is oriented at an angle to the first portion.

The present invention therefore provides for mounting needles to injection devices. It may be useful in mounting needles stored in magazines and is particularly useful for injection devices that have a portion that extends past the needle mount. The injection device can be partially inserted into a magazine holding needle assemblies, and may be rotated relative to the magazine by less than a full revolution and may be then removed with the needle assembly attached thereto.

The needle assembly includes a cylindrical hub that has a needle mounted thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a three-dimensional view of a needle hub and a needle mount according to the present invention.

Figure 2 is a cut-away view of the needle mount and needle hub shown in Figure 1.

Figure 3 is a three-dimensional view of a needle assembly and a needle mount which is not according to the present invention.

Figure 4 illustrates the embodiment of Figure 3 when viewed from below.

Figure 5 is a cut-way view of the needle assembly of Figures 3-4.

Figure 6 is an enlarged view of the needle assembly mounting means of the device shown in Figures 3-5.

Figure 7 is a cut through view of a needle mount and needle hub for tacitly determining whether the needle hub is securely mounted on the needle mount.

Figure 8 is a side view of a magazine for storing needles that may be used in combination with the present invention.

Figure 9 is a top view of the magazine shown in Figure 8.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a needle mount (100) for attaching needle hub assemblies to ampoules and injection devices. Typically, a needle hub assembly comprises a needle 510 mounted to a hub 500 (see e.g. Figure 3). As is shown in Figure 1, a needle hub 10 may be generally cylindrically shaped and have an interior wall surface 20. In one embodiment of the present invention, a plurality of protrusions 30 extends radially inward from the interior surface 20.

The needle mount 100 is designed to accept the needle hub 10. (See e.g. Fig. 1). As is shown in Figures 1 and 2, the needle mount 100 may be generally cylindrically shaped and have an exterior wall surface 110. A plurality of grooves or slots 120 are disposed in the exterior surface 110. The grooves 120 have a first end 122 and a second end 125. The grooves 120 have a first portion 130 that defines a passageway that is generally parallel to the cylindrical axis 1000 of the needle mount 100. While the first portion of the groove 130 is shown in the drawings as having a rectangular portion, the exact shape of the groove is not critical so long as it allows the protrusions 30 on the needle hub to move in a direction parallel to the cylindrical axis 1000. Thus, while the groove may have walls that are not necessarily parallel to the cylindrical axis 1000, the groove may still be said to be parallel to the cylindrical axis if it allows the protrusions 30 to move in a direction parallel to the cylindrical axis. The first portion of the grooves 130 may have width that is wider than the remainder of the first portion or the remainder of the groove 130. In embodiments where the groove has walls that are not parallel to the cylindrical axis 1000, the width of the first portion of the groove 130 may be the average width for the first portion of the groove 130.

The first portion 130 may have an entrance 135 that has a width dimension that is greater than the average width of the first portion or is wider than the average width of the entire groove 120. The entrance 135 may act as an alignment means for aligning the needle hub so that the protrusions will enter the groove 120. In most embodiments, but not all, the entrance width is wider than any other point in the groove 120. Typically the width of the groove narrows as the groove is traversed away from the entrance 135. As is shown, the groove may reach a constant width at some distance from the opening. In some embodiments the width of the first portion 130 is widest at the entrance 135 and continues to narrow over the length of the first portion 130. The grooves also have a second portion 150 that is either perpendicular to the cylindrical axis 1000, or lies at angle to the first portion 130. In some embodiments of the present invention the second portion 150 may be comprised of only one surface that is generally perpendicular to the cylindrical axis of the needle mount. Thus, the second portion of the groove 150 need not

be a slot having two sides, but needs only one side to prevent protrusions on the needle hub from moving toward the outer end of the needle mount. As shown in Figure 1, the grooves 120 may also have a third portion 160 that is oriented at an angle to the first portion 130 and the second portion 150.

