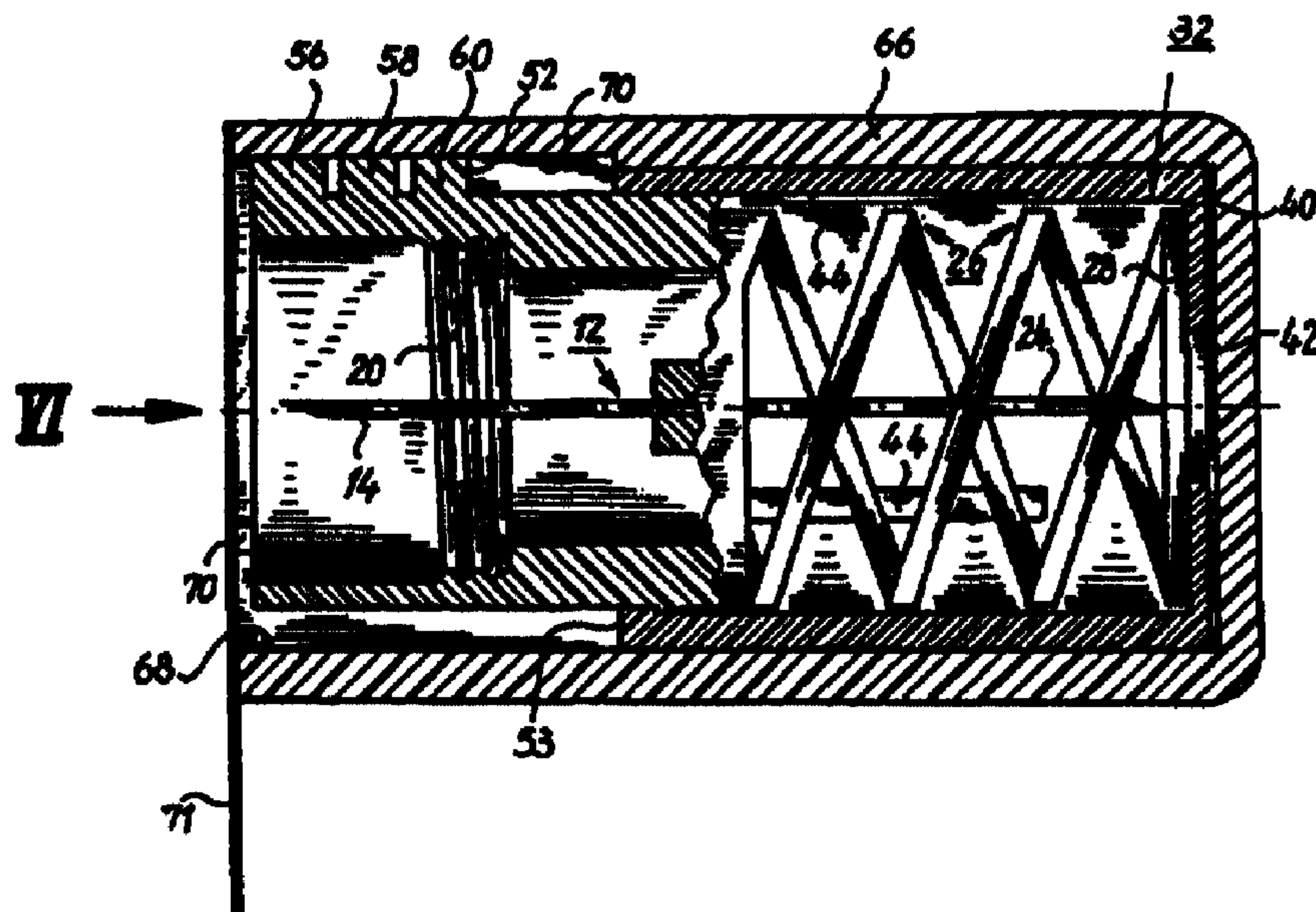


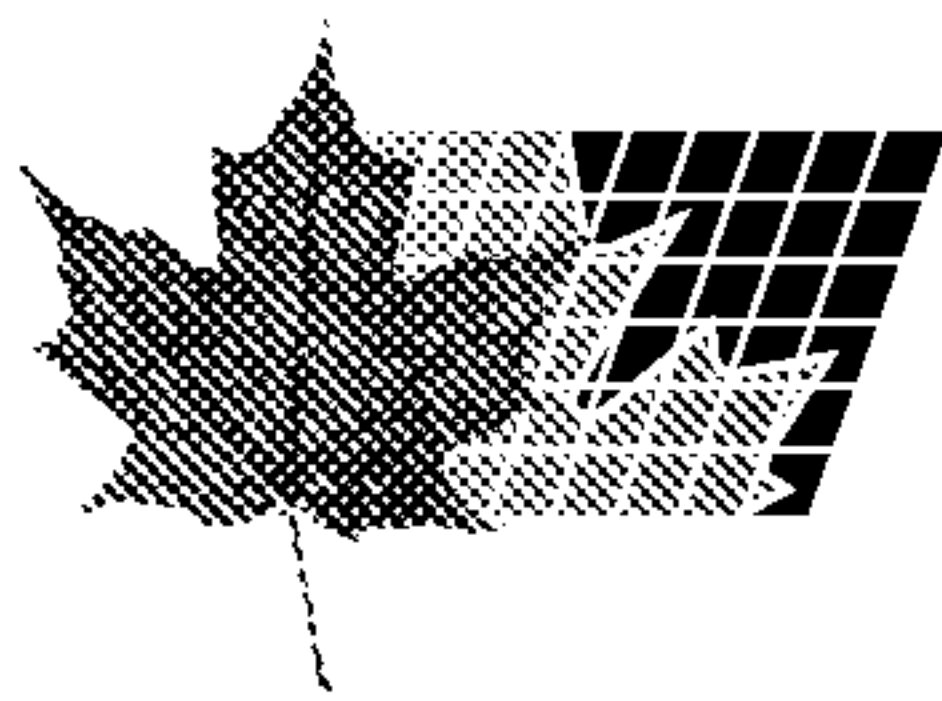
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(54) **CONFIGURATION D'AIGUILLE**
(54) **NEEDLE ARRANGEMENT**



