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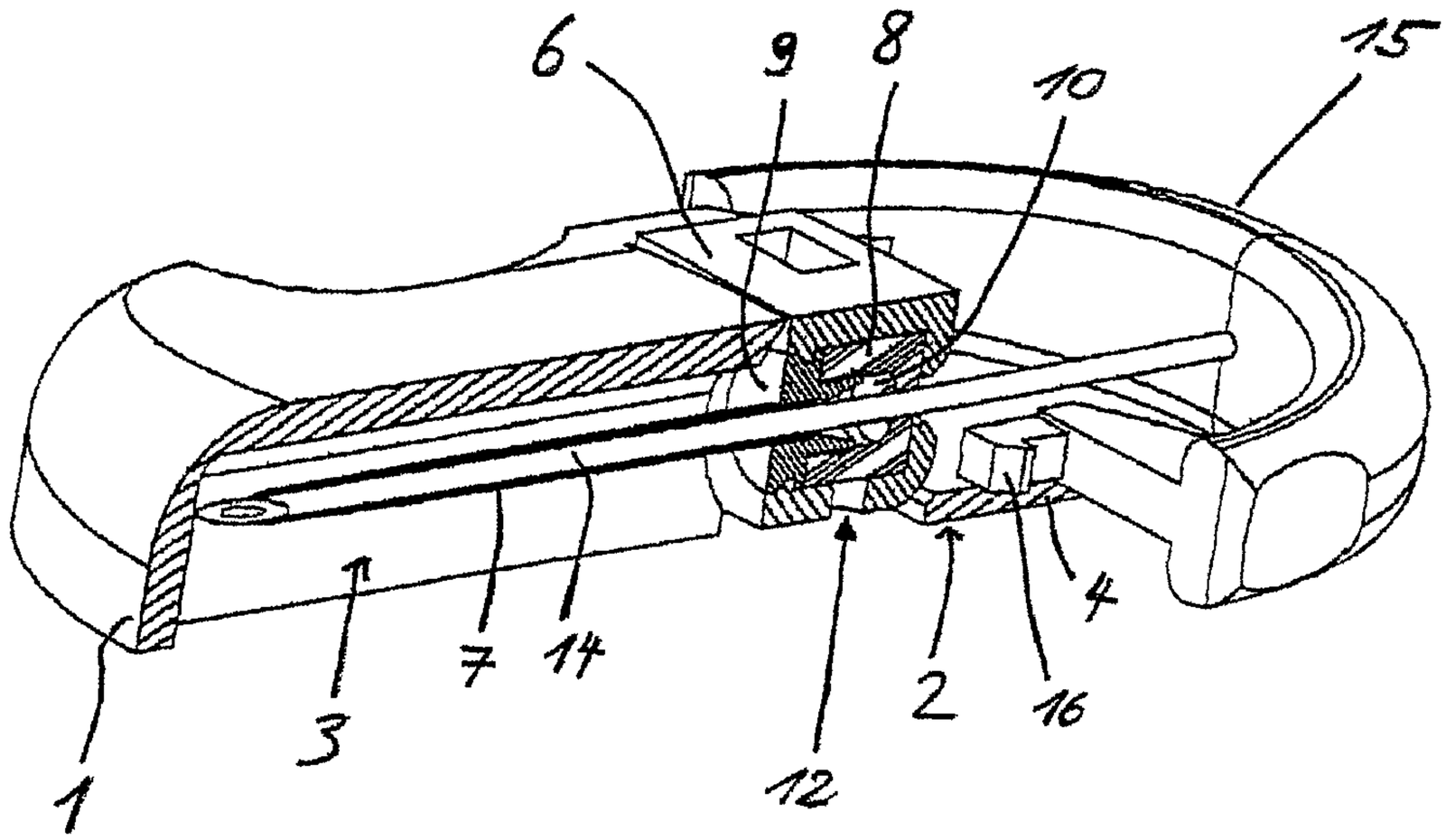
(54) Title: INSERTION HEAD FOR MEDICAL OR PHARMACEUTICAL APPLICATIONS



(57) Abrégé/Abstract:
Disclosed is an insertion head for medical or pharmaceutical applications. Said insertion head comprises: a) a housing (1) with a bottom side (2) that can be positioned on organic tissue; and b) a pricking device (5-16) that is provided with a pricking section (7, 14; 13) with a tip while being retained by the housing (1) in a protected position in which the housing (1) covers the tip as well as in a pricking position in which the tip protrudes from the bottom side (2); c) in the pricking position, the pricking section (7, 14; 13) is in a tilted position relative to the protected position.

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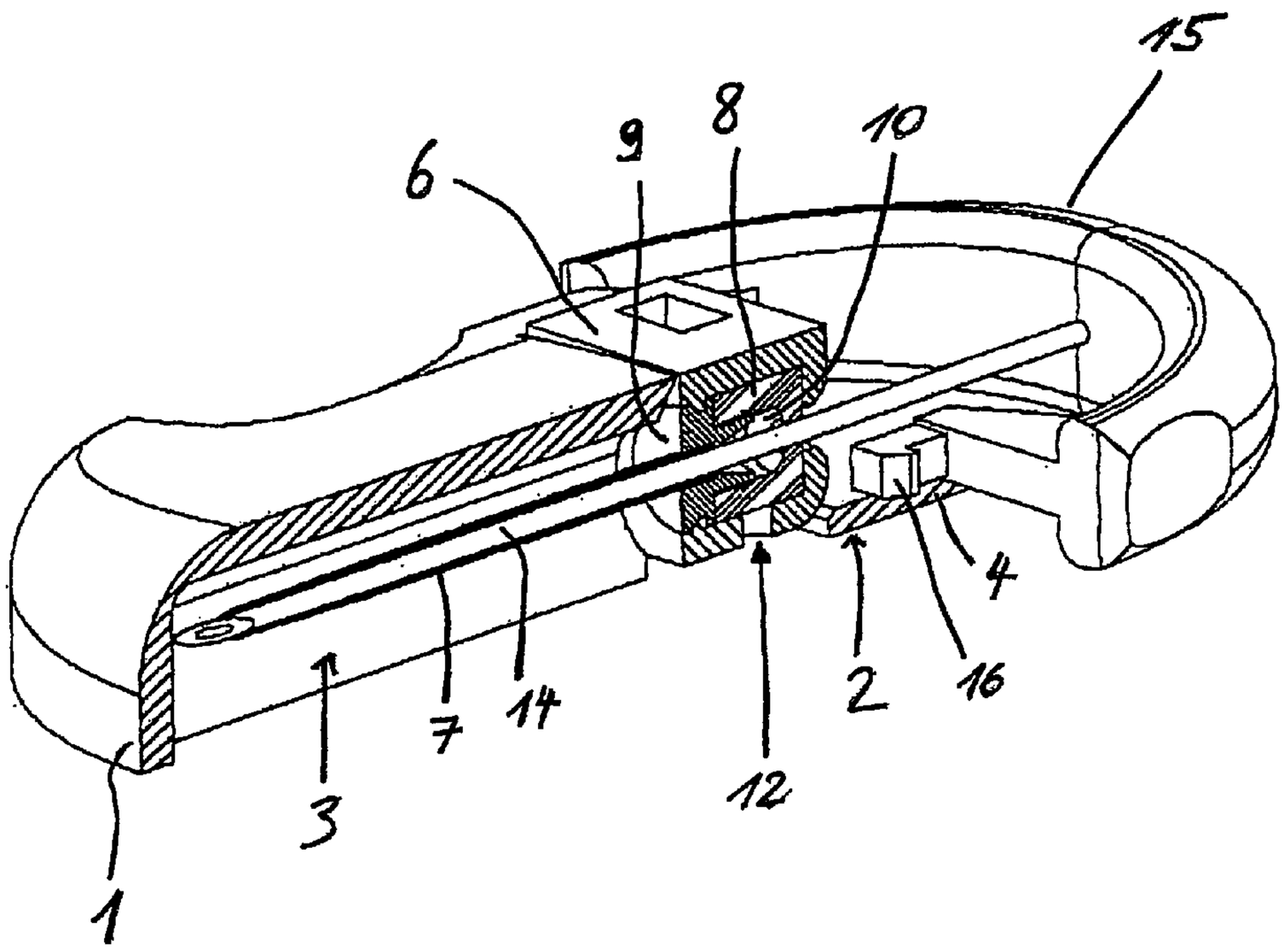
(54) Title: INSERTION HEAD FOR MEDICAL OR PHARMACEUTICAL APPLICATIONS

(54) Bezeichnung: INSERTIONSKOPF FÜR MEDIZINISCHE ODER PHARMAZEUTISCHE ANWENDUNGEN



(57) Abstract: Disclosed is an insertion head for medical or pharmaceutical applications. Said insertion head comprises: a) a housing (1) with a bottom side (2) that can be positioned on organic tissue; and b) a pricking device (5-16) that is provided with a pricking section (7, 14; 13) with a tip while being retained by the housing (1) in a protected position in which the housing (1) covers the tip as well as in a pricking position in which the tip protrudes from the bottom side (2); c) in the pricking position, the pricking section (7, 14; 13) is in a tilted position relative to the protected position.