A means for tacitly determining whether the needle assembly is securely fixed to the hub may be provided. This may be accomplished in numerous different ways, including providing a small projection(s) 439 at the side or in the bottom of the second portion of the grooves 120. (See e.g. Figure 7). The protrusions 30 have to overcome the projections 439 before the needle is fixed. The deformation of the projections may cause a tacitly feel or a sound, such as a clicking sound. Thus, the needle mounting system can be designed so that the needle hub and the needle mount generate a clicking sound when the needle is securely placed on the mount. When the hub is to be remounted from injection device the oblique tactile protrusions can be more sharp at their ends, so that hub is better fixed during injection and handling etc. This also makes it possible for the patient to keep the needle for more injection.

One advantage of the present invention is that the needle mount, may be equipped with standard threads 200 on its exterior surface. (See Fig. 1). The grooves 120 may be cut into the standard threads 200. This allows the needle mount 100 of the present invention to accept not only needle hubs , but also standard, threaded needle-hub assemblies.

While Figure 1 shows the grooves on the needle mount and the protrusions on the needle hub, the needle mount may be configured with the grooves located on the interior surface of the needle hub and the protrusions extending outward from the exterior wall of the needle mount. It may be advantageous to size and shape the protrusions so that they fit between standard threads used with existing needle hubs. The protrusions may then be arranged on the exterior wall of the needle mount to allow not only needle hub assemblies having grooves in their interior wall to be attached, but also standard, threaded needle hubs.

As is shown in Figures 3-6, which do not show embodiments according to the invention, the needle hub assembly 500 has a needle 510 mounted thereto. The needle hub 550 may be generally cylindrically shaped and has an interior wall surface 600 and a closed top end 610. The closed top end 610 has an inside surface 620. A cylindrical member 650 protrudes from the inside surface 620 and has an outer surface 660. See Fig. 5. Protrusions 670 extend radially outward from the outer surface 660. The protrusions may take various forms and shapes, including the triangular prism shape shown in the drawings.

The needle hub assembly shown in Figures 3-5 may be used with a modified needle mount, 700. As is shown in Figures 3 - 6, the needle mount 700 may be generally cylindrically shaped and have a top end, an interior surface, an exterior surface, and a plurality of locking elements (which may be additional protrusions) extending from the interior surface inward. The locking elements may be arranged to form passageways for the protrusions 500 on the needle mount, thereby forming a plurality of grooves for accepting the protrusions from the needle hub assembly 500. As is shown in Fig. 6, the grooves may have a first portion 561 that defines a passageway that is generally parallel to the cylindrical axis of the needle mount, a second portion 571 that is perpendicular to the cylindrical axis and a third portion 588 that connects the second 571 and first portions 561. The first portion 561 may be widest at its opening and thus act as an alignment mechanism for the protrusions on the needle hub. The needle mount may have a mounting surface 581 on which a portion of the needle hub rests when the needle hub is mounted on the needle mount. The mounting surface may be a top edge of the top end of needle mount, or it may be the exterior wall surface 599 of the needle mount or both. The embodiment shown in Figures 2-4 also advantageously allows the outer surface of the needle mount to have threads so that standard prior-art needle hubs may be used with the improved needle mount of the present invention.

The present invention enables various methods for attaching a needle-hub assembly to an ampoule or injection device. For example, a needle mount can be inserted into a needle hub, the needle hub can be rotate relative to the needle mount less than one revolution - typically between 5 and 30 to 60 degrees. A clicking noise or vibration or other tactile feedback will be provided to indicate that the needle is securely mounted to the hub. In some embodiments little rotation is necessary. In some embodiments, it is possible that no rotation is needed. The surface of the locking element 777 could simply force the hub to rotate upon insertion of the mount into the interior of the hub 500. In other embodiments, more rotation may be required.

