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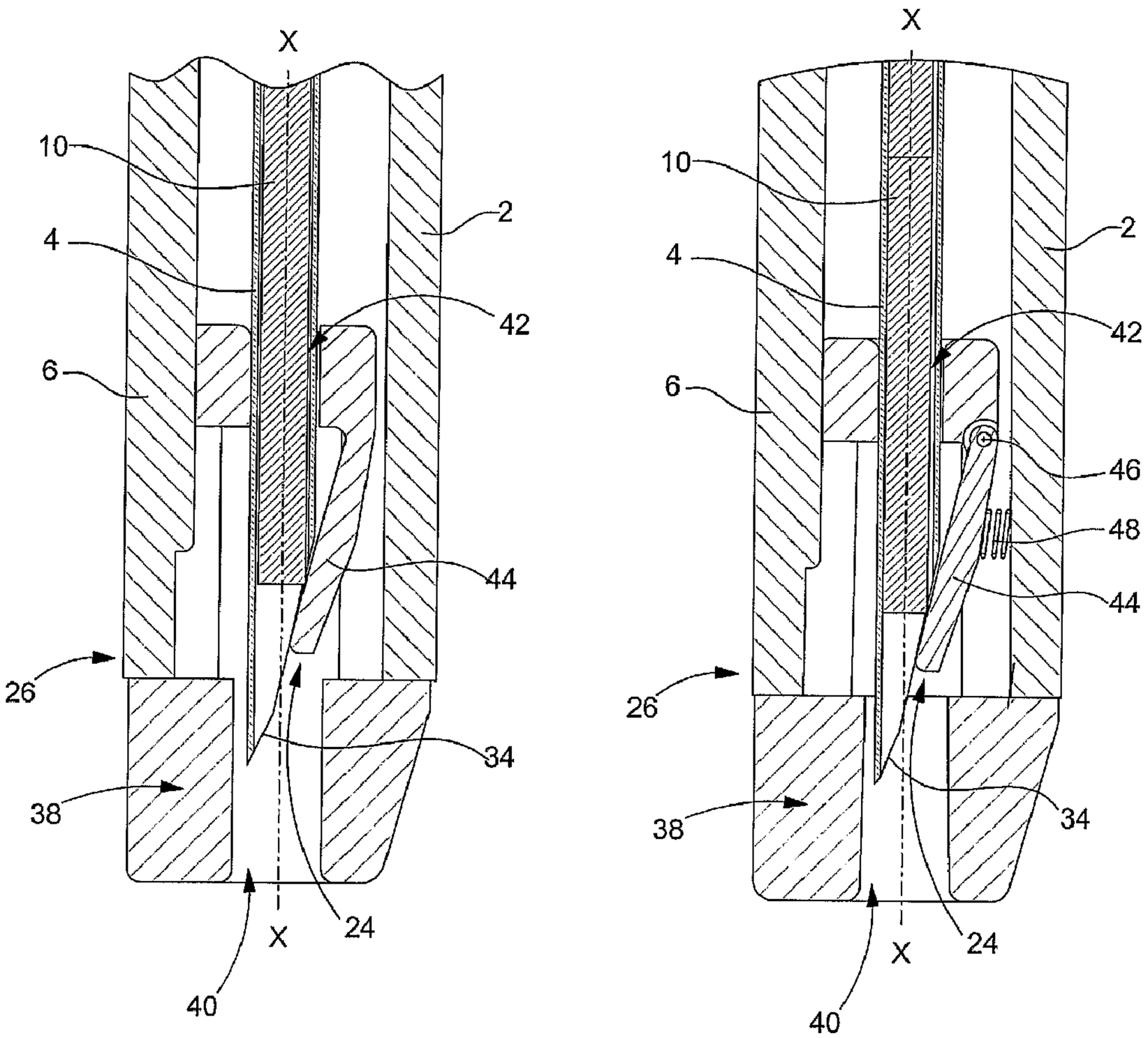
(54) Titre : DISPOSITIF POUR L'INJECTION D'UN PRINCIPE ACTIF PHARMACEUTIQUE
(54) Title: DEVICE FOR INJECTING A PHARMACEUTICAL ACTIVE PRINCIPLE



(57) Abrégé/Abstract:
The invention concerns a device for injecting a solid medicine (10) comprising a body (2) inside which moves along a general forward moving axis (X-X) a bevelled (34) needle (4) wherein is introduced the medicine (10), said injection device (1) further

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(57) Abrégé(suite)/Abstract(continued):
comprising retaining means for preventing the medicine from falling (10) prior to being injected. The invention is characterized in that the medicine (10) is retained through an elastic deformation imparted to the needle (4) by the retaining means or by an elastic deformation of the retaining means themselves, or still by the combined flexibility of those two means.

ABSTRACT

DEVICE FOR INJECTING A PHARMACEUTICAL ACTIVE PRINCIPLE

The invention concerns a device for injecting a solid medicine (10) comprising a body (2) inside which moves along a general forward moving axis (X-X) a bevelled (34) needle (4) wherein is introduced the medicine (10), said injection device (1) further comprising retaining means for preventing the medicine from falling (10) prior to being injected. The invention is characterized in that the medicine (10) is retained through an elastic deformation imparted to the needle (4) by the retaining means or by an elastic deformation of the retaining means themselves, or still by the combined flexibility of those two means.

Figures 2A, 3A

Case 2353 PCT
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DEVICE FOR INJECTING A PHARMACEUTICAL ACTIVE PRINCIPLE

The present invention concerns an injection device and, in particular, a device for the intramuscular or subcutaneous injection of an active pharmaceutical principle.

In numerous cases, the parenteral administration of active pharmaceutical principles may be preferred to oral absorption, particularly when the medicine to be administered partially or totally decomposes in the digestive system or when a rapid response of the organism is sought.

Parenteral administration of medical principles has, however, certain drawbacks. One of these drawbacks lies in the discomfort experienced by the patient to whom the active principle is being administered. Indeed, parenteral preparations generally take the form of a large volume of liquid in which the medicine is in suspension or dissolved. When the medicine is not very soluble or difficult to pass into suspension, or even when the active principle has to be administered in large doses, a relatively large volume of liquid has to be injected. The ratio between the active principle and the excipient is usually comprised between one percent and one per thousand. The discomfort experienced by the patient thus results both from the size of the needle and the volume of liquid to be injected. In some cases, the very nature of the excipient can also cause the patient suffering.

