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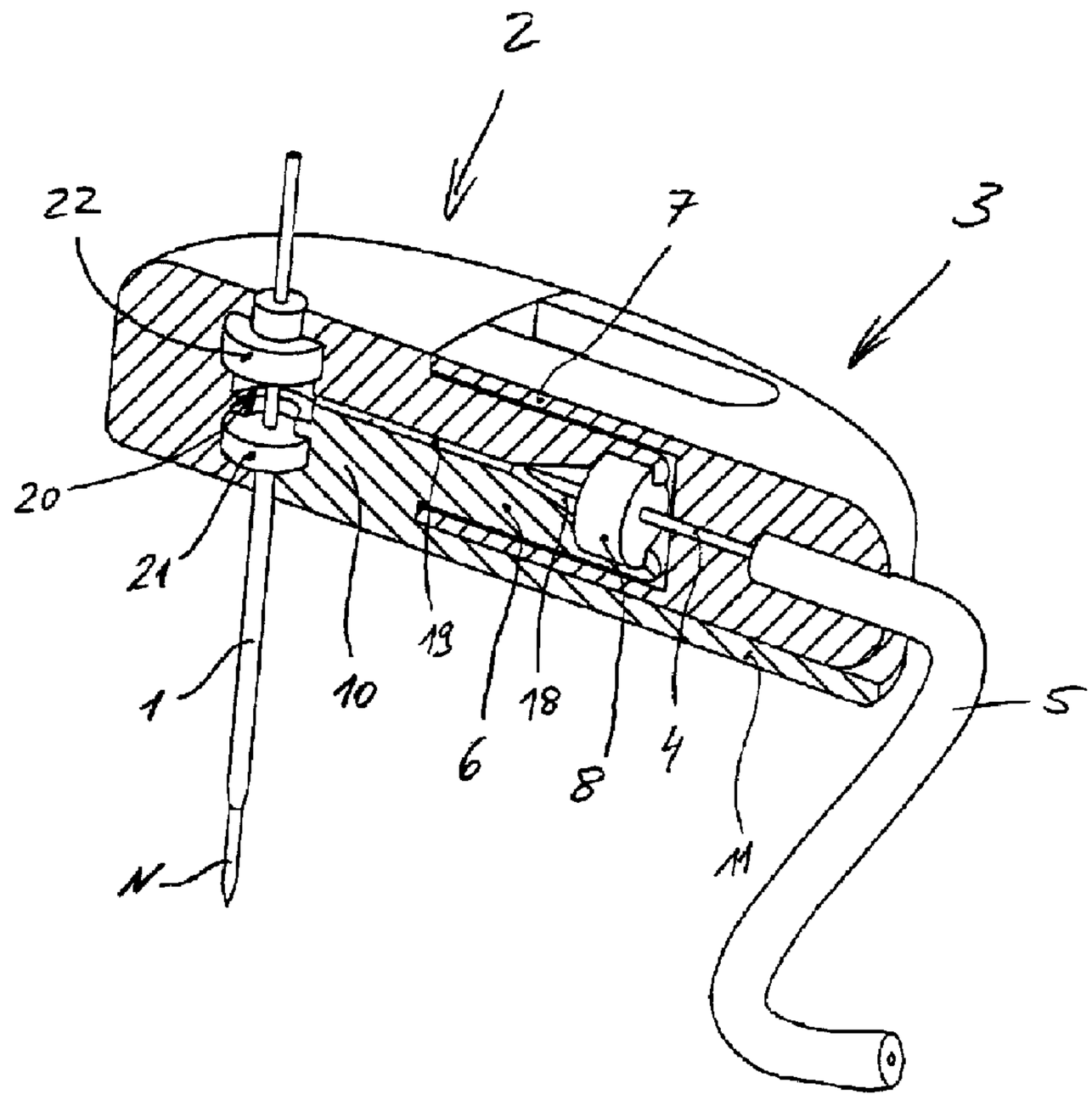
(72) Inventeur/Inventor:
MARGGI, ROLF, CH

(73) Propriétaire/Owner:
DISETRONIC LICENSING AG, CH

(74) Agent: GOWLING LAFLEUR HENDERSON LLP

(54) Titre : TETE DE CATHETER POUR L'ADMINISTRATION SOUS-CUTANEE D'UNE SUBSTANCE ACTIVE
(54) Title: CATHETER HEAD FOR SUBCUTANEOUS ADMINISTRATION OF AN ACTIVE SUBSTANCE



(57) Abrégé/Abstract:
A guide means is formed on the needle holder for a catheter head by a guide sleeve axially surrounding the connecting needle, the guide sleeve being pushed or narrowly slide-guided over a cylindrical extension of the cannula housing upon the needle holder and the cannula housing being connected, i.e. upon the connecting needle being introduced. The cylindrical extension surrounds the inlet and a section of the passage channel of the cannula housing connected to the same. The invention ensures secure introduction of the connecting needle without the need of forming additional guide pins. In addition, the guide sleeve represents a means of protection for handling, both for the needle and the user. The guide sleeve may have openings, but is preferably designed as a closed sleeve body.

ABSTRACT

A guide means is formed on the needle holder for a catheter head by a guide sleeve axially surrounding the connecting needle, the guide sleeve being pushed or narrowly slide-guided over a cylindrical extension of the cannula housing upon the needle holder and the cannula housing being connected, i.e. upon the connecting needle being introduced. The cylindrical extension surrounds the inlet and a section of the passage channel of the cannula housing connected to the same. The invention ensures secure introduction of the connecting needle without the need of forming additional guide pins. In addition, the guide sleeve represents a means of protection for handling, both for the needle and the user. The guide sleeve may have openings, but is preferably designed as a closed sleeve body.

CATHETER HEAD FOR SUBCUTANEOUS ADMINISTRATION OF AN ACTIVE SUBSTANCE

FIELD OF THE INVENTION

The invention relates to a catheter head for subcutaneous administration of an active substance, in particular a medically active substance, such as insulin.

BACKGROUND OF THE INVENTION

A catheter head comprises a cannula housing with a cannula and a needle holder, to be connected to the cannula housing, including a feed line for feeding the active substance to the catheter head. The cannula projects from the cannula housing and is placed in tissue. The cannula may be an integral part of the cannula housing. In another preferred embodiment, it is attached and/or anchored inside the cannula housing. It may be designed as a rigid element, such as a steel cannula or a flexible, in particular a pliable element. In the cannula housing a passage channel to the cannula is formed for the active substance. The cannula housing is designed to allow flush or mould positioning on the tissue, into which the cannula is placed, and it is prepared for fixing on to the tissue.

