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(71) Applicant: **NOVO NORDISK A/S** [DK/DK]; Novo Allé,
DK-2880 Bagsværd (DK).

(72) Inventors: **GROTH, Lars, Mørch**; Kovangen 117,
DK-3480 Fredensborg (DK). **HVID, Niels**; Birkebo 3B,
DK-2950 Vedbæk (DK). **LARSEN, Carsten, Gerner**;
Skeltoftevej 4, st.tv., DK-2800 Lyngby (DK).

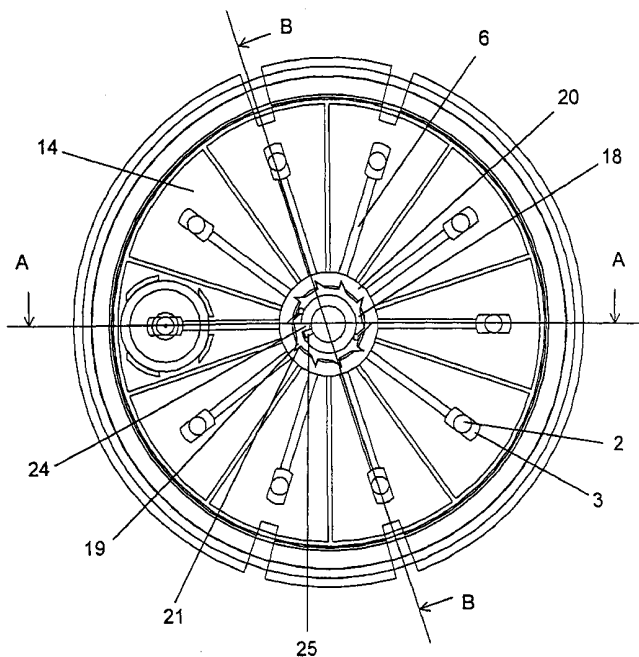
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(54) Title: A NEEDLE MAGAZINE



(57) **Abstract:** The system is a semi automatic needle magazine mounted on, or as a part of a medication delivery system. It comprises of a plurality of confinements each containing an injection needle. The needle magazine can be rotated in order to position one injection needle at the time in front of a cartridge located in the medication delivery system. Once the injection needle is located in front of the cartridge the needle magazine can be pushed towards the medication delivery system whereby the injection needle penetrates the septum of the cartridge.



WO 01/93927 A1

A needle magazine

The invention relates to a needle magazine for storing and dispensing a plurality of needle assemblies for use on an injection device.

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Medical injection devices are used to deliver selected doses of medication to patients. Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. In order to prevent infections it is recommended to use a sterile needle assembly for each injection. Needle assemblies are often delivered in magazines where each magazine contains only one needle assembly in a sterile compartment. Such a magazine is described in US patent 5.971.966. Using a needle assembly of this kind requires the patient to open the magazine and to fasten the needle assembly on to the injection device prior to each injection. The storage of sterile needle assemblies of this type and the final disposal of used needle assemblies present a problem, since new sterile needle assemblies are often carried loosely in purses or briefcases, and used needle assemblies are often disposed of unsafely.

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To overcome these problems a needle magazine for storage and dispensing a plurality of needle assemblies has been developed. This prior art magazine is shown in US patent 5.829.589 and is made up from a container having a plurality of confinements each containing a needle assembly. A cover is rotatably mounted on top of the container. When aligning a slot in the cover with the confinement, the user can access the confinement. The needle assembly is connected to the injection device by forcing the tip of the injection device into the confinement where the needle assembly is force fit, e.g. by a well-known luer-coupling, onto the tip of the injection device. The needle assembly can then be detached from the magazine. When the used needle is to be placed in the magazine the user has to conduct the same procedure again.

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The prior art magazine is attached to the injection device by fitting the entire magazine into an open end of the removable cap of a pencil-shaped injection device. Due to the dimensions of a pencil-shaped injection device only five needle assemblies can be contained in the magazine. An ordinary disposable injection device usually contains 300 IU of insulin. For many diabetes patients this is sufficient for 10 to 20 injections, therefore one magazine of needle assemblies are not enough for the lifetime of one disposable injection device, which is very inconvenient.

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For sight-impaired people it is difficult to see the location of the slot in the cover into which the tip of the injection device has to be placed, making the person holding the magazine vulnerable to accidental needle-stick injuries.

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It is also somewhat difficult to use the prior art magazine since it requires the ability to push forward the injection device and to rotate it. This is especially difficult for elderly people with limited strength and reduced mobility of the hands. In general it is difficult for most people to handle the small needles of the prior art magazine.

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It is an object of the present invention to provide a needle magazine for storing and dispensing a plurality of needle assemblies by which a great number of needle assemblies can be contained in the magazine and which magazine overcomes the inconveniences of the prior art magazines.

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It is further an object of the present invention to provide a needle magazine for storing and dispensing a plurality of needle assemblies, and by which there are no or only limited risk of accidental needle-stick injuries.

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Finally it is the object of the present invention to provide a needle magazine where the needle assemblies can be positioned onto the injection device in a simple and easy manner making it suitable for sight-impaired people and for people with only limited physical strength or motoricity.