Because the mounting of a needle hub to a needle mount does not require that the hub be rotated a full revolution relative to the mount (i.e. either the hub is rotated and the mount is held stationary or the mount is rotated and the hub is held stationary, or both are turned in opposite direction), the present invention enables and provides for mounting of needle-hub assemblies stored in magazines, similar to that shown in Figures 8 and 9, to injection devices where their shape would not allow the device to be rotated relative to the magazine by a full revolution. In one embodiment, a portion of an injection device 3000, usually the portion containing a needle mount 3010, is inserted into a needle magazine 3050. The device 3000, without being rotated a full revolution is then removed with a needle fully attached to it. In some embodiments audible or tactile

feedback is provided to indicate that the need is securely mounted to the device. In some embodiments, the portion of the device that is inserted into the magazine may be an end portion of an ampoule that extends from the device. Some methods of using the present invention may be performed using the needles that are stored in a magazine having a flush surface 3070 and the needle and hub assemblies 3080 are located below the surface 3070, usually - but not necessarily - in recessed cavities 3090 (see Figure 9).

The foregoing is a brief description of some exemplary embodiments of the present invention and is intended to be illustrative and not exhaustive of the present invention. Those of skill in the art will recognize the nature of language makes it impossible to capture the essence of all aspects of the present invention and unimportant and insubstantial substitutes for various elements are intended to be included within the scope of the invention as defined by the following claims.

Patentkrav

1. Nålemonteringsorgan (100), der omfatter:

en cylindrisk ydre væg (110), der har en øvre ende og gevind (200), som er anbragt på den cylindriske ydre væg (110) til derpå at optage en med standardgevind forsynet nålekonstruktion, og en flerhed af riller (120), der er anbragt i den cylindriske ydre væg (110) og begynder ved enden af den cylindriske ydre væg (11) samt afgrænser en gennemgangsvej, der i hovedsagen er parallel med den cylindriske ydre vægs (110) cylinderakse (1000),

kendetegnet ved, at

mindst én rille (120) i nålemonteringsorganet (100) endvidere omfatter en første del (130) og en anden del (150), der er orienteret under en vinkel til den første del (130).

2. Nålemonteringsorgan (100) ifølge krav 1, kendetegnet ved, at vinklen mellem den første del (130) og den anden del (150) er 90 grader eller mindre.

3. Nålemonteringsorgan (100) ifølge krav 1 eller 2, kendetegnet ved, at rillen (120) er bredest ved den øverste ende af nålemonteringsorganet (100) og danner en indgang (135).

4. Anvendelse af en nålekonstruktion (500) til montering af konstruktionen på et nålemonteringsorgan, hvilken konstruktion omfatter en kappe (10), der er fæstnet til en nål (510), hvor kappen (10) har en indre cylindrisk væg (20) med en flerhed af fremspring (30), der strækker sig radialt indad fra den indre cylindriske væg (20), hvor anvendelsen omfatter tilvejebringelse af et nålemonteringsorgan ifølge et hvilket som helst af kravene 1 til 3 og montering af nålekonstruktionen på nålemonteringsorganet.

5. Anvendelse af en nålekonstruktion (500) ifølge krav 4, kendetegnet ved, at fremspringene (30) omfatter en cirkulær overflade.

6. Anvendelse af en nålekonstruktion (500) ifølge krav 4 eller 5, kendetegnet ved, at fremspringene (30) strækker sig vinkelret på en cylinderakse (1000).

7. Anvendelse af en nålekonstruktion (500) ifølge et hvilket som helst af kravene 4 til 6, kendetegnet ved, at fremspringene (30) er placeret i nærheden af en proximal ende af kappen (10) modsat den øvre ende.