A connecting needle is rigidly attached to the needle holder. The connecting needle is introduced into the passage channel of the cannula housing for obtaining a connection. Both the cannula and the cannula housing will stay on the site of attachment in and on the tissue, whereas the needle holder may be repeatedly connected to the cannula housing and separated from the same again. During assembly, the cannula housing and the needle holder are preferably automatically engaging into each other, in particular due to the needle holder detachably anchoring itself to the cannula housing. Guide means are provided for positioning the connecting needle in relation to the passage channel of the cannula housing and for introducing the connecting needle into the passage channel, with the guide means guiding the needle holder at the cannula housing.

A typical catheter head is described in U.S. Patent No. 5,522,803. The guide means of this known catheter head are formed by a pair of guide pins projecting on either side of the connecting needle and parallel to the same from the needle holder. Accordingly, the cannula housing is provided with guide shafts on either side of an inlet into the passage channel into which one each of the guide pins for introducing the connecting needle is inserted. The

connecting needle is positioned in relation to the inlet by the interaction of the guide pins with the guide shafts and guided in centered position during introduction into the passage channel. In the course of advancement of the connecting needle in the passage channel, the needle holder is anchored by an automatically engaging snap-on connection to the cannula housing.

It is the object of the invention to provide a catheter head for subcutaneous administration of an active substance, a cannula housing and needle holder of which may be simply and correctly connected to each other, and which is easy to manufacture.

SUMMARY OF THE INVENTION

According to the invention, a guide means is formed on the needle holder for a catheter head of the type described above, by a guide sleeve axially surrounding the connecting needle, said guide sleeve being pushed narrowly slide-guided over a cylindrical extension of the cannula housing upon the needle holder and the cannula housing being connected, i.e. upon the connecting needle being introduced. The cylindrical extension surrounds the inlet and a section of the passage channel of the cannula housing connected to the same. The invention ensures secure introduction of the connecting needle without the need of forming additional guide pins. In addition, the guide sleeve represents a means of protection for handling, both for the needle and the user. The guide sleeve may have openings, but is preferably designed as a closed sleeve body.

In a preferred embodiment, the cannula housing comprises a compact front section, from the underside of which the cannula projects and from the rear of which a disc-shaped section and the cylindrical extension project, the disc-shaped section extending the underside of the cannula housing placed on the tissue. An upper side of the disc-shaped rear section of the cannula housing facing the cylindrical extension and an underside of the needle holder are acting as additional guide means upon the cannula housing and the needle holder are being connected, preventing rotation of the needle holder in relation to the cannula housing around the longitudinal axis of the connecting needle.

Preferably, an additional passage is formed in the cannula housing for a piercing needle for the cannula. When the cannula housing and the needle holder are connected, this passage points at an angle in relation to the connecting needle. The passage channel for the

connecting needle leads into this additional passage which extends the passage channel up to the cannula after the cannula has been placed and the piercing needle retracted. Owing to the fact that a piercing needle need not be retracted from the passage channel, into which the connecting needle is introduced after placing the cannula and fixing the cannula housing, complete precharging of the catheter head up to the cannula, i.e. priming, is possible in the state of the cannula housing and the needle holder being connected.

In another embodiment, a flexible cannula extends the passage channel, but flush. In a third embodiment, the cannula is formed by the piercing needle itself.

In a preferred manufacturing process, the prefabricated cannula is moulded into the cannula housing when injection-moulding the cannula housing. For this purpose, a rear section of the cannula is preferably provided with a widened section, anchoring the cannula in the cannula housing during injection. The cannula is preferably made of a soft plastic material, in particular Teflon. A thermoplastic material may be used both as a material for the cannula housing and for the needle holder.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following, preferred embodiments of the invention are described by means of figures, where

Figure 1 is a catheter head in assembled condition;

Figure 2 is a catheter head in accordance with Figure 1, with components of the catheter head being shown individually and removed from their assembled position;

Figure 3 is the catheter head according to Figure 2 directly prior to assembly;

Figure 4 is a longitudinal section of the catheter head according to Figures 1 to 3 in assembled condition;

Figure 5 is a second embodiment of a catheter head; and

Figure 6 is a longitudinal section of the catheter head according to figure 5.

DETAILED DESCRIPTION

Figure 1 shows a catheter head comprising a cannula 1, extending vertically from an underside of the catheter head. The cannula 1, made of a soft plastic material, Teflon in the

embodiment, closely surrounds a piercing needle N, projecting through the catheter head vertically in relation to its level underside. The catheter head of figure 1 forms the front end of a catheter 5, as marked in figures 2 to 4. The catheter with the catheter head is set by the user himself, for instance a diabetic. For this purpose, the piercing needle N and the cannula 1 are inserted vertically under the skin into the tissue, and the catheter head, with its underside, is mould positioned and fixed on to the skin. Fixation is effected by means of a self-adhesive pad or plaster. The said pad enlarges the underside of the catheter head available for adhesion. Should this underside as such provide an adhesive area of a sufficient size, provision of such an underside will be sufficient as an adhesive area. After placing the cannula 1, the piercing needle N is retracted from the catheter head, with only the thin, flexible, in particular pliable, cannula 1 remaining in the tissue.

The catheter head comprises a cannula housing 2, remaining at the point of piercing together with the cannula 1, in particular therefore comprising the underside required for fixing the catheter head, and a needle holder 3, forming the front end of the catheter 5. The cannula housing 2 and the needle holder 3 are combined in a plug-in connection that may be repeatedly connected and disconnected.

In figure 2, the cannula housing 2 and the needle holder 3 are shown separated from each other, but have been aligned in relation to each other for being plugged together. Furthermore, the components of the catheter head to be manufactured separately have been shown separated from their installed positions. All individual components have been aligned in relation to each other in accordance with their specific installation positions.

The active substance is fed to the needle holder 3 through the catheter 5. It is passed through a connecting needle 4 within the needle holder 3 into a passage channel in the cannula housing 2, then to the cannula 1 and through the cannula 1 to the specified site into the issue. The piercing needle N shown in figures 1 to 4, has been previously removed in this instance. An inlet 9 and an adjacent section of the passage channel of the cannula housing 2 are surrounded by a cylindrical extension 6, projecting from a rear side of the cannula housing 2. The passage within the catheter head can be best seen in detail from the longitudinal section of figure 4.