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This is obtained by a needle magazine for storing and dispensing a plurality of needle assemblies for use on an injection device having a housing accommodating a cartridge containing medicine for a number of dosed injections and which needle magazine can be carried on the injection device, which needle magazine comprises;

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a plurality of confinements each containing a needle assembly having a first distal end, which is sharpened for piercing the skin of the user and an opposite proximal end and a side wall there between, which confinements each has a first distal surface and an opposite proximal surface,

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a shell connecting the confinements side by side, and

means for supporting each needle assembly in an upright position, having the first distal end pointing towards the first distal surface and the opposite proximal end pointing towards the opposite proximal surface,

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Which needle magazine according to the invention is Characterized in that

the shell can be rotated in order to index the needle assemblies and to position one of the needle assemblies above the cartridge, and that

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the shell can be activated for bringing the proximal end of the positioned needle assembly into contact with the cartridge, and the distal end of the needle assembly into a position where the distal end of the needle assembly is located outside the magazine, whereby the medicine can be injected.

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The needle assemblies in the needle magazine are confined in separate, sterile confinements. These confinements are connected in a side-by-side relation. In use one needle assembly is positioned above the cartridge containing the medicine to be expelled. When activating the shell, the shell impacts the hub of the needle assembly while the distal end of the needle unit passes through the distal surface of the confinement. At the same time the proximal end of the needle is forced to pass through the proximal surface of the confinement and further into the cartridge, where it pierces the elastomeric seal.

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After the injection is done the shell is brought back to the original position and can be rotated which brings the next needle assembly in position above the cartridge.

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The magazine can either be a loose part, which is connected to the injection device; in this case the entire magazine is disposed off when all the needle assemblies in the magazine are used. The magazine however could also be made as an integral part of the injection device, is this case the injection device including the needle magazine is disposed off when all the needle assemblies in the magazine is used, or when all the medicine contained in the cartridge is used.

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When, as disclosed in claim 2, the shell connecting the confinement can be shifted between a first position where the needle assembly is fully confined inside the confinement and a

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second position in which the positioned needle assembly penetrates the distal surface and the proximal surface, it is ensured that the sterile barrier is penetrated.

When, as disclosed in claim 3, the shell is shifted between the first position and the second
5 position by moving the shell towards the injection device, it is ensured that the magazine can be operated in a simple manner.

When, as disclosed in claim 4, the magazine has means locking the shell in the second position against the force of a spring, and that the means can be released whereby the shell
10 travels back into the first position under influence of the spring, it is ensured that the shell in an easy way can be shifted between the parked position and the injection position.

When, as disclosed in claim 5, the means supporting the needle assemblies in an upright position is either connected to a hub located on the side wall of each needle assembly inside
15 the confinement or supporting the hub from outside the confinement, it is ensured that the needle assemblies are held in the correct upright position at all times. The means can either be a number of arms provided on the shell as disclosed in claim 6, which arms is made up from several parts connected together through a number of film-hinges allowing the arm to flex as disclosed in claim 7, or the means for supporting the needle assemblies could, as
20 disclosed in claim 8, be a number of circular walls projecting from the shell

When, as disclosed in claim 9 the confinements is a plurality of cavities each having the form of a circular segment, which segments together forms a full circle, it is ensured that shell has a circular appearance. Each circular segment must be able to fit over the cartridge, when the
25 shell is pushed backward against the injection device prior to an injection.

When, as disclosed in claim 10 each confinement is a bag, and that a plurality of such bags each containing one needle assembly is connected together. Instead of dividing the shell into circular segments, the needle assemblies can be provided packed in sterile bags. These
30 bags are preferably connected together to form a string.

When, as disclosed in claim 11 the magazine has means preventing the shell from being rotated in one rotational direction, it is ensured that the shell cannot be rotated backwards in order to reuse the needle assemblies. The means preferably being a number of pawls lo-

cated on the housing of the magazine and which pawls engage a pawl wheel, preferably a star-shaped pawl wheel, on the interior surface of the shell.

When, as disclosed in claim 12 the magazine has means preventing the shell from rotating more than approximately 360 degrees, it is ensured that the shell is limited to one full rotation, thereby preventing reuse of the needle assemblies once the content of the magazine is used once. .

The invention will be explained more fully below in connection with a preferred embodiment and with reference to the drawings in which:

Figure 1 Shows a schematically top-view of the needle magazine according to the invention.

Figure 2 Shows a view along the line A-A in figure 1 with the shell in the parked position.

Figure 3 Shows a view along the line A-A in figure 1 with the shell in the injection position.

Figure 4 Shows a view along the line B-B in figure 1 with the shell in the injection position.

Figure 5 Shows a schematically top-view of the needle magazine according to another embodiment of the invention.

Figure 6 Shows a view along line C-C in figure 5 with the shell in the parking position.

Figure 7 Shows a view along the line C-C in figure 5 with the shell in the injection position.

Figure 8 Shows a view along the line D-D in figure 5 with the shell in the injection position.

The figures are schematic and simplified for clarity, and they just show details, which are essential to the understanding of the invention, while other details are left out. Throughout, the same reference numerals are used for identical or corresponding parts.

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Figure 1 shows a top-view of the needle magazine 1 according to the invention. Each needle assembly consist of a needle cannula 2 and a hub 3. Each hub 3 is connected to a circular wall 20 surrounding the centre-axis of the shell 5 through a thin arm 6, which arm is made flexible by a number of film-hinges 7.

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Figure 2 shows a view along line A-A in figure 1 with the shell 5 in the parked position. The magazine 1 is shown and explained as being integral with the injection device 8, which device 8 contains a cartridge 9, but the magazine 1 could as well be a loose part comprising a shell 5 and a housing, which housing then could be connected to the injection device 8 e.g. by a thread connection.