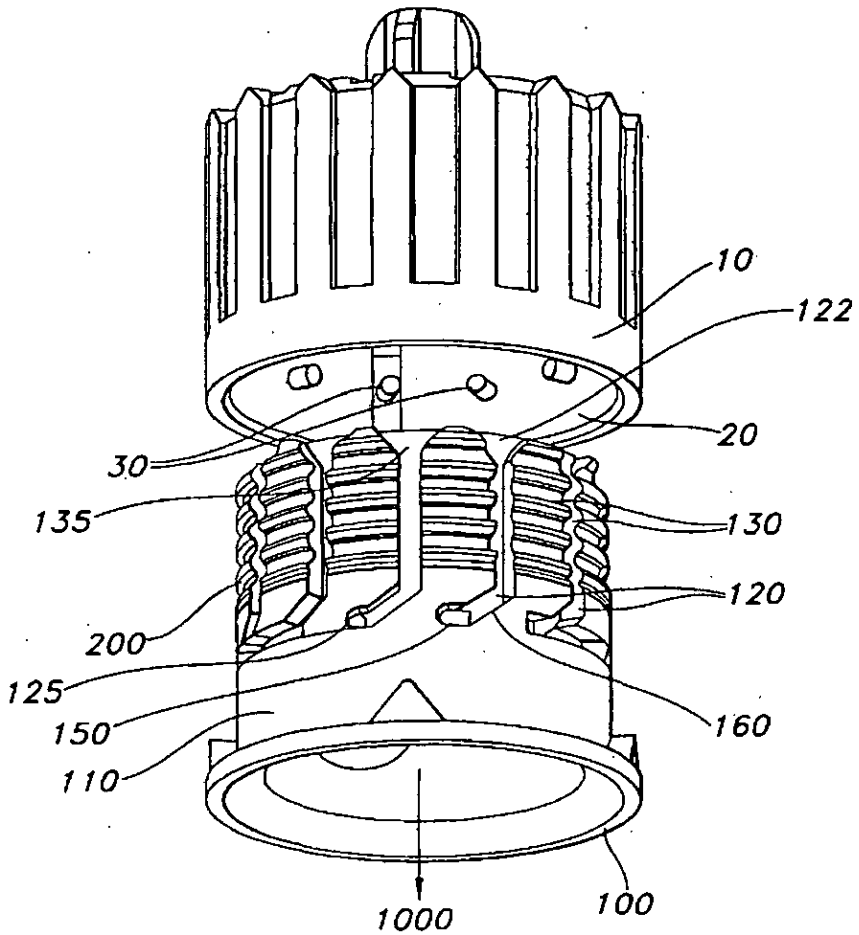

FIG. 1

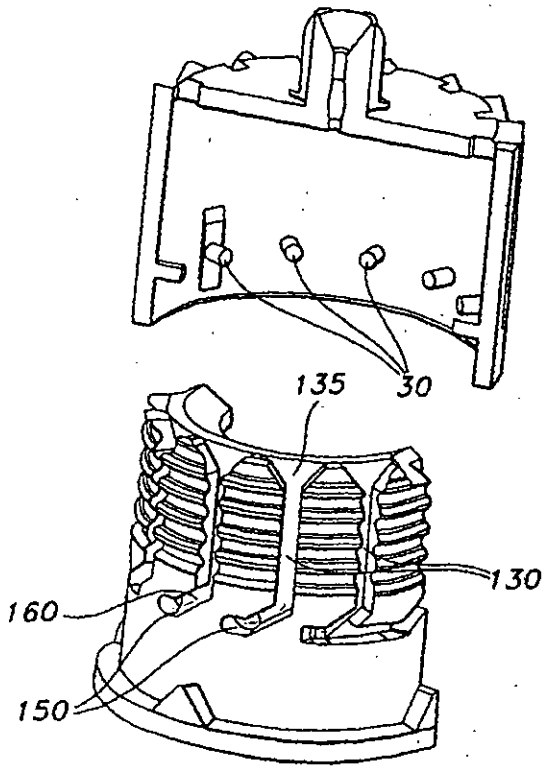

