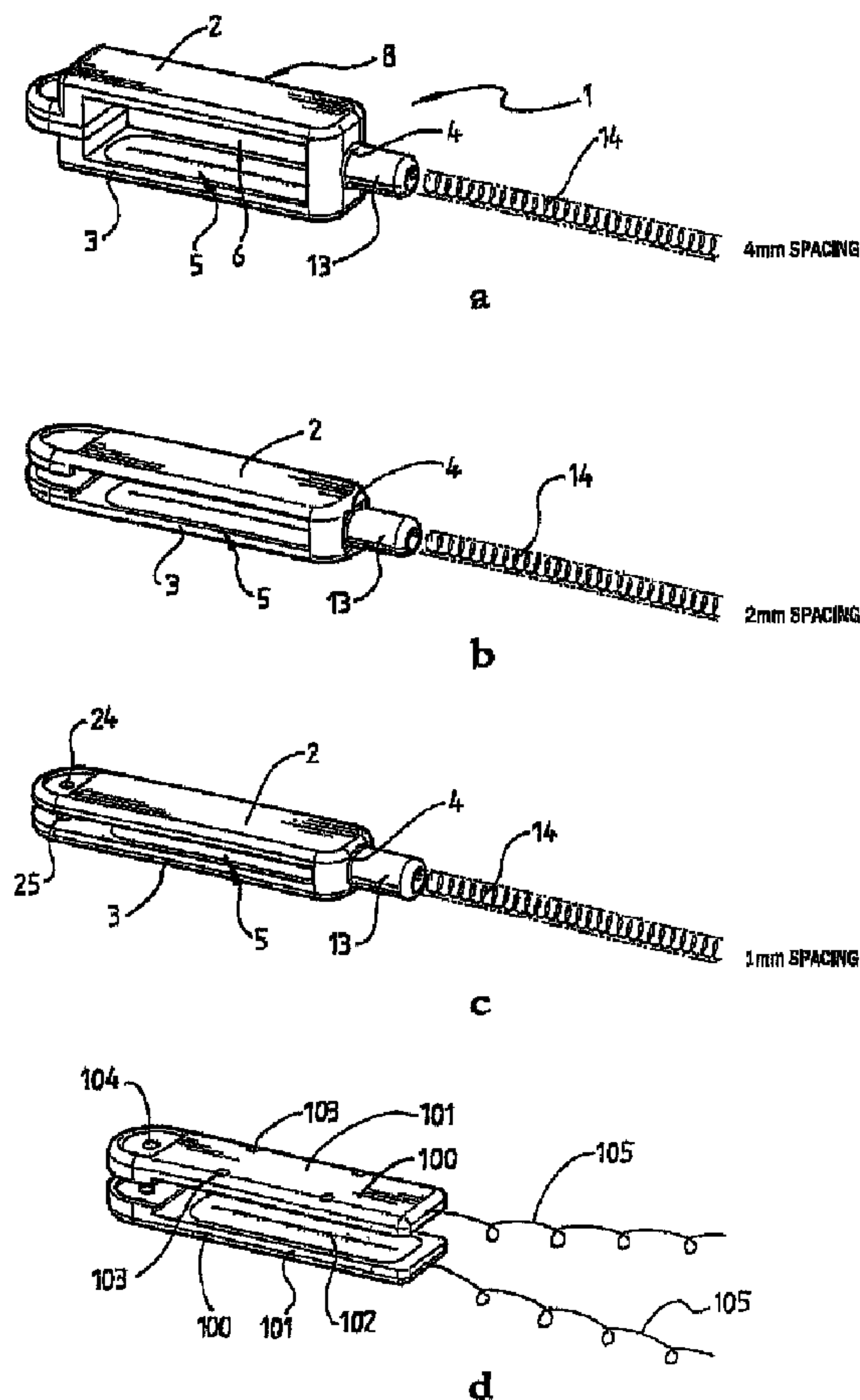




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(54) Titre : DISPOSITIF A ELECTRODE IMPLANTABLE POUR CONTROLER L'INCONTINENCE
(54) Title: AN IMPLANTABLE ELECTRODE ARRANGEMENT



(57) Abrégé/Abstract:

An implantable electrode arrangement (1) for stimulating excitable tissue, in particular the neosphincter to control urinary incontinence. The electrode is in the form of a extending peg with a pair of electrode elements (2, 3) extending from a base (4). The



(57) **Abrégé(suite)/Abstract(continued):**

elements are arranged to fit over the tissue to be stimulated and have electrodes (5, 6) on the inner surfaces of the peg portions. The tissue located between the peg portions receives stimulation. Also disclosed are methods of treating urinary incontinence by electrically stimulating a band of smooth muscle and electrode having an insulating member and electrodes on the inner surface such that an electric field applied to tissue is confined.

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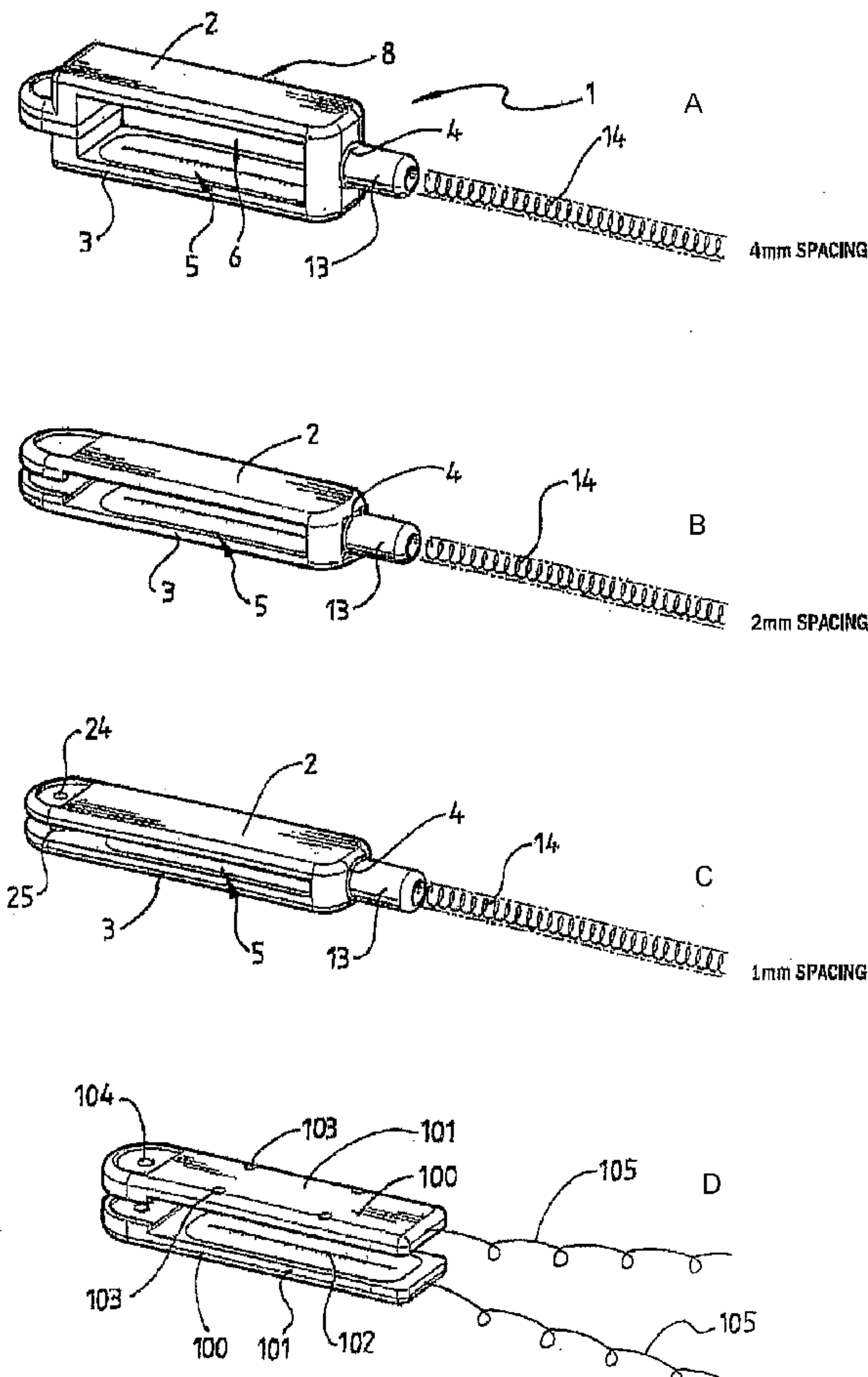
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(54) Title: AN IMPLANTABLE ELECTRODE ARRANGEMENT



(57) Abstract: An implantable electrode arrangement (1) for stimulating excitable tissue, in particular the neosphincter to control urinary incontinence. The electrode is in the form of an extending peg with a pair of electrode elements (2, 3) extending from a base (4). The elements are arranged to fit over the tissue to be stimulated and have electrodes (5, 6) on the inner surfaces of the peg portions. The tissue located between the peg portions receives stimulation. Also disclosed are methods of treating urinary incontinence by electrically stimulating a band of smooth muscle and electrode having an insulating member and electrodes on the inner surface such that an electric field applied to tissue is confined.

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-AN IMPLANTABLE ELECTRODE ARRANGEMENT

The disclosure of International patent application WO01/10357 is herein incorporated in its entirety by
5 reference.

Field of the Invention

The present invention relates to an electrode
10 arrangement for stimulating excitable tissue, and more particularly, but not exclusively, to an implantable electrode arrangement for use in treating urinary incontinence, to a method of stimulating excitable tissue and, more particularly, but not exclusively, to a method
15 of treating urinary incontinence.

Background of the Invention

Electrodes for implanting into humans or animals
20 (implantable electrodes) have been proposed for several treatments of medical conditions. The best known are probably electrodes used for cardiac stimulation (eg. in cardiac pacemaking applications). Implantable electrodes have been proposed for use in other areas, including for
25 management of chronic pain and for management of specific types of urinary incontinence (for example, sacral nerve stimulation for urge incontinence).

Various configurations of electrodes have been
30 proposed. These include "cuff" electrodes which are designed to wrap around nerves to electrically stimulate the nerve. Other electrode designs use "active tips" that can be placed against the excitable tissue (for example, transvenous pacemaker leads which are placed in contact
35 with the inner surface of the heart).

International patent application WO01/10357 (the

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disclosure of which is herein incorporated in its entirety
by reference) proposes a method and an apparatus for
treating incontinence in humans, which includes the steps
of forming a neosphincter from smooth muscle tissue taken
5 from elsewhere in the patient's body, and wrapping the
neosphincter around the urethra. An implantable stimulator
provides electrical signals to the neosphincter by way of
two or more electrodes. The electrical signals stimulate
the neosphincter to maintain tone about the urethra to
10 prevent emptying of the bladder until the user wishes to
urinate. The stimulator may provide a further electrical
signal (or stop providing signals) to allow the
neosphincter to relax and so enable the individual to
urinate.

15

One advantage of using innervated smooth muscle is
that such tissue requires only low power electrical
signals to be applied to produce a continuous contraction.
The implantable stimulator device may therefore operate
20 with relatively low power consumption to produce a
superior sphincter action.

It is believed, however, that current electrode
arrangements proposed for stimulation of the neosphincter
25 in WO01/10357 could be improved upon.

Summary of the Invention

In accordance with an embodiment, the present
30 invention provides an implantable electrode arrangement,
for stimulating contractile tissue, the electrode
arrangement comprising first and second electrode elements
being arranged, in use, to extend with respect to each
other so as to form a gap between them arranged for
35 receiving contractile tissue, the first and second
electrode elements including first and second electrodes
respectively, the first and second electrodes being
positionable, in use, in proximity to each other and being

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arranged, when an electrical signal is applied to them, to apply an electric field between them to stimulate the contractile tissue between them.

5 In one embodiment, the first and second electrodes are positionable opposite to each other. They may be directly opposite to each other or they may be somewhat offset from opposite.

10 In one embodiment each electrode element has a length dimension and a width dimension, the length dimension being longer than the width dimension. The length dimension is, in one embodiment, substantially longer than the width dimension so each electrode element can be said
15 to be elongate. The length may be greater than twice the width, and, in one embodiment may be greater than two and a half times the width. In one embodiment, the length may be greater than four times the width, in another embodiment greater than three times the width. In one
20 embodiment, the length can be in a range of anywhere from six times the width to one and a half times the width.

 The length may be governed in one embodiment by the extent of the tissue which is wished to be simulated.
25 Where the tissue is a sphincter, such as a neosphincter as described in the above-referenced PCT application, the length of the electrode element may depend on the length of the neosphincter, and in one embodiment, the length may be the same as or greater than the neosphincter.

30 The electrode elements have a depth dimension that, in one embodiment, is smaller than the width dimension, so that the elements are substantially flat in profile. In one embodiment, the flatness of the electrode element
35 facilitates avoiding irritation of tissue that may be in contact with the electrode element in use.

 In one embodiment, the first and second electrode

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elements are mounted at proximal ends thereof to a mounting. In an embodiment, the electrode elements are in the form of fingers extending from the mounting. The mounting forms a base connecting the fingers at their proximal ends. The fingers define a gap there within which the tissue may be seated. The electrodes may be formed on inner surfaces of the fingers, in use contacting opposite sides of the tissue. The electrodes may present a substantially flat external surface to the tissue. In an embodiment, the electrode elements extend substantially parallel to each other.

In one embodiment, the surface of the electrode element contacting the tissue to be stimulated may be slightly convex in the transverse direction. A radius of curvature of the convex surface may be in a range between 1mm and 50mm. The convex from surface may improve contact with the tissue to be stimulated.

In an embodiment, the electrode elements include insulating material to prevent electrical stimulation being applied to tissues other than the tissue received between the electrode elements. The insulating material may be provided on the outer surface of the electrode elements, in use facing away from the tissue.

In one embodiment, insulating material is also provided on the inner surface of the electrode elements. In this embodiment an opening is provided in the insulating material on the inner surface and the electrode is provided within the opening. In one embodiment, the opening is elongate, and may be in the form of a slit in the insulation.

In an embodiment, the first and second electrodes are arranged to create a confined electric field between them

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when an electrical signal is applied to them, in order to stimulate the tissue. In one embodiment, the electric field is confined to the extent that stimulation of tissue external to the tissue desired to be stimulated is
5 minimised or avoided.

In an embodiment, the electrode elements are flexible. This enables them to adapt to conform with the profile of the received tissue and/or external tissue they
10 may be seated against. It also preferably enables them to flex to accommodate profile changes which may occur in use, for example due to contraction and relaxation of the tissue between the electrode elements.

15 In an embodiment, the surfaces of the electrode elements are smooth so as to reduce the risk of erosion or trauma to tissue.

The tissue that the electrode arrangement may
20 stimulate may be smooth muscle tissue, innervated smooth muscle tissue, or any other contractile tissue. The tissue may be artificially produced, eg grown in an artificial medium.

25 In one application, the electrode arrangement is arranged for positioning about a neosphincter forming part of a system for controlling incontinence, such as described in international patent application number WO01/10357. The electrode arrangement may be implanted so
30 that a portion of the neosphincter is received between the electrode elements. The electrode arrangement may be implanted such that the electrodes lie between 30° and 90°, preferably perpendicular to nerves within the innervated smooth muscle so that the muscle tissue receives maximum
35 electrical field intensity between the electrodes when an electrical signal is delivered. The electrical field may then be confined between the electrodes to efficiently

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stimulate the neosphincter.

Although in some configurations it is most desirable that the electrode lie at right angles to a substantial number of nerves within the innervated smooth muscle, the electrode can lie at any angle with respect to the smooth muscle and still provide benefit. The electrode/nerve angle may vary in one embodiment between 60° either side of perpendicular. In one embodiment the angle is in a range 40° either side of the perpendicular. In another embodiment the angle is in a range 30° either side of the perpendicular and in another embodiment 20° either side of the perpendicular.

In one embodiment, the electrode arrangement of the present invention has the advantage of being suited for stimulation of innervated smooth muscle tissue so that low stimulus currents are required to stimulate nerves running close to the surface of the smooth muscle tissue. A further advantage of some embodiments is that the electrodes intimately contact the surface of the smooth muscle without causing mechanical damage to the tissue (erosion). Further, the electrode elements may be built in a range of varying lengths/mechanical configurations to deal with a range of smooth muscle sizes which may be required in a range of applications to treat medical conditions (fecal incontinence, gastric reflux, heart conditions etc).