Another drawback of administering medicine dissolved or in suspension in a liquid medium lies in the fact that the medicine is often unstable in the liquid. The medicine and the liquid must thus be mixed shortly prior to the injection. This can prove particularly disadvantageous when, for example, hundreds of people have to be treated in a small period of time to wipe out an epidemic (administration of a vaccine).

In order to overcome the aforementioned drawbacks, medicines in solid rather than liquid form have been used in order to develop slow release or controlled release preparations. The preparation takes the form of an implant or a rod that is directly injected using a trocar. This type of implant has to enclose the daily dose of medicine multiplied by the number of days of activity, and the quantity of medium sufficient to control the speed of release of the medicine for the time period concerned. Consequently, these solid preparations for injection require a much larger needle than the needles ordinarily used with syringues, which leads to painful injections.

The security injection device disclosed in European Patent No. 0 783 342 overcomes this last drawback. It will be briefly described in conjunction with Figure 1 annexed to the present Patent Application, which is a cross-section of this type of injection device in the rest position thereof.

Designated as a whole by the general reference numeral 1, the injection device

shown in Figure 1 includes a body 2, which is fixed to a needle 4 via coupling means 6. A rod 8 is driven in translation inside needle 4 and is stopped against a dose 10 of medicinal substance arranged inside said needle 4. A hollow sheath 12 surrounds needle 4 such that the latter is not exposed prior to use. Rod 8 includes a raised portion 14, which limits the travel thereof in body 2. The body 2 includes a collar 16 for facilitating withdrawal of device 1 after injection. A piston 18 is secured to the proximal end of rod 8 and is arranged to slide in a proximal end of body 2. It includes a collar 20. Hollow sheath 12 is placed so as to slide at the distal end of body 2 to enclose needle 4 when it is in the exit position.

The operation of injection device 1 briefly described above is as follows. When the device is pressed against the patient's skin, sheath 12 slides over body 2, thereby exposing needle 4 and allowing the latter to penetrate the skin, while piston 18 and rod 8, arranged as to be able to slide, hold the medicine under the skin when needle 4 is removed.

The solid medicine to be injected is for immediate assimilation by the body. Thus, since the injected quantities are only those necessary to obtain an immediate effect, the needle can be as fine as those of conventional syringes. The injection is less painful insofar as the volume injected is considerably less than the volume necessary for an injection in liquid form. Moreover, the needle of the injection device is not exposed to external elements. Consequently, the needle cannot collect contaminating agents present in the atmosphere or prick anyone inadvertently. Likewise, it is not possible to inadvertently inject a fraction of the medicine or the patient's blood into a member of hospital personnel.

A seal 22 can seal aperture 24 via which needle 4 emerges from injection device 1 in order to preserve the sterility of said needle 4 and the medicinal dose 10. This seal 22 can be made of a brittle material such as biocompatible and biodegradable wax. Alternatively, aperture 24 can be sealed using a cap completely covering sleeve 12.

These means for sealing injection device 1 are not satisfactory. In the case of a wax cap, since there is a non-negligible risk of some of the material remaining caught on the needle and injected into the patient's skin, the manufacturer has to demonstrate the absence of any interaction between the wax and the injected medicine. In the case of a cap, there is a risk of the implant falling at the moment when the said cap is removed.

There therefore existed a need, in the state of the art, for means of preventing the implant falling prior to use of the injection device, particularly during periods of storage and during handling of said injection device prior to carrying out the actual

injection.

It is an object of the present invention to answer this need in addition to others by providing an injection device for injecting a solid medicine, including a body inside which there moves a bevelled needle, into which the medicine is introduced, this injection device further including retaining means for preventing the medicine falling prior to injection, characterized in that the medicine is retained via an elastic deformation of the needle imparted by the retaining means or via an elastic deformation of the retaining means themselves, or via a combination of the flexibility of these two means.

Owing to these features, the present invention provides a device for injecting a solid medicine also called an implant, which can be handled without any excessive precautions without any risk of the implant falling out. In particular, if the open end of the injection device via which the needle exits is sealed with a cap, it is possible, when preparing to carry out the injection, to remove the cap without any fear of the implant falling out. Moreover, since use is made of the elasticity of the needle and/or the retaining means, there is no need to resort to complicated manipulations in order to remove said retaining means before being able to use said device. Moreover, the retaining means do not interfere in any way with the proper operation of the injection device.

According to a complementary feature of the invention, the retaining means temporarily seal the needle bevel in the rest position, thereby preventing the implant from exiting the needle and falling out.

According to a first embodiment of the invention, the retaining means move the aperture through which the needle exits off-centre relative to the general axis of forward movement of said needle inside the injection device.

According to a second embodiment, the retaining means include an elastic tongue that temporarily abuts against the needle bevel.

Other features and advantages of the present invention will appear more clearly from the following detailed description of two embodiments of the injection device according to the invention, these examples being given purely by way of non-limiting illustration, in conjunction with the annexed drawing, in which:

- Figure 1, already mentioned, is a cross-section of a device for injecting a solid medicine;

- Figures 2A and 2B are cross-sections of the distal end of an injection device fitted with means for preventing the medicine falling out according to a first embodiment of the invention, the needle being respectively in the rest position and in the out position;

- Figures 3A and 3B are cross-sections of the distal end of an injection device provided with means for preventing the medicine falling out according to a second embodiment of the invention, the needle being respectively in the rest position and in the out position, and

- Figures 4A and 4B are cross-sections of the distal end of an injection device provided with means for preventing the medicine falling out according to a third embodiment of the invention, the needle being respectively in the rest position and in the out position.

The present invention proceeds from the general inventive idea that consists in fitting a device for injecting a solid medicine also called an implant with means for preventing the medicine falling out during periods of storage or just before the injection is carried out. By employing the elasticity of the needle or their own elasticity, these means do not require the user to resort to complicated manipulations to make said device operational. Moreover, while guaranteeing that the implant will not fall out in the rest position of the needle, the retaining means according to the invention in no way interfere with the exit of the needle and the general proper operation of the injection device.