Figure 3 shows the cannula housing 2 and the needle holder 3 with the individual components at their sites, each also arranged for assembly in a suitable position in relation to each other. From this position, the needle holder 3 is advanced in a straight line in longitudinal direction of the connecting needle 4, pointing towards the inlet 9, towards the cannula housing 2 and attached. The feed and attaching direction of the needle holder 3 mainly extends parallel to the skin surface. The catheter is therefore leading away parallel to the skin surface, however, it may also point away in an angle to the skin surface.

In assembled condition, the overall shape of the catheter head is a semi-ovaloid, comprising a level underside 12, being curved towards its edge, descending from the skin and ending in an upper side above, being in parts convex and in parts concave. The cannula housing 2, on which the underside 12 placed on the skin is formed, comprises a rear disc-shaped section 11 and a front section 10 thickened in relation to the same, from the underside 12 of which the cannula 1 and from the rear of which the cylindrical extension 6 and, facing the same, the disc-shaped section 11 project towards the rear into the direction of the needle holder 3, to be advanced towards the same. The upper side 13 of the rear section 11 is concave and rounded in shape, adapted to the curved underside 14 of the needle holder 3, curved accordingly outwards. In contrast, the upper side of the front section 10 is curved convexly outwards. The needle holder 3 is of a symmetrical shape, i.e. its upper side and underside 14 are identically curved outwards. In addition, the needle holder 3 is symmetrical in plan view in relation to its central axis. The underside and the upper side of the needle holder 3 may be exchanged due to their symmetry when being plugged together with the cannula housing. This simplifies handling, due to correct alignment being verifiable easily by touch alone.

During interaction with a guide sleeve 7 provided on the needle holder 3, the cylindrical extension 6 acts as a guide means for positioning the connecting needle 4 in relation to the inlet 9 and for correct straight guidance of the connecting needle 4 within the section of the passage channel following the inlet 9. Thus, according to the invention, a part of the cannula housing 2 surrounding the passage channel, namely the cylindrical extension 6, is formed to project from the cannula housing 2 and allows to be used as a guide means for inserting the connecting needle 4. The guide means on the needle holder 3, interacting with the same, is formed by the guide sleeve 7, simultaneously protecting the connecting needle 4, coaxially arranged in the same, against damage. In addition, it protects the user against possible injury due to a projecting needle, for instance, when verifying alignment by touch and generally due

to a lack of attention during handling. The guide sleeve 7 projects over the connecting needle 4 in its longitudinal direction.

The guide sleeve 7 is formed by forming two longitudinal slots 17, i.e. it remains between these two slots 17 as a sleeve-shaped extension. In principle, the guide sleeve 7 could be formed by the needle holder 3 as a whole, i.e. being formed as a straight cylindrical recess in an otherwise full needle holder 3, which would then be regarded in total as a guide sleeve.

However, two elastic snap-on fingers 16 are formed by the slots 17 on either side of the guide sleeve 7, projecting over the guide sleeve 7. When attaching the needle holder 3, the snap-on fingers 16 engage with appropriate guide shafts 15, provided on either side of the cylindrical extension 6 in the cannula housing 2. During the connecting needle 4 being inserted, the snap-on fingers 16 slide over guide faces of their guide shafts 15 tapered towards each other and are bent by the same towards each other. The elastically bendable snap-on fingers 16 are snapping out by their engaging tabs behind projections formed in the guide shafts 15 upon the connecting needle 4 having been completely inserted, thus anchoring the needle holder 3 at the cannula housing 2 by gripping behind the appropriate projections of the guide shafts. The snap-on connection is released by pressing the snap-on fingers 16 towards each other in their knurled sections. After having released the grip from behind in this way, the needle holder 3 may be retracted from the cannula housing 2.

Figure 4 is a longitudinal section of the catheter head. The guide sleeve 7 is completely pushed over the cylindrical extension 6, with its front edge contacting the rear of the cannula housing 2, from which the cylindrical extension 6 projects. In this condition, the snap-on fingers 16 grip behind the appropriate tabs in the guide hafts 15. Therefore accidental release of the needle holder 3 is not possible.

When attaching the needle holder 3, the underside 14 of the needle holder 3 slides along the curved upper side 13 of the cannula housing 2. The guide sleeve 7 is positioned flush with the cylindrical extension 6 for positioning the connecting needle 4, wherein the needle holder 3 is displacable while being supported on the upper side 13 of the cannula housing 2. The cylindrical extension 6 is centered in the guide sleeve 7 when first being pushed over the cylindrical extension 6, due to the front edge of the cylindrical extension 6 being slightly rounded. Thereafter, the needle holder 3 is pushed forward over the cylindrical extension 6

with its guide sleeve 7, whereby the connecting needle 4 pierces a septum 8 directly arranged behind the inlet 9 in the passage channel of the cylindrical extension 6. The septum 8 is designed to hermetically seal the passage channel of the cannula housing 2 even after repeatedly being pierced. Directly behind the septum 8, the passage channel is provided with a domed section 18 into which the connecting needle 4 projects. A straight channel section 19, leading into a cavity 20 in the front section 10 of the cannula housing 2, arranged flush with the connecting needle 4, follows the domed section 18. The cannula 1, too, ends in the said cavity 20. The piercing needle N projects through the cavity, forming a right angle in this embodiment to the connecting needle 4 and the channel section 19. The piercing needle N projects through the cannula housing 2, extending in an angle, in the embodiment in a right angle to its underside 12. In this arrangement, the piercing needle N is advantageoulsy not guided through that part of the passage channel of the cannula housing 2 into which the connecting needle 4 is introduced. In this arrangement, the piercing needle N need not be removed in order to be able to introduce the connecting needle into the cannula housing. This is of particular advantage for so-called priming, during which the catheter head is being filled as far as possible completely with the active substance prior to placing the cannula 1. This considerably simplifies handling.

The cannula 1 is designed as a thin tube, comprising a flange-type widened section 21 at one end. The flange-type widened section 21 is placed in a disc-shaped recess of the cannula housing 2, thus anchoring the cannula 1.

Another septum 22 is inserted opposite the cannula inlet in the cavity 20, sealing the cavity 20, which forms part of the passage channel of the cannula housing 2, after retracting the piercing needle N. The function of the septum 22 is comparable with that of the septum 8. The shape of the cavity 20 is mainly cylindrical, with the flange-type widened section 21 of the cannula 1 and the septum 22 forming the opposite faces of the cylindrical cavity 20, between which the channel section 19 ends. For priming, the piercing needle N comprises an opening in its section located between the flange-type widened section 21 and the septum 22.