FIG. 2

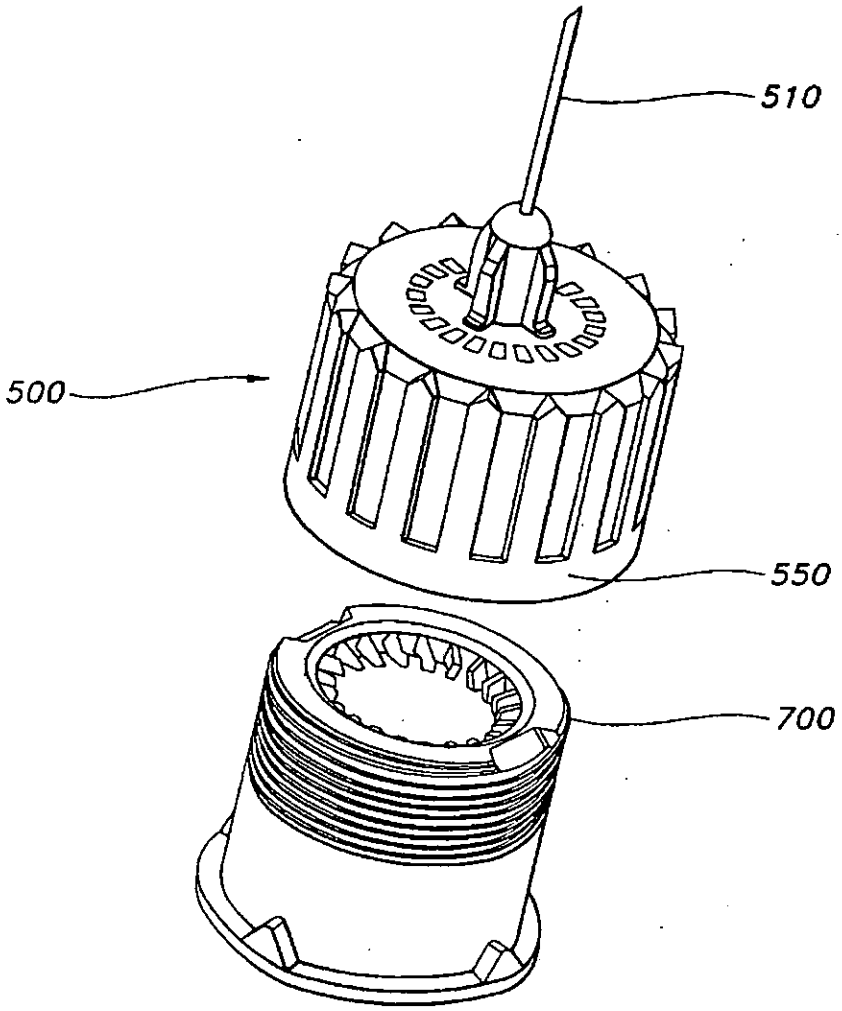

FIG. 3

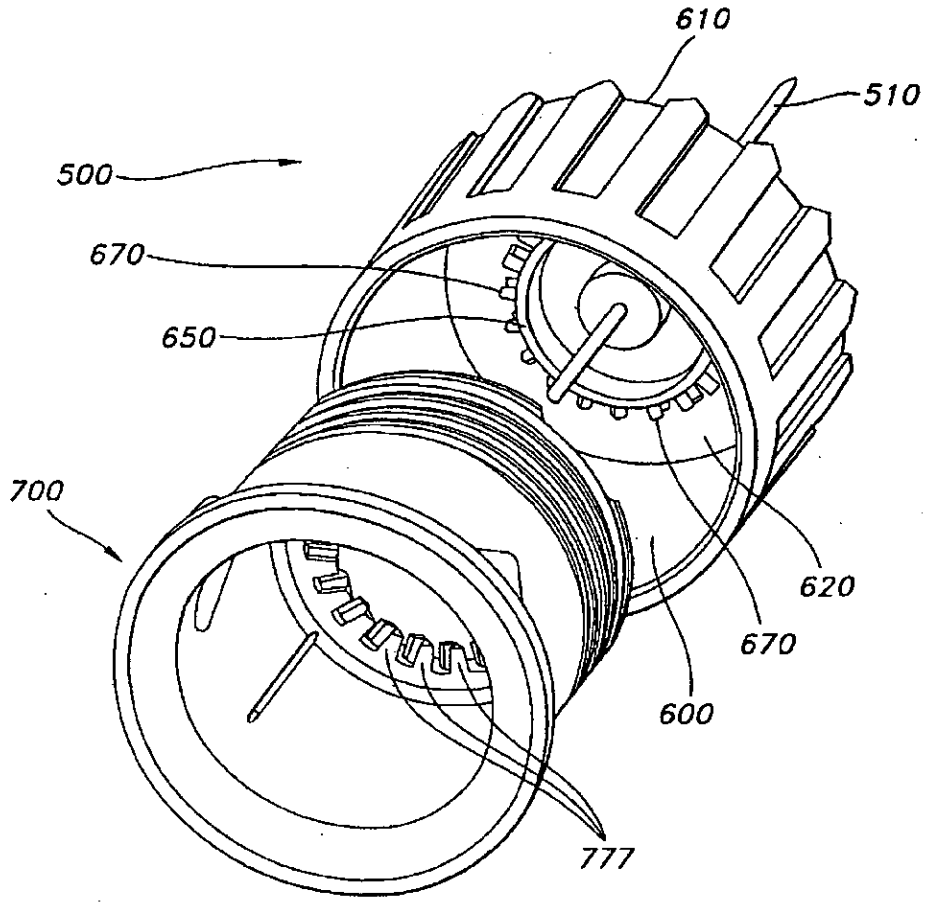