A first embodiment of the retaining means according to the invention is illustrated in Figures 2A and 2B. In the following description, the elements that have already been described with reference to Figure 1 will be designated by the same reference numerals. Injection device 1 described in relation to Figure 1 is an example given purely by way of non-limiting illustration of the type of injection device to which the present invention could apply.

The distal end 26 of body 2 of the injection device is profiled with an insert 28. This insert 28 is made of a biocompatible plastic material that can be sterilised for example by irradiation, such as a polycarbonate. It is introduced inside body 2 via aperture 24 through which needle 4 exits. Insert 28, of generally cylindrical shape, has an external diameter adapted to the inner diameter of body 2, such that the friction forces between these two parts is sufficient to prevent any risk of said insert 28 inadvertently falling out.

As can be seen upon examining the Figures, insert 28 includes at the base thereof an aperture 30 through which needle 4 exits. This aperture 30 is off-centre relative to the general axis of forward movement X-X of needle 4. Insert 28 thus has, on the face thereof opposite said needle 4, an inclined plane 32, which, from top to bottom, moves closer to the axis of forward movement of said needle 4 until it intercepts the latter and leads to aperture 30. Thus, in the rest position (Figure 2A), needle 4 abuts via its bevelled aperture 34 against inclined plane 32, which prevents

the dose 10 of medicinal substance from falling out. During the exit movement of needle 4 (Figure 2B), the latter slides over inclined plane 32 by deforming. This movement is made possible owing to the flexibility of needle 4. Bevelled aperture 34, which forms the sharp part of needle 4 is inclined at an angle α relative to axis X-X. This bevelled aperture 34 is preceded by a sliding surface 36 inclined relative to axis X-X at an angle β less than angle α via which said needle 4 slides over inclined plane 32. Advantageously, the inclined plane 32 of insert 28 is inclined relative to axis X-X at an angle β' substantially equal to angle β. Consequently, contact is avoided between the sharp part of needle 4 and the inclined plane 32 of insert 28, which could cause a piece of plastic to be torn off.

A second embodiment of the retaining means according to the invention is shown in Figures 3A and 3B. The distal end 26 of body 2 of the injection device is fitted with an insert 38. As in the preceding case, insert 38 is made of a plastic material such as polycarbonate and is introduced inside body 2 through aperture 24 through which needle 4 exits. Insert 38 is securely retained inside body 2 via the friction forces between said insert 38 and the inner wall of said body 2.

Insert 38 has two through apertures 40 and 42 aligned on the general axis of forward movement X-X of needle 4 inside body 2. The first of these apertures 40 allows needle 4 to exit body 2 of the injection device at the moment that the injection is carried out (see Figure 3B). The second aperture 42 allows insert 38 to be fitted onto needle 4 at the moment of assembly of said insert 38. During the movement of axial introduction of insert 38 inside body 2, needle 4 moves an elastic tongue 44 away from its rest position. Via the effect of the elastic return force, tongue 44 abuts against the bevelled face 34 of said needle 4, preventing dose 10 of medicinal substance from falling out. During the injection, needle 4 moves forward relative to insert 38 and pushes back elastic tongue 44 (see Figure 3B).

Figures 4A and 4B are cross-sections of a variant of the insert 38 described above. Instead of being integral with insert 38, elastic tongue 44 is pivoted on said insert 38 via a hinge 44 and held abutting against bevelled face 34 of needle 4 via the effect of the elastic return force of a spring 48. When needle 4 moves forward, tongue 44 withdraws, which causes spring 48 to compress.

It goes without saying that the present invention is not limited to the embodiments that have just been described and that various simple alterations and variants could be envisaged by those skilled in the art without departing from the scope of the invention as defined by the annexed claims.

CLAIMS

1. Injection device for injecting a solid medicine (10) including a body (2) inside which there moves, along the general axis of forward movement (X-X) a bevelled (34) needle (4) into which the medicine (10) is introduced, said injection device (1) further including retaining means for preventing the medicine (10) from falling prior to being injected, characterized in that the retaining means are placed on the path of the needle (4), the needle (4) deforming relative to the general axis of forward movement (X-X) thereof in the injection device (1) when it passes the retaining means.

2. Injection device for injecting a solid medicine (10) including a body (2) inside which there moves, along the general axis of forward movement (X-X) a bevelled (34) needle (4) into which the medicine (10) is introduced, said injection device (1) further including retaining means for preventing the medicine (10) from falling prior to being injected, characterized in that the retaining means include an elastic member, which, in the rest position, seals the needle (4) and which moves away when the needle (4) moves forward.

3. Injection device including retaining means according to claims 1 or 2.

4. Injection device according to any of claims 1 to 3, characterized in that the retaining means temporarily seal the bevel (34) of the needle (4), thereby preventing the medicine from exiting the needle (4) and falling.

5. Injection device according to claim 4, characterized in that the retaining means include an aperture (30) through which the needle (4) exits and which is off-centre relative to the general axis of forward movement (X-X) of said needle (4) inside the body (2).

6. Injection device according to claim 5, characterized in that, opposite the bevel (34) of the needle (4), the retaining means have an inclined plane (32) which moves closer to the axis of forward movement (X-X) of said needle (4) until it intercepts the latter and which leads to the aperture (30).

7. Injection device according to claim 6, characterized in that the needle has a sliding surface (36) whose inclination is substantially equal to that of the inclined plane (32).

8. Injection device according to claim 2, characterized in that the retaining means include an elastic tongue (44) which temporarily abuts against the bevel (34) of the needle (4).

9. Injection device according to claim 8, characterized in that, while exiting, the needle (4) pushes back the elastic tongue (44).

10. Injection device according to any of claims 8 or 9, characterized in that the elastic tongue (44) is integral with the retaining means.

11. Injection device according to any of claims 8 or 9, characterized in that the elastic tongue (44) is pivoted on the retaining means via a hinge (46) and is held abutting against the bevel (34) of the needle (4) via the effect of the elastic return force of a spring (48).

12. Injection device according to any of claims 8 to 10, characterized in that the retaining means have a first through aperture (40) that allows the needle (4) to exit, and a second through aperture (42) via which said retaining means are fitted onto said needle (4), said two apertures (40, 42) being aligned on the general axis of forward movement (X-X) of the needle (4) inside the body (2).