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(57) Zusammenfassung: Insertionskopf für medizinische oder pharmazeutische Anwendungen, der Insertionskopf umfassend: a) ein Gehäuse (1) mit einer auf organischem Gewebe platzierbaren Unterseite (2), b) und einer Einstecheinrichtung (5-16), die einen Einstechabschnitt (7, 14; 13) mit einer Spitze aufweist, und von dem Gehäuse (1) in einer Schutzposition, in der das Gehäuse (1) die Spitze verdeckt, und in einer Einstechposition, in der die Spitze über die Unterseite (2) vorragt, gehalten wird, c) wobei der Einstechabschnitt (7, 14; 13) in der Einstechposition eine relativ zu der Schutzposition gekippte Lage einnimmt.

INSERTION HEAD FOR MEDICAL OR PHARMACEUTICAL APPLICATIONS

The invention relates to an insertion head for medical or pharmaceutical applications which may be positioned on organic tissue, in particular human skin, and comprises a puncturing device which penetrates the tissue when the insertion head is positioned on the tissue or as the case may be also only after the insertion head has been positioned on the tissue. The insertion head may, in particular, be a component of an infusion set for administration of a medicament.

Such an insertion head is known from DE 198 21 723 C1. The insertion head comprises a housing, a flexible cannula which projects from an underside of the housing and a puncturing needle which serves for positioning the flexible cannula subcutaneously in the tissue of a patient. For inserting into the tissue, the puncturing needle projects through the cannula and the cannula closely surrounds the puncturing needle. In order to protect a user of the insertion head from puncturing injuries, a needle protector is releasably fastened to the housing, which projects from the housing enclosing the cannula and the puncturing needle. The puncturing needle projecting from the underside of the insertion head with the surrounding cannula and, in particular, also the needle protector considerably increase the volume of the insertion head and thereby also the packaging thereof.

One object of the invention is to reduce the packaging volume for an insertion head which comprises a puncturing device and a protective device for the puncturing device.

The invention is based on an insertion head for medical or pharmaceutical applications which comprises a

housing with an underside which may be positioned on organic tissue and a puncturing device. The puncturing device comprises a puncturing section with a tip for penetrating the tissue. The puncturing section preferably projects from the underside of the housing. In principle, however, it may instead also project from one side of the housing, provided that it projects sufficiently far beyond the underside for penetrating the tissue. The puncturing section preferably projects beyond the underside of the housing, preferably directly from the underside, by a length adapted to subcutaneous applications. For applications inside the skin or in intramuscular tissue, the puncturing section is correspondingly shorter or longer. The puncturing section is understood to be the longitudinal section of the puncturing device which, during application, projects into the tissue.

The insertion head is preferably a component of an infusion set for administering insulin, a pain killer or another medicament which may be administered by infusion. The insertion head may also be used for diagnostic purposes instead of for an administration of medicaments or, in principle, even of a different product which can be administered. In such applications, the puncturing section may serve as a carrier for a sensor for measuring, for example, the concentration of glucose in a body fluid or a different physical and/or biochemical variable which is crucial or may be crucial for the state of health of a patient. The insertion head may, for diagnostic purposes, also be formed as a perfusion device. In such an embodiment, a rinsing fluid flows through the puncturing section after insertion into the tissue, which rinsing fluid absorbs one or more specific constituents of the body fluid when flowing through, in order to analyze the rinsing fluid enriched with the relevant constituent or the plurality of constituents. Finally, the insertion head may form a combined device for the administration

of a product and a diagnostic device. The puncturing section can be formed for the delivery of a product, which may be, in particular, a medicament or a rinsing fluid, or for the removal of a body fluid or only one or a plurality of specific constituents of a body fluid, i.e. in such an application the puncturing section forms at least one cross section of flow. The puncturing section may also serve for the delivery and removal of substances in combination. If the insertion head is merely formed as a measuring device, the puncturing section may also only serve for positioning of a sensor or a part of a sensor, i.e. purely as mechanical insertion device. In a development as a measuring device, it may also serve in addition to the mechanical inserting for the transmission of control signals to the sensor and/or of measuring signals from the sensor. Finally, in combined applications it may posses at least one cross section of flow for the transport of substances, i.e. a flow line, and at least one signal line. The signal line may be dispensed with if the sensor is designed for the wireless reception of control signals and/or the wireless dispatching of measuring signals. Finally, the puncturing device may also comprise two or more puncturing sections, which project separately. Thus a first puncturing section may serve for the transportation of substances into the tissue and a further, second puncturing section may serve for the transportation of substances out of the tissue or only for inserting a sensor or a part of a sensor. With a plurality of puncturing sections, which each comprise a flow section, various substances may be administered with the same insertion head. This may also be realized by means of a puncturing section which forms a plurality of separate cross-sections of flow.

In order to protect the user from puncturing injuries, a protective device is provided, which covers at least the tip of the puncturing section, preferably the entire puncturing section, in a first state of the

insertion head. In a second state, into which the insertion head may be brought for the application, the tip of the puncturing section is exposed and may be stabbed into the tissue.

According to the invention, the housing itself forms the protective device, i.e. the insertion head is provided with an integrated protective device. The puncturing device may adopt at least two predetermined positions relative to the housing, namely a first position in the first state of the insertion head and a second position in the second state of the insertion head. In both positions, the puncturing device is held by the housing, i.e. in both positions it is sufficiently fixedly connected to the housing in order to form a unit with the housing with regard to handling. The first position of the puncturing device is hereinafter denoted as the protected position and the second position as the puncturing position.

In the protected position, the puncturing section adopts a tilted position relative to the puncturing position, so that the housing covers the tip of the puncturing section.

In preferred embodiments, the puncturing device is permanently connected to the housing in a movable manner. The fact that the puncturing device is permanently connected to the housing means that at least for the movement from the protected position into the puncturing position and/or from the puncturing position into the protected position it is not released from the housing. Preferably the puncturing device is permanently connected to the housing even in the sense that it may not be released at all from the housing, at least not without the exertion of an outstanding force or only by destruction.

Preferably, the puncturing device is connected to the housing in such a manner that the puncturing section may be pivoted relative to the housing. Advantageously, the puncturing section may be pivoted into the housing so that at least the tip thereof, preferably the entire puncturing section, is set back behind the housing, preferably the underside thereof, and as a result is covered by the housing. In principle, however, it is also conceivable as an alternative that the puncturing section has a flexural elasticity which is sufficiently high to bend the puncturing section with the tip thereof towards the housing, so that the tip projects into a receptacle of the housing and is releasably catched therewith in the housing, or otherwise is releasably held in this bending state counter to the restoring elasticity thereof. Such an embodiment is, in particular, conceivable when the puncturing section in the puncturing position encloses an acute angle with the underside of the housing. It is also conceivable that, for such a bending, the puncturing section is fastened to the housing a small distance behind the underside of the housing, in order to obtain a certain bending length already inside the housing. It is advantageous, on the other hand, if the puncturing section in the puncturing position projects directly from the underside in contact with the tissue surface during use, i.e. is clamped to the underside in such a manner, preferably fixedly or optionally axially movably and otherwise fixedly, that a when penetrating the tissue flexible length of the insertion section is as short as possible. This applies, in particular, when the puncturing section, as preferred, is a thin needle. A puncturing section projecting directly from the underside is, in any case, preferred when the puncturing section does not have to be distorted for the protected position. In still a further alternative, the housing may form a displacement guide for the puncturing device, on which the puncturing device is guided in a translatory manner during its movement from

the protected position into the puncturing position and/or from the puncturing position into the protected position. Or the puncturing device is releasably fastened in a first connection to the housing in the protected position and preferably also releasably fastened in a further, second connection in the puncturing position, wherein the respective connection for the transfer into the respective other position is released, the puncturing device is separated from the housing and subsequently the new connection is established. The two connections may, in particular, be a respective plug connection and/or catching connection.

In the preferred embodiment in which the puncturing section may be pivoted relative to the housing, the puncturing device and the housing form with one another an articulation with an axis of articulation pointing transversely to the puncturing section. The puncturing device may be rotated about the axis of articulation relative to the housing. For the formation of such an articulation, the housing or the puncturing device may form a bearing bush and the other component may form the bearing pin. The bearing bush has to enclose the bearing pin over an angle of more than 180° when the puncturing device is to be fixedly held by the housing.

Although, in principle, it is sufficient for the puncturing device to be movable relative to the housing in only one direction, i.e. once, then preferably from the protected position into the puncturing position, it is preferred if the puncturing device is optionally movable to and fro between the two positions, so that the puncturing device may be moved into the puncturing position for use and again into the protected position for disposal. The connection between the puncturing device and the housing preferably is, or comprises, a positive connection, which in particular may form an articulation. The connection may alternatively,

however, also be purely non-positive or even produced by material bond, for example when the puncturing section is bent into the protected position.