(57) L'invention concerne une configuration d'aiguille destinée à un dispositif d'injection (16). Cette conception est caractérisée par un support (10) auquel est fixé une canule (12) et destiné à être fixé de façon amovible au dispositif d'injection (16). La configuration d'aiguille a un bouchon (32) qui s'enfonce sur le support (10) approximativement parallèlement à la longueur de la canule (12), qui est doté sur son extrémité proximale d'un trou (42) destiné à la canule (12) et qui, dans sa position finale proximale recouvre sensiblement la canule (12). Un ressort à pression (26) est placé entre le support (10) et le bouchon (32) pour faire coulisser le

(57) A needle arrangement for an injection device (16) has a cannula carrier (10) to which a cannula (12) is secured and which is designed to be removably secured to the injection device (16). The needle arrangement has a cap (32) which can slide on the cannula carrier (10) in an approximately parallel direction to the length of the cannula (12), is provided at its proximal end section with a through hole (42) for the cannula (12) and in its proximal end position covers the cannula (12). A pressure spring (26) is arranged between the cannula carrier (10) and the cap (32) for moving the cap (32) into its proximal end position. Also provided is a covering



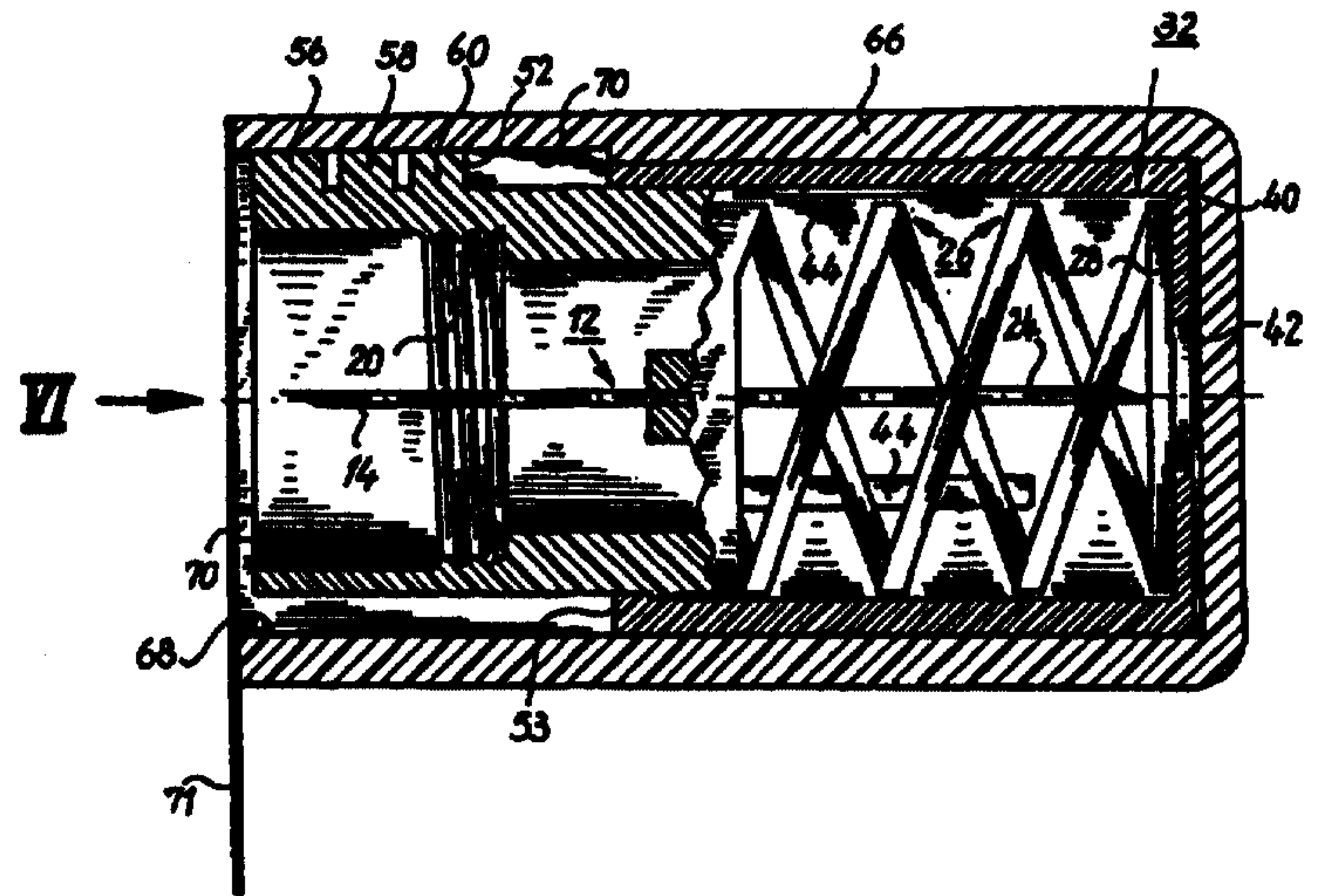
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bouchon (32) dans sa position finale proximale. En outre, un capuchon (66) englobe le bouchon (32) coulissant, la canule (12) et le support (10). Son côté ouvert est fermé de façon stérile par un organe de fermeture (71) que l'utilisateur peut enlever. Une telle configuration peut facilement être échangée après une injection et elle améliore la coopération du patient car ce dernier ne voit à aucun moment la canule (12). Le ressort à pression peut être conçu sous forme de ressort plastique (26) et est, de préférence, réalisé d'une seule pièce avec le support (10), ce qui simplifie la fabrication.

cap (66) which encloses the sliding cap (32), the cannula (12) and the cannula carrier (10), and is closed in a sterile manner by a closure member (71) which can be removed by a user from the open side of the covering cap (66). This needle arrangement can be easily replaced after an injection. It improves compliance because the patient never sees the cannula (12). The pressure spring can be designed as a plastic spring (26). It preferably forms a single piece with the cannula carrier (10), thus simplifying manufacture.