It is a particular advantage of at least embodiments of the electrode arrangement of the present invention that they are suited for use in the stimulation of tissues forming sphincters, such as the neosphincter described in the above-referenced PCT application, and other sphincters which may be used for treating other conditions, such as fecal incontinence, gastric reflux, cardiac conditions etc.

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The electrode arrangement of the present invention is not limited to application in controlling urinary incontinence. It may be suited to other applications, in particular, applications for stimulating contractile tissue, in particular applications in which nerves within a smooth muscle organs or the smooth muscle itself is required to be stimulated, in a person or animal.

In accordance with a further embodiment, the present invention provides an electrode arrangement for controlling urinary incontinence, including an electrode arrangement in accordance with the first aspect of the present invention, dimensioned to be implantable in a patient to stimulate contractile tissue to control urinary incontinence.

In accordance with a further embodiment, the present invention provides a method of stimulating contractile tissue, comprising the steps of operating an electrode arrangement in accordance with the first aspect of the invention, wherein contractile tissue lies between the electrode elements, and applying a electrical stimulus to the electrodes so as to create a confined electric field between the electrodes to stimulate the tissue.

In an embodiment, the tissue is a muscle neosphincter for controlling incontinence, as discussed in WO01/10357.

In accordance with a further embodiment, the present invention provides a method of surgically implanting an electrode arrangement such as the electrode arrangement discussed above, comprising the steps of implanting the electrode arrangement in a patient so that tissue to be stimulated is received between the first and second electrode elements.

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In an embodiment, the step of securing includes the step of fixing distal ends of the electrode elements together.

5 In accordance with a further embodiment, the present invention provides a method of treating urinary incontinence, comprising the steps of surgically implanting an electrode arrangement as discussed above so that the electrode elements extend about a portion of a
10 contractile tissue sphincter arranged about the urethra, and providing electrical signals to the electrodes causing the sphincter to contract and maintain tone preventing urine from passing through the urethra.

15 In an embodiment, the step of implanting the electrode arrangement includes the step of implanting the electrode arrangement so that the electrodes run at an angle to the nerves within the tissue. In an embodiment, the electrodes run at an angle of between 30° and 150° to
20 the nerves within the tissue. In an embodiment, the angle is 40° to 140°. In a further embodiment the angle is 50° to 130°. In a further embodiment the angle is 60° to 120°. In a further embodiment the angle is 70° to 110°. In a further embodiment the angle is 80° to 100°. In a further
25 embodiment the angle is substantially 90°.

In accordance with a further embodiment, the present invention provides a method of treating urinary incontinence, comprising the steps of electrically
30 stimulating a smooth muscle sphincter arranged about the urethra, the step of electrically stimulating including electrically stimulating a band of muscle of the smooth muscle sphincter, the band extending across the width of the smooth muscle sphincter.

35

The band preferably extends in a direction which is between 30° and 150° angle to nerves running within the

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smooth muscle sphincter. In an embodiment the angle is 40° to 140°. In a further embodiment the angle is 50° to 130°. In a further embodiment the angle is 60° to 120°. In a further embodiment the angle is 70° to 110°. In a further
5 embodiment the angle is 80° to 100°. In a further embodiment the angle is substantially 90°.

In accordance with a further embodiment, the present invention provides a method of controlling innervated
10 smooth muscle tissue comprising the steps of electrically stimulating a portion of the smooth muscle tissue in the form of a band extending in the smooth muscle tissue.

In an embodiment, the band extends at an angle of
15 between 30° and 150° to nerves running within the smooth muscle. In an embodiment, the angle is 40° to 140°. In a further embodiment the angle is 50° to 130°. In a further embodiment the angle is 60° to 120°. In a further embodiment the angle is 70° to 110°. In a further
20 embodiment the angle is 80° to 100°. In a further embodiment the angle is substantially 90°.

In accordance with a further embodiment, the present invention provides an apparatus for stimulating human or
25 animal excitable tissue, the apparatus comprising an implantable electrode arrangement as discussed above, and a stimulator, the stimulator being arranged to provide signals to the first and second electrodes for stimulation of the excitable tissue.

30

In one embodiment, the apparatus further comprises a stimulator controller, the stimulator controller arranged to be operable to control the stimulation signals provided by the stimulator.

35

In one embodiment, the apparatus further comprises a stimulator programmer, the stimulator programmer being

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arranged to program control parameters of the stimulator.

In the above aspects of the present invention, the electrode arrangement includes a pair of electrode elements which, in one embodiment, are mounted together by a mounting at proximal ends thereof. In a further embodiment, the present invention may include a single electrode element which may be used on its own or together with other similar electrode elements in the form of a "set", to provide appropriate stimulation to, for example, contractile tissue.

In accordance with a further embodiment, the present invention provides an electrode element for stimulating excitable tissue, the electrode element comprising an insulating member having an inner surface, at least one active electrode being provided on the inner surface, the electrode element being positionable adjacent tissue to be stimulated and the electrode being arranged to provide a electric field to stimulate the tissue, when a signal is applied to the electrode.

In an embodiment, the electrode is arranged to create a confined electric field, to eliminate or limit stimulation to tissues adjacent to the tissue which it is desired to stimulate.

A single electrode element may be used to stimulate tissue appropriately, or may be used with other similar electrode elements in the form of a "set" to stimulate tissue.

In accordance with a further embodiment, the present invention provides a set of electrode elements, including a plurality of electrode elements in accordance with the ninth aspect of the present invention, the set being arranged so that at least a pair of the electrode elements

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can be placed in proximity to each other to enable the respective electrodes to create a confined electric field between them across excitable tissue to be stimulated.

5 In an embodiment, the electrode is arranged to create a confined electric field, to eliminate or limit stimulation to tissues adjacent to the tissue which it is desired to stimulate.

10 The electrode elements may be arranged to be placed substantially opposite each other.

In accordance with a further embodiment, the present invention provides a method of treating a disorder in a
15 patient, comprising the steps of utilising the electrode arrangement as discussed above, in order to stimulate contractile tissue in the patient to treat the disorder.

In accordance with a further embodiment, the present
20 invention provides an electrode apparatus for controlling a disorder in a patient, the electrode apparatus comprising an electrode arrangement as discussed above, arranged for the stimulation of contractile tissue to treat the disorder.

25 In accordance with a further embodiment, the present invention provides an apparatus for stimulating excitable tissue, the apparatus comprising an implantable electrode element as discussed above, and a stimulator, the
30 stimulator being arranged to provide signals to the electrode for stimulation of the excitable tissue.

In accordance with a further embodiment, the present invention provides a method of treating a disorder in a
35 patient, comprising the steps of utilising an electrode element as discussed above, in order to stimulate contractile tissue in the patient to treat the disorder.

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In accordance with a further embodiment, the present invention provides an electrode apparatus for controlling a disorder in the patient, the electrode apparatus comprising an electrode element as discussed above, arranged to stimulate contractile tissue to treat the disorder.

In accordance with a further embodiment, the present invention provides a method of treating a disorder in a patient, comprising the steps of stimulating contractile tissue in the patient to treat the disorder, the step of stimulating contractile tissue including stimulation of a band of the contractile tissue.

In accordance with a further embodiment, the present invention provides an electrode arrangement arranged to treat a disorder in a patient by the stimulation of contractile tissue, the electrode arrangement including stimulation means for stimulating a band of the contractile tissue.

The different embodiments of the present invention disclosed above may be combined in different combinations and with other aspects or features of the present invention and still fall within the scope of the disclosed invention. The above embodiments should not read as limiting the inventions disclosed in this application.

Brief Description of the Drawings.

Features and advantages of the present invention will become apparent from the following description of embodiments thereof, by way of example only, with reference to the accompanying drawings, in which;

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Figures 1a, b, c, d are isometric views of different embodiments of electrode arrangements in accordance with the present invention;

5 Figures 2a, b, c, d are side views of the embodiments of figure 1a, b, c, d;

Figure 3 is a schematic diagram showing an electrode arrangement in accordance with an embodiment of the present invention in situ together with muscle tissue.

Figure 4 is a diagram of an electrode arrangement in accordance with an embodiment of the present invention in situ together with a neosphincter for controlling urinary incontinence;

Figure 5 is a further diagram showing an alternative in situ arrangement of an electrode arrangement in accordance with an embodiment of the present invention with a neosphincter for treating urinary incontinence;

Figure 6 is a schematic view of an electrode arrangement in accordance with a further embodiment of the present invention;

Figures 6, 7 and 8 are exploded perspective, plan and side views, respectively, of an electrode arrangement in accordance with a further embodiment of the invention;

Figures 9, 10, 11, 12 and 13 are perspective, plan, side section, plan section and detail views of a shroud component of the electrode arrangement of Figures 6, 7 and 8;

Figures 14, 15, 16, 17, 18 are perspective, rear, plan section, side section and plan views of a cover component of the electrode arrangement of Figures 6, 7 and

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8;

Figure 19 is a perspective view from above and one side of an electrode element in accordance with an embodiment of the present invention; and

Figure 20 is a perspective view from above and one side of an electrode element in accordance with a further embodiment of the present invention.

Detailed Description of Embodiments

Referring to figures 1a and 2a, an electrode arrangement 1 in accordance with an embodiment of the present invention is illustrated. The electrode arrangement 1 includes first and second electrode elements 2, 3, which in this example are in the form of elongate rectangular elements which extend from a mounting 4. Mounting 4 acts to secure the electrode elements 2, 3 at their proximal ends.

The electrode arrangement 1 includes electrodes 5, 6, in this embodiment being in the form of conductive plates which extend along the inside of the electrode elements 2, 3 opposite to each other. The electrodes 5, 6, may alternatively be in the form of a printed conductive medium printed on the inside surface of the electrode elements 5, 6.

The electrode elements 2, 3 are arranged so that tissue from a human or animal body may be received therebetween within the gap 7 (figure 2), so tissue is "sandwiched" between the electrode 5, 6 exposed surfaces.

In this embodiment, the electrode element 2, 3 are comprised mainly of insulating material 8 so that the

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outer surface (in this embodiment all surfaces apart from conductive electrodes 5 and 6) are insulated and do not conduct electricity.

5 In this embodiment the inner surface is also insulating material with an elongate opening in the form of a slit. The electrodes are provided at the slit.

10 As is most clearly shown in figure 2a, distal ends 9, 10 of the electrode elements 2, 3 include projecting portions 11, 12 which project inwardly from the electrode elements 2, 3 so that they meet each other. In operation, the ends 9, 10 may be secured together so that the electrode arrangement is firmly secured about the tissue
15 which lies in the gap 7 between the electrode elements 2, 3.

 In this embodiment, mounting 4 includes a strain relief member 13 for receiving an electrical conductor 14
20 within a cable 15 (the cable being insulated), the electrical conductor 14 being arranged for electrical connection between electrodes 5 and 6 and a device (not shown) for providing electrical signals to the electrodes 5, 6. The distal ends of the electrode elements may be
25 fixed (if required to be fixed) by a number of means, including suture holes, press studs or any other arrangement that may not require much surgical access to "lock" the electrode elements closed. Note also, it is not essential for all embodiments that the electrode elements
30 be fixed together at their distal ends.

 In embodiments, insulating parts of the electrode elements may be composed of two sheets of bio compatible material (e.g. silicone) - which acts as an insulator, and
35 surrounds and limits the exposed surface of thin flexible platinum foils that forms the electrodes. The silicone may be reinforced with bio compatible mesh (eg a PET or

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PTFE -like material), so that sutures will not tear through the silicone.

5 In this embodiment, the electrode elements 2, 3 are arranged to flex such that the arrangement is arranged to conform, at least to some limited extent, with the profile of the received tissue and/or external tissue that they may be seated against. The electrode elements 2, 3, are arranged to flex to conform with any changes in the
10 profile of the received tissue which may be due to electrical stimulation.

In this embodiment, the electrode elements may be sufficiently flexible so that they conform with any
15 changes in the profile of the received tissue and also with the profile of external tissue so they do not irritate or erode the external tissue or receive tissue. This has the advantage of increasing the lifetime of the implant.

20

The electrode elements may be semi-flexible or in another embodiment totally flexible.

In a further embodiment, electrodes elements are not
25 flexible (non flexible electrode elements are within the scope of the present invention).

Figure 3 schematically illustrates an electrode in accordance with the present invention in situ about muscle
30 tissue. The same reference numerals have been used in figure 3 as in figure 1a, to designate corresponding components.

It can be seen from figure 3 that the muscle tissue
35 16 is received between electrode elements 2, 3. The electrodes 5, 6 on the inside surfaces of the electrode elements 2, 3 therefore contact the muscle tissue 16.

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Electrical signals may be applied to the electrodes 5, 6 resulting in an electrical field applied across the muscle tissue 16, the electrical field being confined by the electrodes and the electrode elements 2, 3 to the muscle tissue that sits between the electrode elements 2, 3. This creates a band within the smooth muscle in which the nerves are excited - causing the neo-sphincter to contract. Because the outer surfaces of the electrode elements 2, 3 are of insulating material, adjacent tissue will not be stimulated.

Tethers 17 and 18 may be used to hold the electrode arrangement 1 in place to adjacent tissue within the human or animal body.

Note that in the embodiment of figure 3 holes 19 in the electrode element 2 and also (not shown) electrode element 3 are provided to receive the tether in the distal ends of the electrode elements 2, 3 and also tie those ends together. Although the holes were not shown in the embodiment of figures 1a and 2a, they may be provided for this purpose.

Figure 3 also illustrates how the electrode arrangement 1 "flexes" to conform with the surface profile of the muscle tissue 16.

In the embodiment of figure 1a, electrode elements 2, 3 are in the form of fingers extending from a base formed by the mounting 4. The gap 7 is defined between the fingers, 2, 3, for receiving muscle tissue. The gap has no sides as there are no side walls extending between the fingers 2, 3. This enables the arrangement to be slid over the muscle tissue from one end, in an analogous manner to a clothes peg over clothes. This advantageously facilitates implantation of the electrode arrangement. This can facilitate the type of surgery and speed with

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which the surgery is carried out.

One application of the embodiment of figure 1a is in stimulation of a neosphincter such as used in the method
5 of treating incontinence disclosed in WO01/10357. Referring to figure 3, muscle tissue 16 in such an application would be a portion of the neosphincter surrounding the urethra. In the application disclosed in WO01/10357, the neosphincter is innervated smooth muscle,
10 and the nerves run coincident with the length of the muscle 16. The electrode elements 2, 3, run substantially at right angles to the direction of the nerves and the confined electrical field therefore provides optimum stimulation. Note that the electrode elements may not run
15 precisely at right angles to the direction of the nerves, but may run within an angular range of 90° to the angles of the nerves. In one embodiment the angular range may be 80° to 100° of the majority of the nerves running in the smooth muscle sphincter. In another embodiment, the angle may be
20 70° to 110°. In another embodiment the range is 40° to 140°. In a further embodiment the range is 50° to 130°. In a further embodiment the range is 60° to 120°. In a further embodiment the angle is substantially 90°.

25 The embodiment of figure 1a is sized for the neosphincter application. Dimensions are given in the drawings in millimetres (figure 2a). The gap 7 is approximately 4 millimetres, and length of the electrode arrangement is 24.3 millimetres.

30 Other embodiments are shown in figures 1b and c and 2b and c. The same reference numerals as used in figures 1 and 2a have been used to designate corresponding components and no further description will be given of
35 these components. The embodiments of figures 1 and 2b and c are dimensioned to be suitable for neosphincters over a range of thicknesses. As far as this may enable the

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electrode arrangement to deal with a number of different sizes of neosphincters which may be used for a number of different applications other than urinary incontinence e.g. esophageal reflux, treatment of cardiac conditions, fecal incontinence etc. (see later).

In the embodiment of figure 1b, the distal ends 20, 21 include shallower projections than the embodiment of figure 1a.

In the embodiment of figure 1c, the distal ends 22, 23, do not have any projections, as the dimension of the gap 7 is small enough not to require them (with the flexing provided by the electrode elements 2,3). The distal ends 22, 23 are provided with holes 24, 25 facilitating securing by way of a tether (as in figure 3).

Figure 4 is a diagram showing an electrode arrangement 1 on a smooth muscle neosphincter 30. In accordance with the application disclosed in WO 01/10357 the neosphincter 30 is shown wrapped around the urethra 31. The bladder 32 is illustrated positioned just above the neosphincter 30. The electrode elements 2, 3 receive between them a band of neosphincter 30. Electrodes 5, 6 (not shown in figure 4) contact the band of muscle tissue. Nerves in the innervated neosphincter 30 run in a direction which is substantially at right angles to the electrode elements 2, 3.