Figure 4 clearly shows the flush support of the needle holder 3 over the full surface of the upper side 13 of the disc-shaped rear section 11 of the cannula housing 2. In addition, it is shown that a clearance remains between the upper side 13 and the cylindrical extension 6 into which the guide sleeve 7 enters upon the needle holder 3 being plugged-on. In principle, the

said clearance between the disc-shaped section 11 and the cylindrical extension 6 is not required. The cylindrical extension 6 could, for instance, be located flat directly on the disc-shaped section 11. In this design, the underside of the guide sleeve 7 would be suitably open. The internal jacket face, being the actual slideway for the guide sleeve 7 and the external jacket face of the cylindrical extension 6 need not be circular cylindrical in shape, although this is preferred. It is essential, however, that sufficient straight cylindrical slideway faces are available for positioning and neatly guiding the connecting needle 4. Guidance and in particular security of the needle holder 3 against rotation in relation to the fixed cannula housing 2, is even improved by the upper side 13 of the cannula housing 2 and the underside 14 of the needle holder 3 acting as slideways. The shape of these two guide faces 13 and 14 ensures correct alignment, in particular centering, during assembly.

Figures 5 and 6 show a modified embodiment, in which the piercing needle is pierced through the same passage channel of the cannula housing 2 into which the connecting needle 4 is to be inserted after placing the cannula 1. With the exception of the arrangement of the piercing needle and the cannula 1, the catheter heads of figures 5 and 6 correspond to the arrangement described above. Reference is therefore made to that description.

In both embodiments according to the invention, the cannula housing 2 is produced in a single injection moulding cycle. For this purpose, the prefabricated cannula 1 including its widened section 21 and possibly the septum 8 and the septum 22, are inserted into the injection moulding tool and directly moulded into the same as an integral part of the cannula housing 2. The required attachments in the shape of all-round shoulders surrounding the afore-mentioned components, are specified by the injection moulding tool. The septums 8 and 22 may also be inserted into the cannula housing 2, whereby the cannula housing 2 is remoulded in another production cycle for retaining the septums 8 and 22. Moulding the cannula 1 in particular is a considerable simplification of the process for manufacturing the cannula housing 2.

I claim:

1. A catheter head for subcutaneous administration of an active substance, comprising:

a cannula housing (2) having a cannula (1) to be placed in tissue, a passage channel (18, 19) to said cannula (1) for conveying an active substance in said cannula housing (2); said cannula housing (2) having an underside (12) for mould positioning and which is prepared for fixing on to the tissue;

a needle holder (3) including a catheter (5) for feeding the active substance and a connecting needle (4) to be inserted into said passage channel (18, 19) of said cannula housing (2), to permit said needle holder (3) and said cannula housing (2) to be detachably fixed to each other; and

guide means for positioning said connecting needle and, during insertion of said connecting needle (4) into said passage channel (18, 19) of said cannula housing (2), for guiding said needle holder (3) to said cannula housing (2), wherein

said needle holder (3) forms a guide sleeve (7) axially surrounding said connecting needle (4), said guide sleeve being narrowly side-guided over a cylindrical extension (6) of said cannula housing (2), sheathing both an inlet (9) and a section of said passage channel (18, 19) of said cannula housing (2) following said inlet.

2. A catheter head as claimed in claim 1, wherein said guide sleeve (7) includes a closed jacket surface surrounding said connecting needle (4).

3. A catheter head as claimed in claim 1 or 2, wherein said cannula housing (2) includes a disc-shaped rear section (11) and a thicker front section (10) forming said passage channel (18, 19), for attachment of said cannula (1), and from which said cylindrical extension (6) projects over said disc-shaped rear section (11).

4. A catheter head as claimed in claim 3, wherein a clearance remains between said cylindrical extension (6) and an upper side (13) of the said disc-shaped rear section (11) for sliding over of the said guide sleeve (7).

5. A catheter head as claimed in claim 4, wherein the upper side (13) forms, during insertion of the connecting needle (4), a support and an additional slideway for said needle holder (3).

6. A catheter head as claimed in claim 5, wherein said upper side (13) is adapted to an underside (14) of said needle holder (3) which is curved in cross direction to said connecting needle (4), said upper side (13) thus forming said additional slideway, said additional slideway extending parallel to said cylindrical extension (6).

7. A catheter head as claimed in any one of claims 1-6, wherein an underside (14) of said needle holder (3) is mould positioned on an upper side (13) of a rear section (11) of said cannula housing (2) during positioning and insertion of said connection needle (4).

8. A catheter head as claimed in any one of claims 1-7, wherein said needle holder (3) comprises an upper side symmetrical to its underside (14), wherein said underside (14) and said upper side are preferably curving outwardly away from each other.

9. A catheter head as claimed in any one of claims 1-8, wherein a piercing needle (N) for said cannula (1) projects through said cannula housing (2) at an angle to the longitudinal direction of said inserted connecting needle (4), wherein said passage channel (18, 19) for said connecting needle (4) leads at an angle into an additional passage (20) for said piercing needle (N).

10. A catheter head as claimed in claims 1-9 wherein the cannula (1) is formed as an integral part of said cannula housing (2) when injection-moulding said cannula housing (2).

11. A catheter head as claimed in any one of claims 1-2 wherein said cannula housing (2) includes a disc-shaped rear section (11) which forms, during insertion of the connecting needle (4), a support and an additional slideway for the needle holder (3).

12. A catheter head as claimed in claim 3, wherein an upper side (13) of the disc-shaped rear section (11) of the cannula housing (2) forms, during insertion of the connecting needle (4), a support and an additional slideway for the needle holder (3).