The puncturing device is sufficiently fixedly held in its at least two different positions. This means that, during puncturing, the user does not have to hold the puncturing section but merely the housing or an insertion aid guiding the housing during puncturing, so that the puncturing section automatically penetrates the tissue when the housing is positioned on the tissue. The puncturing device is also held in the protected position, so that even at light vibrations it does not leave the protected position. In preferred embodiments, the puncturing device catches with the housing in each of the predetermined positions. The catching connection is releasable in the protected position. The catching connection may be releasable or unreleasable in the puncturing position. The catching connection may be formed by a connecting articulation itself, for example by the aforementioned bearing pin and the bearing bush thereof having polygonal cross-sections adapted to one another. The catching elements may instead or additionally, however, also be provided outside the respective articulated connection.

In a preferred development, the puncturing device is connected to the housing such that it is able to adopt two or more predetermined puncturing positions, each of the puncturing positions preferably being predetermined as catching positions. Thus the puncturing section may project in one of the puncturing positions vertically beyond the underside of the housing, i.e. at a right angle, and in a further puncturing position may enclose an angle of less than 90°, preferably an angle of less than 45°, with the underside. The user may freely choose between the predetermined puncturing positions. If the different positions of the puncturing device or only the different puncturing positions are

predetermined to be purely non-positive, so that the puncturing device is held purely non-positively on the housing in the relevant positions, the puncturing section may be moved relative to the underside of the housing into any angular position between 0 and 90°.

For the connection to the housing, the puncturing device preferably comprises a connecting structure from which the puncturing section projects. In preferred embodiments, in the puncturing position the connecting structure forms part of the underside of the insertion head, as the case may be also the entire underside, and rests with the underside thereof or part of the underside thereof, from which the puncturing section projects, on the tissue, when the puncturing section is completely inserted into the tissue. In principle, however, the underside of the connecting structure may also be set back a small distance behind the contact surface of the insertion head.

The housing forms the integrated protective device, preferably in the form of a receptacle which is open towards one outer side of the housing, so that the puncturing section may be pivoted into this receptacle or at least be bent with the tip thereof into the receptacle. It is also conceivable, in principle, that the puncturing device in the first state of the insertion head is received in the receptacle or at least with the tip thereof in the receptacle, and is releasably fastened to the housing in the protected position, preferably by means of a catching connection and is releasable from the housing and in the puncturing position can be connected again to the housing, preferably by means of a catching connection. The receptacle is preferably formed on the underside of the housing. It is further advantageous, particularly for a pivoting-in puncturing section, if the receptacle is not only open towards the respective outer side, preferably the underside, but also to an articulated

connection of the puncturing device. The receptacle may also be open toward the underside and towards another outer side, in order for example to allow pivoting movements about different pivoting axes.

The puncturing section may, in particular, comprise a flexible element, for example in the form of a flexible cannula, and a stabilizing element or be formed solely from these parts. The stabilizing element in such embodiments serves for stabilizing the flexible element during puncturing and may, after the insertion thereof into the tissue, be advantageously removed in order to cause as little irritation as possible in the tissue during use. The stabilizing element preferably forms a puncturing edge of the puncturing section.

A puncturing needle, in particular a steel needle which remains in the tissue during the application, may also form the puncturing section. In preferred subcutaneous applications, in particular such a puncturing section should be as short as possible, preferably at most 12 mm, even more preferably at most 8 mm. The needle should, on the one hand, be as flexible as possible for remaining in the tissue, i.e. elastically flexible but, on the other hand, has to be so rigid that it is able to penetrate into and preferably through the human skin.

In further preferred embodiments, the rigidity of the puncturing section is automatically reduced when the puncturing section is inserted into the tissue. Thus the puncturing section, for example, may be made from a material which, in the range of body temperature, for example when exceeding a temperature of 35 or 36°C, preferably even thereunder, namely in the region of 32° to 34°C, is markedly more flexible than at lower temperatures. Thus the puncturing section may, in particular, be formed as discribed in PCT/EP 04/00310, the PCT/EP 04/00309, the DE 101 17 286 A or the DE 10

2004 002 472. Particularly advantageous is a puncturing section which is formed completely or at least partially from a polymer material which, upon contact with body fluid, becomes softer and, as a result, the puncturing section becomes more flexible, the softening preferably relying solely on an absorption of water and thus on a loosening of secondary bonds of the polymer material associated therewith. In principle, the polymer material may, however, be also partially dissolved and the flexibility thereby increased. The use of a polymer material which can be softened by absorption, which in addition softens in the aforementioned temperature range due to the effect of the temperature, is also advantageous. In such embodiments, an additional stabilizing element may be dispensed with and the puncturing section is nevertheless more flexible in the tissue than a conventional puncturing needle.

The insertion head may be a component of an infusion set and/or diagnostic set, which also comprises a supply line and/or discharge line for a transportation of a substance and/or a signal transmission, in addition to the insertion head. For such a supply line and/or discharge line the housing advantageously forms a supporting section which, in particular, may be formed as a support. If the supply line and/or discharge line is releasably connected to the housing or the puncturing device, as preferred, the supporting section of the housing advantageously supports a connector to which the supply line and/or discharge line is connected. It is advantageous if the supporting section forms a guide for the connector which in the positioned state of the insertion head is parallel to the tissue surface, so that the connector in the direction of the tissue surface along the guide can be connected slidingly, fluidically and/or with respect to signalling technique to the housing or preferably

directly to the puncturing device. Mechanically, the connector is preferably connected to the housing.

If additionally to a flexible element the puncturing device comprises a stabilizing element, for example a puncturing needle, preferably a handle part of the stabilizing element is received in the supporting section when the puncturing device adopts its protected position. In such embodiments the handle part of the stabilizing element and the connector use the same supporting section of the housing.

Preferred features which supplement the aforementioned embodiments or which may be supplemented thereby, are also discribed in the dependent claims and the combinations thereof.

A preferred embodiment of the invention is described hereinafter on the basis of figures. Features becoming apparent in the embodiment may advantageously develop the subjects of the claims and also the aforementioned embodiments, either separately or in any combination. It show:

Figure 1 an insertion head of a first embodiment with a puncturing device in a puncturing position before the inserting into organic tissue,

Figure 2 the insertion head with the puncturing device in a protected position,

Figure 3 the insertion head with the puncturing device shown in a view in the protected position,

Figure 4 the insertion head with the puncturing device in the puncturing position and a connected fluid supply line,

Figure 5 an insertion head of a second embodiment in longitudinal section and

Figure 6 the insertion head of the second embodiment in a view.

Figure 1 shows in a first embodiment an insertion head with a housing 1 in longitudinal section and a puncturing device which is shown partially in the same cutting plane and adopts a puncturing position relative to the housing 1. The puncturing device comprises a connecting structure 6 which is permanently connected in a movable manner to the housing 1. The puncturing device further comprises a flexible penetrating element 7 which, in this embodiment, is formed as a cannula with an inner cross section of flow through which, when the insertion head 1 is used as an infusion head of an infusion set, a fluid infusate, for example insulin, flows. The penetrating element 7 is so flexible that, without an additional stabilization, it is not able to penetrate through the skin of a patient and is not even able to penetrate into the skin. For the inserting of the penetrating element 7, a sufficiently rigid stabilizing element 14 in the form of a puncturing needle projects through the connecting structure 6 and the penetrating element 7 projecting therefrom, so that the stabilizing element 14 projects with a free tip beyond the free end of the flexible penetrating element 7. The flexible penetrating element 7 closely surrounds the peripheral outer surface of the stabilizing element 14 with a light tensioness.

The penetrating element 7 and the stabilizing element 14 form a puncturing section of the puncturing device which in the puncturing position shown in Figure 1 projects at right angles beyond an underside 2 of the housing 1. For the application, the insertion head 1 can be moved with the underside 2 thereof in the

direction of the skin, wherein the stabilizing element 14 pierces the skin and the puncturing section 7, 14 penetrates into and through the skin until the insertion head 1 contacts with its underside 2 the skin surface. The underside 2 is preferably formed as an adhesive surface which is covered with a pull-off film, which is pulled-off for the application, in order to expose the adhesive surface. As soon as the underside 2 contacts the skin surface, an adhesive connection is therefore automatically produced.