Figure 5 shows an alternative arrangement, where the neosphincter 30a in this alternative includes an overlapping portion 33 which overlaps the neosphincter 30a. The electrode arrangement 1 in this alternative is positioned so that the electrode elements 2, 3 extend about a band of the overlapping portion 33.

In the arrangement of figure 4 an outer surface of

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electrode element 3 is in contact with the urethra and the bladder neck. In the alternative of figure 5, the outer surface of the electrode element 3 is in contact with outer surface of the neosphincter and does not contact the urethra or bladder neck.

In both the arrangement of figures 4 and 5, the electrode arrangements 1 are shown connected via lead 15 to a stimulator 50. The stimulator 50 includes electronic circuitry arranged to generate signals for transmission to the electrodes and application to the smooth muscle of the sphincter 30, 30a. As described in WO 014/10357, the stimulators 50 include a biocompatible housing 51 mounting the electrical circuitry (not shown).

Also shown schematically adjacent to figures 4 and 5 are a stimulator controller 52 and a stimulator programmer system 53. The stimulator controller 52 includes user operable means 53 (in this case a button) which, when actuated, causes a signal to be transmitted from the stimulator controller 52 to the stimulator 50, to effect the operation of the stimulator 50. For example, if a patient wishes to urinate, they may actuate the controller 52 to cause the stimulator 50 to stop sending stimulation signals to the electrode arrangement, in order to enable the muscle sphincter to relax and the patient to be able to urinate.

The stimulator programmer unit 53 in this embodiment includes a computing system 54 (represented in the drawing as a conventional PC, but may be any type of computing system) and a transmitter 55 arranged to transmit instructions from the computing system 54 to the stimulator 50. The stimulator programmer 53 is used to program and calibrate the stimulator 50 for optimal operation. It may also receive stimulated telemetry information indicative of one or more parameters of the

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stimulator, for monitoring by an operative.

A further embodiment of an electrode arrangement in accordance with the present invention will now be
5 described with reference to figures 6 through 18.

The electrode arrangement of this embodiment comprises a number of components. These include an electrode cover 100 (shown in most detail in figures 13
10 through 17).

The components also include an electrode shroud (shown in best detail in figures 9 through 12) and also an electrode lead 102 (shown in figures 6, 7 & 8, together
15 with the other components of the electrode arrangement).

In this embodiment the first and second electrode elements are formed by the electrode cover 100, which includes insulating elements 103,104 extending from a base
20 105. The insulating extending elements 103,104 are formed with a slot 106,107, respectively, extending substantially along the length of the extending elements 103,104. When the electrode arrangement is assembled, platinum foil electrodes 108,109 (figure 6) are placed on the outer
25 surfaces of the elements of the elements 103,104 so that they are insulated from the gap 110 formed between the elements 103,104 apart from the slots 106,107, which expose portions of the conductive plates 108,109 to the gap 110 (and, in use, to any tissue seated within the
30 gap).

When assembled, the electrode cover 100 and platinum electrode foils 108,109 seat within the electrode shroud 101 as best shown in figures 9, 10, 11 & 12. Figure 12 in
35 particular shown in in-section where the electrode cover seats.

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Electrode shroud 1 is formed from silicone. In order to provide reinforcement, PET mesh covers 111,112 are provided to fit to upper 113 and lower 114 extending portions of the shroud 101. Suture holes 115,116 are provided in the covers 111,112 and also in the elements 113,114 of the shroud 101. Note that the reinforcement can be provided by other means and is not limited to PET mesh. Further, the electrode shroud need not be in silicone but could be of other bio-compatible material and may not require re-inforcement. Further, note that other means for affixing to the tissue may be provided other than suture holes or instead of suture holes.

The electrode lead 102 is a multi-component arrangement which includes an outer insulating cover 120, a tine collar 121 including tines 122 for retaining the lead in position within a patient. It also includes a sutured collar 123 including suture holes 124 for suturing to patient tissue to also facilitate retaining the lead 102 in position. There is also bifurcation moulding 125 which enables the lead to split into two parts 126,127 which may contain separate conductors, and connectors 128,129 which may be arranged to contact to a stimulation device.

In the above embodiments, the electrode arrangement includes a pair of electrode elements which extend away from a base which joins them together at their proximal ends. In a further embodiment, a single electrode element which is not joined at any base is provided. This single electrode element may be used to provide stimulation to contractile tissue on its own, or may be used together with one or more similar electrode elements to provide stimulation.

Referring to Figure 1d and Figure 2d, a pair of electrode elements in accordance with this embodiment are

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illustrated. The electrode element 100, comprises
elongate insulating member 101 which mounts on its inner
surface an electrode 102, in this embodiment being in the
form of a long thin line extending substantially the
majority of the length of the electrode element 100.
Suture holes 103 are provided to enable the electrode
element 100 to be secured to tissue. A further suture
hole 104 is provided at one end of the electrode element
100 in order to enable it to be secured to a similar end
of a similar electrode element 100. Holes may also be
provided for this purpose at the opposite end (not shown
in the drawings). A lead 105 extends from the electrode
element 100 to a stimulator (not shown). In Figure 1
there are two electrode elements 100 shown. In such an
arrangement they may be used as a "set", for example
secured either side of a contractile tissue sphincter,
operating in a similar manner to the embodiments of Figure
1, a, b, c.

In the above described embodiments, each electrode
element is provided with a single electrode. The single
electrode is an elongate electrode extending substantially
the majority of the length of the electrode element.

One advantage of having thin electrodes bounded by
insulating material on either side is that the arrangement
operates to confine the electric field produced by the
electrode to the tissue immediately adjacent the
electrode. This reduces or prevents stimulation of tissue
that it is not desirable to stimulate eg. tissue external
to a contractile tissue sphincter being controlled.

The extent of confinement of the electric field may depend
upon the application to which the electrode is being put.
It is desirable that confinement be sufficient to prevent
or substantially avoid stimulation of tissues other than

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the tissue for which stimulation is required e.g. it should avoid stimulation of external tissues.

5 The present invention is not limited to the electrode element having a single electrode, however. There may be multiple electrodes, including electrodes side by side or electrodes arranged in an array. Further, the electrodes need not be "thin line" shaped electrodes, but may be any shape, including square, rectangular, round, etc.

10

Figure 19 is an embodiment of an electrode arrangement in accordance with the present invention which includes an electrode element 110 formed of insulating material and being provided with three electrodes 110, 112 and 113. These are "thin line" electrodes, similar to the electrodes of previous embodiments. In this case, however, electrode 112 is the active electrode and electrodes 111 and 110 form "shield" electrodes. This facilitates confinement of the electrical field provided by electrode 112 to the tissue which it is desired to stimulate.

Figure 20 is an embodiment of an electrode arrangement in accordance with the present invention which includes an array of electrodes 114. The array of electrodes 114 is provided on an electrode element 115 similar to that described in previous embodiments. In this example, the array of electrodes includes a row 115 of three electrodes and a column 116 of three electrodes. The column can be considered to be a single "thin line" electrode broken up into three separate electrodes. The ends 117 of the electrodes provide field concentration points providing better current density and concentration and this may facilitate lower currents for appropriate stimulation.

35

In the above-described embodiments the electrode

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elements are substantially rectangular in form. They may be other shapes than rectangular eg cylindrical, rounded.

5 The electrode arrangement of the present invention is not limited to application in incontinence control in accordance with the system of WO01/10357. The electrode arrangement may be used for stimulating smooth muscle in other incontinence control systems, or other applications in which nerves within smooth muscle organs or the smooth
10 muscle itself is required to be stimulated. The dimensions (eg. particularly the length of the electrode elements and the dimensions of the gap between them, and also their widths) may be varied according to the application and are not limited to the dimensions disclosed in relation to the
15 specifically described embodiments.

Other applications for which an electrode arrangement in accordance with the present invention may be useful include pacing the stomach and other organs, for treating
20 gastro-esophageal reflux problems and faecal incontinence.

The electrode arrangement in accordance with the present invention may be used to simulate any excitable tissue. In particular, it may be utilised to stimulate
25 contractile tissue for applications such as faecal incontinence, reflux problems, cardiac disorders, and any other disorder where the use of contractile tissue, such as a contractile tissue sphincter, for example, may be useful.

30

In the embodiments described above, a lead 15 is provided housing a conductor 14 for conducting electrical signals to the electrodes. In an alternative embodiment, a signal generator may be housed in a body which is adjacent
35 to or part of the electrode arrangement, obviating the need for a lead to connect to a stimulator implanted elsewhere in the body.

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The electrode arrangements of the described embodiments are bipolar configurations. The electrode arrangements of the present invention are not limited to
5 bipolar configurations, and electrode arrangements including tripolar and multi-polar configurations may be utilised. A tripolar or multi-polar arrangement may be used to stimulate different muscle nerve areas, and/or for sensing purposes to, for example, provide feedback on the
10 effects of stimulation. Tripolar or multi-polar arrangements may be formed by forming separated conductive plates on the electrode elements. Another alternative is to provide more than two electrode elements. For example, three or four electrode elements could be provided in the
15 form of three or more fingers extending from the mounting 4.

In yet a further embodiment, which may be suited for applications with tissues and sphincters for treating
20 urinary incontinence (such as disclosed in the above-referenced PCT application), fecal incontinence, gastro-esophageal reflux problems and cardiac conditions etc, a monopolar electrode may be provided. The monopolar electrode may be in the form of a single electrode on a
25 single electrode element such as described above. The electrode may be a single point electrode or a thin line electrode provided by current density, or relatively high current density to the edges. Current focus may be provided by a further return electrode placed in another
30 part of the patient.

In yet a further embodiment, a point electrode may be placed on the inner surface of the smooth muscle (or other contractile tissue) and the return electrode in another
35 part of the body.

Figure 6A is a schematic diagram of an electrode

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arrangement in accordance with a further embodiment of the present invention. The schematic diagram illustrates multi-polar electrodes on the inner surfaces of electrode elements 2, 3. The electrodes include stimulating
5 electrodes 40, 41 and sensing electrodes 42, 43.

A further alternative electrode, as discussed above, may include a monopolar arrangement including a single electrode placed on the elements described in relation to
10 Figures 19 and 20.

In the treatment of a cardiac condition, an electrode arrangement in accordance with an embodiment of the present invention may be used in a counter-pulsation
15 application. In counter-pulsation, a contractile tissue sphincter is placed on the ascending aorta and stimulated in order to facilitate blood flow, particularly for conditions such as angina and congestive heart failure.

20 An electrode arrangement of the present invention may also be utilised in stimulation of tissues that are not in a patient but may be, for example, for the purpose of evaluating physiological properties of such tissues or for using them as test systems for the development of
25 therapeutic agents or techniques. Electrodes of the present invention may be useful for such in vitro techniques.

Some of the embodiments of the electrode arrangement
30 described above include extending electrode elements joined at one end to a mounting. Embodiments (described above) are envisaged where the electrode elements may not be joined at a mounting but may, instead, be separated. In use, they may be separately fixed (eg sutured) to the
35 tissue so that they are opposite each other and function to provide the appropriate electric field.

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In some of the applications described above, the electrode arrangement is used to stimulate a "band" of contractile tissue. For example, where a contractile tissue forms a neosphincter, the band extends usually
5 across the neosphincter. The band may not extend all the way across the neosphincter in some embodiments, but may only extend partly across the neosphincter.

It is to be understood that, if any prior art
10 publication is referred to herein, such reference does not constitute an admission that the publication forms a part of the common general knowledge in the art, in Australia or any other country.

15 For the purposes of this specification it is to be clearly understood that the word "comprising" means "including but not limited to", and that the word "comprises" has a corresponding meaning.

20 It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments
25 are, therefore, to be considered in all respects as illustrative and not restrictive.

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CLAIMS:

1. An implantable electrode arrangement, for stimulating contractile tissue, the electrode arrangement comprising
5 first and second electrode elements being arranged, in use, to extend with respect to each other so as to form a gap between them arranged for receiving contractile tissue, the first and second electrode elements including first and second electrodes respectively, the first and
10 second electrodes being positionable, in use, in proximity to each other and being arranged, when an electrical signal is applied to them, to apply an electric field between them to stimulate the contractile tissue between them.
- 15 2. An implantable electrode arrangement in accordance with claim 1, the first and second electrodes being positionable, in use, opposite to each other.
- 20 3. An electrode arrangement in accordance with claim 1 or claim 2, wherein each electrode element has a length dimension and a width dimension, and the length dimension is substantially longer than the width dimension, so that the electrode elements are of elongate form.
- 25 4. An electrode arrangement in accordance with claim 3, wherein the length dimension of each electrode element is at least as twice as long as the width dimension.
- 30 5. An electrode arrangement in accordance with claim 4, wherein the length dimension is at least two and a half times as long as the width dimension.
- 35 6. An electrode arrangement in accordance with any one of claims 3, 4 or 5, wherein a depth dimension of the electrode elements is smaller than the width dimension.
7. An electrode arrangement in accordance with claim 6,

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the electrode elements being substantially flat in profile.

8. An electrode arrangement in accordance with any one
5 of the preceding claims, wherein the first and second
electrodes are provided on inner surfaces of the first and
second electrode elements, in use being arranged to
contact opposite parts of the tissue so that a portion of
the tissue lies between them.

10

9. An electrode arrangement in accordance with claim 8,
wherein an inner surface of each electrode element is
formed from a layer of insulating material, the layer
having an opening therein, the electrodes being provided
15 at the openings.

10. An electrode arrangement in accordance with claim 9,
wherein the openings are in the form of elongate slits.

20 11. An electrode arrangement in accordance with any one
of the preceding claims, wherein at least one of the first
and second electrode elements mounts a plurality of
electrodes.

25 12. An electrode arrangement in accordance with claim 11,
wherein the plurality of electrodes are mounted side by
side on the inner surface of the electrode element.

30 13. An electrode element in accordance with claim 12,
wherein the plurality of electrodes include three or more
electrodes, two of the electrodes comprising shield
electrodes arranged to shield an active electrode mounted
between them.

35 14. An electrode arrangement in accordance with claim 13,
wherein the active electrode is the first or second
electrode.

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15. An electrode arrangement in accordance with any one of claims 11 to 14, wherein the plurality of electrodes are in the form of relatively thin lines.

5

16. An electrode arrangement in accordance with any one of claims 11 to 15, wherein the plurality of electrodes are elongate and extend the majority of the length of the electrode element.

10

17. An electrode arrangement in accordance with any one of claims 11 to 15, wherein the plurality of electrodes are provided as an array of four or more electrodes.

15 18. An electrode arrangement in accordance with claim 17, wherein the array includes six or more electrodes.

19. An electrode arrangement in accordance with claim 17 or claim 18, the electrodes being arranged in a plurality
20 rows and a plurality of columns.

20. An electrode arrangement in accordance with claim 19, including three columns of electrodes and three rows of electrodes.

25

21. An electrode arrangement in accordance with any one of the preceding claims, the first and second electrode elements each including an insulating material mounting conductive members, the conductive members being arranged
30 to provide the first and second electrodes.

22. An electrode arrangement in accordance with claim 21, wherein the insulating material is silicone.

35 23. An electrode arrangement in accordance with claim 21 or claim 22, each electrode element being provided with a reinforcement member mounted to the electrode element.

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24. An electrode arrangement in accordance with claim 23, wherein the reinforcement member is mounted to an outer surface of the electrode element.

5

25. An electrode arrangement in accordance with claim 24, wherein the reinforcing member is a PET mesh.

26. An electrode arrangement in accordance with any one
10 of the preceding claims, each electrode element including securing means enabling securing of the electrode element to the tissue.

27. An electrode arrangement in accordance with claim 26,
15 wherein the securing means includes suture holes.

28. An electrode arrangement in accordance with claim 26
or claim 27, wherein the securing means include means at
at least one end of the electrode elements arranged to
20 enable securing of the electrode elements about the
tissue.

29. An electrode arrangement in accordance with any one
of the preceding claims, the first and second electrode
25 elements being mounted at proximal ends thereto to a
mounting, from which they extend with respect to each
other so as to form a gap between them for receiving the
tissue.

30. An electrode arrangement in accordance with claim 29,
the electrode elements being in the form of fingers
extending from the mounting, the mounting forming a base
connecting the fingers at their proximal ends.