FIG. 4

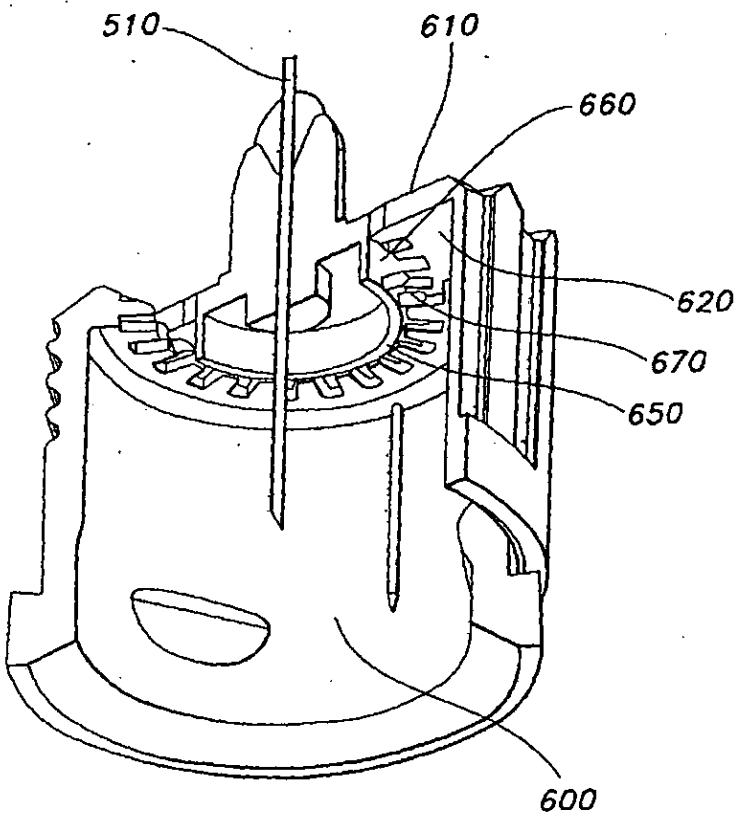

FIG. 5