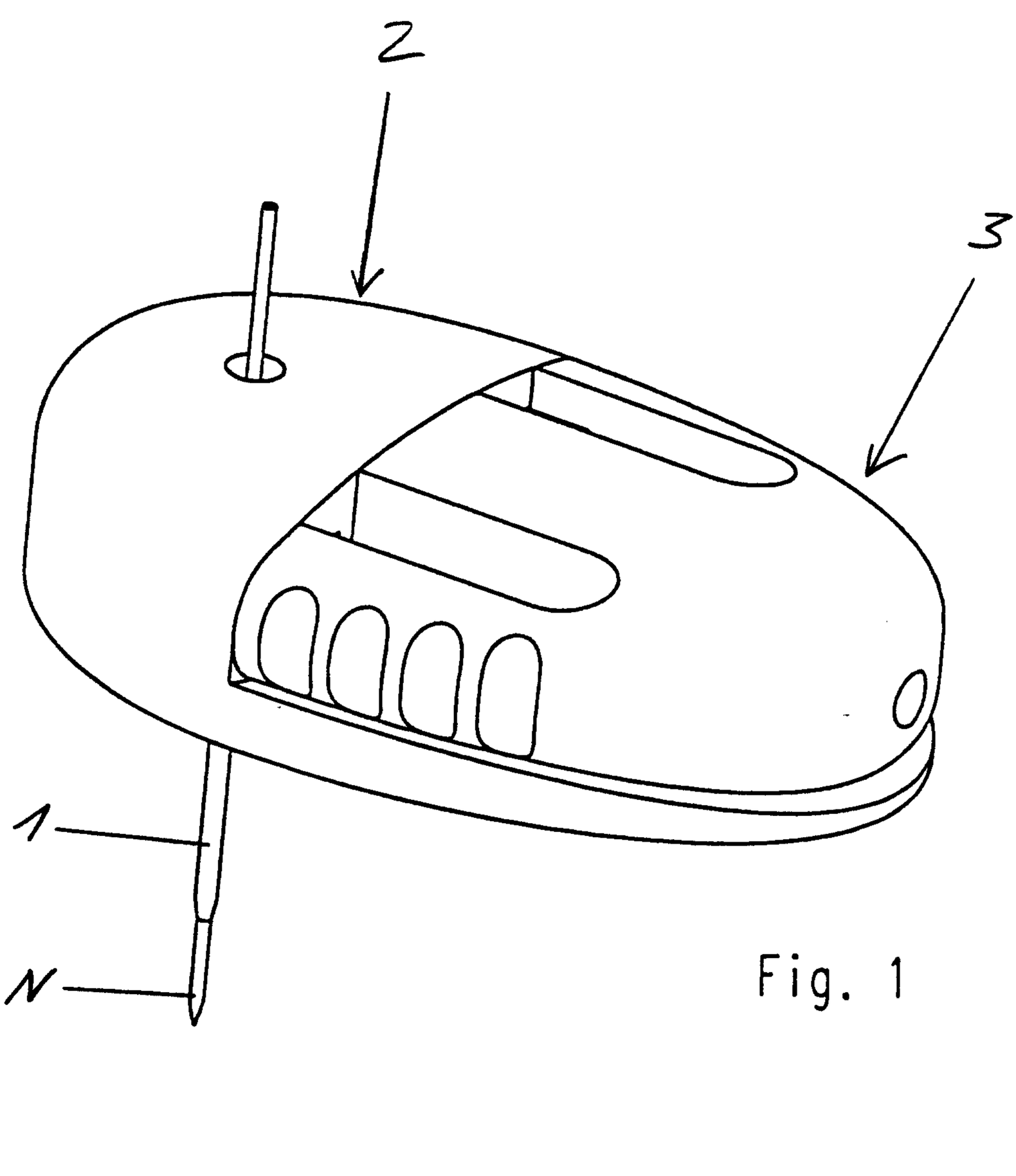


Fig. 1

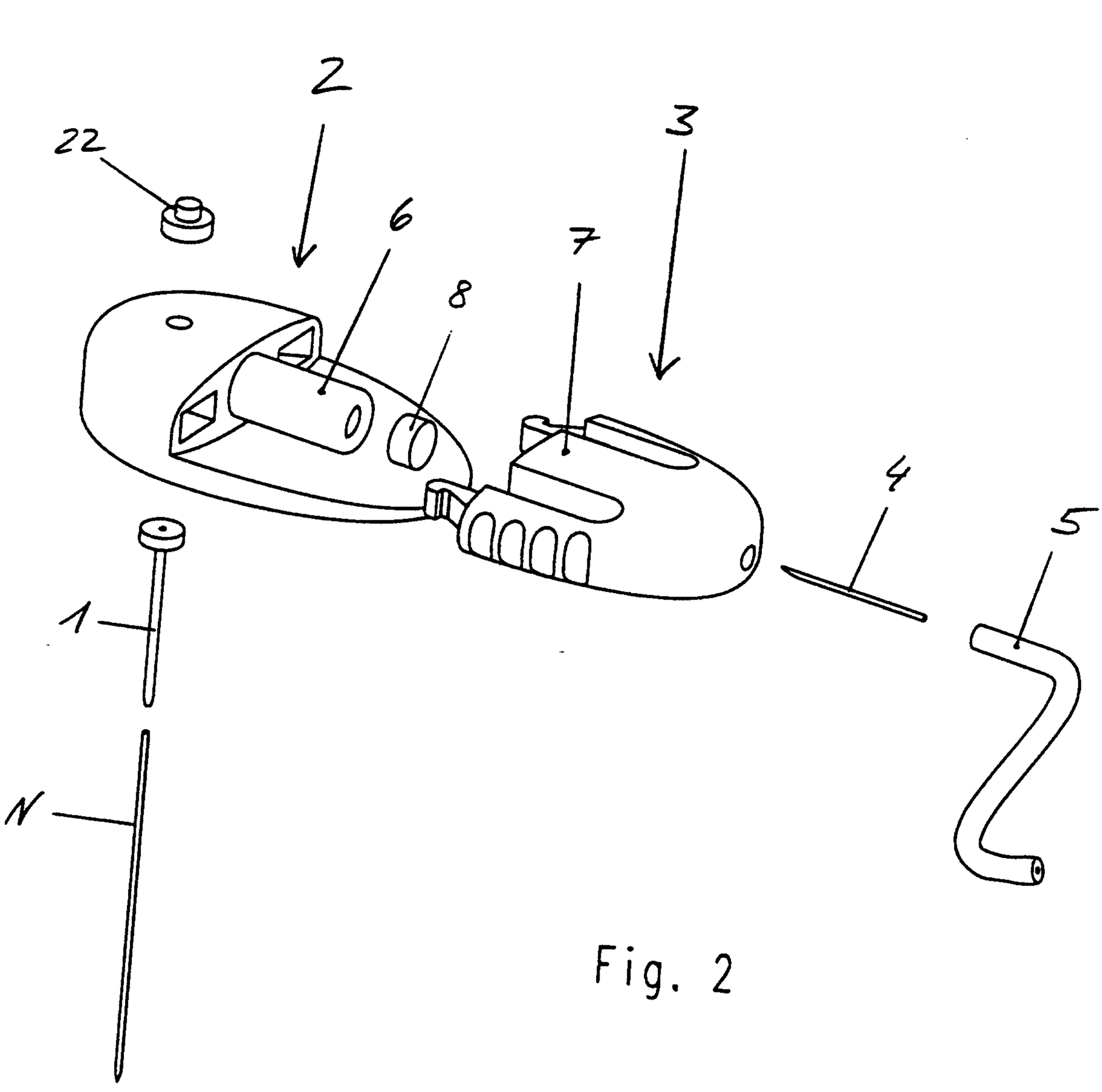


Fig. 2