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The magazine is on the top covered by a cover 33 that snaps around the magazine 1. A, preferably helical, spring 11 is located in an enclosure 17 along the centre-axis of the injection device 8. This spring 11 urges the shell 5 in a direction away from the injection device 8, but is retained locked on to the injection device 8 by a circumferentially snap-coupling, made up by a hook-shaped part 12 formed in the shell 5 which is prevented from further forward movement by another hook-shaped part 13 provided in the injection device 8.

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Each needle assembly is captured in a sterile confinement 14, which has an upper surface 25 15 and a bottom surface 16. Both surfaces 15, 16 comprise of a sterile barrier e.g. a polymeric film, a metallic film or simply a paper sheet, which can be penetrated by the needle cannula 2 as later explained. Both the upper surface 15 and the bottom surface 16 can be composed of other materials, as long as the part of the surfaces 15, 16 located right below and right above the needle cannula 2 is made from a material which can easily be penetrated by the very thin needle cannula 2. The upper surface 15 of the shell 5 can be provided 30 with a hole 10 only allowing passage of the needle cannula 2. If so wanted the bottom surface can be provided with a similar hole allowing passage of the cartridge 9.

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The wall 18 surrounding the enclosure 17 has on the outside a somewhat star-shaped appearance with a number of peaks 19 equalling the number of needles 2. The shell 5 is around the centre-axis provided with a circular wall 20 fully surrounding the centre-axis. This wall 20 has an identical star-shaped appearance at least on a part of the inside surface with
5 a number of indentations 21 equalling, or being a product of, the number of needle assemblies. When the shell 5 is pushed towards the injection device 8 the star-shaped inner-surface of the circular wall 20 fits tightly over the outside surface of the wall 18. By making the peaks 19 and the indentations 21 parallel to the needle cannulas 2 and to the cartridge 9 in the longitudinal direction and on line with the needle cannulas 2 in the radial direction it is
10 ensured that the shell 5 can only be moved towards the injection device 8, when each needle cannula 2 are correctly located above the cartridge 9.

When the shell 5 is in the parked position as shown in figure 2 the peaks 19 of the injection device 8 and the indentations 21 of the shell 5 is disengaged from each other and the shell 5
15 can be rotated relatively to the injection device 8. On top of the enclosure 17 one or more pawls 22 is provided, which pawls engages the indentations 21 of the star-shaped inner-surface of the circular wall 20 of the shell 5, ensuring only one rotational direction of the shell 5 relatively to the wall 18, thereby avoiding reuse of the needle assemblies

20 The enclosure 17 is on top of the wall 18 closed by a rim 23 having a smaller diameter than the enclosure 17. A centrally located stud 26 provided on the shell 5 projects through this smaller diameter and into the enclosure 17. The stud 26 is inside the enclosure 17 provided with a protrusion 25. The injection device 8 is also provided with a similar protrusion 24, as shown in figure 1. These protrusions 24, 25 abut each other when the shell has been rotated
25 approximately 360 degrees, thereby preventing the user from reusing the used needle assemblies.

Figure 3 and figure 4 both shows the magazine 1 in the injection position. When the shell 5 is pushed towards the injection device 8, the distal part of the needle cannula 2 passes
30 through the upper surface 15, and the proximal part of the needle cannula 2 passes through the bottom surface 16 and further through the elastomeric barrier in the cartridge 9. When the shell 5 is pushed all the way back and the injection device 8 is ready for injection, the hook-shaped part 12 is arrested by a third hook-shaped part 27, which holds the shell 5 in the injection position until the shell is manually released.

In the injection position the arm 6 carrying the hub 3 is bended in the film-hinges 7, and the hub 3 is squeezed in between the cartridge 9 and the upper surface 15. The distal part of the needle cannula 2 projects through the hole 10 outside the boundaries of the shell 5 and the proximal end of the needle cannula 2 projects through the elastomeric barrier of the cartridge 9 and into the cartridge 9.

Releasing the shell 5 is done by pressing on the sidewalls 28 connecting the hook-shaped part 27 to the injection device 8. When released the spring 11 urges the shell back to the parked position shown in figure 2, where the hook-shaped part 12 is arrested by the hook-shaped part 13 provided in the injection device 8.

When the shell 5 is released after the injection and moves forward under influence of the spring, the needle cannula 2 is first retained in the cartridge 9 due to the friction between the elastomeric barrier of the cartridge 9 and the needle cannula 2. When the distal end of the needle cannula 2 is retracted into the magazine 1, the design of the film-hinges 7 prevents the needle cannula 2 from moving further backwards, and the needle assembly will end up located in the middle of the magazine 1, as shown in figure 2. Alternatively a stop preventing the needle cannula from moving backwards out of the shell 5 could be provided.

In the parked position, the shell 5 can be manually rotated until the next needle assembly is indexed above the cartridge 9. The correct position being when the next peak 19 drops into the next indentation 21. At the same time the pawl 22 prevents the shell 5 from being rotated backwards. Torsion means that rotates the shell 5 a few degrees when the shell 5 is released could be provided. This would render it impossible to use the same needle cannula 2 again, since the shell 5 and thereby the used needle cannula 2 cannot be rotated backwards.

When all the needle assemblies are used, the magazine 1 is disposed of. In the explained embodiment, where the needle magazine is integral with the injection device, both the injection device and the magazine is disposed off.