The stabilizing element 14 is provided with a handle part 15. The handle part 15 has the shape of one half of a ring. The stabilizing element 14 projects from a central area from the inner side of the handle part 15 and beyond the ring ends of the handle part 15. In the two outer end regions of the handle part 15 in each case one connecting element 16 projects radially inwards from the inner side thereof, which serves for the fastening of the handle part 15 and thus jointly of the stabilizing element 14 to the connecting structure 6. The two connecting elements 16 of the handle part 15 each form a hook-shaped catching element, which releasably catches with a corresponding counter element in a recess of the connecting structure 6. The catching engagement of the two connecting elements 16 can be released by the two ring ends of the handle part 15 being pressed towards one another, counter to the restoring elasticity thereof, and the handle part 15 is then moved away from the connecting structure 6. In this case, the stabilizing element 14 is pulled out of the flexible penetrating element 7 so that after the removal of the stabilizing element 14 only the penetrating element 7 still remains in the tissue.

The connecting structure 6 forms a hollow space which is open on one side, from which the penetrating element 7 projects, and further comprises a passageway 11 for the stabilizing element 14 opposite the open side and

further comprises a second passageway 12 for the connection of an infusate supply line. In the hollow space a sealing element 8 is arranged which seals the two passageways 11 and 12. The flexible penetrating element 7 projects from a holder 9, which closes the hollow space of the connecting structure 6, apart from the cross section of flow of the penetrating element 7, on the open side thereof and is held there positively and non-positively on the connecting structure 6. At the same time, the holder 9 also holds the connecting element 8 within the hollow space of the connecting structure 6 in position, so that, by pressing against the two passageways 11 and 12, it sealingly closes same. The sealing element 8 forms together with the holder 9 in the hollow space a chamber 10 through which, during an infusion, the infusate flows into the flexible penetrating element 7. The sealing element 8 is formed such that it may be pierced by the stabilizing element 14 and both in the pierced state and after pulling out of the stabilizing element 14 seals the passageways 11 and 12.

The housing 1 in the section plane shown comprises three sections. In a central section of the three sections, the housing 1 holds the connecting structure 6. To the one side of the central section, the housing 1 forms a receptacle 3 in the form of a hollow space which opens towards the underside 2 of the housing 1 and towards the connecting structure 6. The connecting structure 6 is held by the housing 1 in such a manner that it is set back a small distance behind the underside 2. To the other side of the central section, the housing 1 forms a supporting section 4 in the form of a plate-shaped or disc-shaped flat part.

Figure 2 shows the insertion head in the same sectional view as Figure 1, wherein the puncturing device nevertheless adopts a protected position, in which its entire puncturing section 7, 14 is received in the

receptacle 3. The transfer from the puncturing position into the protected position takes place by a rotary movement of the connecting structure 6 about a rotational axis pointing transversely to the puncturing section 7, 14.

By means of the rotational movement of the connecting structure 6 the puncturing section 7, 14 is pivoted into the hollow space 3. The handle part 15, which beyond the connecting structure 6 lies opposite the puncturing section 7, is used by the user not only as a handle for pulling out of the stabilizing element 14 but also as a pivoting handle. In the protected position of the puncturing device the handle part 15 rests on the upper side of the supporting section 4, which thus forms a support for the handle part 15.

The insertion head is delivered with the puncturing device located in its protected position. Figure 2 thus shows the insertion head in the delivery state. In this state, the height of the insertion head is only low, measured onto the underside 2. The volume of the sterile packaging of the insertion head can be accordingly small. The length and width of the insertion head measured in the plain of the underside 2 can correspond to the corresponding dimensions of conventional insertion heads. The minimum height is predetermined by the connecting structure 6, which is provided with the connections 11 and 12 for the stabilizing element 14 and an infusate supply line, with a connecting device for the connection to the housing 1 and with a connecting device for the handle part 15. The supporting section 4 and the handle part 15 pivoted thereon, together have approximately the height of the housing section provided with the receptacle 3.

Figure 3 shows the insertion head with the puncturing device located in the protected position thereof.

Whilst the housing section forming the hollow space 3 is shown again in the longitudinal section of Figures 1 and 2, Figure 3 shows the connecting structure 6 completely in a perspective view. The connecting structure 6 forms on two sides opposing one another in each case one pivot pin 5. The two pivot pins 5 project transversely to the puncturing section 7, 14. The housing 1 forms for each of the pivot pins 5 in each case one articulated bush. The connecting structure 6 and the housing 1, therefore, form in each case one articulated element of a simple swivel joint with a single axis of articulation, about which the connecting structure 6 rotatably and the puncturing section 7, 14 thereby pivotably is connected to the housing 1. The connecting structure 6 may, therefore, also be denoted as a rotary head. The connection with the housing 1 is further designed such that the connecting structure 6 forms, both in the protected position as well as in the puncturing position, in each case a catching connection with the housing 1.

Figure 4 shows the insertion head with the attached infusate supply line 19. The supply line 19 can, in particular, be formed by a flexible catheter. The stabilizing element 14 is released from the connecting structure 6 and can, for example, be placed in the packaging of the insertion head.

The infusate supply line 19 is fixedly connected to a connector 18 which serves the connection of the infusate supply line 19 to the connecting structure 6 and thereby to the flexible penetrating element 7. The connector 18 forms two connecting elements 16 for the mechanical fastening to the housing 1 of which one is shown in the longitudinal section of Figure 4. Alternatively, the positive connection of the connector 18, assuming appropriate modifications, could be formed with the connecting structure 6. The longitudinal section plane shown in Figure 4 forms a plane of

symmetry of the insertion head including the connector 18. The two connecting elements 16 are flexural elastic and at their ends in each case provided with one catching element in the form of a hook. The connector 18 further comprises an underside which is shaped to correspond to the upper side of the supporting section 4, so that the connector can be slidably pushed over the upper side of the supporting section 4 towards the connecting structure 6, until the connection to the puncturing device and a catching connection with the housing 1 are established. For the fluidic connection, the connector 18 forms a connecting needle 20 which, at least substantially parallel to the underside of the connector 18, protrudes therefrom in the pushing forward direction thereof and, upon pushing forward of the connector 18 up to the connecting structure 6, penetrates the sealing element 8 thereof, so that the connecting needle 20 projects with its tip into the chamber 10. The connecting needle 20 is hollow and the connector 18 forms a cross-section of a line which connects the infusate supply line 19 to the connecting needle 20. In this manner, after the connection, a fluid-tight connection is established from the infusate supply line 19 up to the free end of the penetrating element 7.

The typical application sequence of the insertion head is as follows:

The insertion head reaches the user packaged in a sterile manner in the delivery state shown in Figure 2. The user opens the packaging and removes the insertion head. Due to the integrated protective device formed by the housing 1 in the form of the receptacle 3 and the puncturing device located in the protected position thereof, the user is protected from puncturing injuries and the puncturing section 7, 14 is protected from damage.

In a next step, the pull-off film is pulled-off from the underside 2 of the housing 1, so that the adhesive surface of the underside 2 is exposed. For the application, the user holds the housing 1 with one hand and grips the handle part 15 with the other hand. He pivots the handle part 15 about the rotational axis formed by the swivel joint and as a result pivots the puncturing device into the puncturing position shown in Figure 1, in which the puncturing section 7, 14 projects beyond the underside 2 of the housing. In this state, the user presses the insertion head against the skin, so that the puncturing section 7, 14 penetrates into the skin and penetrates through the skin, until the insertion head contacts the skin surface with the underside 2 thereof and thereby adheres to the skin surface by adhesive forces. The free end of the flexible penetrating element 7 is automatically positioned in the tissue, preferably subcutaneously, by puncturing. The stabilizing element 14 can now be removed by the user pressing together the two ring ends of the handle part 15, bringing the connecting elements 16 thereof out of engagement with the connecting structure 6, and pulling out the handle part 15 with the stabilizing element 14 fastened thereto of the connecting structure 6 and, in particular, of the penetrating element 7. The sealing element 8 ensures that the cross section of flow of the penetrating element 7 is sealed in a sterile manner from the surroundings even after the pulling out. The insertion head is now ready for the connection of the infusate supply line 19 (Figure 4). For the connection, the connector 18, resting on the supporting section 4 of the housing 1, is pushed forward, with the connecting needle 20 ahead, onto the connecting structure 6. During this pushing movement, the connecting needle 20 penetrates through the passageway 12 and the sealing element 8 into the chamber 10. At the same time, the connecting elements 21 of the connector 18 come into catching engagement with the housing 1 so that firstly

the fluidic connection and secondly the mechanical connection of the infusate supply line 19 to and with the flexible penetrating element 7 is established, as shown in Figure 4.

If the pull-off film has a cut-out in the region of the receptacle 3, the pull-off film can also only be removed after pivoting away the puncturing section 7, 14.

After the application, the connector 18 is released from the housing 1. The insertion head is released from the skin surface and thus the flexible penetrating element 7 is pulled out of the tissue.

Figure 5 shows an insertion head of a second embodiment with a puncturing device located in the protected position in longitudinal section. Figure 6 shows the insertion head of the second embodiment in the same state in a view.