31. An electrode arrangement in accordance with claim 30,
35 wherein the gap is open on all sides apart from where the
electrode elements are joined at the base, so that the

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arrangement may be placed over the tissue from one end, in an analogous manner to a peg.

5 32. An electrode arrangement in accordance with any one of the preceding claims, wherein the electrode elements are flexible, whereby to enable them to adapt to the shape of the received tissue and/or external tissue that they may be seated against in use.

10 33. An electrode arrangement in accordance with any one of the preceding claims, the first and second electrodes being arranged to create a confined electric field between them when an electrical signal is applied to them, in order to stimulate the tissue.

15 34. An electrode arrangement in accordance with claim 33, wherein the confined electric field is such as to reduce or avoid stimulation of tissues external to the tissue which requires stimulation.

20 35. An electrode arrangement in accordance with any one of the preceding claims, further comprising an electrode lead including conductors arranged to connect the first and second electrodes to a stimulator.

25 36. An electrode arrangement in accordance with claim 35, wherein the electrode lead includes securing means to secure the lead in position, in use within a patient.

30 37. An electrode arrangement in accordance with claim 36, wherein the securement means includes a collar about the electrode lead, the collar including one or more tabs provided with suture holes.

35 38. An electrode arrangement in accordance with claim 36 or claim 37, the securement means including one or more tines.

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39. An electrode arrangement for controlling urinary incontinence, including an electrode arrangement in accordance with any one of the preceding claims, arranged to be implantable in a patient to stimulate contractile
5 tissue to control urinary incontinence.

40. An electrode arrangement in accordance with claim 39, being arranged such that the first and second electrode elements are positionable either side of a band of tissue
10 forming a portion of a neosphincter wrapped around the urethra, the neosphincter being arranged to contract on stimulation by the electrodes, in order to maintain continence.

41. A method of stimulating contractile tissue, comprising the steps of operating an electrode arrangement in accordance with any one of claims 1 to 38, wherein contractile tissue lies between the electrode elements, and applying an electrical stimulus to the electrodes to
20 create a confined electric field between the electrodes to stimulate the tissue.

42. A method in accordance with claim 41, wherein the contractile tissue is formed into a neosphincter about the
25 patient's urethra, for controlling urinary incontinence.

43. A method of surgically implanting an electrode arrangement in accordance with any one of claims 1 to 38, comprising the steps of implanting the electrode
30 arrangement in a patient so that tissue to be stimulated is received between the first and second electrode elements.

44. A method in accordance with claim 43, comprising the
35 further step of securing the electrodes in position with

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respect to the tissue.

45. A method in accordance with claim 44 wherein, the
step of securing includes the step of fixing the ends of
5 the electrode elements together.

46. A method in accordance with claim 44 or 45, wherein
the step of securing includes suturing the electrode
elements to the tissue.

10

47.. A method of treating urinary incontinence, comprising
the steps of surgically implanting an electrode
arrangement in accordance with any one of claims 1 to 38,
so that the electrode elements extend about a portion of a
15 contractile tissue sphincter arranged about the urethra,
and providing electrical signals to the electrodes causing
the sphincter to contract and prevent urine from passing
through the urethra.

20 48. A method in accordance with claim 47, wherein the
contractile tissue is smooth muscle.

49. A method in accordance with claim 48, wherein the
step of implanting the electrode arrangement includes the
25 step of implanting the electrode arrangement so that the
electrodes run substantially at right angles to the nerves
of the smooth muscle tissue.

50. A method of treating urinary incontinence, comprising
30 the steps of electrically stimulating a smooth muscle
sphincter arranged about the urethra, the step of
electrically stimulating including electrically
stimulating a band of muscle of the smooth muscle
sphincter.

35

51. A method in accordance with claim 50, wherein the
band extends across the width of the smooth muscle

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sphincter.

52. A method in accordance with claim 50 or claim 51,
wherein the band extends in a direction substantially at
5 90° to nerves running within the smooth muscle sphincter.

53. A method of controlling innervated smooth muscle
tissue comprising the steps of electrically stimulating a
portion of the smooth muscle tissue in the form of a band
10 extending in the smooth muscle tissue.

54. A method in accordance with claim 53, wherein the
band extends substantially at 90° to nerves running within
the smooth muscle.

15

55. An electrode element for stimulating excitable
tissue, the electrode element comprising an insulating
member having an inner surface, at least one active
electrode being provided on the inner surface, the
20 electrode element being positionable adjacent tissue to be
stimulated and the electrode being arranged to provide a
confined electric field to stimulate the tissue, when a
signal is applied to the electrode.

25 56. An electrode element in accordance with claim 55,
being arranged to create the confined electric field in
the tissue between the electrode element and a further
electrode element placeable opposite the electrode element
so that the tissue is positioned between the electrode
30 element and the further electrode element.

57. An electrode element in accordance with claim 55 or
claim 56, wherein the electrode element has a length
dimension and a width dimension, and the length dimension
35 is substantially longer than the width dimension, so that
the electrode element is of elongate form.

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58. An electrode element in accordance with claim 57, wherein the length dimension of the electrode element is at least twice as long as the width dimension.
- 5 59. An electrode element in accordance with claim 58, wherein the length dimension is at least two and a half times as long as the width dimension.
60. An electrode element in accordance with any one of
10 claims 57 to 59, wherein a depth dimension of the electrode element is smaller than the width dimension.
61. An electrode element in accordance with claim 60, the
15 electrode element being substantially flat in profile.
62. An electrode element in accordance with any one of
claims 55 to 61, wherein an inner surface of the electrode
element is formed from a layer of insulating material, the
layer having an opening therein, the electrode being
20 provided at the opening.
63. An electrode element in accordance with claim 62,
wherein the opening is in the form of an elongate slit.
- 25 64. An electrode element in accordance with any one of
claims 55 to 63, mounting a plurality of electrodes.
65. An electrode element in accordance with claim 64,
wherein the plurality of electrodes are mounted side by
30 side on the inner surface of the electrode element.
66. An electrode element in accordance with claim 65,
wherein the plurality of electrodes include three or more
electrodes, two of the electrodes comprising shield
35 electrodes arranged to shield the active electrode mounted
between them.

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67. An electrode element in accordance with any one of claims 64 to 66, wherein the plurality of electrodes are in the form of relatively thin lines.
- 5 68. An electrode element in accordance with any one of claims 64 to 67, wherein the plurality of electrodes are elongate and extend the majority of the length of the electrode element.
- 10 69. An electrode element in accordance with any one of claims 64 to 67, wherein the plurality of electrodes are provided as an array of four or more electrodes.
- 15 70. An electrode element in accordance with claim 69, wherein the array includes six or more electrodes.
71. An electrode element in accordance with claim 69 or claim 70, the electrodes being arranged in a plurality rows and a plurality of columns.
- 20 72. An electrode element in accordance with claim 71, including three columns of electrodes and three rows of electrodes.
- 25 73. An electrode element in accordance with any one of claims 55 to 74, the electrode elements each including insulating material mounting a conductive member, the conductive member being arranged to provide the electrode.
- 30 74. An electrode element in accordance with claim 73, wherein the insulating material is silicone.
75. An electrode element in accordance with claim 73 or claim 74, being provided with a reinforcement member
- 35 mounted to the electrode element.
76. An electrode element in accordance with claim 75,

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wherein the reinforcement member is mounted to an outer surface of the electrode element.

5 77. An electrode element in accordance with claim 75, wherein the reinforcing member is a PET mesh.

78. An electrode element in accordance with any one of claims 55 to 77, including securement means enabling securing of the electrode element to the tissue.

10

79. An electrode element in accordance with claim 78, wherein the securement means includes suture holes.

15 80. An electrode element in accordance with any one of claims 55 to 79, wherein the electrode element is flexible, whereby to enable it to adapt to the shape of the tissue and/or external tissue that it may be seated against in use.

20 81. An electrode element in accordance with any one of claims 55 to 80, wherein the confined electric field is such as to reduce or avoid stimulation of tissues external to the tissue which requires stimulation.

25 82. A set of electrode elements, including a plurality of electrode elements in accordance with any one of claims 55 to 81, the set being arranged so that at least a pair of the electrode elements can be placed opposite each other to enable the respective electrodes to create a confined electric field between them across excitable tissue to be stimulated.

30 83. An apparatus for stimulating excitable tissue, the apparatus comprising an implantable electrode arrangement in accordance with any one of claims 1-38, and a stimulator, the stimulator being arranged to provide signals to the first and second electrodes for stimulation

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of the excitable tissue.

84. An apparatus in accordance with claim 83, further comprising a stimulator controller, the stimulator
5 controller arranged to be operable to control the stimulation signals provided by the stimulator.

85. An apparatus in accordance with claim 83 or claim 84, further comprising a stimulator programmer, the stimulator
10 programmer being arranged to program control parameters of the stimulator.

86. A method of treating a disorder in a patient, comprising the steps of utilising an electrode arrangement
15 in accordance with any one of claims 1 to 38, in order to stimulate contractile tissue in the patient to treat the disorder.

87. A method in accordance with claim 86, wherein the
20 contractile tissue is in the form of a sphincter.

88. A method in accordance with claim 85 or claim 86, wherein the disorder is urinary incontinence and the contractile tissue is arranged to affect the urethra.
25

89. A method in accordance with claim 86 or claim 87, wherein the disorder is fecal incontinence and the contractile tissue is arranged to affect the colorectum or anus.
30

90. A method in accordance with claim 86 or claim 87, wherein the disorder is gastro-esophageal reflux, and the contractile tissue is arranged to affect the esophagus.

91. A method in accordance with claim 86 or claim 87, wherein the disorder is a cardiac disorder and the contractile tissue is arranged to affect the
35

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cardiovascular system.

92. A method in accordance with claim 91, wherein the contractile tissue is arranged to affect counter
5 pulsation.

93. An electrode apparatus for controlling a disorder in a patient, the electrode apparatus comprising an electrode arrangement in accordance with any one of claims 1 to 38,
10 arranged for stimulation of contractile tissue to treat the disorder.

94. An apparatus in accordance with claim 93, wherein the disorder is fecal incontinence, and the electrode
15 arrangement is arranged for stimulation of contractile tissue affecting the anal passageway.

95. An apparatus in accordance with claim 93, wherein the disorder is gastro-esophageal reflux and the electrode
20 arrangement is arranged for stimulation of contractile tissue affecting the esophagus.

96. An apparatus in accordance with claim 93, wherein the disorder is a cardiac disorder, and the electrode
25 arrangement is arranged for stimulation of contractile tissue affecting the cardio-vascular system.

97. An apparatus in accordance with claim 96, wherein stimulation of the contractile tissue is arranged to
30 affect counter pulsation.

98. An apparatus for stimulating excitable tissue, the apparatus comprising an implantable electrode element in accordance with any one of claims 55 to 81, and a
35 stimulator, the stimulator being arranged to provide signals to the electrode for stimulation of the excitable tissue.

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99. An apparatus in accordance with claim 98, further comprising a stimulator controller, the stimulator controller arranged to be operable to control the stimulation signals provided by the stimulator.

100. An apparatus in accordance with claim 98 or claim 99, further comprising a stimulator programmer, the stimulator programmer being arranged to program control parameters of the stimulator.

101. A method of treating a disorder in a patient, comprising the steps of utilising an electrode element in accordance with any one of claims 55 to 81, in order to stimulate contractile tissue in the patient to treat the disorder.

102. A method in accordance with claim 101, wherein the contractile tissue is in the form of a sphincter.

103. A method in accordance with claim 101 or claim 102, wherein the disorder is urinary incontinence and the contractile tissue is arranged to affect the urethra.

104. A method in accordance with claim 102 or claim 103, wherein the disorder is fecal incontinence and the contractile tissue is arranged to affect the colorectum or anus.

105. A method in accordance with claim 101 or claim 102, wherein the disorder is gastro-esophageal reflux, and the contractile tissue is arranged to affect the esophagus.

106. A method in accordance with claim 101 or claim 102, wherein the disorder is a cardiac disorder and the contractile tissue is arranged to affect the cardiovascular system.

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107. A method in accordance with claim 106, wherein the contractile tissue is arranged to effect counter pulsation.

5

108. An electrode apparatus for controlling a disorder in a patient, the electrode apparatus comprising an electrode element in accordance with any one of claims 55 to 81, arranged for stimulation of contractile tissue to treat
10 the disorder.

109. An apparatus in accordance with claim 108, wherein the disorder is fecal incontinence, and the electrode element is arranged for stimulation of contractile tissue
15 affecting the colorectum or anus.

110. An apparatus in accordance with claim 108, wherein the disorder is gastro-esophageal reflux and the electrode element is arranged for stimulation of contractile tissue
20 affecting the esophagus.

111. An apparatus in accordance with claim 108, wherein the disorder is a cardiac disorder, and the electrode element is arranged for stimulation of contractile tissue
25 affecting the cardio-vascular system.

112. An apparatus in accordance with claim 111, wherein the stimulation of a contractile tissue is arranged to effect counter pulsation.

30

113. A method of treating a disorder in a patient, comprising the steps of stimulating contractile tissue in the patient to treat the disorder, the step of stimulating contractile tissue including stimulation of a band of the
35 contractile tissue.

114. A method in accordance with claim 113, wherein the

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contractile tissue is in the form of a sphincter.

115. A method in accordance with claim 113 and claim 114,
wherein the contractile tissue is smooth muscle tissue,
5 and the band of tissue extends substantially
perpendicularly to nerve fibres running through the smooth
muscle tissue.

116. A method in accordance with claim 113, 114 or 115,
10 wherein the disorder is urinary incontinence, and the
contractile tissue is arranged to affect the urethra.

117. A method in accordance with claim 113, 114 or 115,
wherein the disorder is fecal incontinence and the
15 contractile tissue is arranged to affect the colorectum or
anus.

118. A method in accordance with claim 113, 114 or 115,
wherein the disorder is gastro-esophageal reflux, and the
20 contractile tissue is arranged to affect the esophagus.

119. A method in accordance with claim 113, 114 or 115,
wherein the disorder is a cardiac disorder, and the
contractile tissue is arranged to affect the cardio-
25 vascular system.

120. A method in accordance with claim 118, wherein
contractile tissue is arranged to effect counter
pulsation.

30

121. An electrode arrangement arranged to treat a disorder
in a patient by the stimulation of contractile tissue, the
electrode arrangement including stimulation means for
stimulating a band of the contractile tissue.

35

122. An electrode arrangement in accordance with claim
112, wherein the contractile tissue is in the form of a

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sphincter.

123. An electrode arrangement in accordance with claim 121 or claim 122, wherein the contractile tissue is smooth muscle, and the band of tissue extends substantially perpendicularly to the direction of nerve fibres running through the smooth muscle.

124. An arrangement in accordance with claim 121, claim 122 or claim 123, wherein the condition is urinary incontinence and the contractile tissue is arranged to affect the urethra.