13. Injection device according to any of claims 1 to 12, characterized in that the retaining means take the form of an insert (28; 38).

14. Injection device according to claim 13, characterized in that the insert (28; 38) is made of a biocompatible material able to be sterilised.

15. Injection device according to claim 14, characterized in that the insert (28; 38) is made of a plastic material.

16. Injection device according to claim 15, characterized in that the insert (28; 38) is made of polycarbonate.

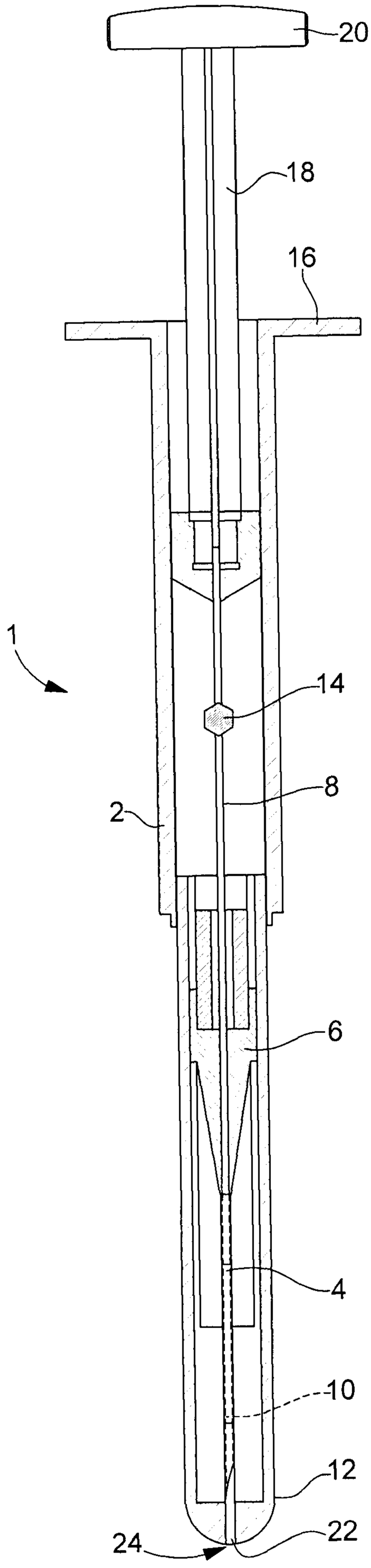


Fig. 1

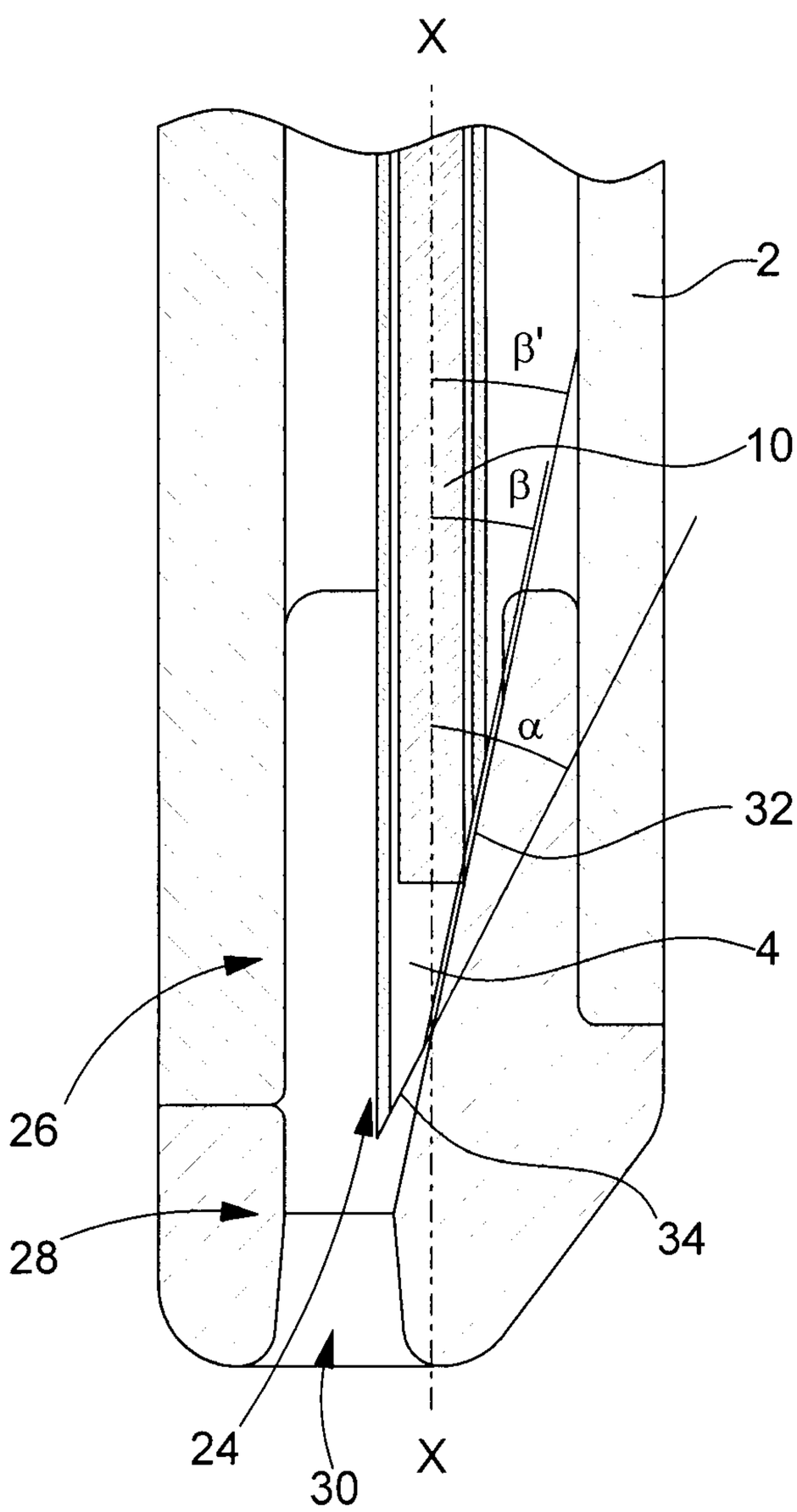


Fig. 2A

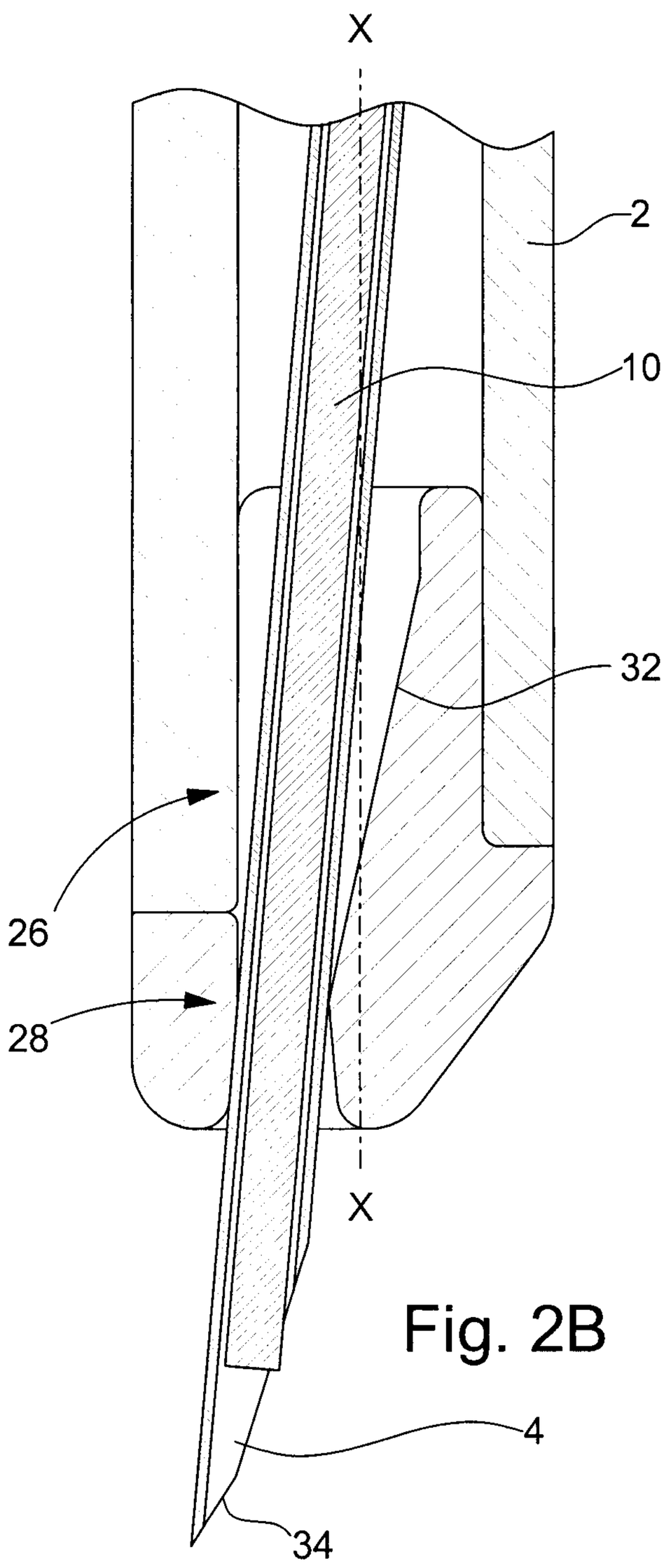


Fig. 2B