**PCT**WELTORGANISATION FÜR GEISTIGES EIGENTUM
Internationales BüroINTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE
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(21) Internationales Aktenzeichen: PCT/EP98/07230 (22) Internationales Anmeldedatum: 11. November 1998 (11.11.98) (30) Prioritätsdaten: 297 20 513.7 19. November 1997 (19.11.97) DE (71) Anmelder (für alle Bestimmungsstaaten ausser US): MEDICO DEVELOPMENT INVESTMENT COMPANY [CH/CH]; Via delle Scuole, 19, CH-6612 Ascona (CH). (72) Erfinder; und (75) Erfinder/Anmelder (nur für US): GABRIEL, Jochen [DE/DE]; Im Falkenrain 1, D-70192 Stuttgart (DE). POLZIN, Ulf [DE/DE]; Schulstrasse 42, D-70771 Leinfelden (DE). (74) Anwalt: RAIBLE, Hans; Schoderstrasse 10, D-70192 Stuttgart (DE).		(81) Bestimmungsstaaten: CA, JP, US, europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Veröffentlicht <i>Mit internationalem Recherchenbericht.</i> <i>Vor Ablauf der für Änderungen der Ansprüche zugelassenen Frist; Veröffentlichung wird wiederholt falls Änderungen eintreffen.</i>
(54) Title: NEEDLE ARRANGEMENT (54) Bezeichnung: NADELANORDNUNG (57) Abstract A needle arrangement for an injection device (16) has a cannula carrier (10) to which a cannula (12) is secured and which is designed to be removably secured to the injection device (16). The needle arrangement has a cap (32) which can slide on the cannula carrier (10) in an approximately parallel direction to the length of the cannula (12), is provided at its proximal end section with a through hole (42) for the cannula (12) and in its proximal end position covers the cannula (12). A pressure spring (26) is arranged between the cannula carrier (10) and the cap (32) for moving the cap (32) into its proximal end position. Also provided is a covering cap (66) which encloses the sliding cap (32), the cannula (12) and the cannula carrier (10), and is closed in a sterile manner by a closure member (71) which can be removed by a user from the open side of the covering cap (66). This needle arrangement can be easily replaced after an injection. It improves compliance because the patient never sees the cannula (12). The pressure spring can be designed as a plastic spring (26). It preferably forms a single piece with the cannula carrier (10), thus simplifying manufacture.		



NEEDLE ARRANGEMENT

The invention relates to a needle arrangement for an injection device.

A needle arrangement of this kind is known from EP 0 749 758 A1 or from DE-U1-8 909 799.8. In it, a hollow needle that is mounted on a hollow
5 needle holder is used. The latter is screwed onto an external thread at the proximal end of the injection device. A special apparatus which makes the hollow needle invisible to the user, so as to eliminate his or her anxiety regarding injections, is then slid over this hollow needle.

It is the object of the invention to make available a new needle
10 arrangement for an injection device.

According to the invention, this object is achieved by the subject matter of Claim 1.

A needle arrangement of this kind is very easy to utilize, since in practice it uses nothing more than a replaceable hollow needle. Easy adjustment of the
15 penetration depth is also achieved, since the necessary penetration depth may be different depending on the patient's constitution. Its adjustment is possible, in a simple manner, by adjustment of the stop element which cooperates with the distal end segment of the first cap.

Another manner of achieving the stated object is evident from the
20 subject matter of Claim 9.

A needle arrangement of this kind can very easily be kept sterile until used. The covering cap is usable as an assembly aid, additionally facilitating use by the patient. It is preferable to provide the removable closure element as a peelable foil, because that makes its use very simple and understandable.

25 A further manner of achieving the stated object is evident from the subject matter of claim 23. This represents an additional safety feature, since if the cap has fallen off or, due to improper handling, has been removed, the needle is still surrounded by the integrally formed plastic spring/needle carrier structure, which represents some protection, albeit reduced, against injury or
30 contamination from the needle, analogous to a cage surrounding the needle. This cage is not relied upon in the normal case, but rather represents a "second line of defense."

Each time the patient thrusts the hollow needle in, prior to an injection, the displaceable cap is displaced in the distal direction against the force of the

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spring, and when the hollow needle is pulled out it moves back into its proximal end position under the action of the spring, so that the patient does not see the hollow needle during the entire injection procedure. Because of the detachable mounting on the injection device, a needle arrangement of this kind can very easily be replaced, after an injection, with a new, sterile needle arrangement.

Further details and advantageous developments of the invention are evident from the exemplary embodiment, which is described below and depicted in the drawings and is in no way to be understood as a limitation of the invention, and from the dependent claims. In the drawings:

- FIG. 1 is a longitudinal section through a preferred embodiment of a needle arrangement according to the present invention, in an exploded and greatly magnified depiction;
- FIG. 2 shows a view similar to that of FIG. 1 but in the assembled state, the hollow needle being concealed by the arrangement;
- FIG. 3 shows a view similar to that of FIG. 2 but with the needle thrust in, the penetration depth being labeled D;
- FIG. 4 shows a view similar to that of FIG. 2, additionally depicting an outer covering cap 66 which serves to encase the needle arrangement in sterile fashion;
- FIG. 5 shows a view of a complete, packaged needle arrangement according to a preferred embodiment of the invention;
- FIG. 6 is a plan view looking in the direction of arrow VI of FIG. 5;
- FIG. 7 is a view showing the adjustment of the penetration depth by way of the external covering cap 66;
- FIG. 8 is a sectional view along line A-A of FIG. 7;
- FIG. 9 is a sectional view along line B-B of FIG. 7; and
- FIG. 10 is a sectional view through a defined breakpoint for a stop element, viewed along line C-C of FIG. 7.