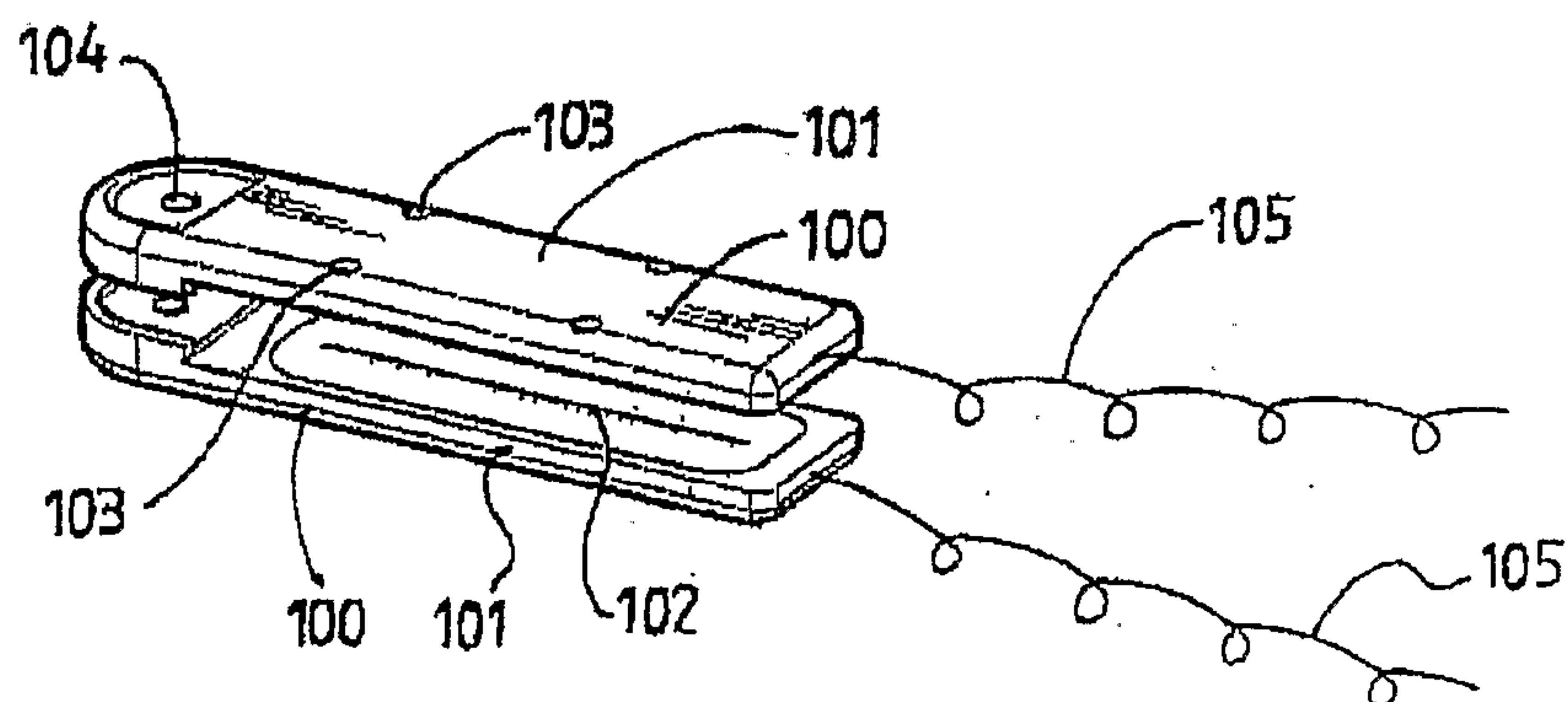
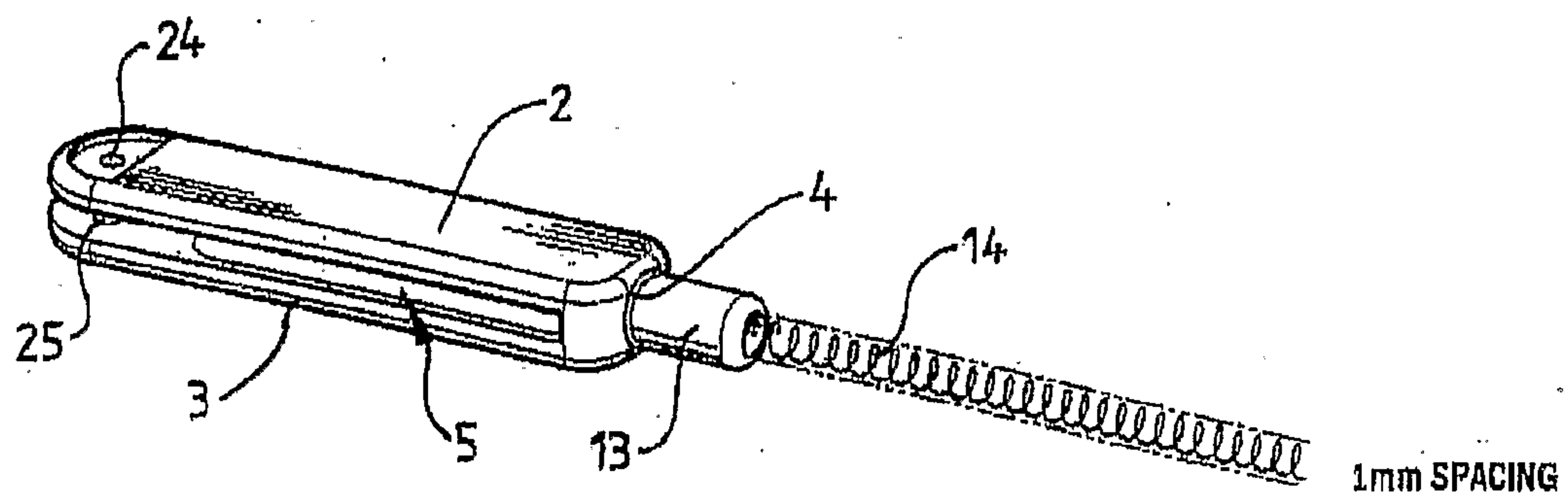
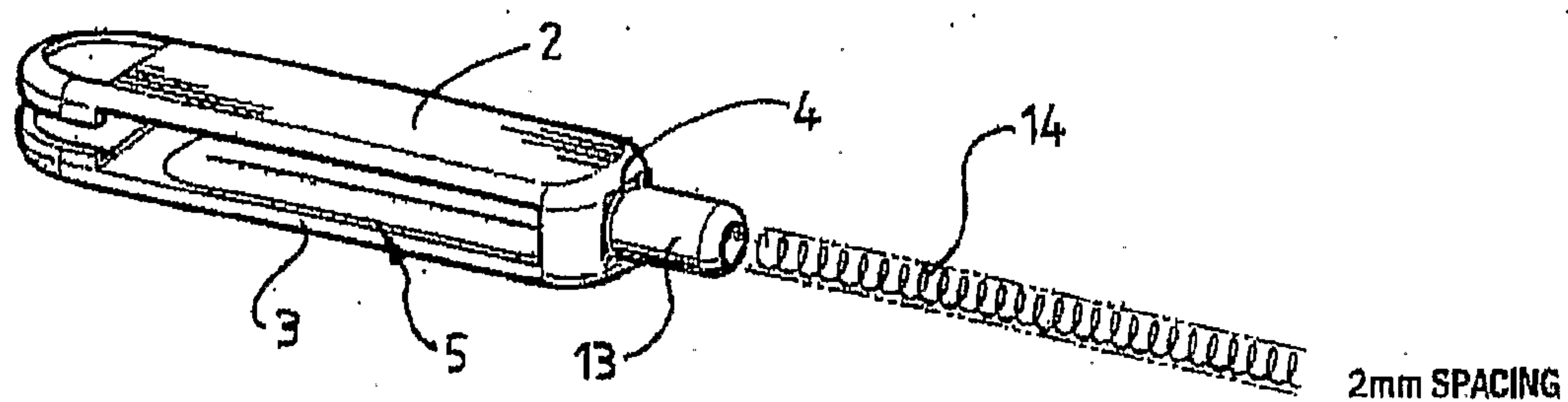
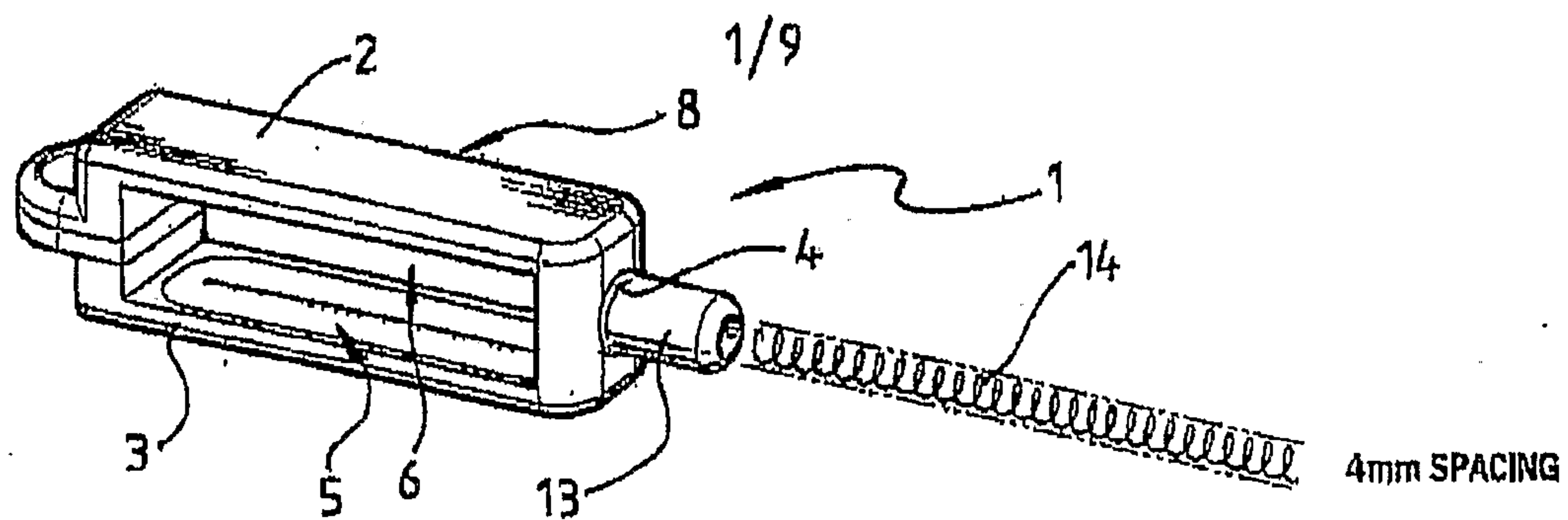
125. An electrode arrangement in accordance with claim 121, 122 or 123, wherein the disorder is fecal incontinence, and the contractile tissue is arranged to affect the colorectum or anus.

126. An electrode arrangement in accordance with claim 121, 122 or 123, wherein the disorder is gastro-esophageal reflux, and the contractile tissue is arranged to affect the esophagus.

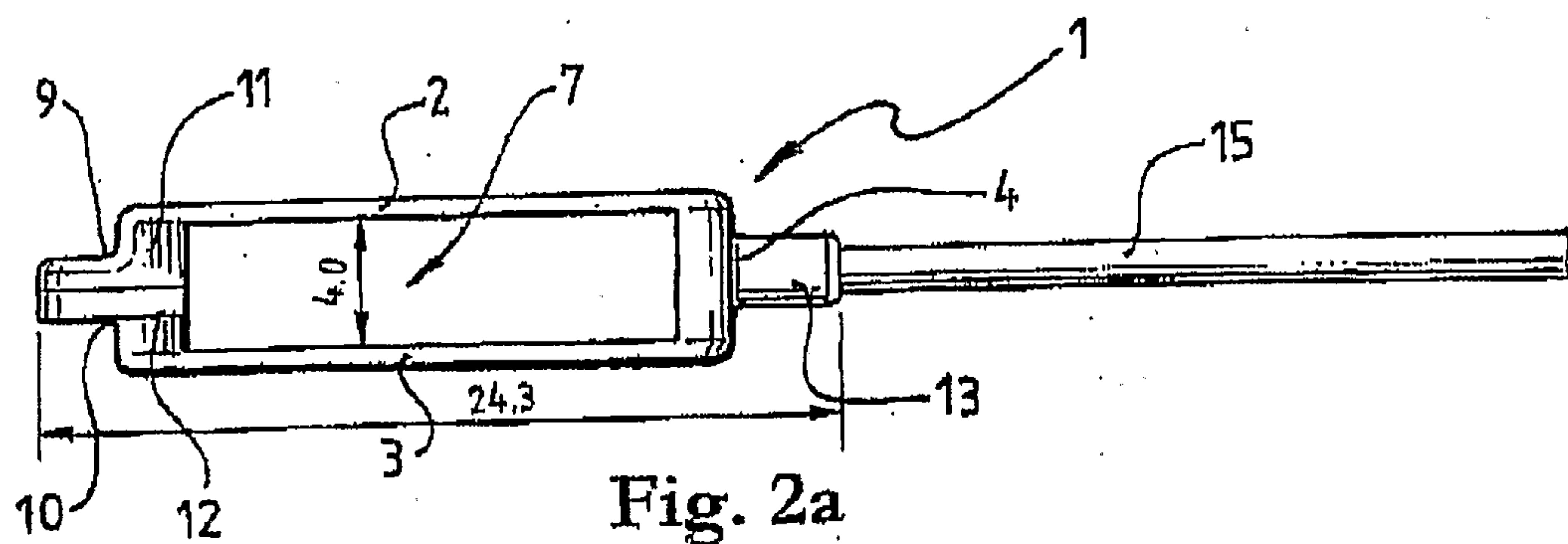
127. An electrode arrangement in accordance with claim 121, 122 or 123, wherein the disorder is a cardiac disorder, and the contractile tissue is arranged to affect the cardio-vascular system.