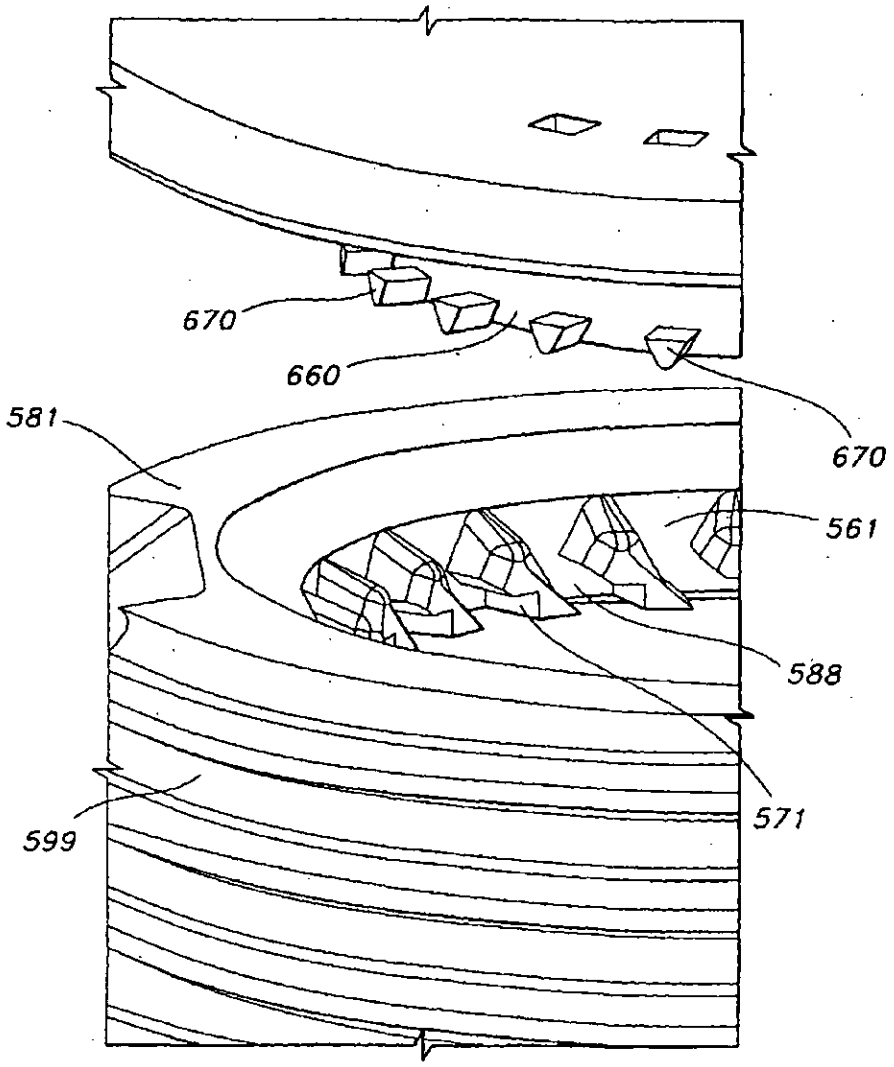

FIG. 6

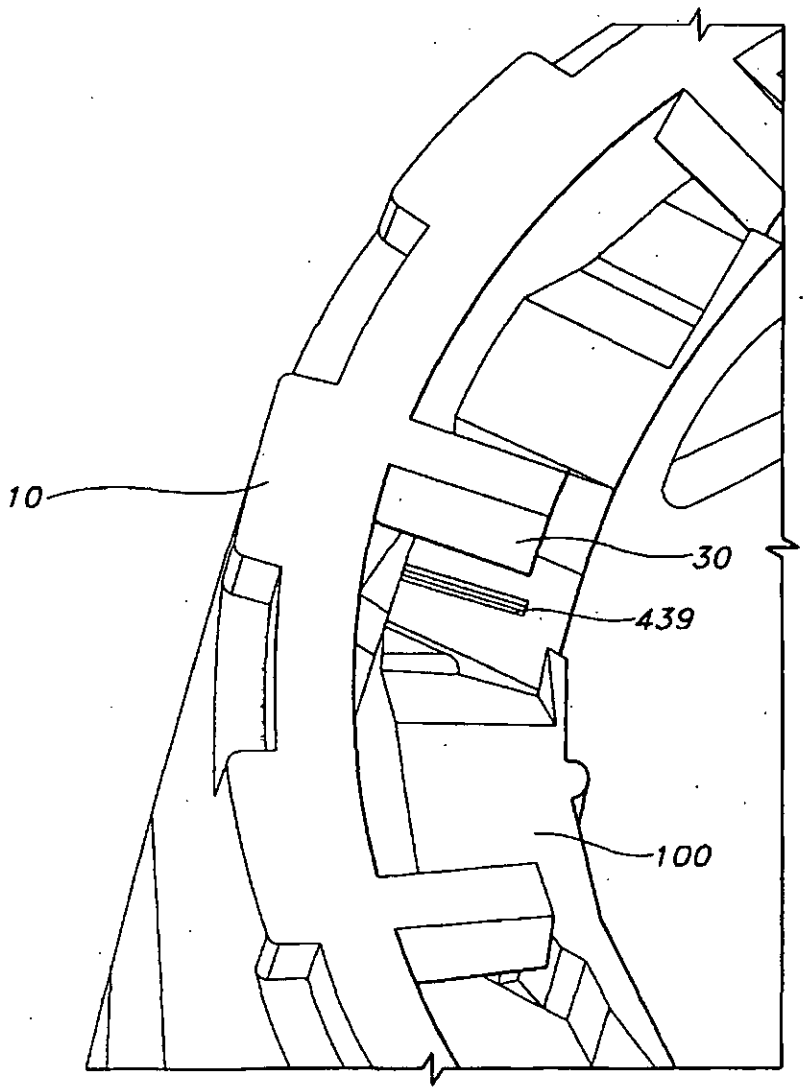

FIG. 7