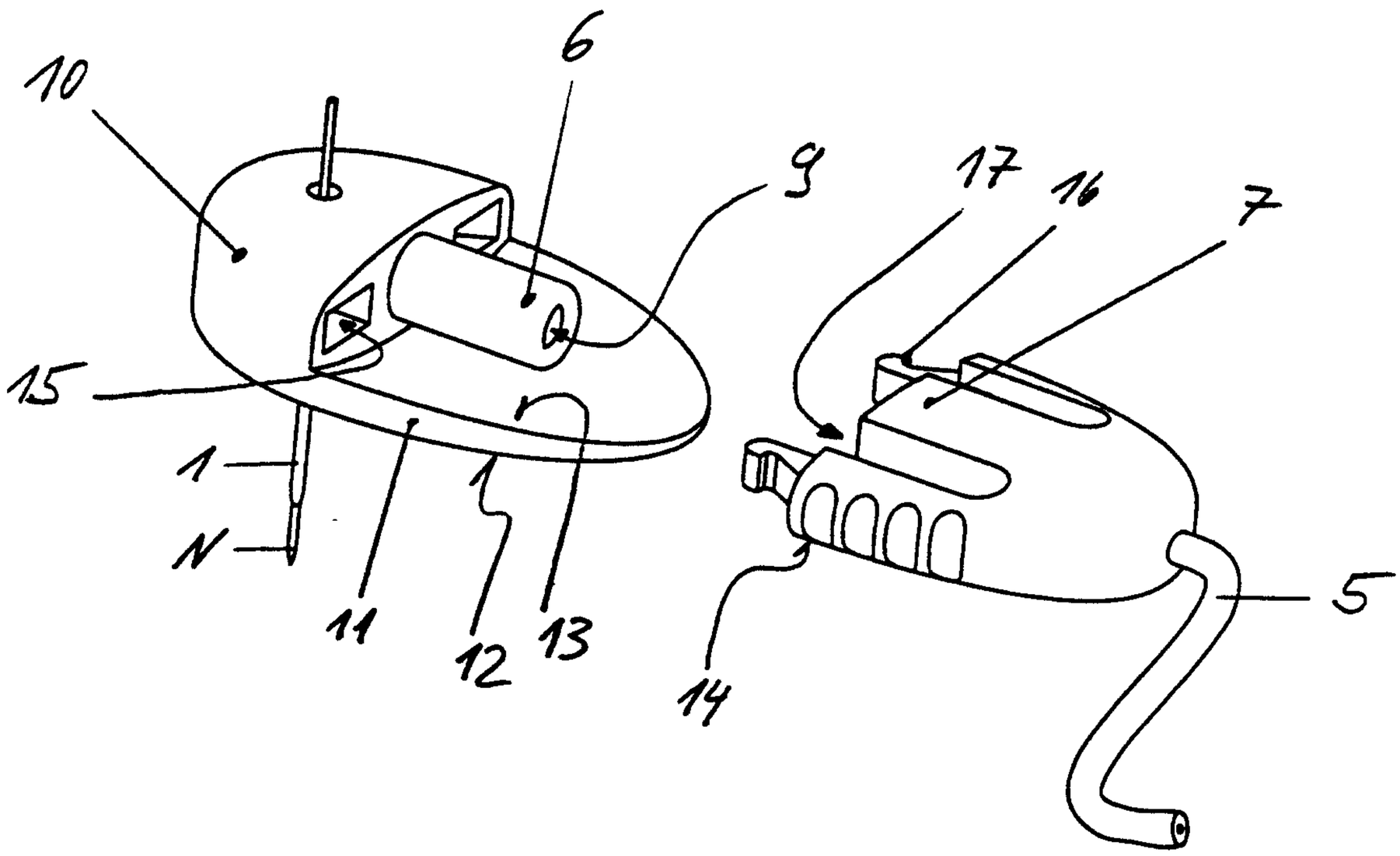


Fig. 3

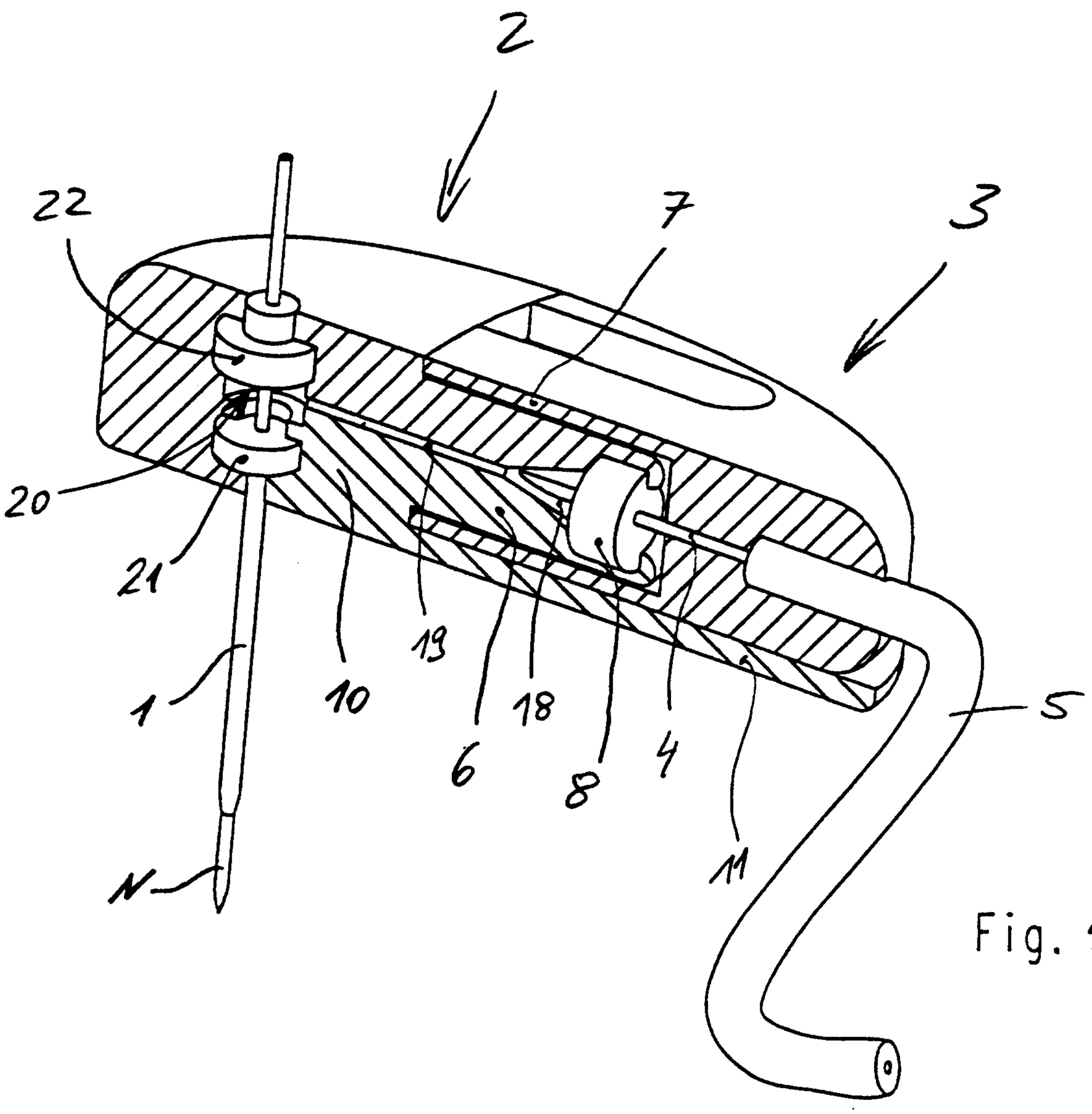