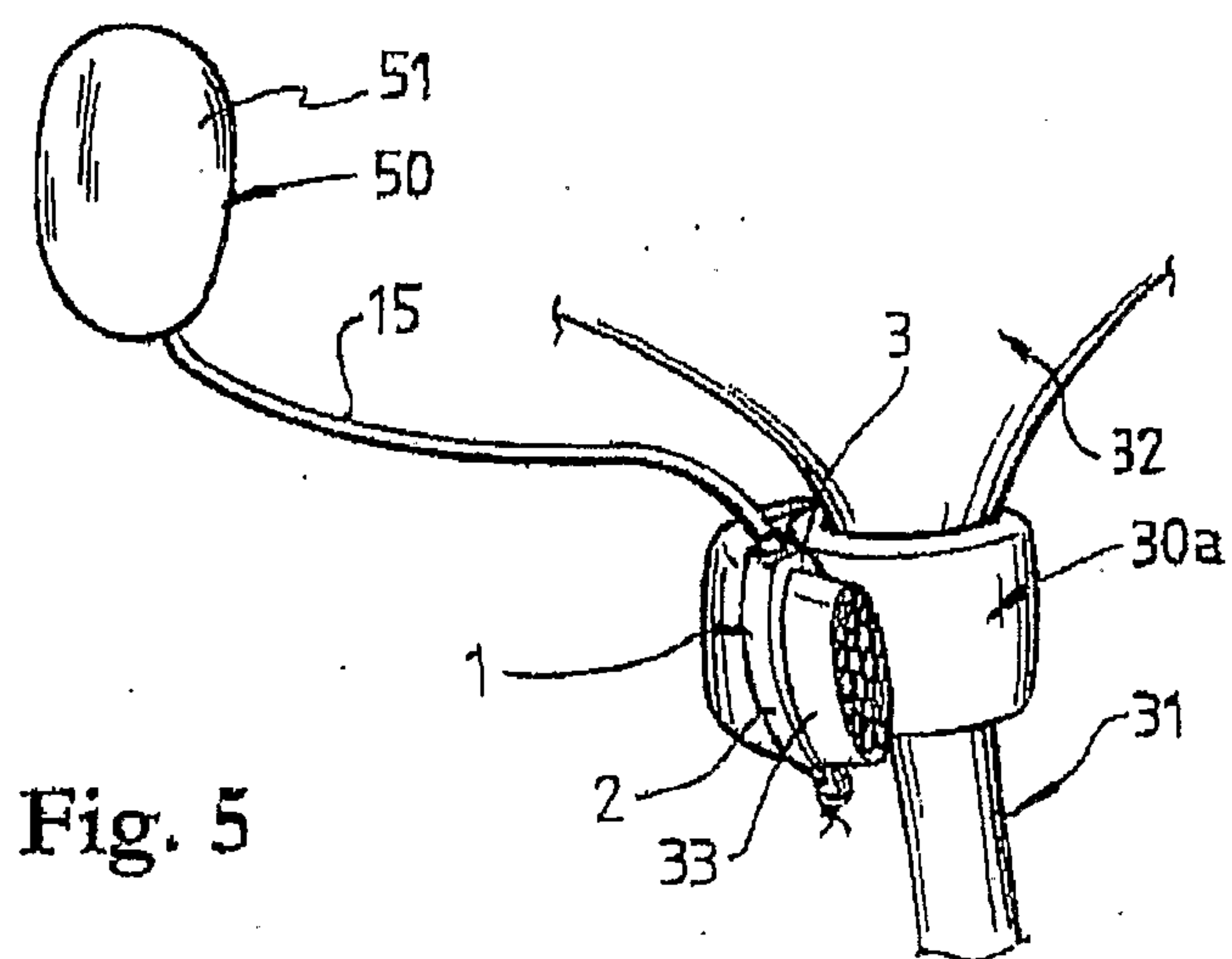
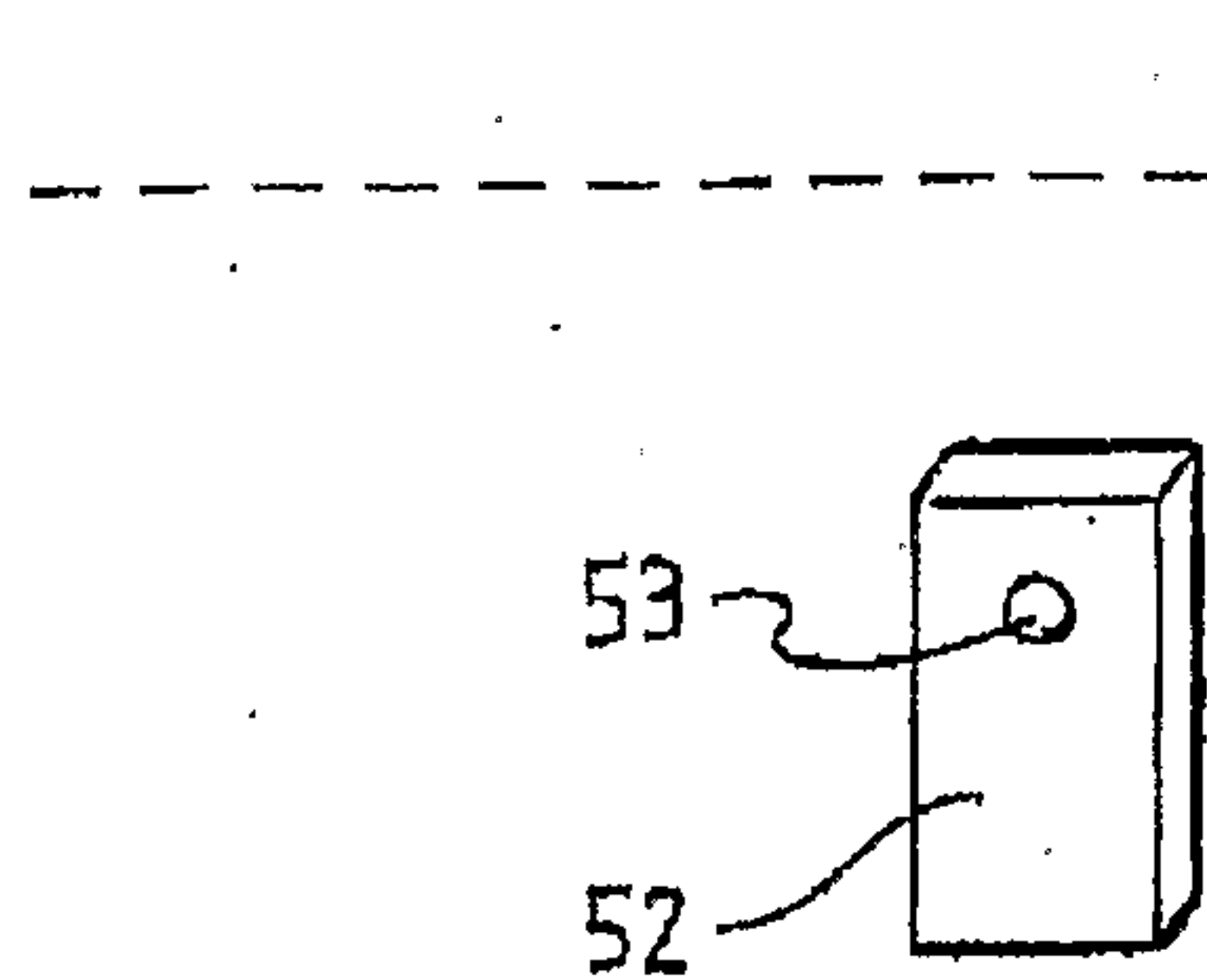
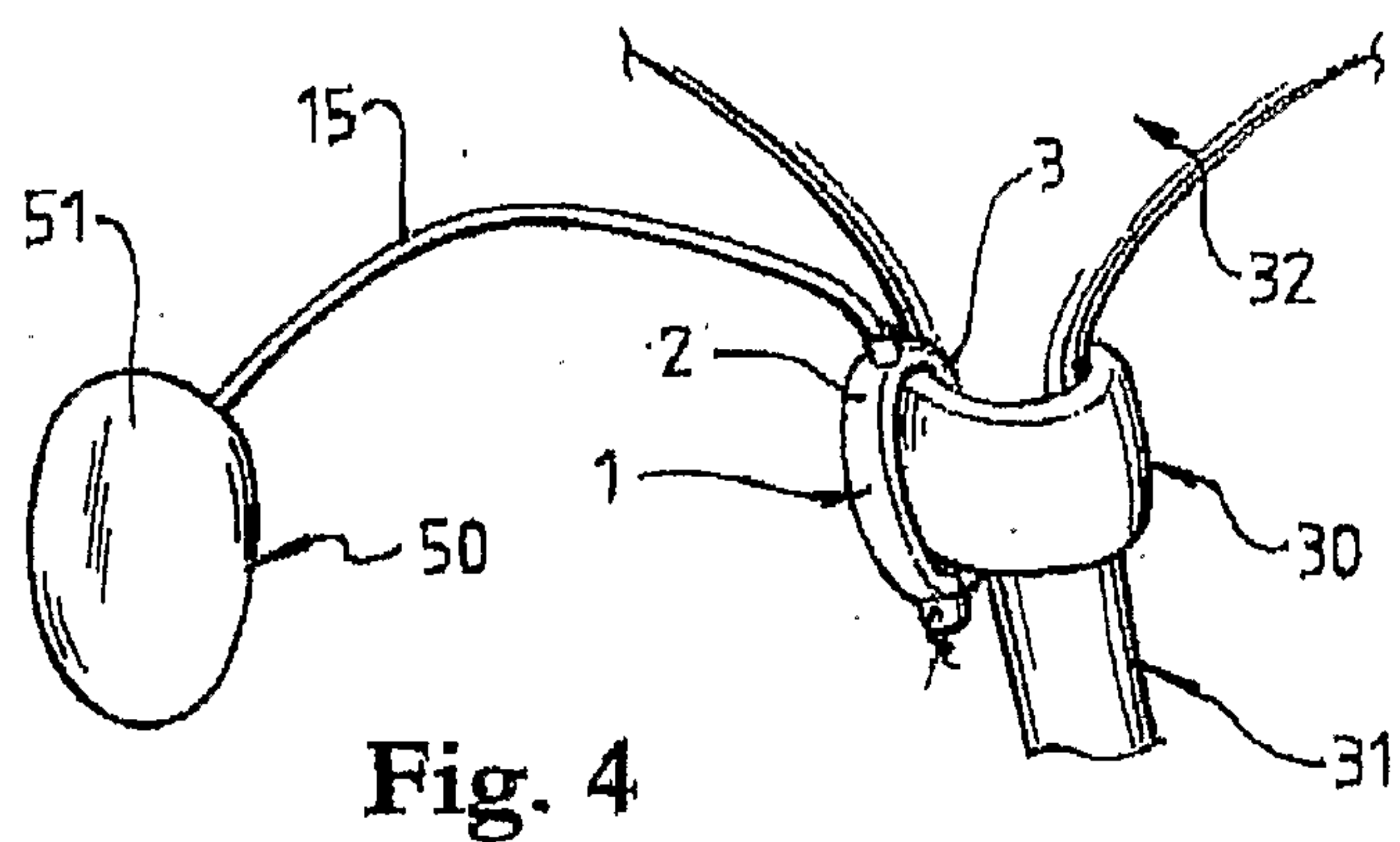
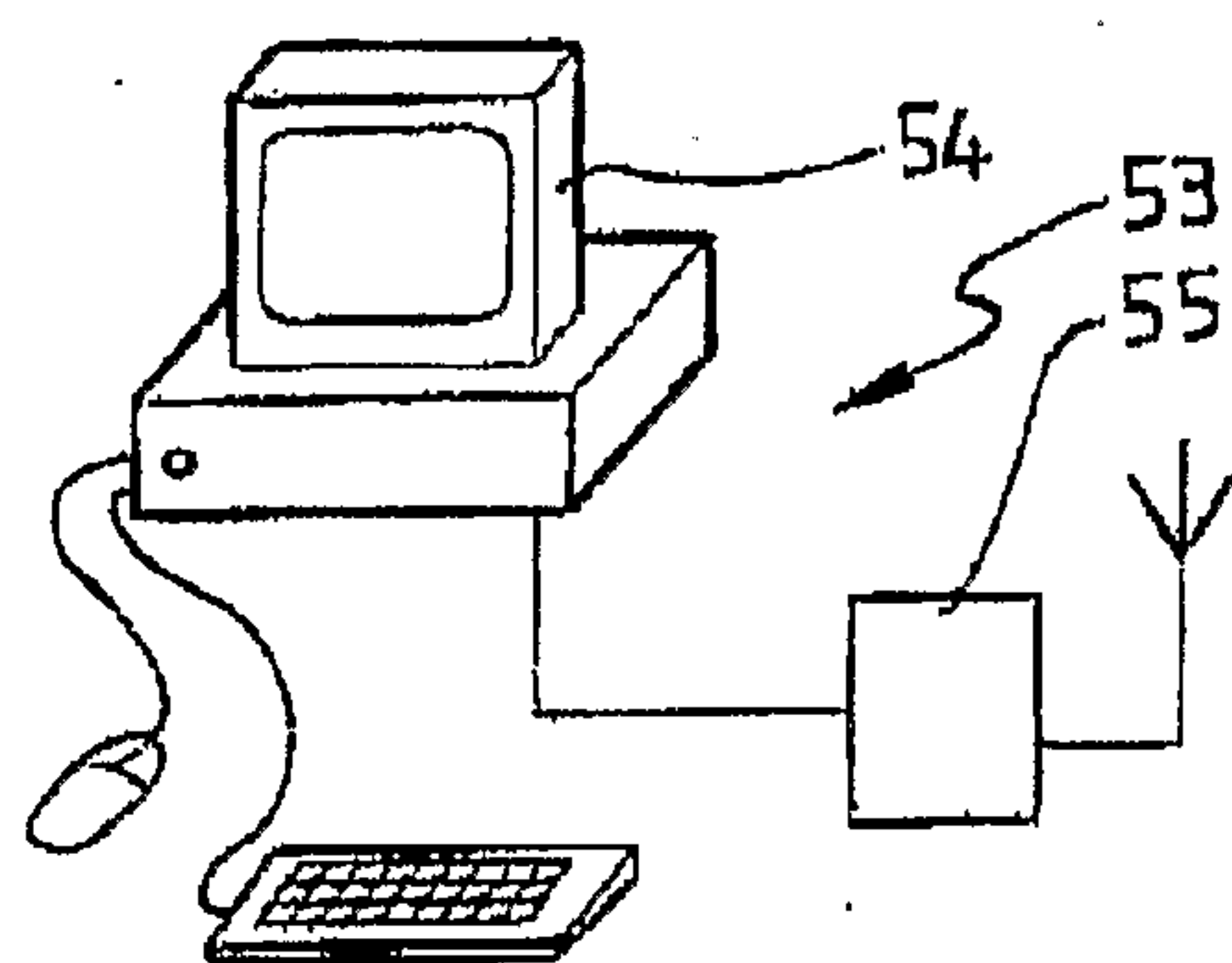
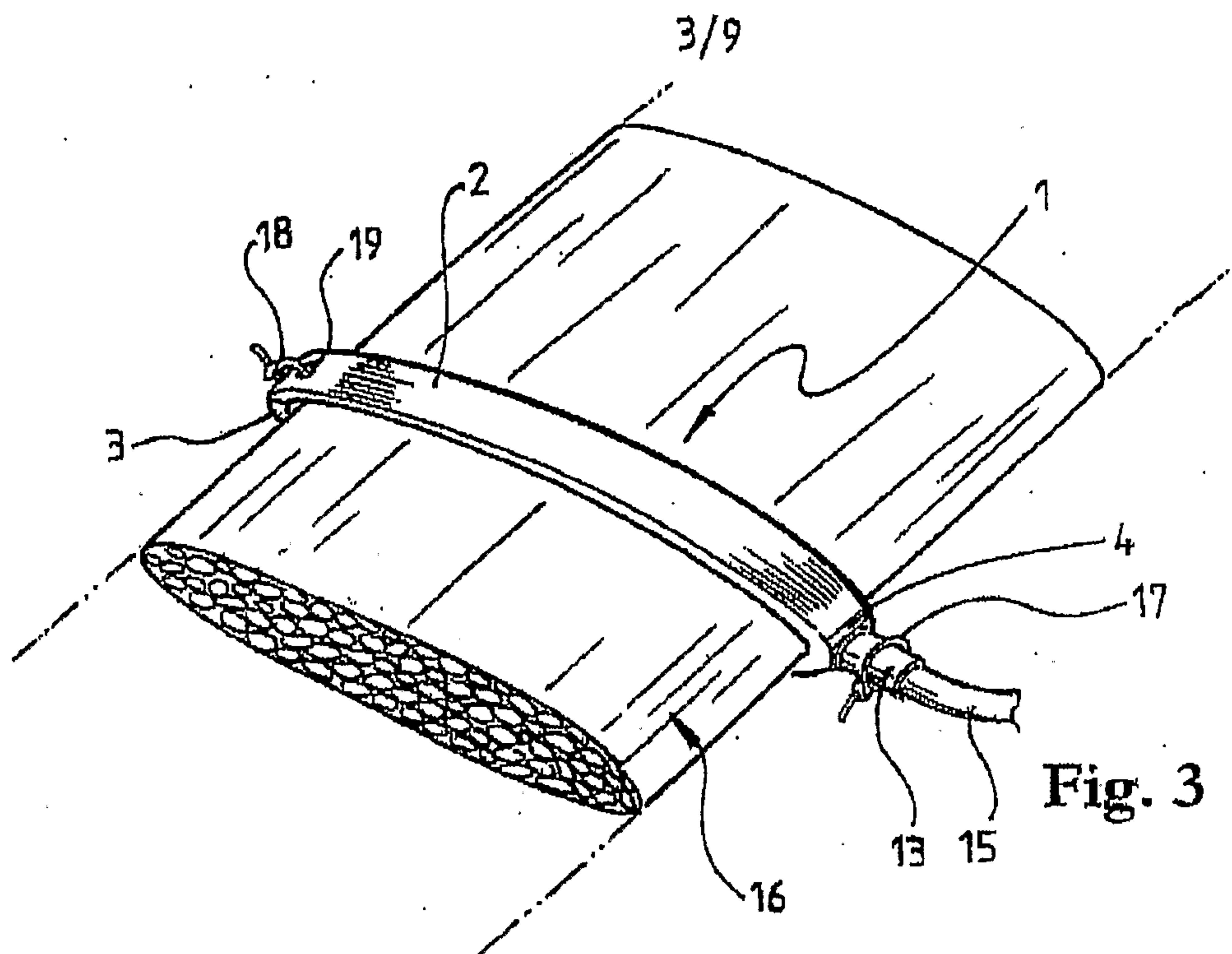
128. An electrode arrangement in accordance with claim 127, wherein the contractile tissue is arranged to effect counter pulsation.

129. A method of in vitro testing of tissue, utilising electrode arrangement in accordance with any one claims 1 to 38 or an electrode element of any one of claims 55 to 81.