The insertion head of the second embodiment comprises a one-piece puncturing section 13, which even during the application, in this embodiment the administration of a product, remains in the tissue. The stabilizing element 14 of the first embodiment is dispensed with. The puncturing section 13 may be formed as a conventional puncturing needle, in particular piercing cannula, for example as steel needle. Such a puncturing section 13 should be as flexible as possible, in order to cause as little irritation as possible in the tissue. However, it has to have a minimum amount of flexural strength, in order to be able to penetrate in and preferably through the skin further into the tissue. In a preferred development, the puncturing section 13 which remains in the tissue, which also in the development forms a cutting element for penetrating into the tissue, at least partially consists of a material which as a result of contact with the tissue becomes more

flexible. Suitable materials are, in particular, polymers, which bind at least one component of the body fluid, with which the puncturing section 13 comes into contact or is in contact, respectively, in the tissue.

Preferably, this bindable component is water. As a result of the binding the respective material becomes softer, but maintains its integrity to such an extent that the cross section of flow formed by the puncturing section 13 remains continuously open for the transportation of the product.

The insertion head of the second exemplary embodiment comprises a handle 15a which is modified relative to the first embodiment. The handle 15a with regard to the shape corresponds to the handle 15 of the first embodiment, but is no longer connected to a stabilizing element, but formed as a pure handle part 15a. The handle 15a serves for the transfer of the puncturing device into the puncturing position, and as the case may be also again for the return from the puncturing position into the protected position. The handle 15a may further be used, as the handle 15 of the first embodiment, as handle for the entire insertion head, in order to position same on the tissue, in particular human skin. The handle 15a may further also serve as a handle when releasing the insertion head from the tissue. During the application itself, the handle 15a is released from the remainder of the insertion head, so that said represents a flat component on the tissue surface. For releasing from the tissue surface the handle 15a can again be catched to the connecting structure 6 and be used as a handling aid for the release. The handle 15a may also be used as an additional part for releasing the insertion head of the first embodiment.

Moreover, the insertion head of the second embodiment corresponds to that of the first, wherein merely for

the sake of completeness it is pointed out that the connecting structure 6 naturally does not have to have a passageway for the stabilizing element 14, due to the omission of the stabilizing element 14. The passageway 11 is accordingly dispensed with, but could in principle, with corresponding sealing, remain in the connecting structure 6.

The fluid chamber 10 could, in particular, in the second embodiment, be converted into a simple cross section of flow which continuously lengthens the puncturing section 13 up to the passageway 12 and in which preferably is arranged a sealing disc, in order to seal the passageway or the connection 12, respectively, from the surroundings.

Reference Numerals:

1	Housing
2	Underside
3	Receptacle
4	Support, guide, supporting section
5	Articulated element, bearing pin
6	Connecting structure
7	Flexible penetrating element, line element
8	Seal
9	Holder
10	Fluid chamber
11	Passageway
12	Connection, passageway
13	Puncturing section, puncturing needle
14	Stabilizing element
15	Handle
15a	Handle
16	Connecting element
17	-
18	Connector
19	Line element, infusate supply line
20	Connecting needle

Claims

1. Insertion head for medical or pharmaceutical applications, the insertion head comprising:

a) a housing (1) with an underside (2) which can be positioned on organic tissue

b) and a puncturing device (5-16) which comprises a puncturing section (7, 14; 13) with a tip, and is held by the housing (1) in a protected position in which the housing (1) covers the tip and in a puncturing position in which the tip projects beyond the underside (2),

c) wherein the puncturing section (7, 14; 13) in the puncturing position adopts a position which is tilted relative to the protected position.

2. Insertion head according to the preceding claim, characterized in that the puncturing device (5-16) is permanently connected to the housing (1) in a manner such that it is movable from the protected position into the puncturing position.

3. Insertion head according to one of the preceding claims, characterized in that the puncturing section (7, 14; 13) is connected to the housing (1) in a swivelling manner.

4. Insertion head according to one of the preceding claims, characterized in that the puncturing device (5-16) and the housing (1) form with one another an articulation (5) with an axis of articulation pointing transversely to the puncturing section (7, 14; 13) about which the puncturing device (5-16) is rotatable relative to the housing (1).

5. Insertion head according to one of the preceding claims, characterized in that the housing (1) also holds the puncturing device (5-16) in a

predetermined further puncturing position, wherein the puncturing section (7, 14; 13) in one of the puncturing positions has an inclination with respect to the bottom side (2) which is different from that in the other puncturing position.

6. Insertion head according to one of the preceding claims, characterized in that the housing (1) holds the puncturing device (5-16) positively and/or non-positively, preferably in a catching connection in at least one of the positions.

7. Insertion head according to one of the preceding claims, characterized in that the housing (1) comprises a receptacle (3) which in the protected position of the puncturing device (5-16) receives at least the tip of the puncturing section (7, 14; 13).

8. Insertion head according to the preceding claim, characterized in that the receptacle (3) is open towards one outer side (2) of the housing (1).

9. Insertion head according to the preceding claim, characterized in that the receptacle (3) is open towards the underside (2).

10. Insertion head according to one of the three preceding claims, characterized in that the puncturing device (5-16) comprises a connecting structure (6) which is connected to the housing (1) in an articulated manner and from which the puncturing section (7, 14; 13) projects, and in that the receptacle (3) opens towards the connecting structure (6).

11. Insertion head according to one of the preceding claims, characterized in that the puncturing section (7, 14; 13) comprises or is a line element (7) for a fluid.

12. Insertion head according to the preceding claim, characterized in that the puncturing device (5-16) comprises a fluid chamber (10) with a fluid connection (12), which is connected to the line element (7), and a seal (8) for the fluid connection (12).

13. Insertion head according to one of the preceding claims, characterized in that the puncturing device (5-16) comprises a connecting structure (6) which is connected to the housing (1), from which the puncturing section (7, 14; 13) projects.

14. Insertion head according to the preceding claim, characterized in that the connecting structure (6) has a connection (12) for a fluid or signals.

15. Insertion head according to one of the two preceding claims, characterized in that the housing (1) and the connecting structure (6) form with one another an articulation (5) in which the puncturing device (5-16) is movably connected to the housing (1), preferably between catching positions in which the connecting structure (6) and the housing (1) catch.

16. Insertion head according to one of the three preceding claims, characterized in that the puncturing device (5-16) for a transfer into the puncturing position or into the protected position comprises a handle (15a; 15) projecting from the connecting structure (6), which is, preferably releasably, connected to the connecting structure (6).

17. Insertion head according to the preceding claim, characterized in that the housing (1) forms a support (4) with a support surface facing away from the underside (2), on which the handle (15a; 15) rests, when the puncturing device (5-16) adopts the protected position.

18. Insertion head according to one of the five preceding claims, characterized in that the puncturing section (7, 14) comprises a flexible penetrating element (7) and a stabilizing element (14) for the penetrating element (7), and in that the stabilizing element (14) is releasably connected to the connecting structure (6).

19. Insertion head according to the preceding claim, characterized in that the puncturing device (5-16) comprises a handle (15) holding the stabilizing element (14) at a proximal end and the housing (1) forms a support (4) with a support surface facing away from the underside (2), on which the handle (15) rests when the puncturing device (5-16) adopts the protected position.

20. Insertion head according to one of the two preceding claims, characterized in that the stabilizing element (14) is attached to the connecting structure (6) by means of a catching connection.

21. Insertion head according to one of the preceding claims, characterized in that a puncturing needle (13), which remains in the tissue during the application, forms the puncturing section (13).

22. Insertion head according to one of the preceding claims, characterized in that the puncturing section (13) is or comprises a puncturing needle (13), which remains in the tissue during the application, and in that the flexibility of the puncturing needle (13) increases upon contact with the tissue.

23. Insertion head according to the preceding claim, characterized in that the puncturing needle (13) consists at least partially of a polymer material, which binds at least one component of a body fluid and

in that the flexibility of the puncturing needle (13) increases as a result of the binding.

24. Insertion head according to one of the preceding claims, characterized in that a handle (15a; 15) is provided which projects from the housing (1) for the handling of the insertion head when positioning on the tissue or releasing from the tissue.

25. Insertion head according to one of the preceding claims, characterized in that the insertion head comprises a connector (18) having a line element (19) for a fluid or signals which can be attached to the puncturing device (5-16).

26. Insertion head according to the preceding claim, characterized in that the connector (18) can mechanically be connected to the housing (1) or to the connecting structure (6).

27. Insertion head according to one of the two preceding claims in combination with one of claims 17 and 19, characterized in that the support (4) forms a guide for the connector (18) when the connector (18) is connected to the puncturing device (5-16).