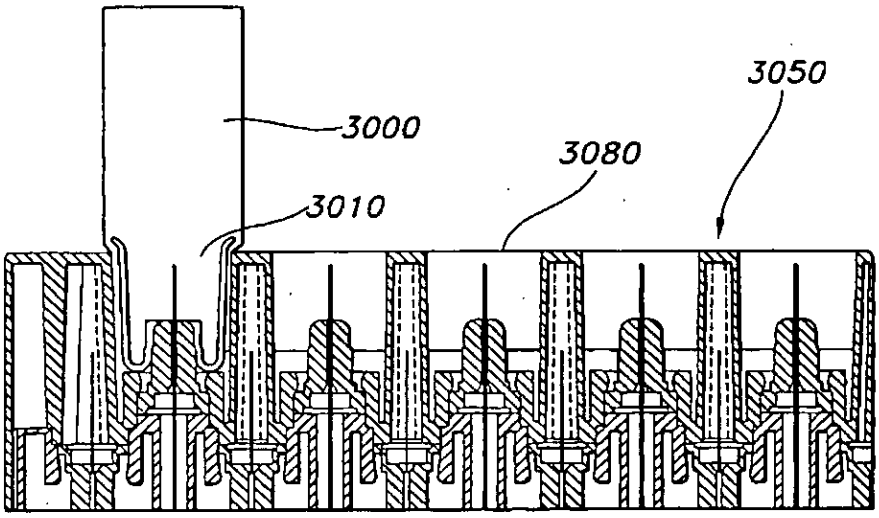

FIG. 8

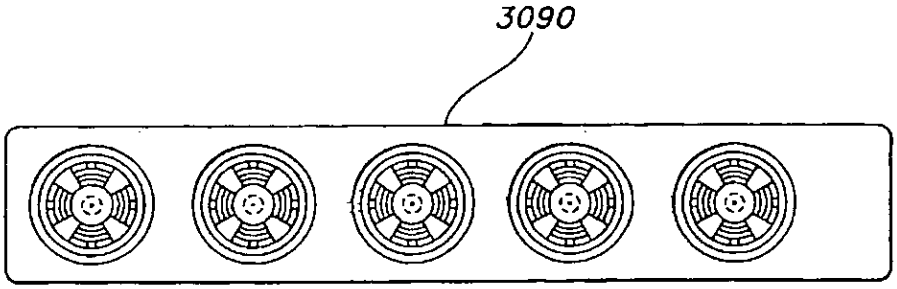

FIG. 9