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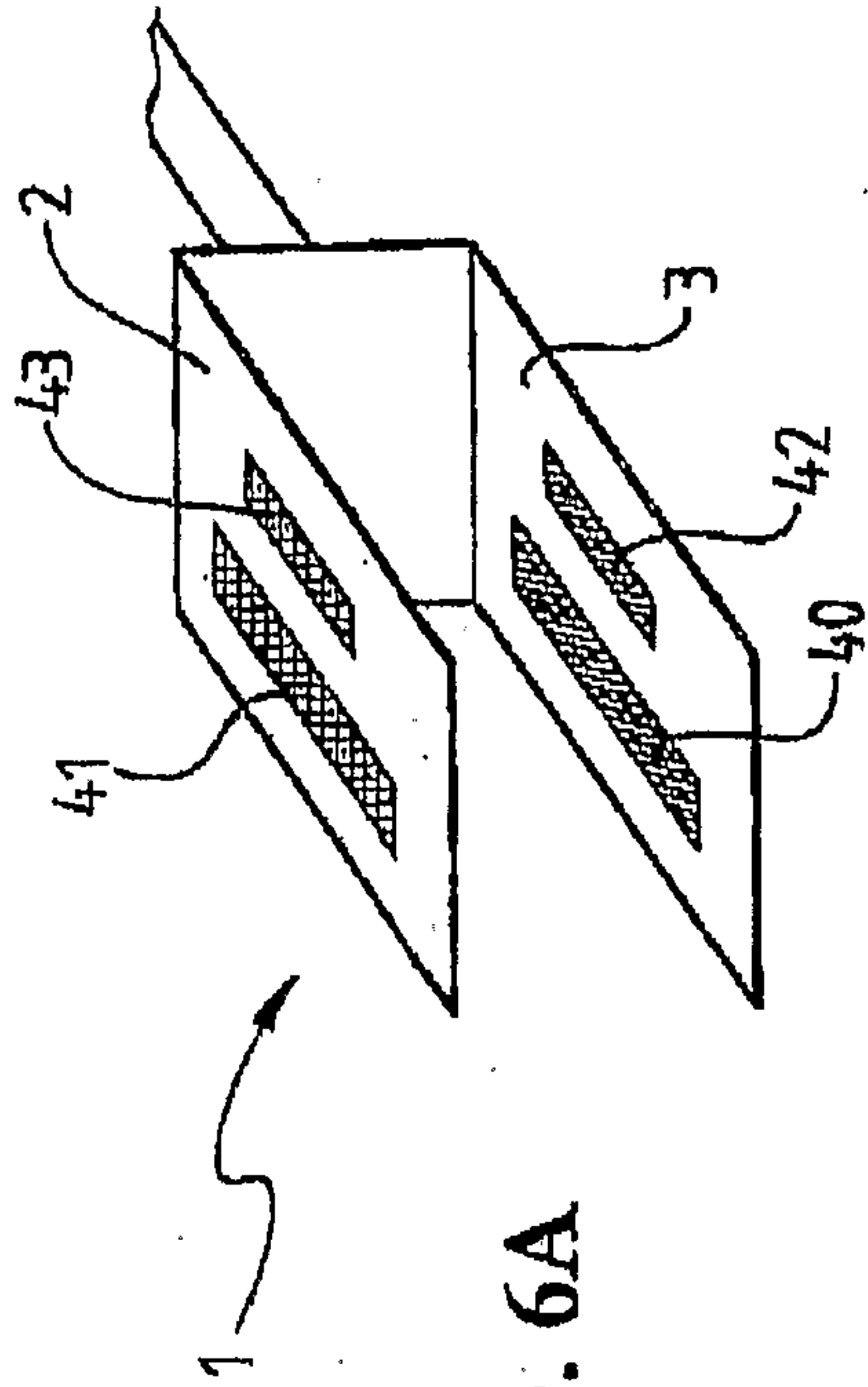


Fig. 6A

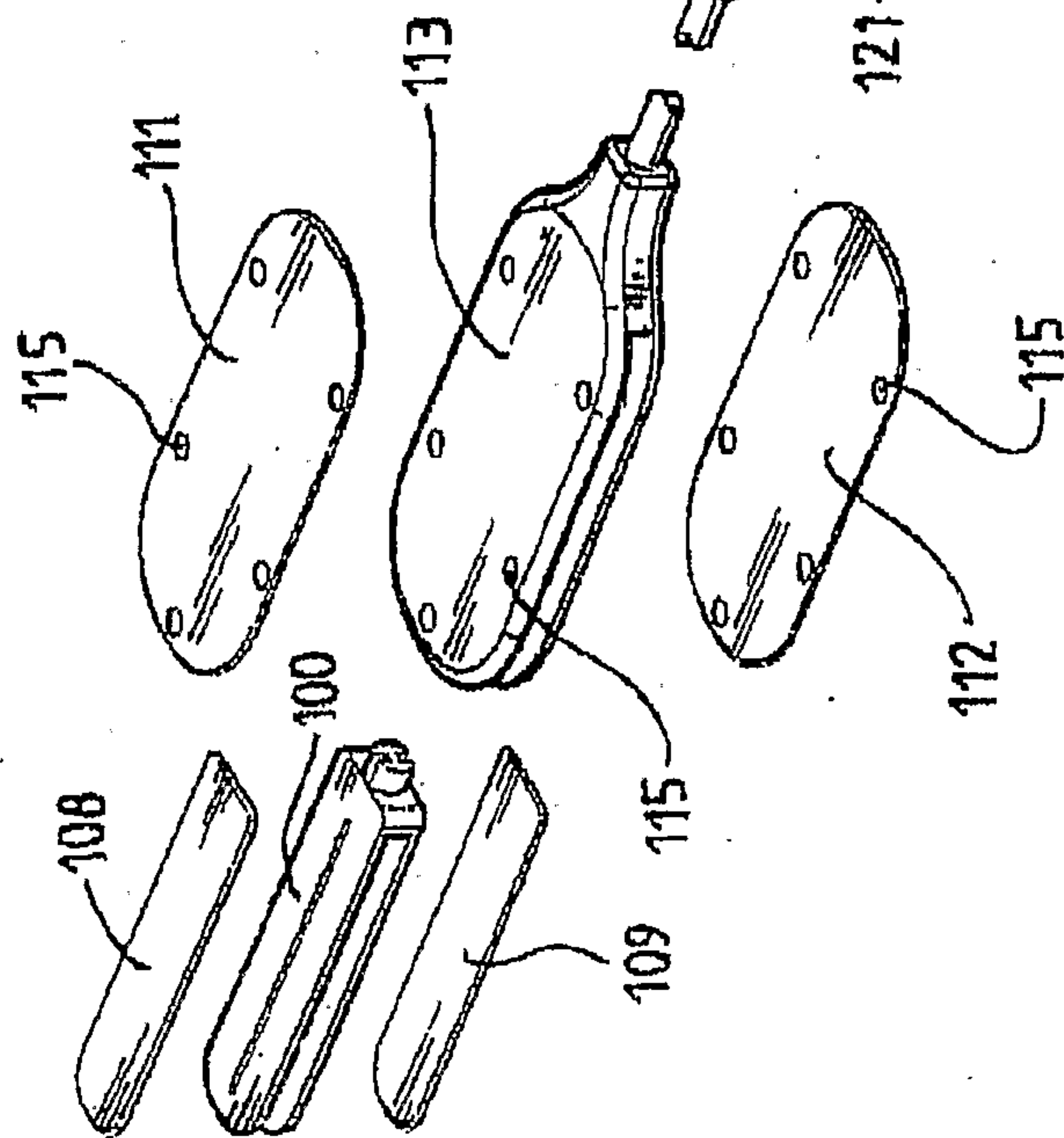
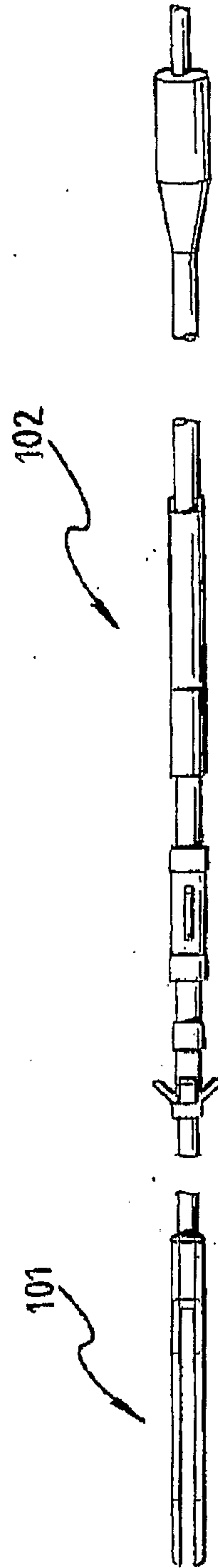
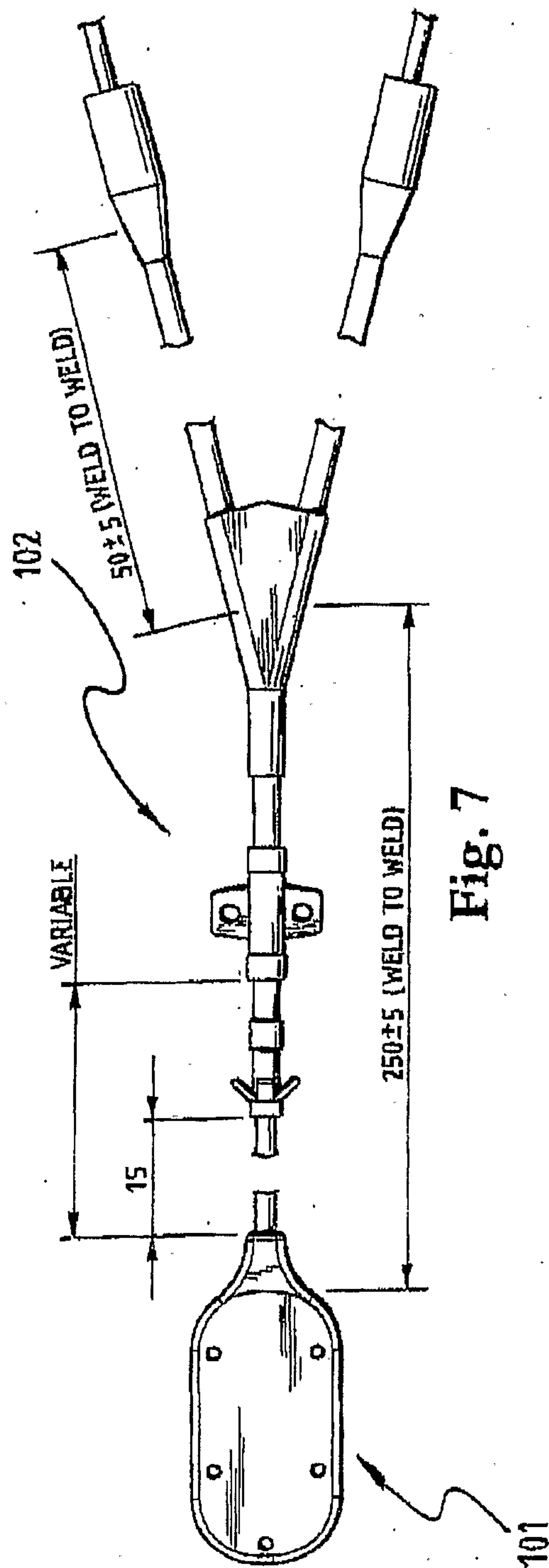


Fig. 6

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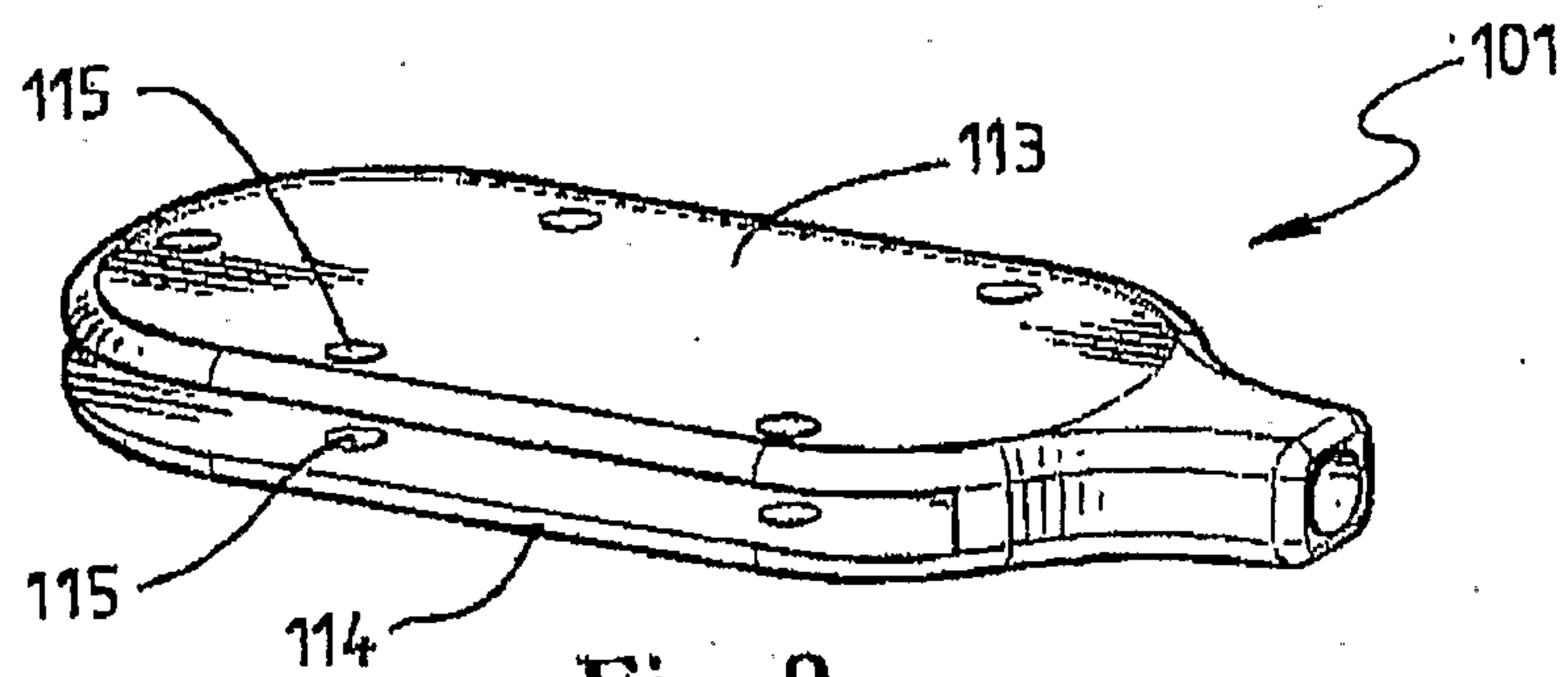