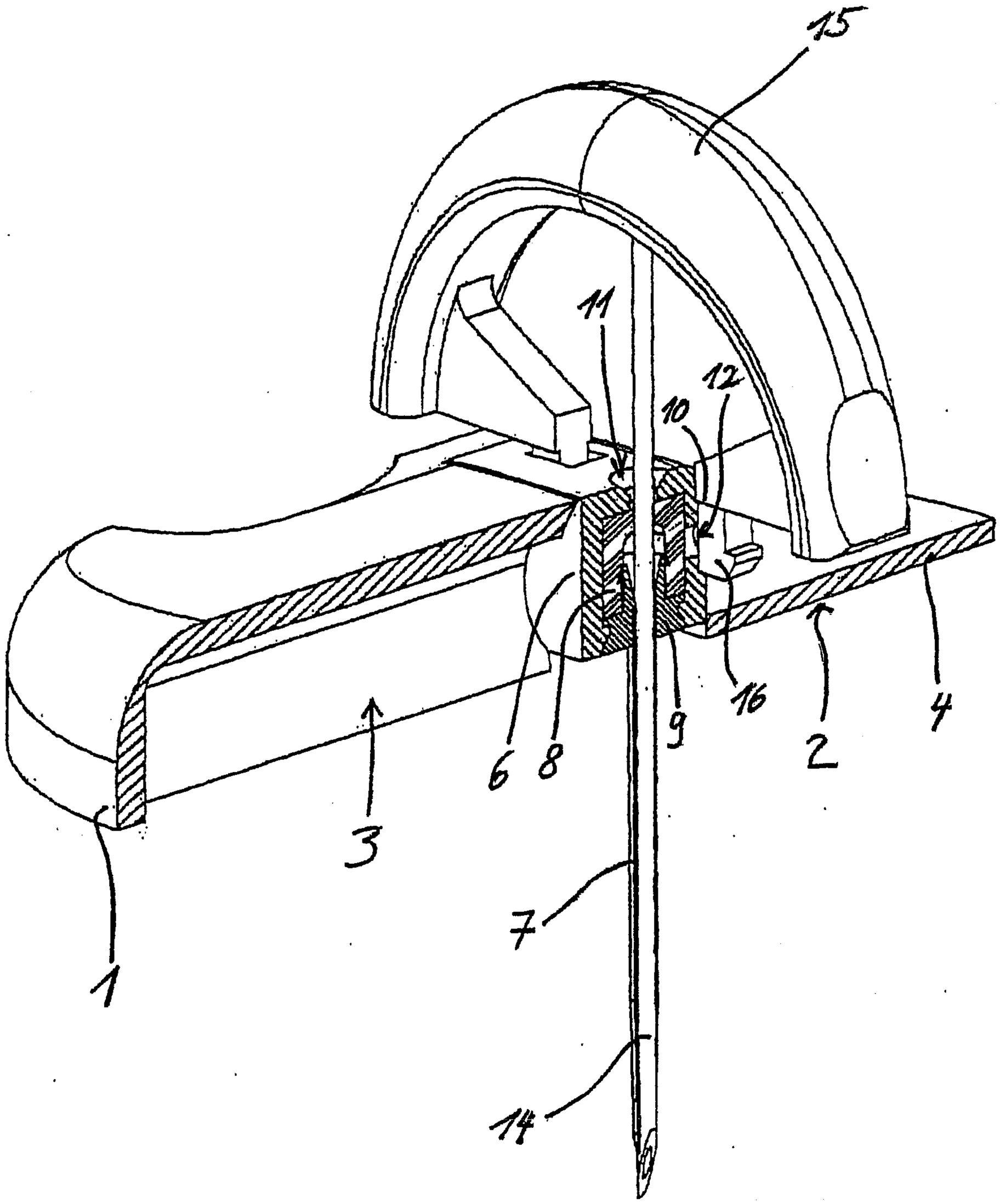


Fig. 1

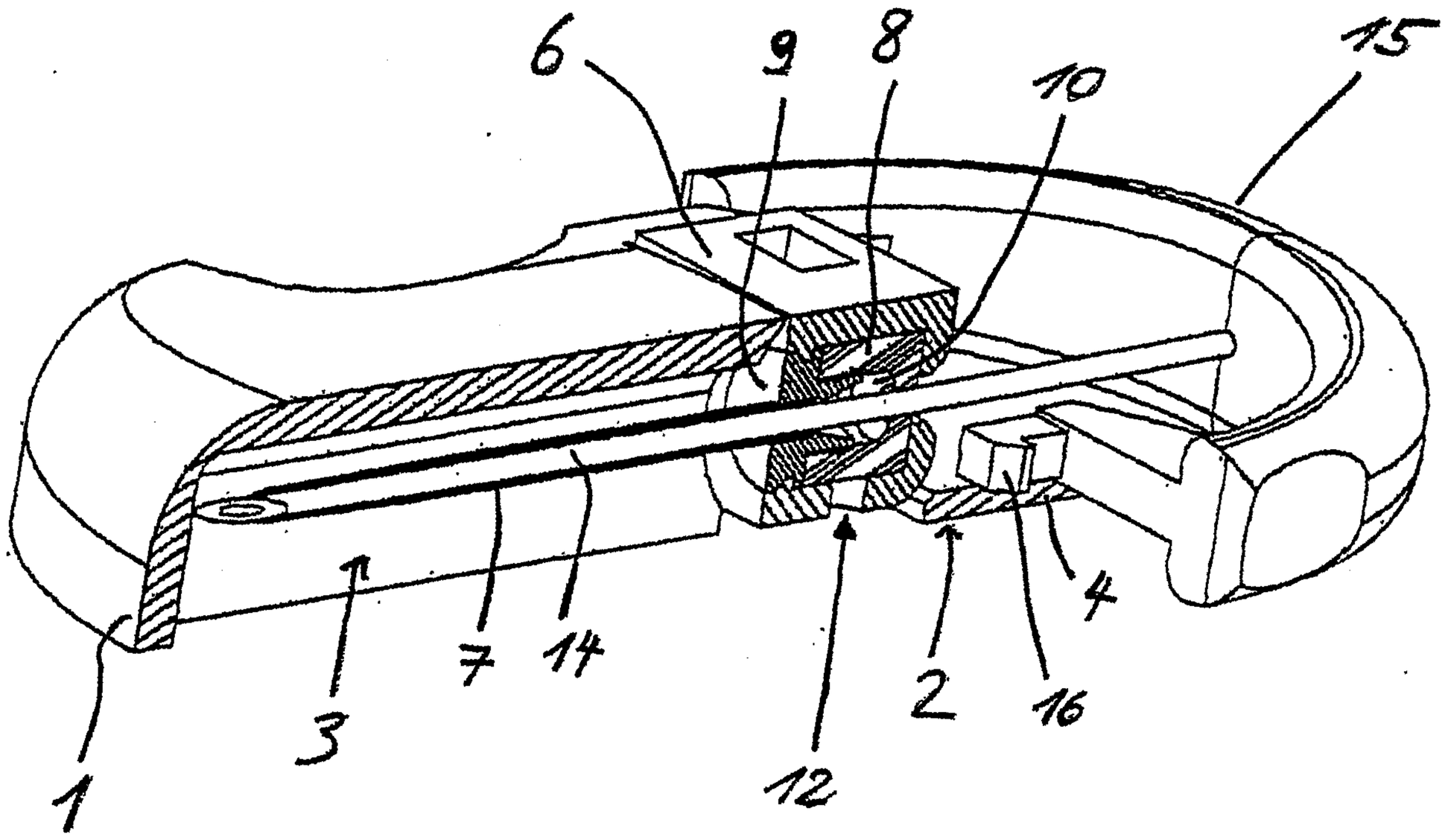


Fig. 2

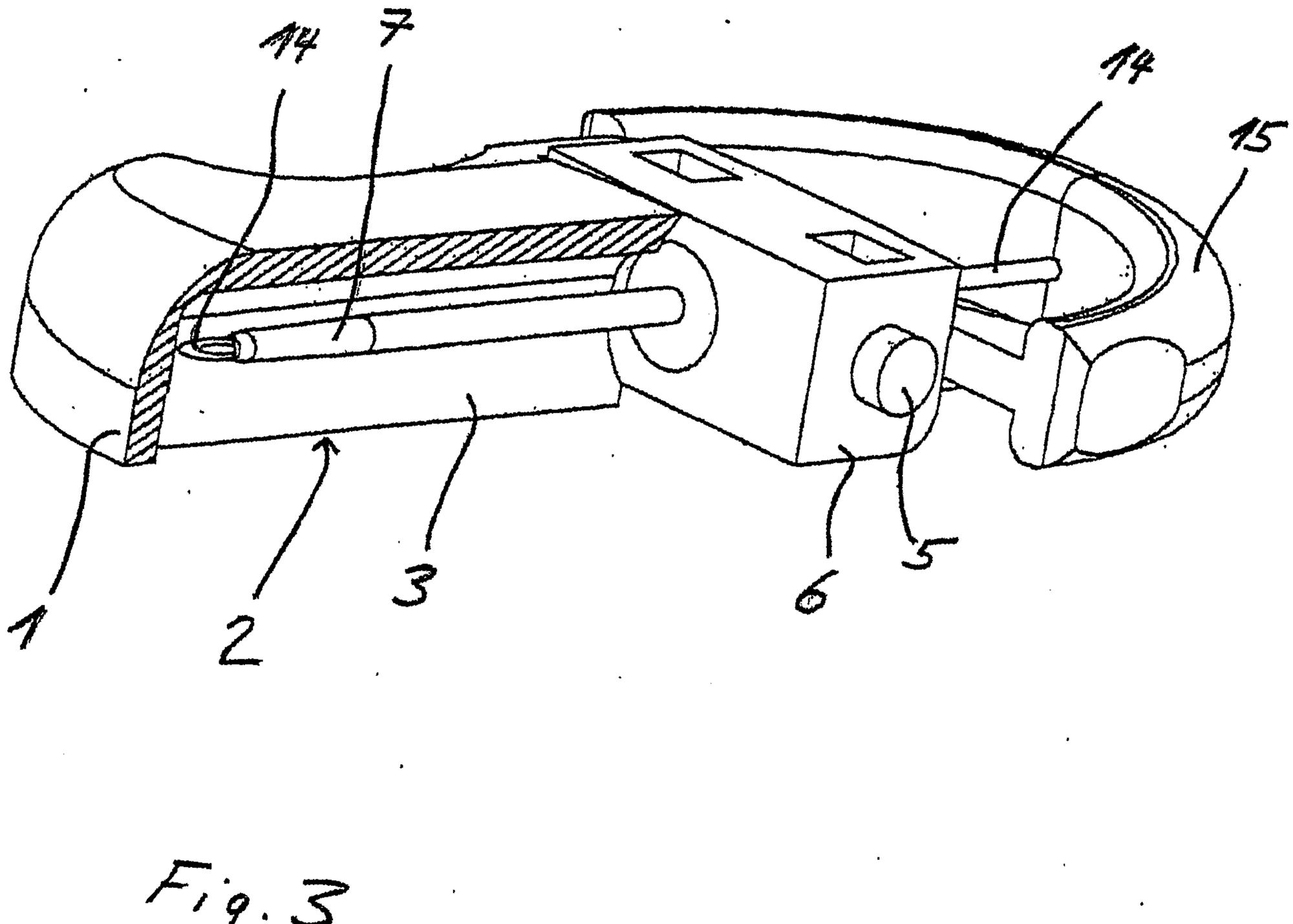