In the description that follows, the terms "proximal" and "distal" will be used in the manner usual in medicine, to wit:

"proximal" = facing toward the patient (the end of the injection device having the needle);

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"distal" = facing away from the patient.

FIG. 1 shows, on the left, a hollow needle carrier 10 made of a suitable plastic, e.g. polyethylene. Secured in this is a hollow needle (injection needle) 12 whose distal end 14 serves to pierce through the rubber membrane (not depicted) on the reservoir of an injection device 16 that is indicated only schematically in FIGS. 2 and 3.

An inner thread 20 of hollow needle 10, which is delimited in the proximal direction by a shoulder 22 serving as a stop, provides detachable mounting on an external thread 18 at the proximal end of injection device 16.

The proximal segment of hollow needle 12 is labeled 24. Extending concentrically around it, in the arrangement as shown in FIG. 1, is a plastic spring 26 that can be configured integrally with hollow needle carrier 10 and that here comprises two helical springs or spirals 26a, 26b, offset 180°, which each transition at their proximal end into a ring 28 with which they can also be integrally configured. Alternatively a separate spring, for example made of metal, could also be used here.

A first sleeve or cap 32 has a substantially cylindrical segment 34 whose cylindrical outer side is labeled 33 and whose cylindrical inner side 35 is configured for sliding displacement on the also cylindrical circumference 36 of hollow needle carrier 10. First cap 32 furthermore has at its proximal end a base 40 in whose center is located a recess 42 through which proximal end 24 of hollow needle 12 can pass during an injection, as shown in FIG. 3.

First cap 32 has on its inner side 35 a total of three longitudinal grooves 44, only two of which are visible in FIG. 1, uniformly distributed on the circumference and providing axial guidance, i.e. rotation prevention. They coact with three projections 45, complementary thereto, on the cylindrical outer circumference 36 of hollow needle carrier 10, as clearly shown by FIGS. 2 and 3.

First cap 32 furthermore has three barbs 46 on its inner circumference 35. These barbs are also uniformly distributed on the circumference, and coact with three corresponding complementary barbs 48

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on outer circumference 36 of hollow needle 10, only one of which is visible in FIG. 1. During assembly, barbs 46 slide over barbs 48 so that parts 10 and 32 are joined to one another nondetachably but axially displaceably; barbs 46, 48 form a stop in the proximal direction, as depicted in FIG. 2, and grooves 44 coact with the complementary projections 45 to provide rotation prevention for first cap 32, so that the latter cannot rotate relative to hollow needle carrier 10.

As clearly shown in FIGS. 1 through 3, there is located on outer circumference 36 of hollow needle carrier 10 a stop arrangement 50 against whose proximal shoulder 52 (as shown in FIG. 3) first cap 32 comes to rest with its distal end 53 when hollow needle 12 is thrust with its proximal end 24 into a body part 54 (indicated only schematically).

Stop arrangement 50 has here a distal stop element 56, a central stop element 58, and a proximal stop element 60. At least proximal stop element 60 and central stop element 58 are each joined integrally to hollow needle carrier 10 by way of a defined break point 76 (FIG. 10), and consequently can be broken off from hollow needle carrier 10 by the user. This increases insertion depth D (FIG. 3) of the proximal hollow needle portion 24. Thus either it is possible to break off only stop element 60, so that first cap 32 then comes to rest against a shoulder 61 when hollow needle 12 is thrust in; or both stop elements 58 and 60 can be broken off, in which case first cap 32 then comes to rest against a shoulder 62 when hollow needle 12 is thrust in. In the latter case, the maximum penetration depth is attained.

FIG. 4 shows, at left, hollow needle carrier 10 on whose circumference stop elements 56, 58, 60 and 56, 58', 60, 56", etc. are arranged at uniform spacings of 120°. FIG. 6 shows the three stop elements 56, 56', and 56" in a plan view according to arrow VI of FIG. 5.

FIG. 4 shows that an outer covering cap 66, which provides sterile covering of the needle arrangement, is also provided. Outer covering cap 66 is depicted in FIG. 4 partially in longitudinal section, and it is evident that its cylindrical inner recess 68, which in the case of the complete needle arrangement shown in FIGS. 5 and 6 is slid over the cylindrical outer side

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33 of first cap 32, has three longitudinal grooves 70 which are distributed uniformly on the circumference of inner recess 68 and are dimensioned such that they can be slid over stop elements 56, 58, 60, 56', 58', 60', 56" etc., as is particularly clearly evident from FIG. 6.

FIG. 5 also shows a protective film 71 with which, in the complete needle arrangement, the opening (FIG. 5, left) of outer covering cap 66 can be sealed in sterile fashion. This film is welded on or adhesively bonded on, and is torn off before use. Film 71 is not depicted in FIG. 6.

FIG. 7 shows how outer covering cap 66 can be slid axially onto first cap 32 in the direction of arrow 72, arriving at a position 66' which is indicated in FIG. 7 with dot-dash lines and is depicted in section in FIG. 8, and in which its longitudinal grooves 70 are in engagement with stop elements 60, 60', 60". If outer covering cap 66 is then rotated in the direction of rotation arrow 74 depicted in FIG. 7, stop elements 60, 60', 60" are broken off along their defined break points 76 (cf. FIG. 10), i.e. penetration depth D (FIG. 3) is correspondingly increased in the manner already described above. In the same manner, it is also possible to break off both stop elements 58, 60 (correspondingly 58', 60', etc.), and thereby to increase penetration depth D even further.