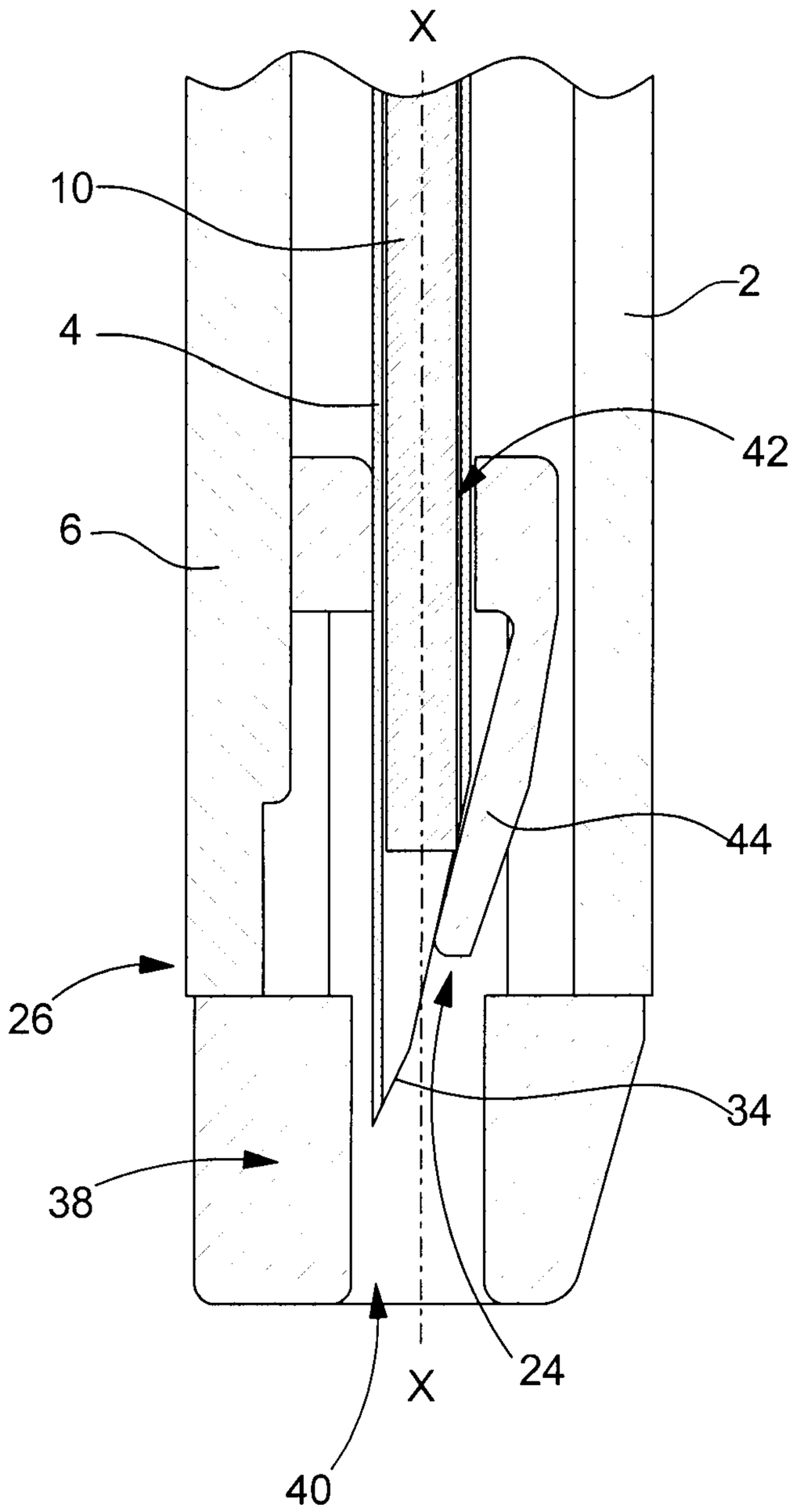


Fig. 3A

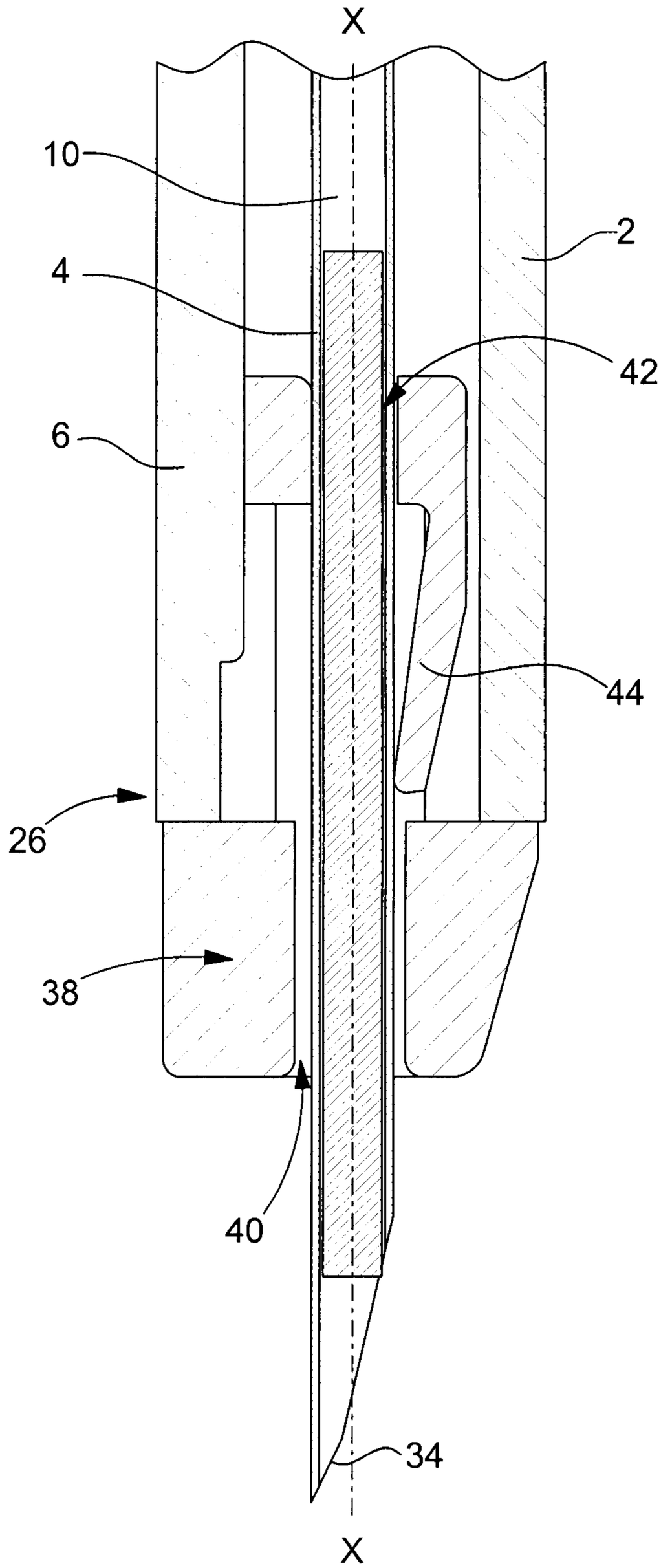


Fig. 3B

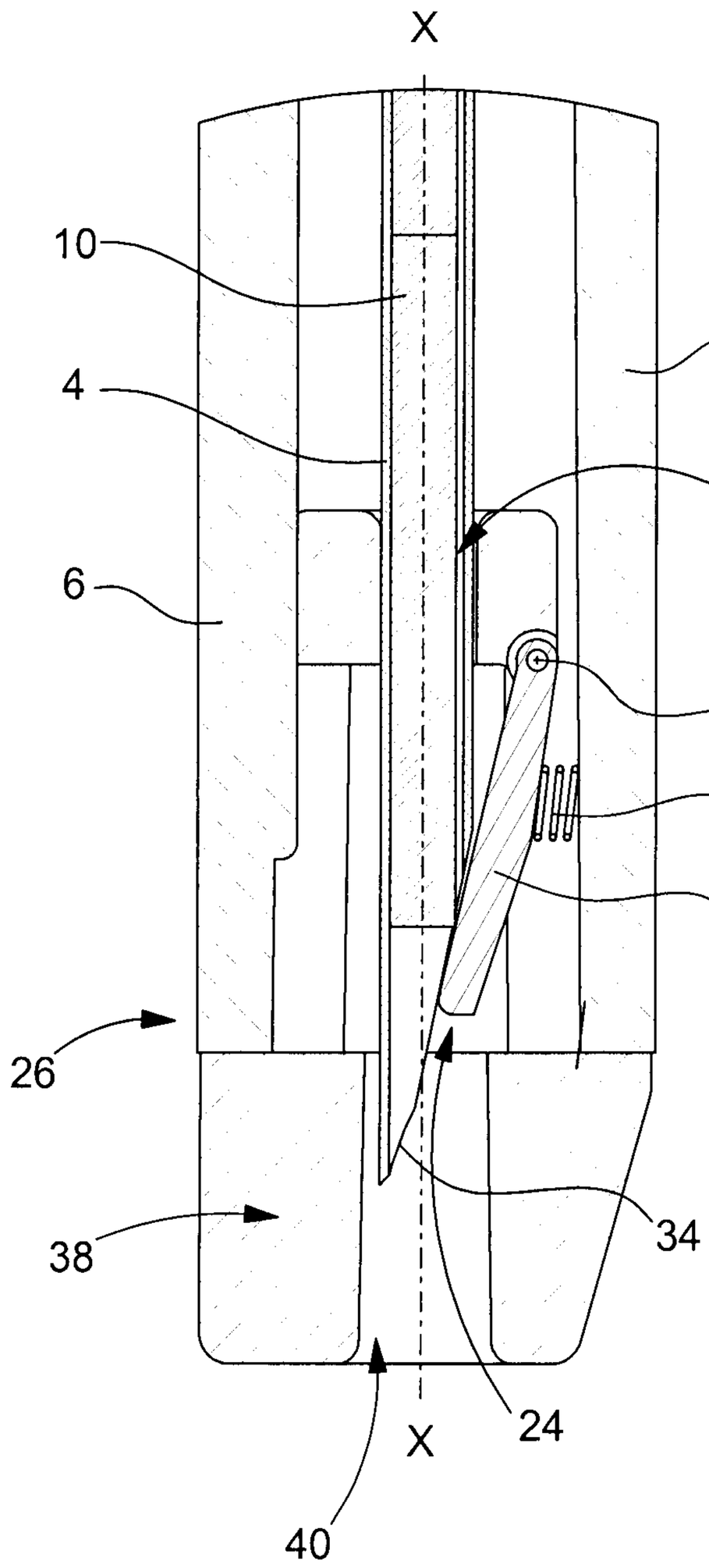


Fig. 4A

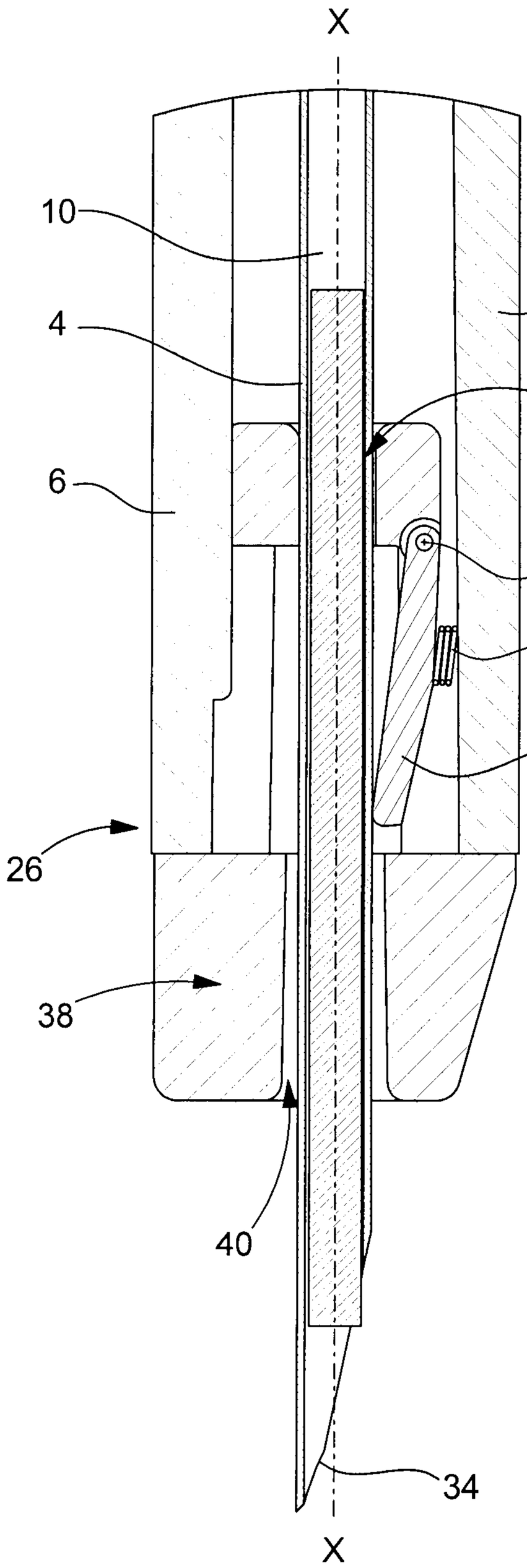
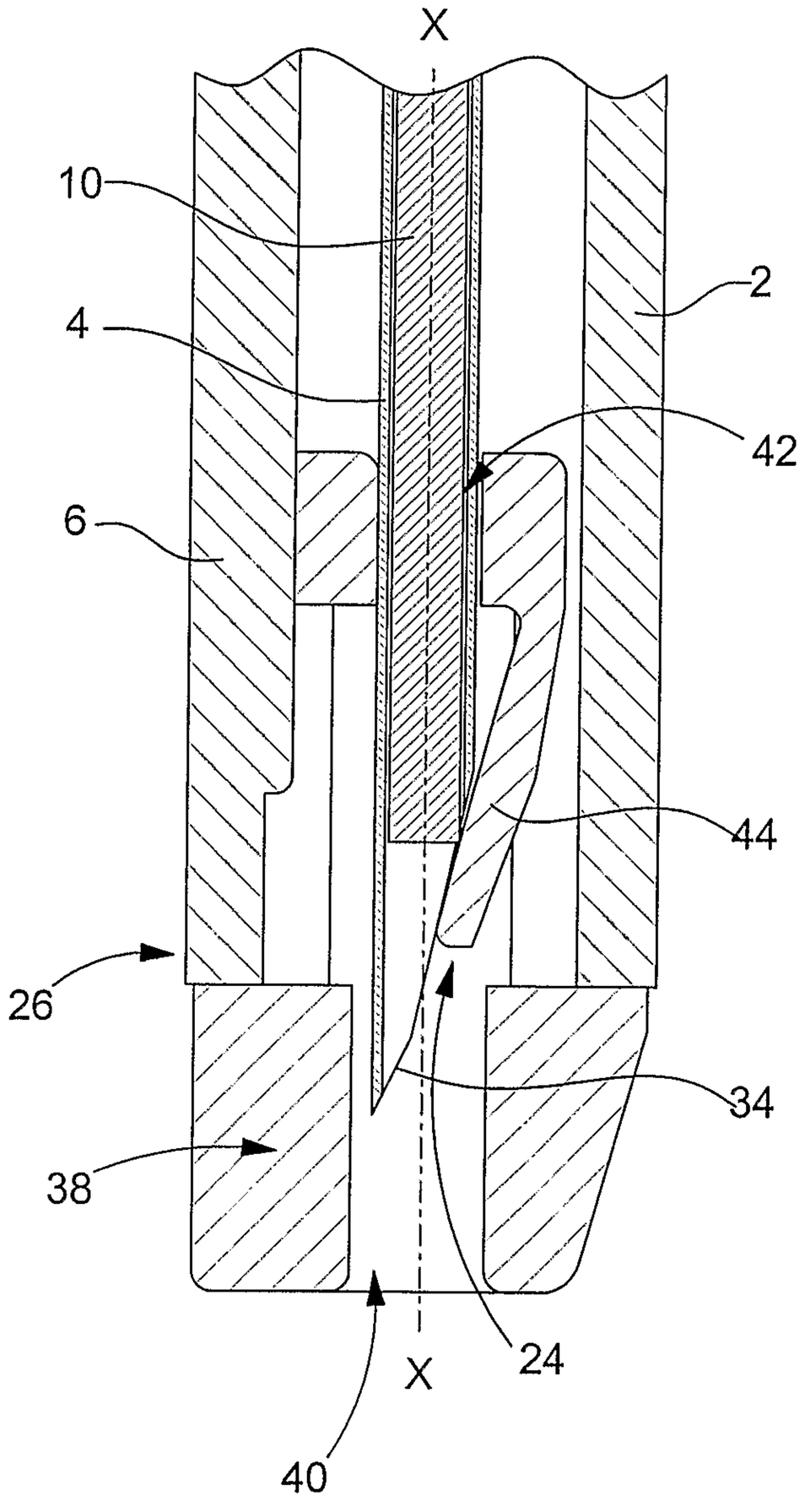