Fig. 3

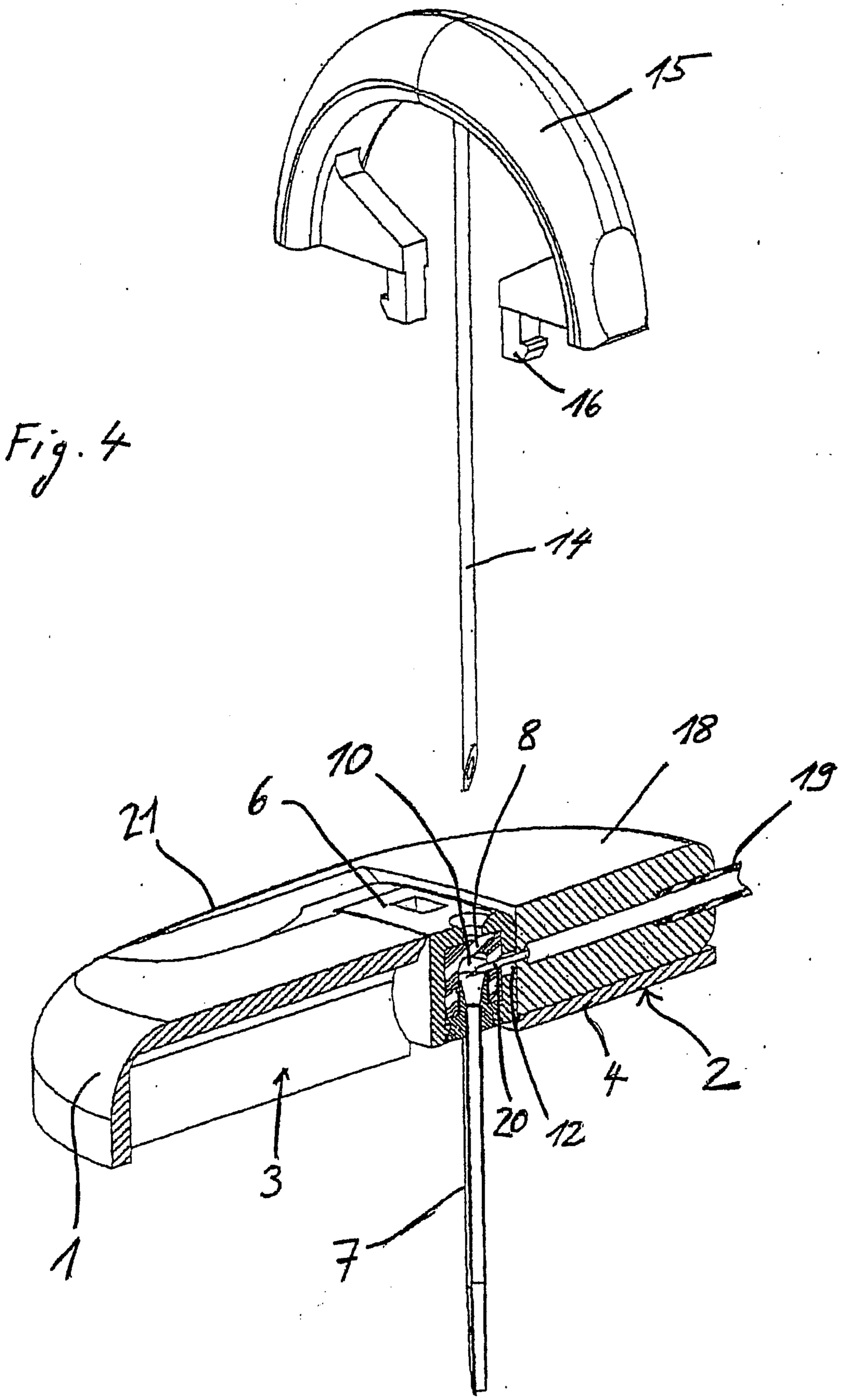


Fig. 4

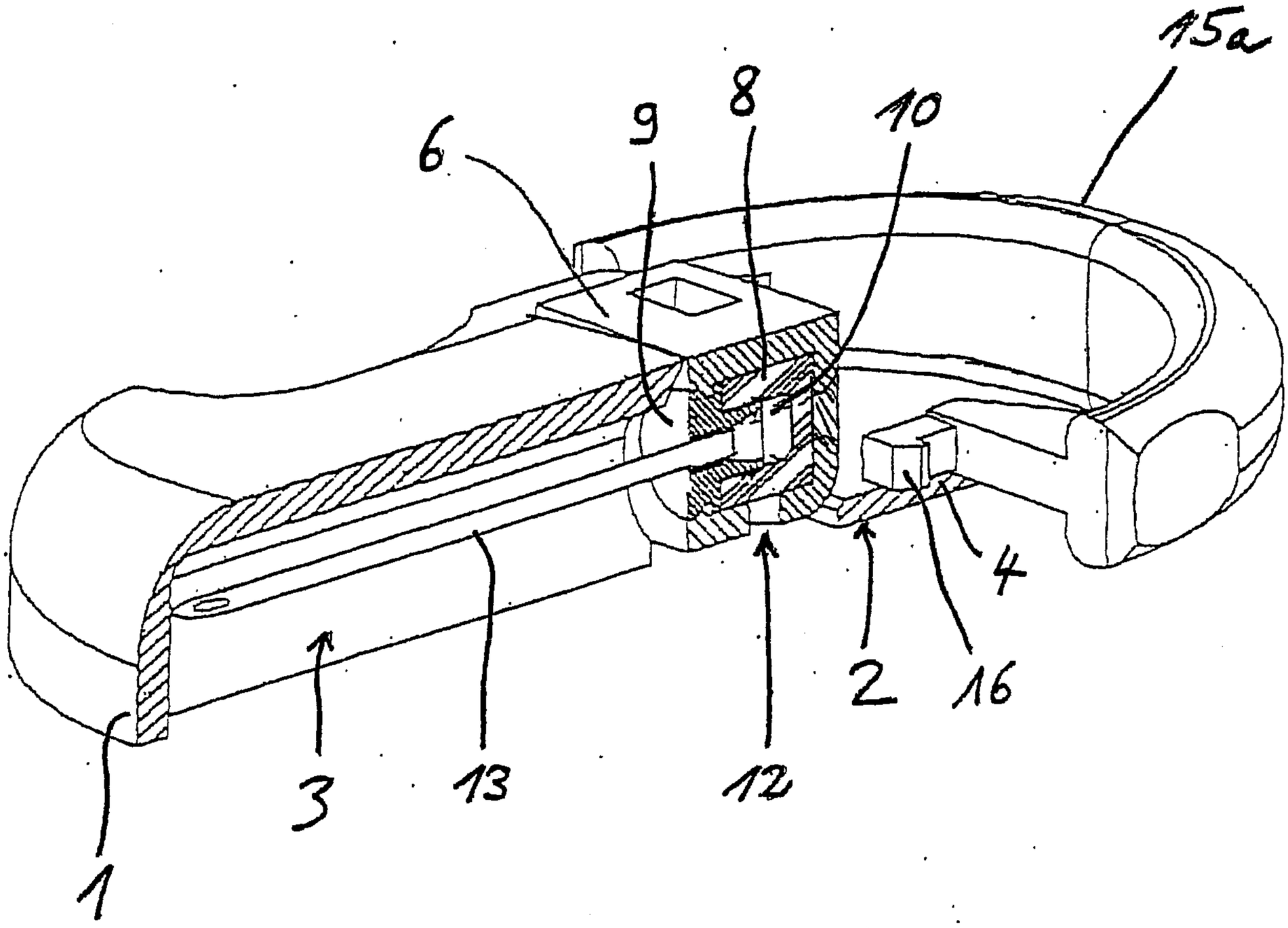


Fig. 5