What is described is thus a needle arrangement for an injection device 16. It has a hollow needle carrier 10 on which a hollow needle 12 is mounted and which is configured for detachable mounting on injection device 16. The arrangement has a cap 32 that is arranged on hollow needle carrier 10 displaceably approximately parallel to the longitudinal extension of hollow needle 12, is equipped at its proximal end segment with a passthrough opening 42 for hollow needle 12, and in its proximal end position substantially conceals hollow needle 12. A compression spring 26 is arranged between hollow needle carrier 10 and cap 32 in order to displace cap 32 into its proximal end position. Also provided is a covering cap 66 which surrounds the displaceable cap 32, hollow needle 12, and hollow needle carrier 10, and on its open side is sealed in sterile fashion by a tear-off sealing member 71. A needle arrangement of this kind can easily be replaced after an injection. It improves compliance because the patient

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does not at any time see hollow needle 12. The compression spring can be configured as plastic spring 26. It is preferably integral with hollow needle carrier 10, which simplifies manufacture.

Many other variants and modifications are, of course, also possible within the scope of the present invention.

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CLAIMS

1 1. A needle arrangement for an injection device (16), having a hollow
2 needle carrier (10) on which a hollow needle (12) is mounted and which is
3 configured for mounting on an injection device (16); having a first cap (32)
4 which is arranged on the hollow needle carrier (10) and displaceably
5 approximately parallel to the longitudinal extension of the hollow needle (12)
6 between a distal and a proximal end position, is equipped at its proximal end
7 segment with a passthrough opening (42) for the hollow needle (12), and in
8 its proximal end position substantially conceals the hollow needle (12);
9 having a compression spring (26), arranged between the hollow needle
10 carrier (10) and the first cap (32), for displacing the first cap (32) into its
11 proximal end position; and having a stop (58, 60, 58', 60'), provided on the
12 outer side (36) of the hollow needle carrier (10) for the distal end position of
13 the first cap (32), which coacts with a distal end segment (53) of the first
14 cap (32) and determines the penetration depth (D) of the hollow needle (12)
15 said stop (56, 58, 60, 56', 58', 60') being of adjustable configuration.

1 2. The needle arrangement as defined in Claim 1, in which a covering
2 cap (66) which substantially surrounds the outer circumference (35) of the
3 first cap (32) is provided as a second cap.

1 3. The needle arrangement as defined in Claim 2, in which the covering
2 cap (66) can be slid onto the first cap (32).

1 4. The needle arrangement as defined in Claim 1 or 2, in which the
2 covering cap (66) extends over the hollow needle carrier (10); and a rotation
3 preventer is provided between it and the hollow needle carrier (10).

1 5. The needle arrangement as defined in Claim 4, in which the rotation
2 preventer (60, 70) has a longitudinal groove (70) which is provided on the
3 covering cap (66) or the hollow needle carrier (10), and a complementary

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4 projection (60) engaging thereto which is provided on the corresponding
5 mating part, i.e. on the hollow needle carrier or covering cap.

1 6. The needle arrangement as defined in one or more of Claims 2
2 through 5, in which the covering cap (66) is sealed in sterile fashion on its
3 open side by a tear-off sealing member (71).

1 7. The needle arrangement as defined in one or more of Claims 2
2 through 6, in which the covering cap (66) is configured to influence a stop
3 (58, 60, 58', 60'), provided on the outer side (36) of the hollow needle
4 carrier (10) in order to adjust the penetration depth (D).

1 8. The needle arrangement as defined in Claim 7, in which the stop
2 (58, 60, 58', 60') provided on the outer side (36) of the hollow needle
3 carrier (10) has at least one stop element (58, 60) which is mounted on the
4 hollow needle carrier (10) via a defined break point (76) which can be
5 broken off by way of a rotary motion (74) of the covering cap (66, 66')
6 brought into engagement with said stop member.

1 9. A needle arrangement for an injection device (16), having a hollow
2 needle carrier (10) on which a hollow needle (12) is mounted and which is
3 configured for detachable mounting on the injection device (16); having a
4 first cap (32) arranged on the hollow needle carrier (10) displaceably
5 approximately parallel to the longitudinal extension of the hollow needle
6 (12), said cap being having at its proximal end segment a passthrough
7 opening (42) for the hollow needle (12) and in its proximal end position
8 substantially concealing the hollow needle (12); having a compression spring
9 (26), arranged between the hollow needle carrier (10) and displaceable first
10 cap (32), for displacing the first cap (32) into said proximal end position;
11 and having a second cap, configured as a covering cap (66), which
12 surrounds the displaceable first cap (32), the hollow needle, and the hollow
13 needle carrier (10), and which on its open side is sealed by a sealing
14 member (71) that is removable by the user.

1 10. The needle arrangement as defined in Claim 9, in which the sealing
2 member removable by the user is configured as a peelable film (71).

1 11. The needle arrangement as defined in one or more of the foregoing
2 claims, in which at least two stop elements (58, 60, 58', 60'), each joined
3 to the hollow needle carrier (10) via a defined break point (76), are provided
4 on the outer side (36) of the hollow needle carrier (10) to limit the distal
5 displacement of the first cap (32).

1 12. The needle arrangement as defined in Claims 9 and 11, in which the
2 covering cap (66) is configured so as to influence at least one stop element
3 (58, 60, 58', 60') of the stop provided on the outer side of the hollow
4 needle carrier (10) in order to adjust the penetration depth (D).

1 13. The needle arrangement as defined in Claim 12, in which the at
2 least one stop element (58, 60) of the stop provided on the outer side of
3 the hollow needle carrier (10) is mounted on the hollow needle carrier (10)
4 via a defined break point (76) which can be broken off by way of a rotary
5 motion (74) of the covering cap (66, 66') brought into engagement with
6 said stop member.

1 14. The needle arrangement as defined in one of Claims 11 through 13,
2 in which the defined break point (76) serves, after it breaks, as axial guide
3 for the displacement of the first cap (32) relative to the hollow needle carrier
4 (10).