Fig. 4B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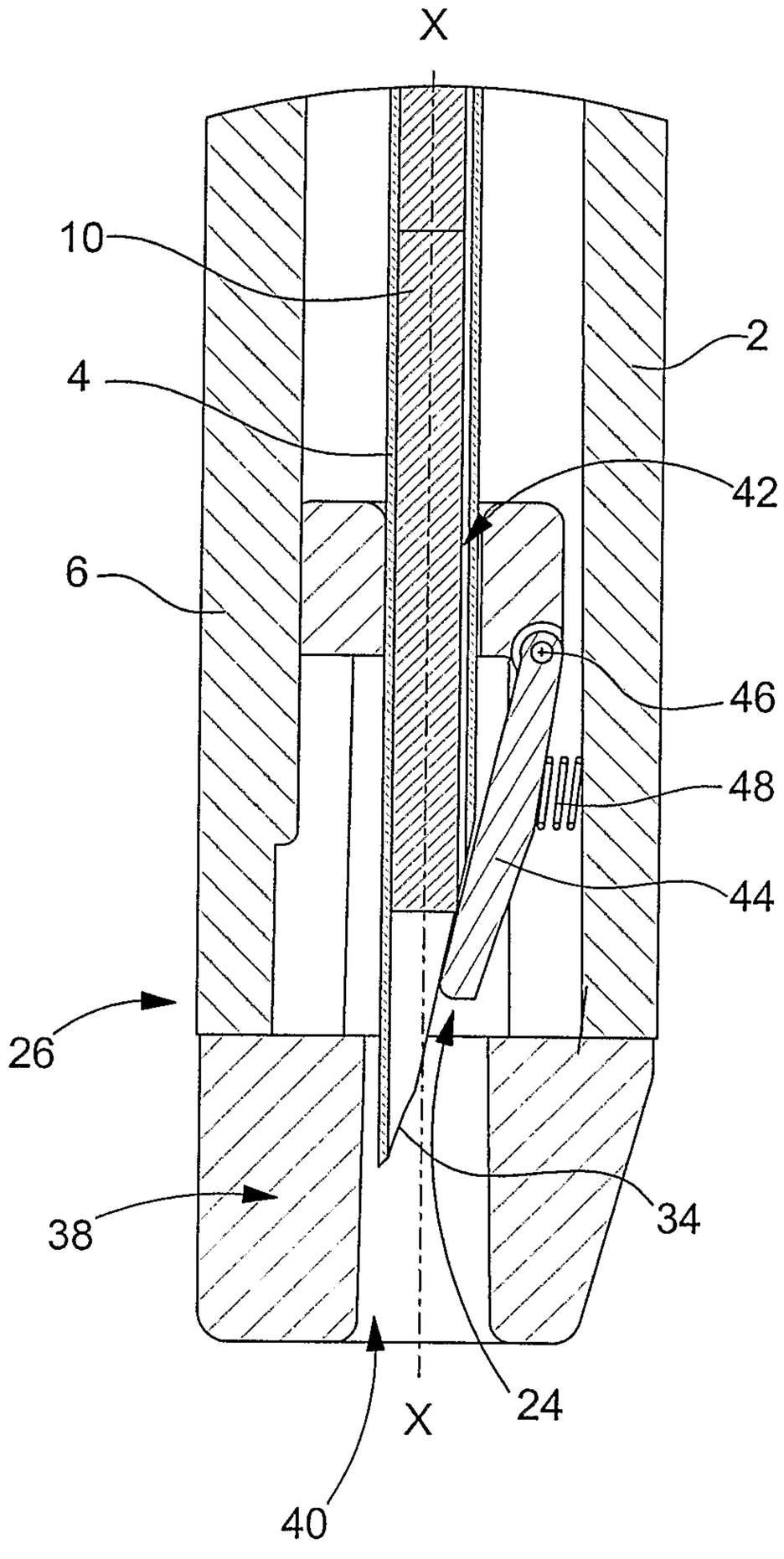
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