The embodiment of the invention shown in figures 5-8 works in the same way as previous described, and the same numerals are used for the same items. The only difference being the confinement containing the needle assemblies. In the embodiment shown in figure 5-8 each needle assembly is confined in a bag 29, having a sterile interior, which bag 29 is made

out of an impermeable material e.g. a polymeric material. A number of such bags 29 are connected together on a string 30. The string 30 connecting the bags 29 could be a separate string 30, as shown in figure 5, or the string 30 could be made up from the material forming the bags 29.

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The string 30 of bags 29 is supported by an inner wall 31 and an outer wall 32 provided on the inside surface of the shell 5. These two walls are located with a distance approximately equal to the diameter of the hub 3. In this way the hub 3 located inside the bag 29 is supported holding the needle cannula 2 in an upright position by the walls 31, 32.

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When the user moves the shell 5 back, as shown in figure 7-8, the distal end of needle cannula 2 penetrates through the distal end of the sterile bag 29 and further out through the distal end of the shell 5. At the same time the proximal end of the needle cannula 2 penetrates through the proximal end of the sterile bag 29 further through the elastomeric barrier of the cartridge 9 and into the cartridge 9.

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In the injection position the bag 29 is folded together and the hub 3 is squeezed between the cartridge 9 and the upper surface 15. The bag 29 is fastened to the hub 3 e.g. by welding. At the same time the bag 29 is secured to the shell 5 e.g. by having a part of the film from which the bag 29 is made secured in a recess 34 provided on the inside surface of the shell 5. A loose ring 35 could be forced into the recess 34 for securing the bag-material onto the shell 5.

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When the shell 5 is released after the injection and moves forward, the needle cannula 2 is first retained in the cartridge 9 due to friction between the elastomeric barrier of the cartridge 9 and the needle cannula 2. When the distal end of the needle cannula 2 is retracted into the magazine 1, the bag 29 both being secured to the shell 5 and to the hub 3 prevents the needle cannula 2 from moving further backwards, and the needle assembly will end up located in the middle of the magazine 1, as shown in figure 6.

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Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims.

Claims

1. A needle magazine for storing and dispensing a plurality of needle assemblies for use on
5 an injection device having a housing accommodating a cartridge containing medicine for a
number of dosed injections and which needle magazine can be carried on said injection de-
vice, said needle magazine comprising:

a plurality of confinements each containing a needle assembly having a first distal end,
10 which is sharpened for piercing the skin of the user and an opposite proximal end and a side
wall there between, said confinements each having a first distal surface and an opposite
proximal surface,

a shell connecting said confinements side by side, and
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means for supporting each needle assembly in an upright position, having said first distal
end pointing towards said first distal surface and said opposite proximal end pointing towards
said opposite proximal surface,

20 Characterized in that

Said shell can be rotated in order to index said needle assemblies and to position one of said
needle assemblies above said cartridge, and that

25 said shell can be activated for bringing said proximal end of said positioned needle assembly
into contact with said cartridge, and said distal end of said needle assembly into a position
where said distal end of said needle assembly is located outside said magazine, whereby
said medicine can be injected.

30 2. A needle magazine according to claim 1, characterized in that said shell connecting said
confinement can be shifted between a first position where said needle assembly is fully con-
fined inside said confinement and a second position in which said positioned needle assem-
bly penetrates said distal surface and said proximal surface.

3. A needle magazine according to claim 2, characterized in that said shell is shifted between said first position and said second position by moving said shell towards said injection device.

5 4. A needle magazine according to claim 3, characterized in that said magazine has means locking said shell in said second position against the force of a spring, and that said means can be released whereby the shell travels back into said first position under influence of said spring.

10 5. A needle magazine according to anyone of the claims 1-4, characterized in that said means supporting said needle assemblies in an upright position is either connected to a hub located on said side wall of each needle assembly inside said confinement or supporting said hub from outside said confinement.

15 6. A needle magazine according to claim 5, characterized in that said means for supporting said needle assemblies is a number of arms provided on said shell.

7. A needle magazine according to claim 6, characterized in that said arms is made up from several parts connected together through a number of film-hinges allowing said arm to flex.

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8. A needle magazine according to claim 5, characterized in that said means for supporting said needle assemblies is a number of circular walls projecting from said shell.

9. A needle magazine according to anyone of the claims 1-7, characterized in that said confinements is a plurality of cavities each having the form of a circular segment, which segments together forms a full circle.

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10. A needle magazine according to anyone of the claims 1-8, characterized in that each confinement is a bag, and that a plurality of such bags each containing one needle assembly is connected together.

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11. A needle magazine according to anyone of the preceding claims, characterized in that said magazine has means preventing said shell from being rotated in one rotational direction.

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12 A needle magazine according to anyone of the preceding claims, characterized in that said magazine has means preventing said shell from rotating more than approximately 360 degrees.