1 15. The needle arrangement as defined in one or more of the foregoing
2 claims, in which the first cap (32) is arranged displaceably on a substantially
3 cylindrical circumferential surface (36) of the hollow needle carrier (10); and
4 a rotation preventer (44, 45) is provided which at least almost prevents any
5 rotation between the hollow needle carrier (10) and the first cap (32).

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1 16. The needle arrangement as defined in Claim 15, in which the
2 rotation preventer (44, 45) has at least one longitudinal groove (44) which
3 is provided on the first cap (32) or hollow needle carrier (10), and a
4 complementary projection (45) engaging thereinto which is provided on the
5 corresponding mating part, i.e. the hollow needle carrier or first cap.

1 17. The needle arrangement as defined in one or more of the foregoing
2 claims, in which the spring is configured as a plastic spring (26).

1 18. The needle arrangement as defined in Claim 17, in which the plastic
2 spring (26) is configured integrally with the hollow needle carrier (10).

1 19. The needle arrangement as defined in Claim 17 or 18, in which the
2 plastic spring (26) is equipped at its proximal end with a ring (28) which is
3 in contact against the first cap (32) and acts upon it in the proximal
4 direction.

1 20. The needle arrangement as defined in Claim 19, in which the ring
2 (28) is configured integrally with the plastic spring (26).

1 21. The needle arrangement as defined in one or more of Claims 17
2 through 20, in which the plastic spring (26) has two helical spring elements
3 (26a, 26b), each of which is configured integrally with the hollow needle
4 carrier (10).

1 22. The needle arrangement as defined in one or more of the foregoing
2 claims, in which an internal thread (20) is provided on the hollow needle
3 carrier (10) for mounting on an external thread (18) of an associated
4 injection device (16).

1 23. A needle arrangement for an injection device (16), having a hollow
2 needle carrier (10) on which a hollow needle (12) is mounted and which is
3 configured for detachable mounting on the injection device (16); having a

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4 cap (32) which is arranged on the hollow needle carrier (10) displaceably
5 approximately parallel to the longitudinal extension of the hollow needle
6 (12), has at its proximal end segment a passthrough opening (42) for the
7 hollow needle (12), and in its proximal end position substantially conceals
8 the hollow needle (12); having a compression spring (26), arranged between
9 the proximal side of the hollow needle carrier (10) and the displaceable cap
10 (32), for displacing said cap (32) into said proximal end position; said
11 compression spring being configured as an integral plastic spring (26) and,
12 in the relaxed state (FIG. 1), surrounding the hollow needle (12) in the
13 manner of a cage.

1 24. The needle arrangement as defined in Claim 23, in which the plastic
2 spring (26) is equipped at its proximal end with a ring (28) that rests against
3 the cap (32) and acts upon it in the proximal direction.

1 25. The needle arrangement as defined in Claim 24, in which the ring
2 (28) is configured integrally with the plastic spring (26).

1 26. The needle arrangement as defined in one or more of Claims 23
2 through 25, in which the plastic spring (26) has two helical spring elements
3 (26a, 26b), each of which is configured integrally with the hollow needle
4 carrier (10).