Fig. 4

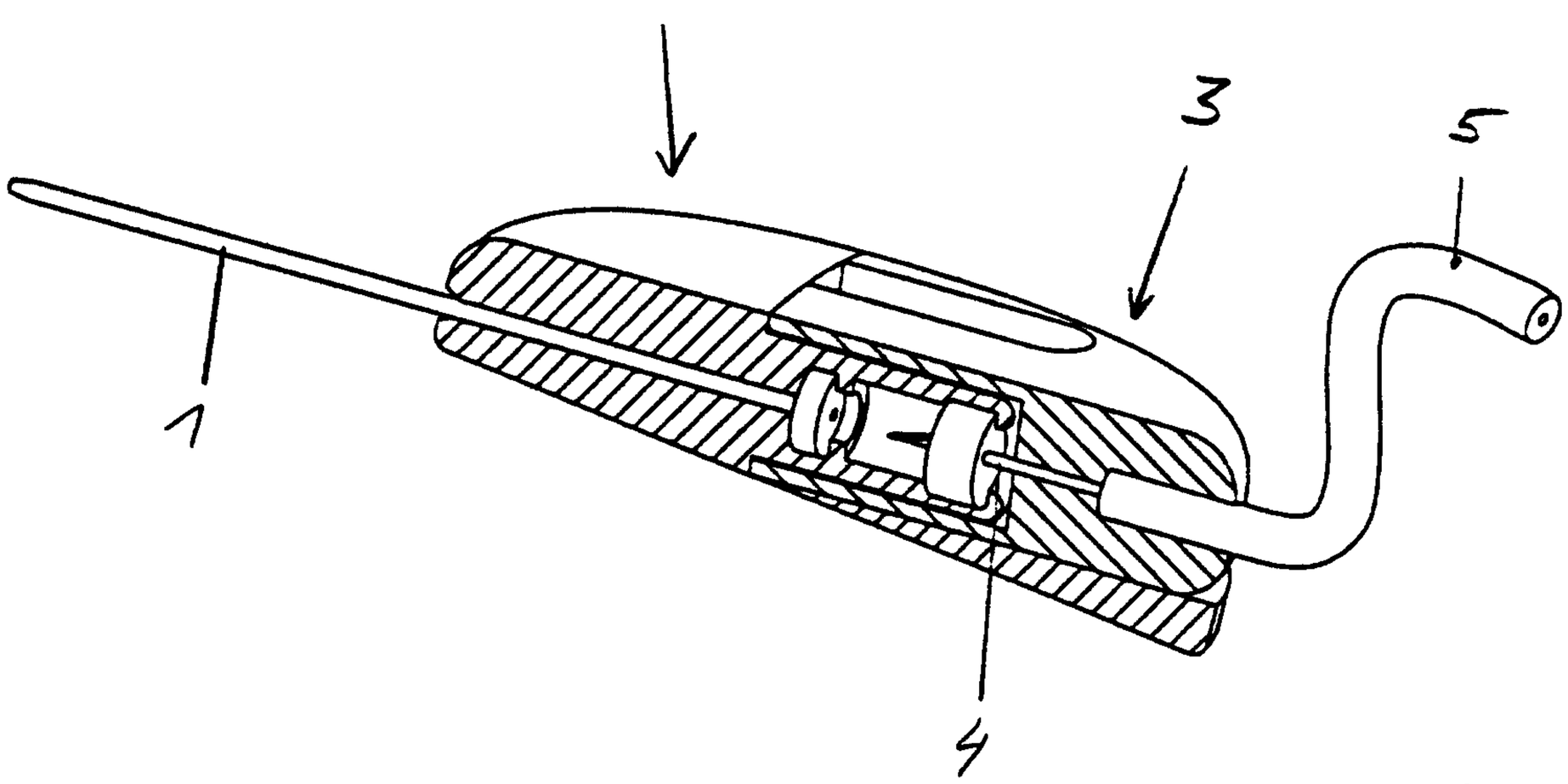


Fig. 5

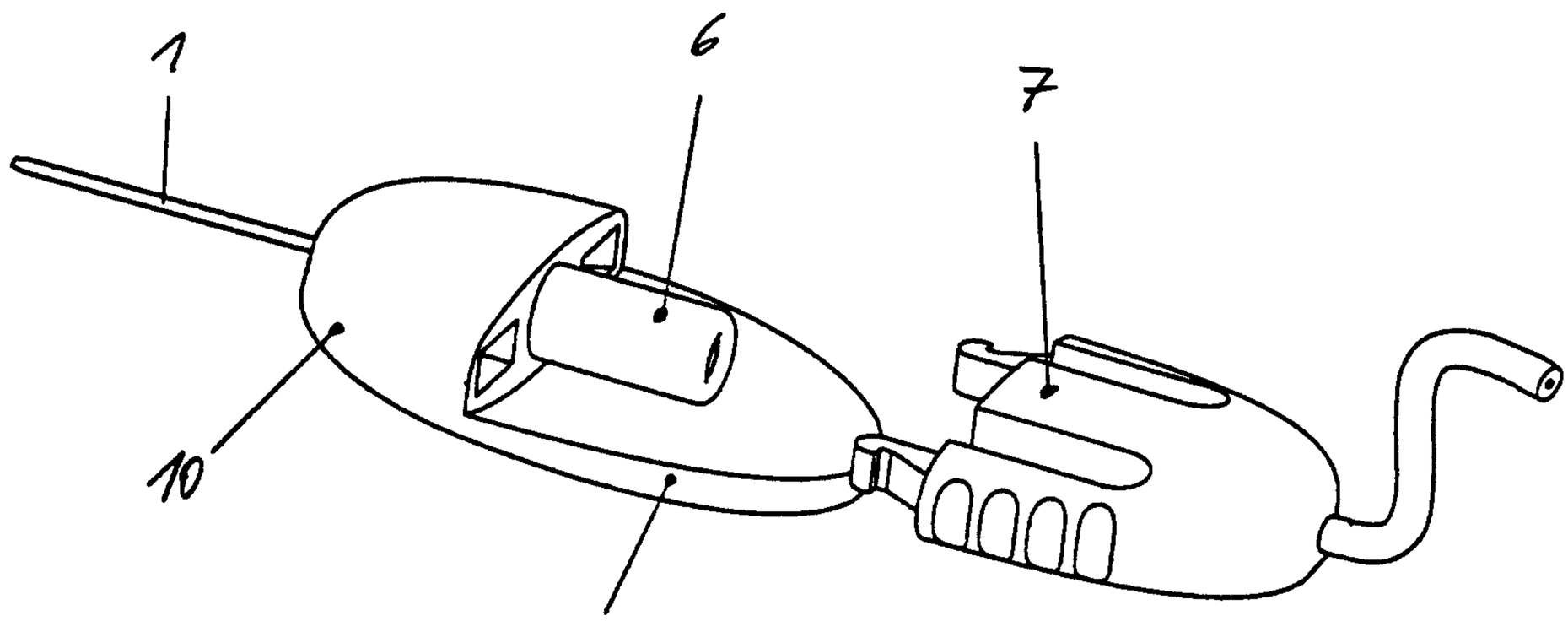