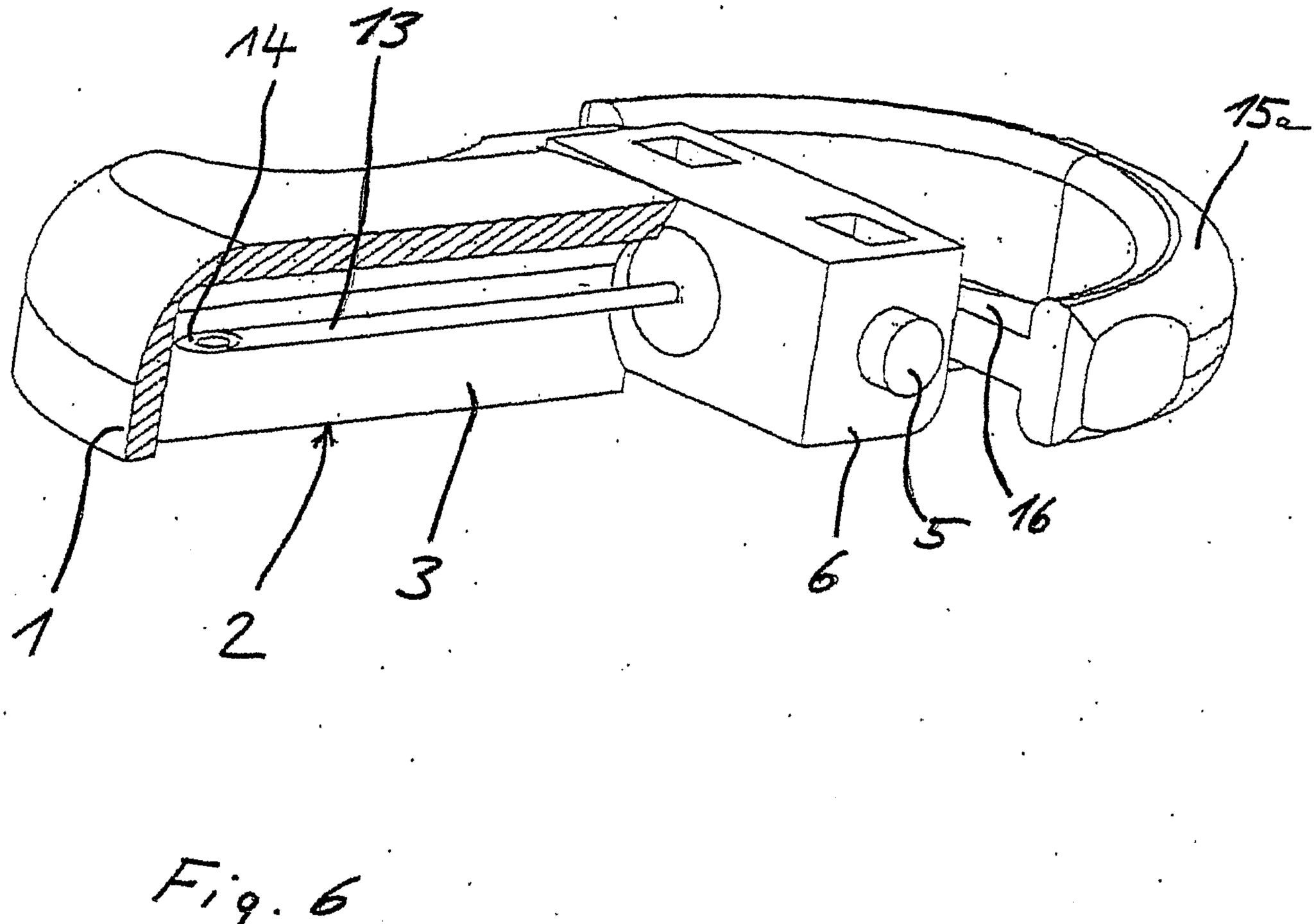
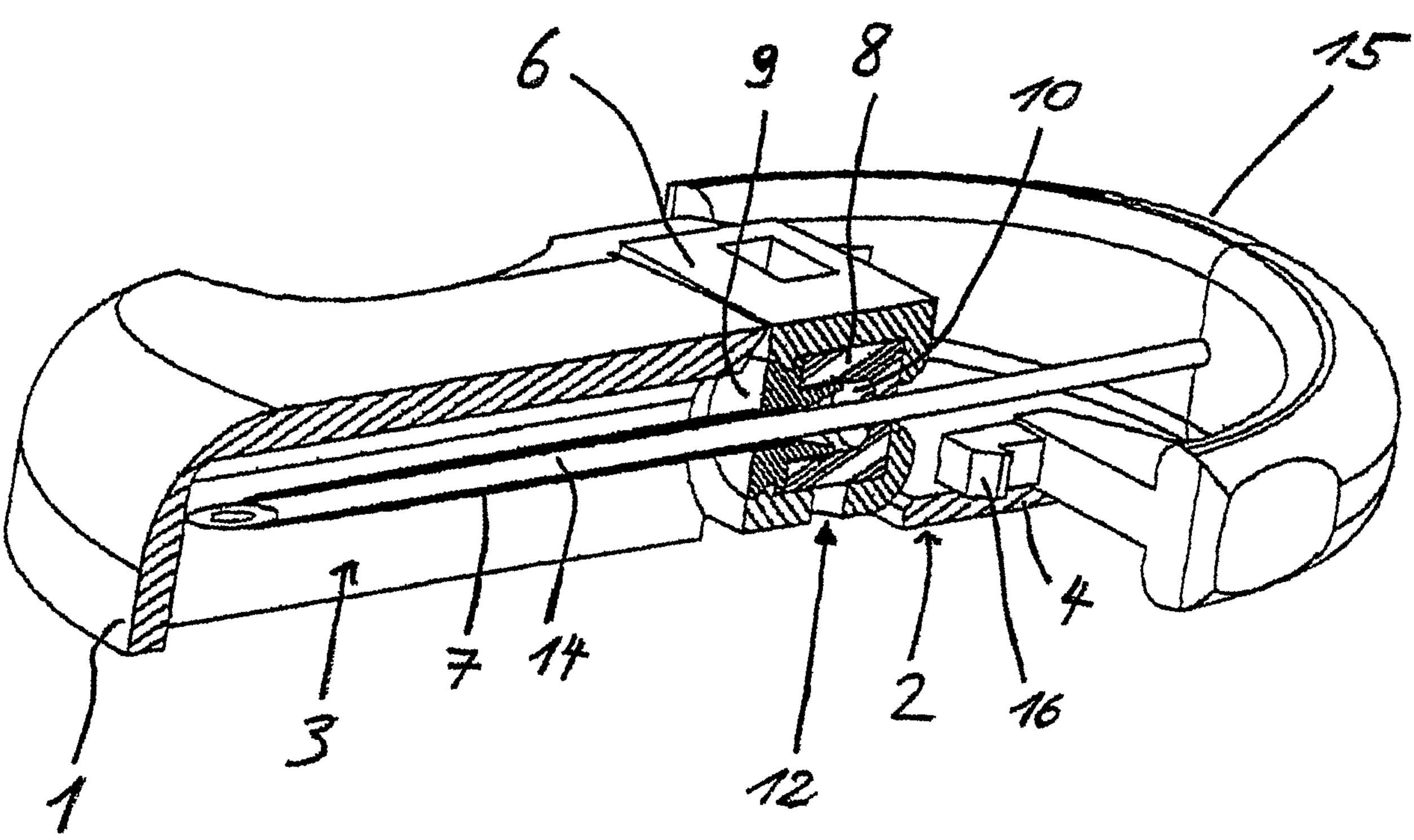


Fig. 6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