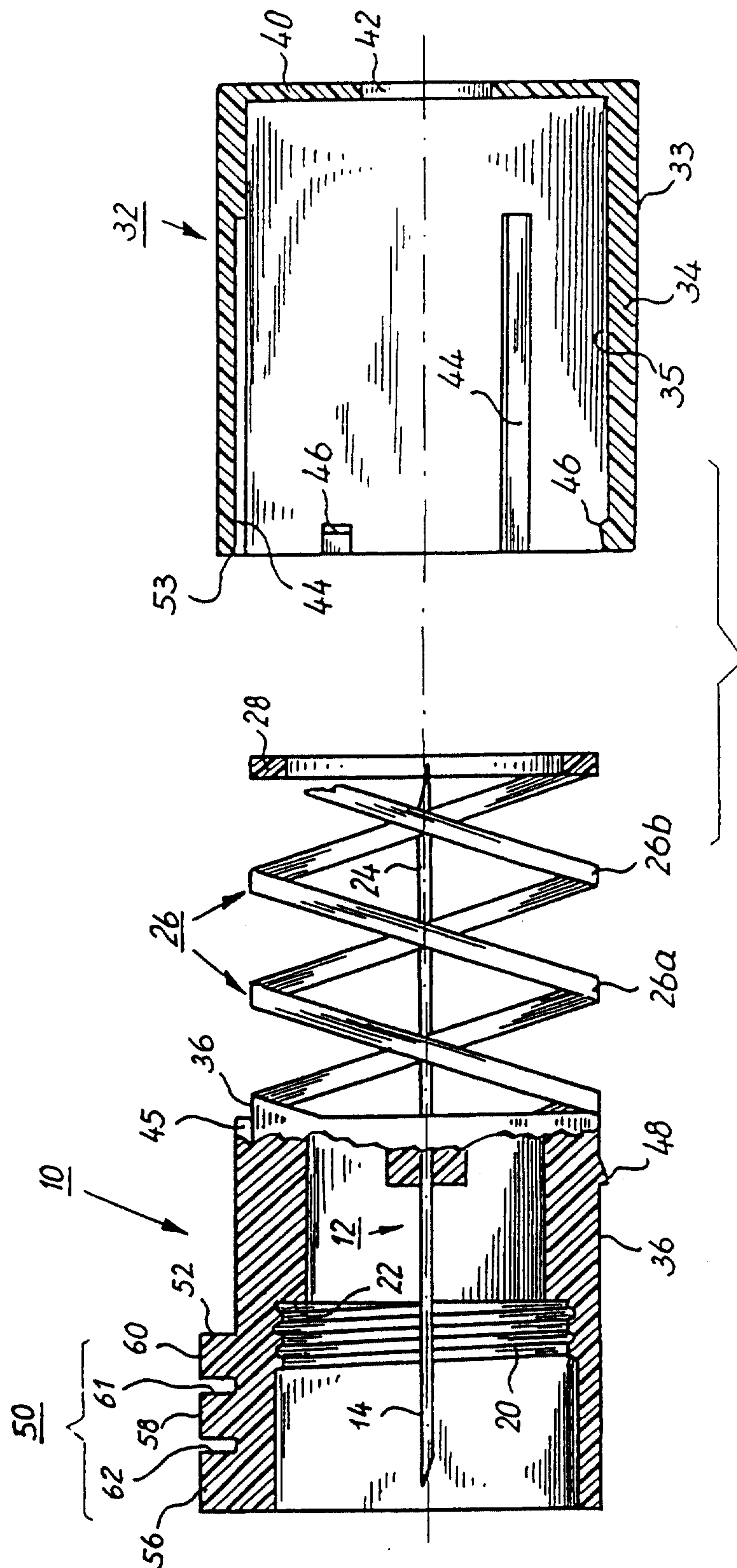
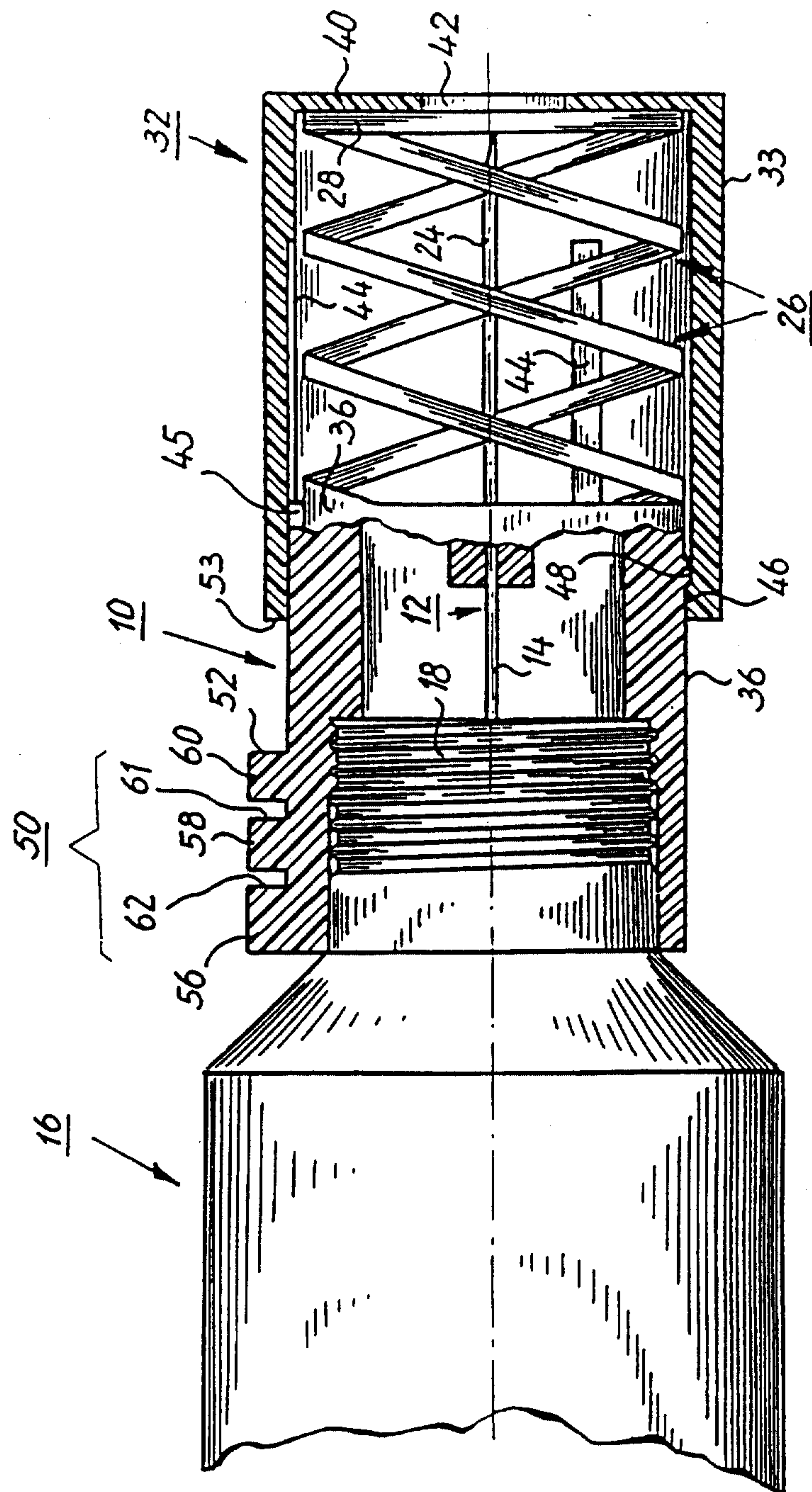
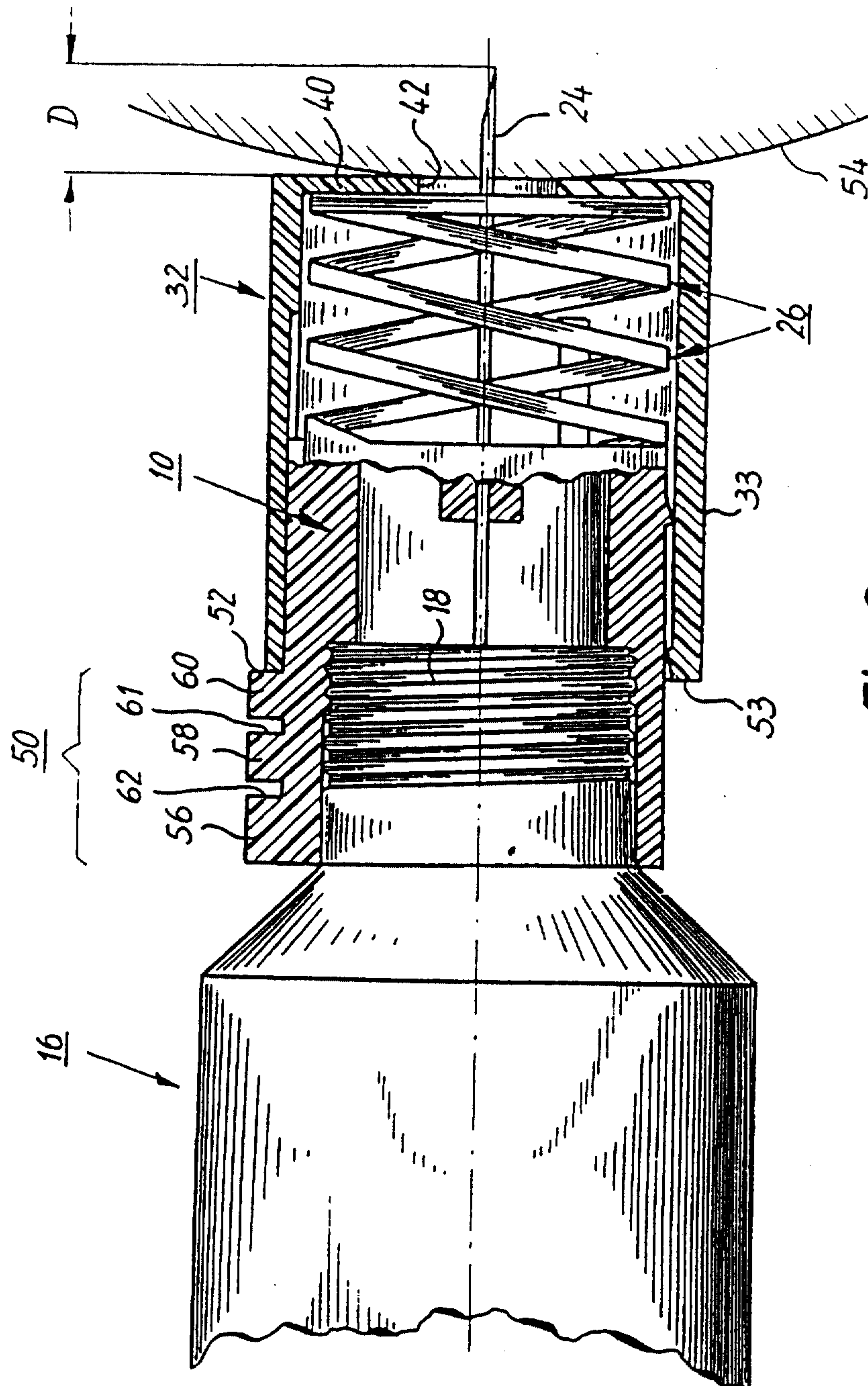