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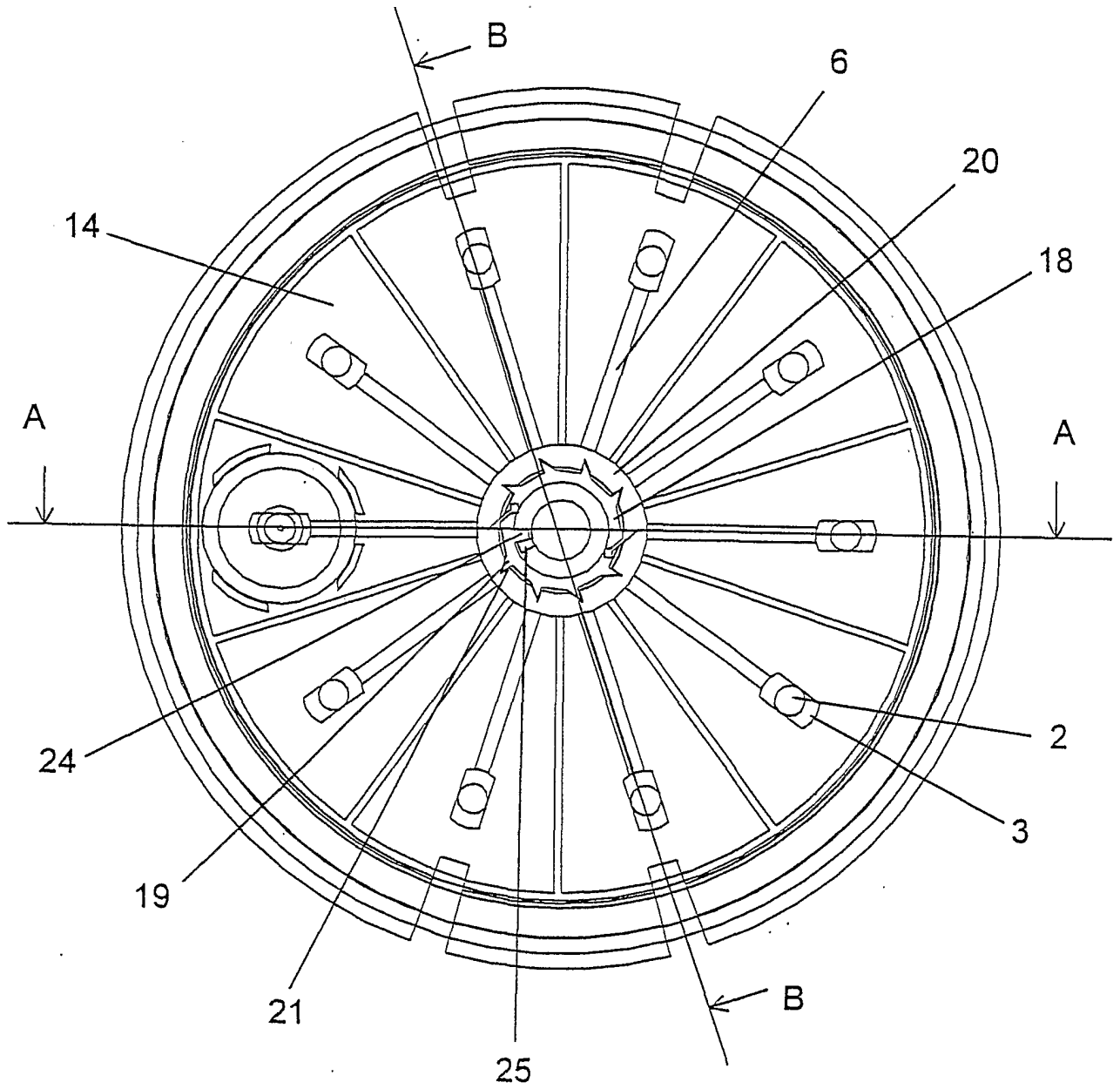