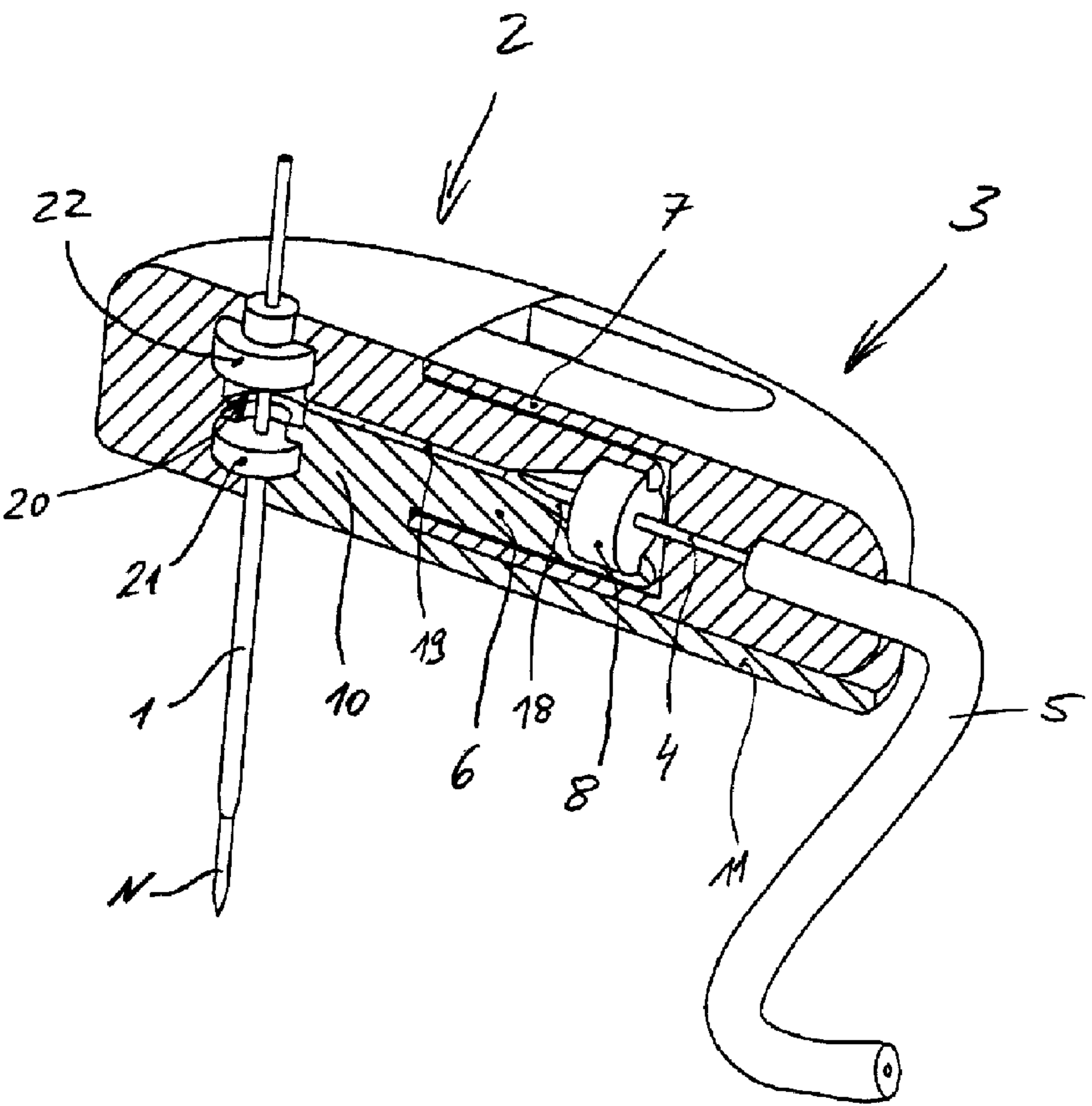


Fig. 6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