Fig. 1





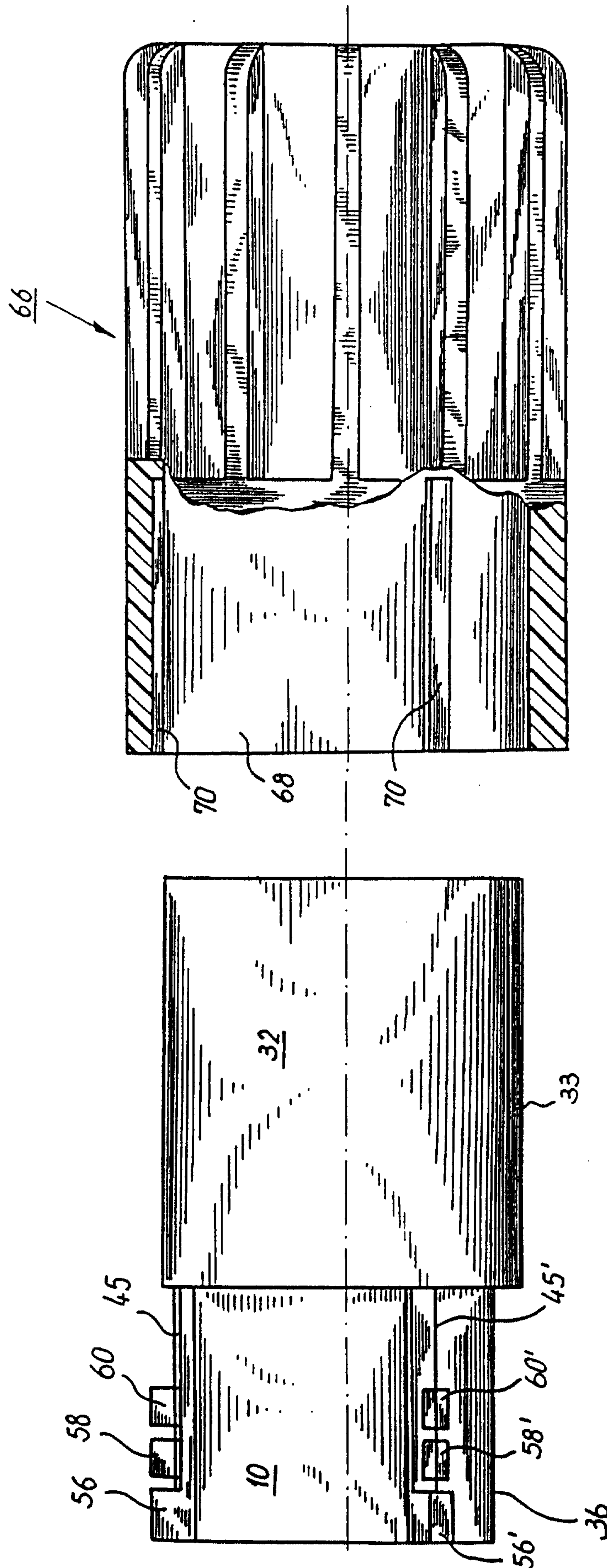


Fig. 4