Fig. 1

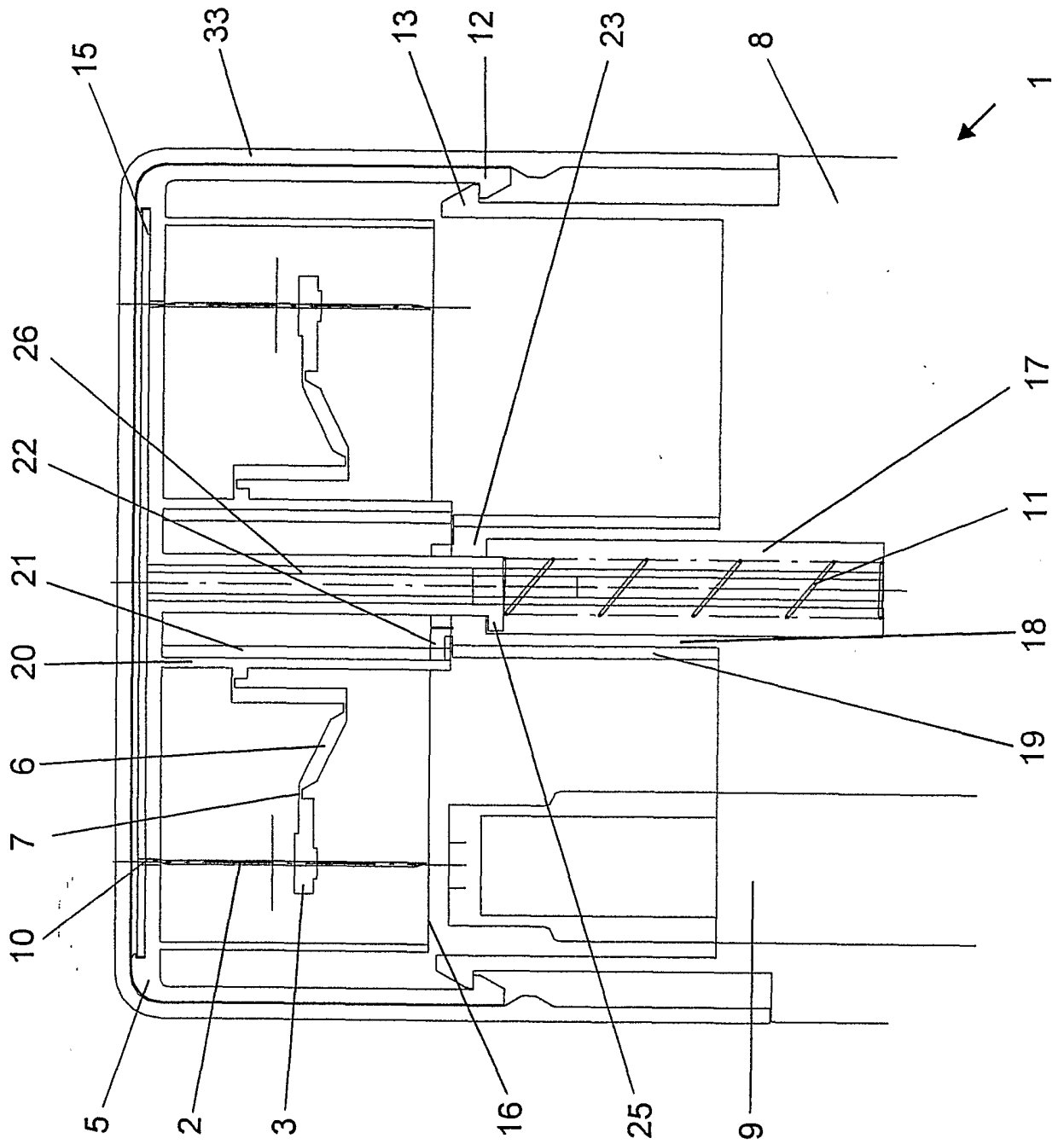


Fig. 2

3/6

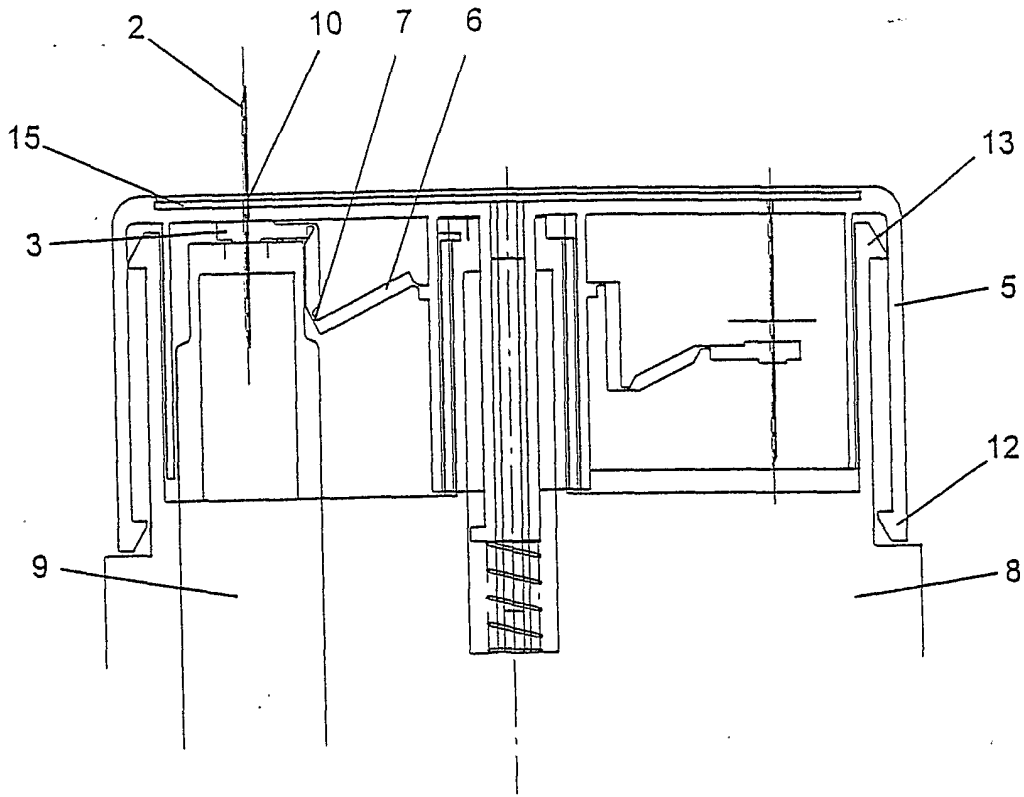


Fig. 3

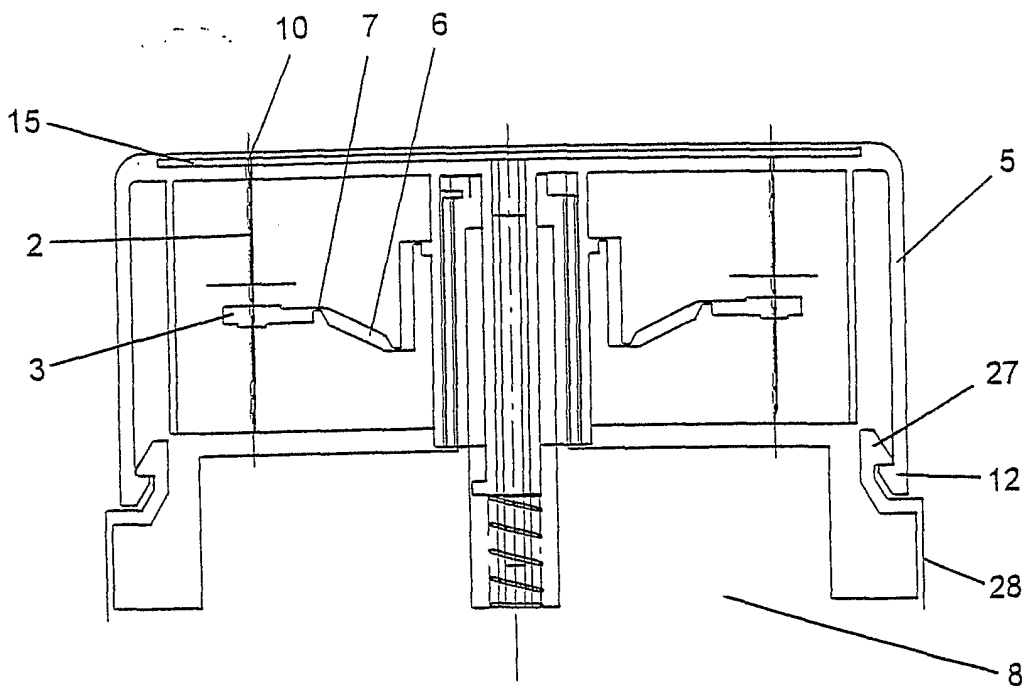


Fig. 4

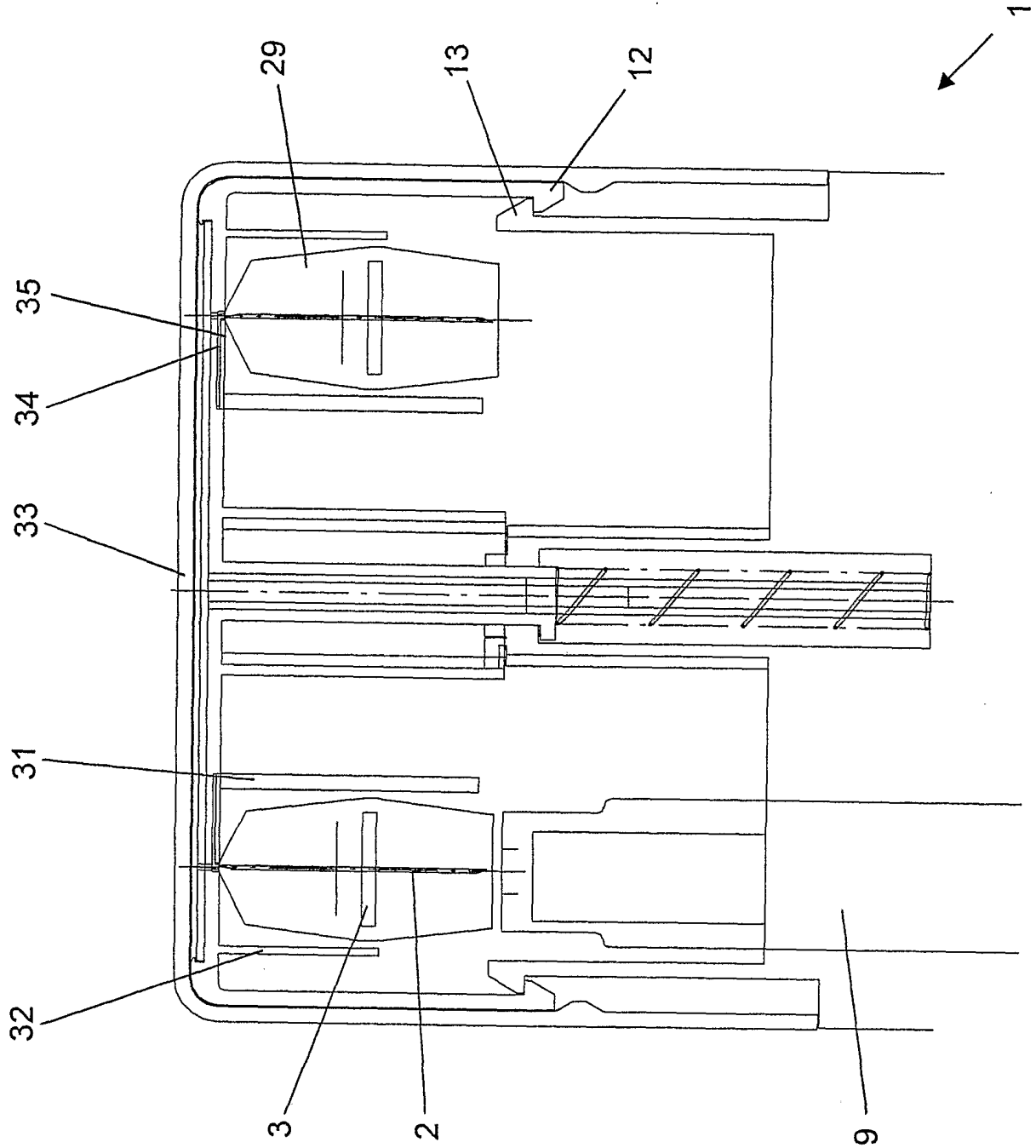


Fig. 6

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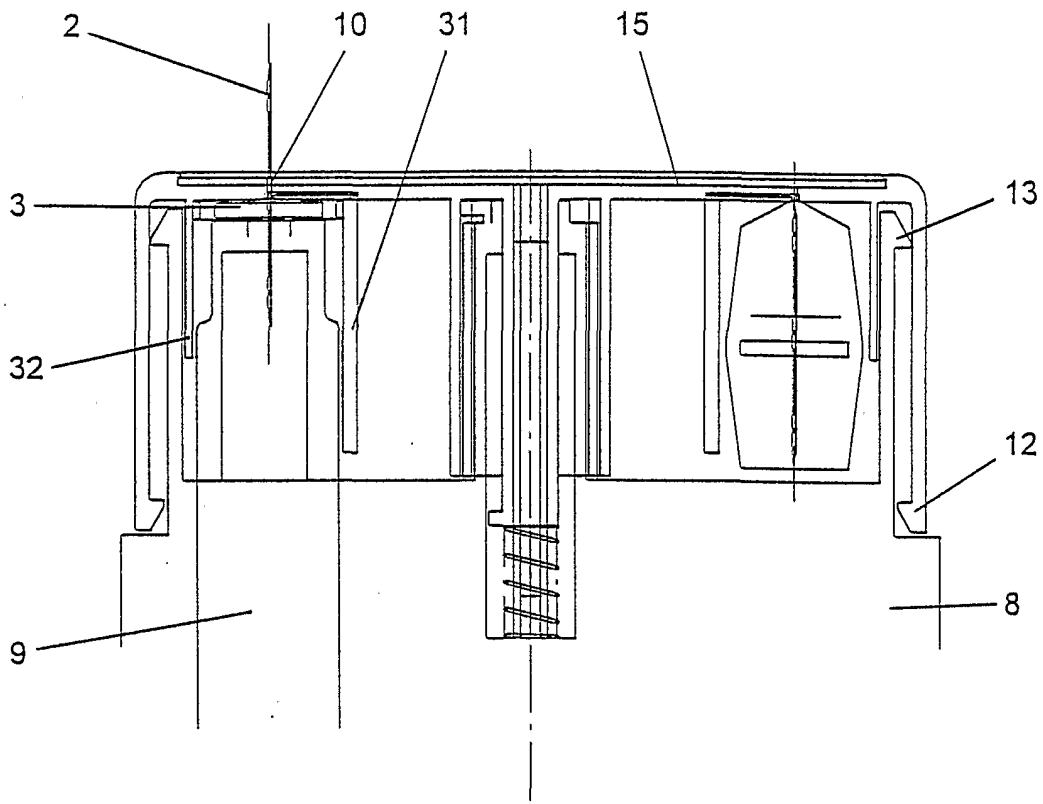


Fig. 7

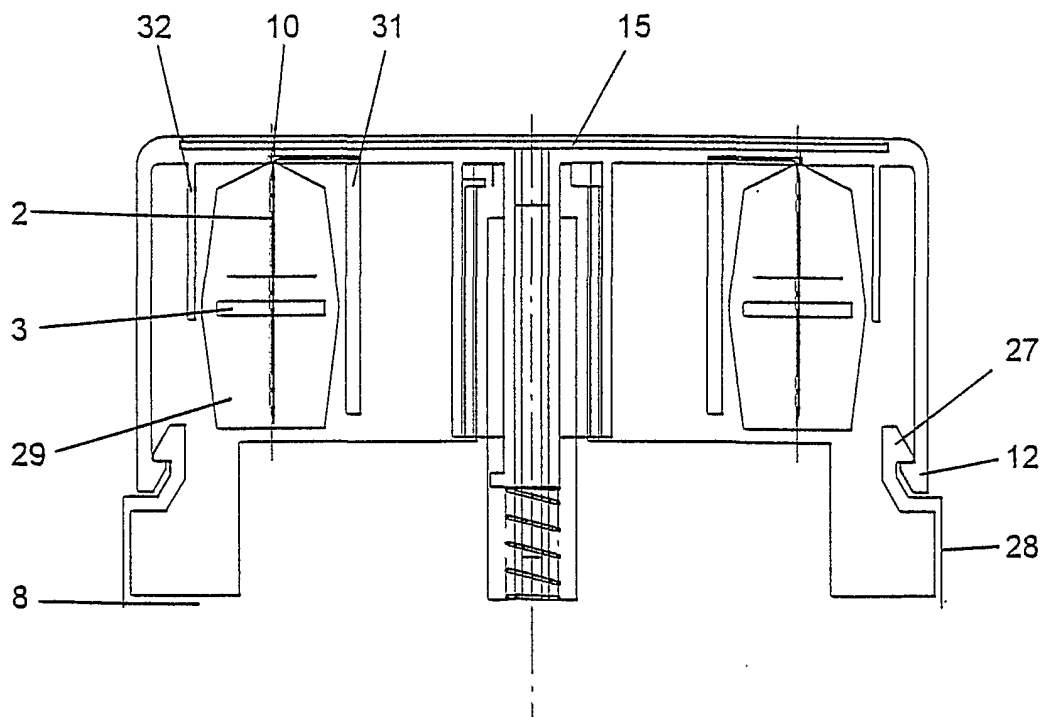


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 01/00334

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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 Further documents are listed in the continuation of Box C.
 See patent family annex.

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| Date of the actual completion of the international search 28 August 2001 | Date of mailing of the international search report 24. 09. 2001 |
| Name and mailing address of the International Searching Authority European Patent Office P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel(+31-70)340-2040, Tx 31 651 epo.nl, | Authorized officer JACK HEDLUND/E1s Telephone No. |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/DK 01/00334

| Patent document cited in search report | | | Publication date | Patent family member(s) | | | Publication date |
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