Fig. 9

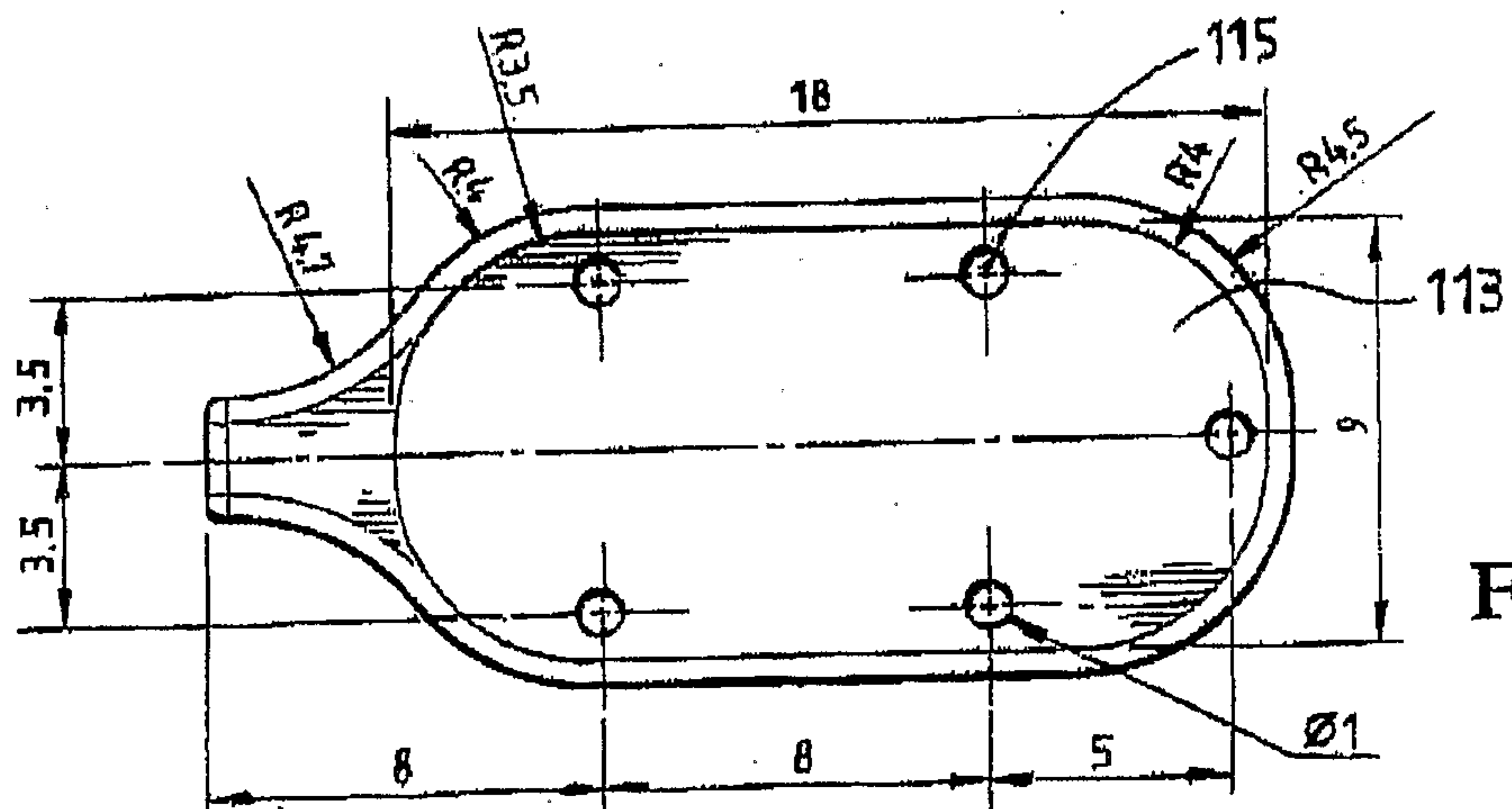


Fig. 10

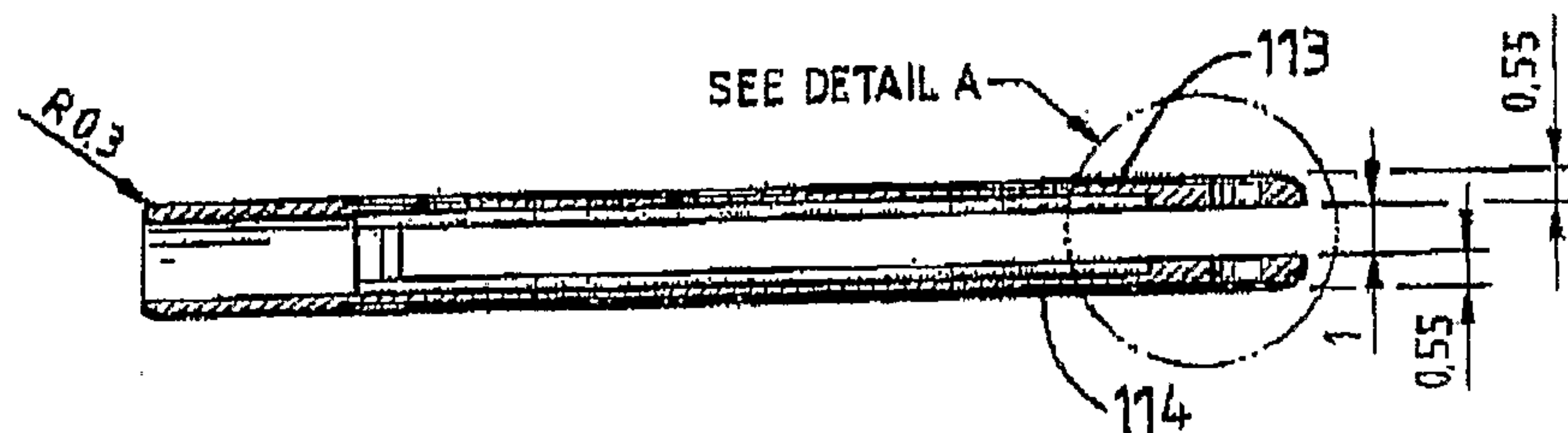


Fig. 11

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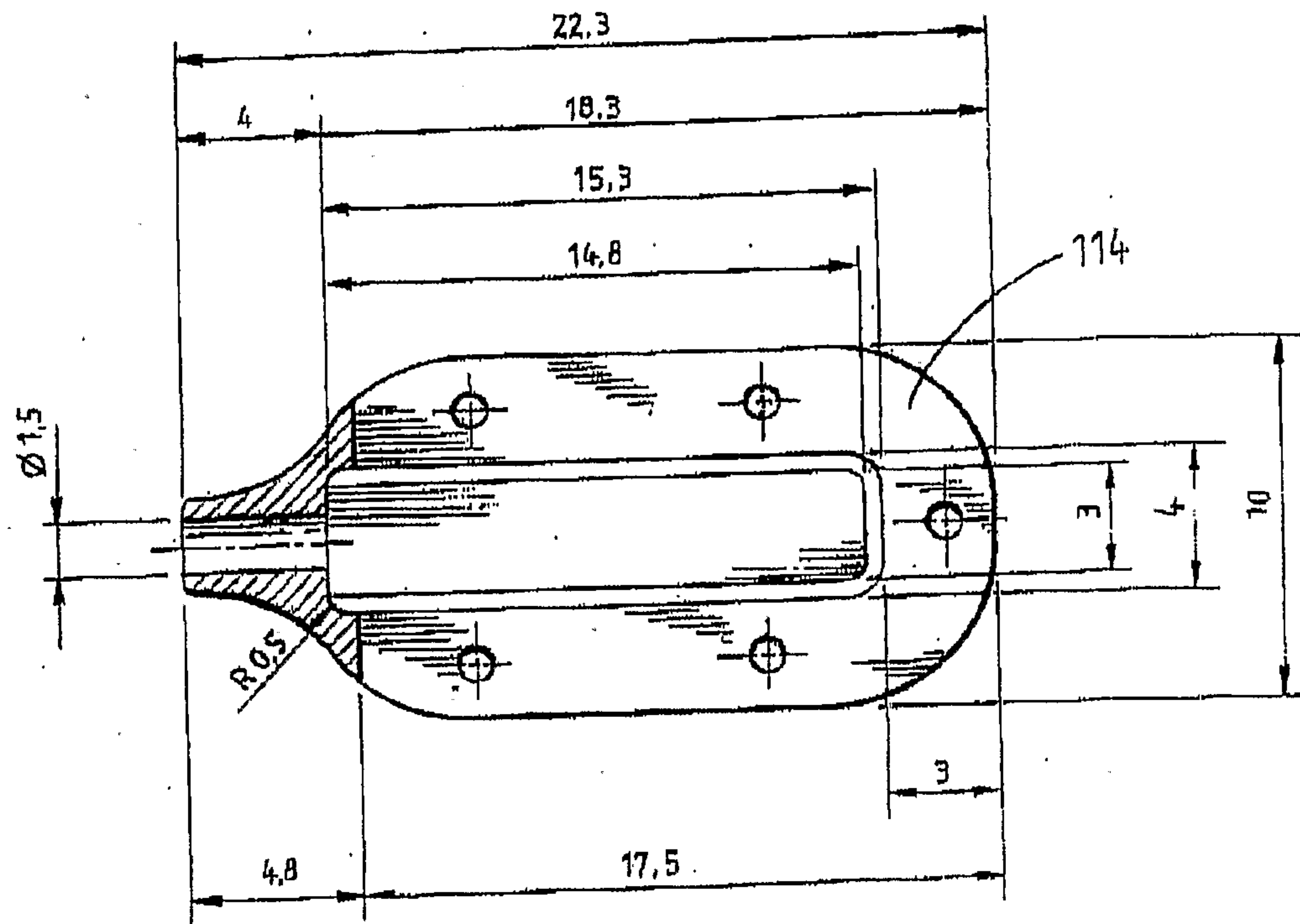


Fig. 12

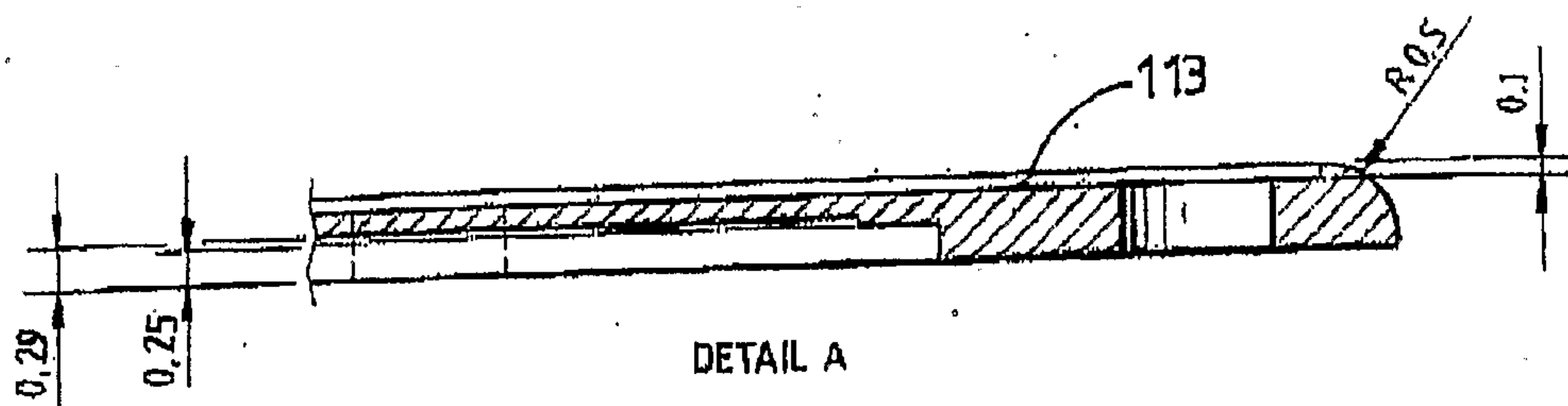


Fig. 13

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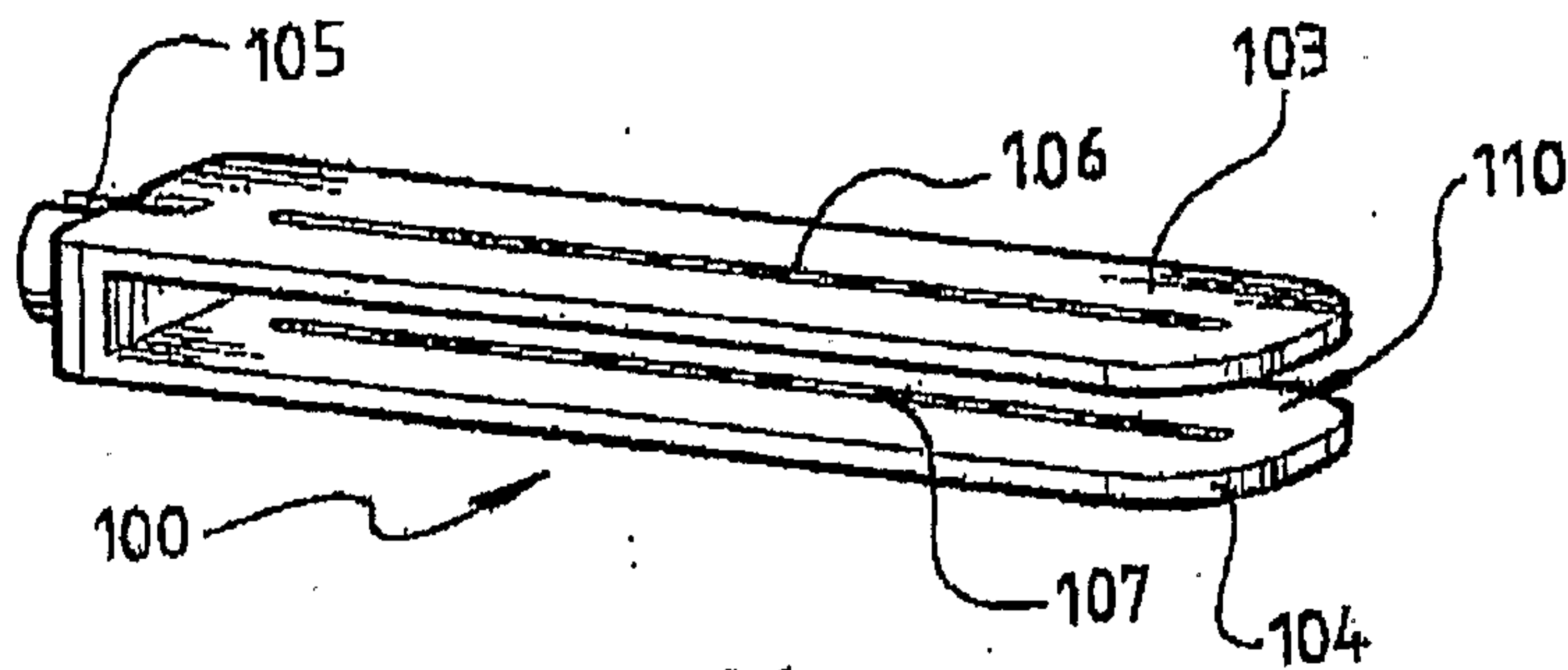


Fig. 14

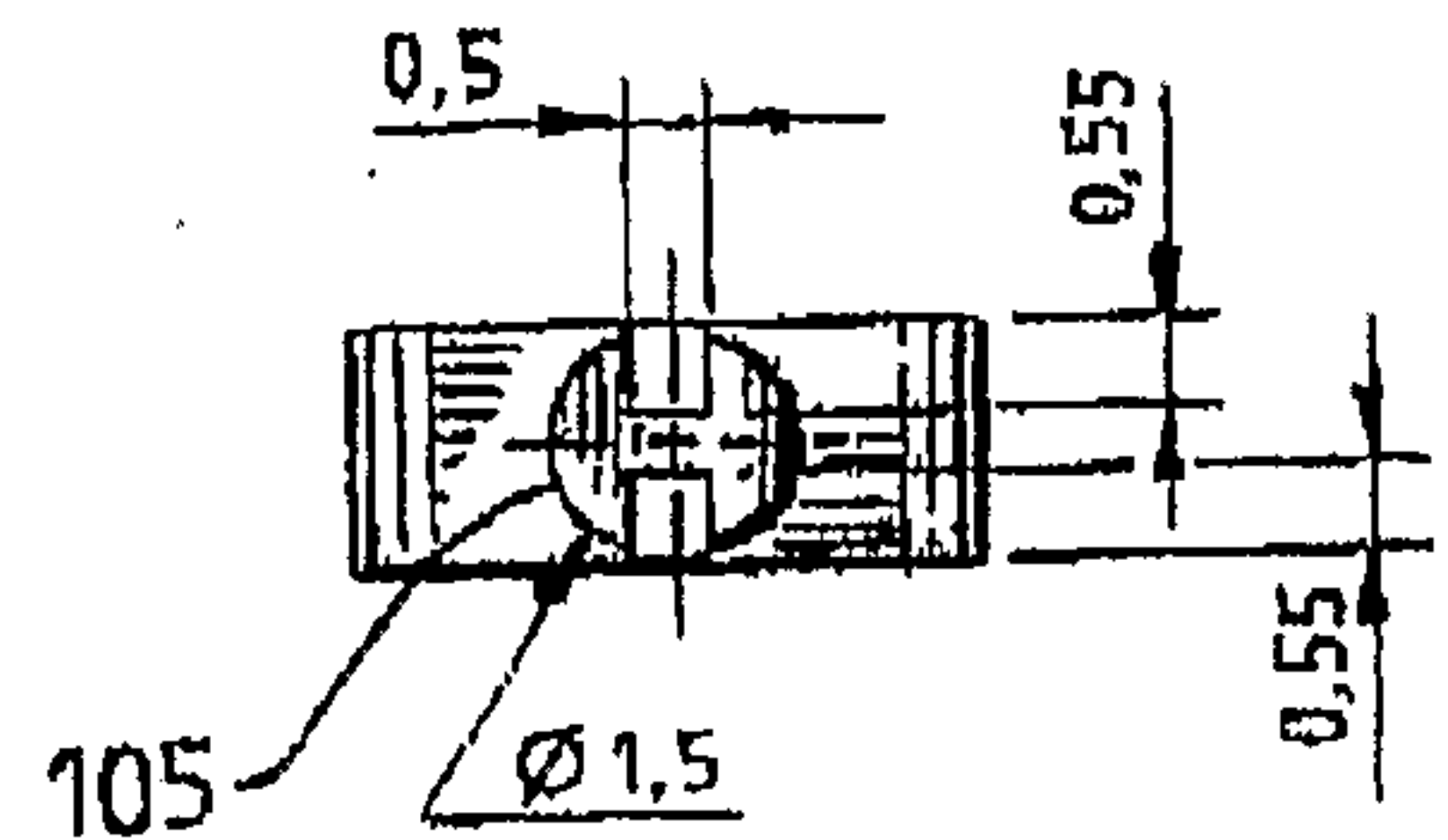


Fig. 15

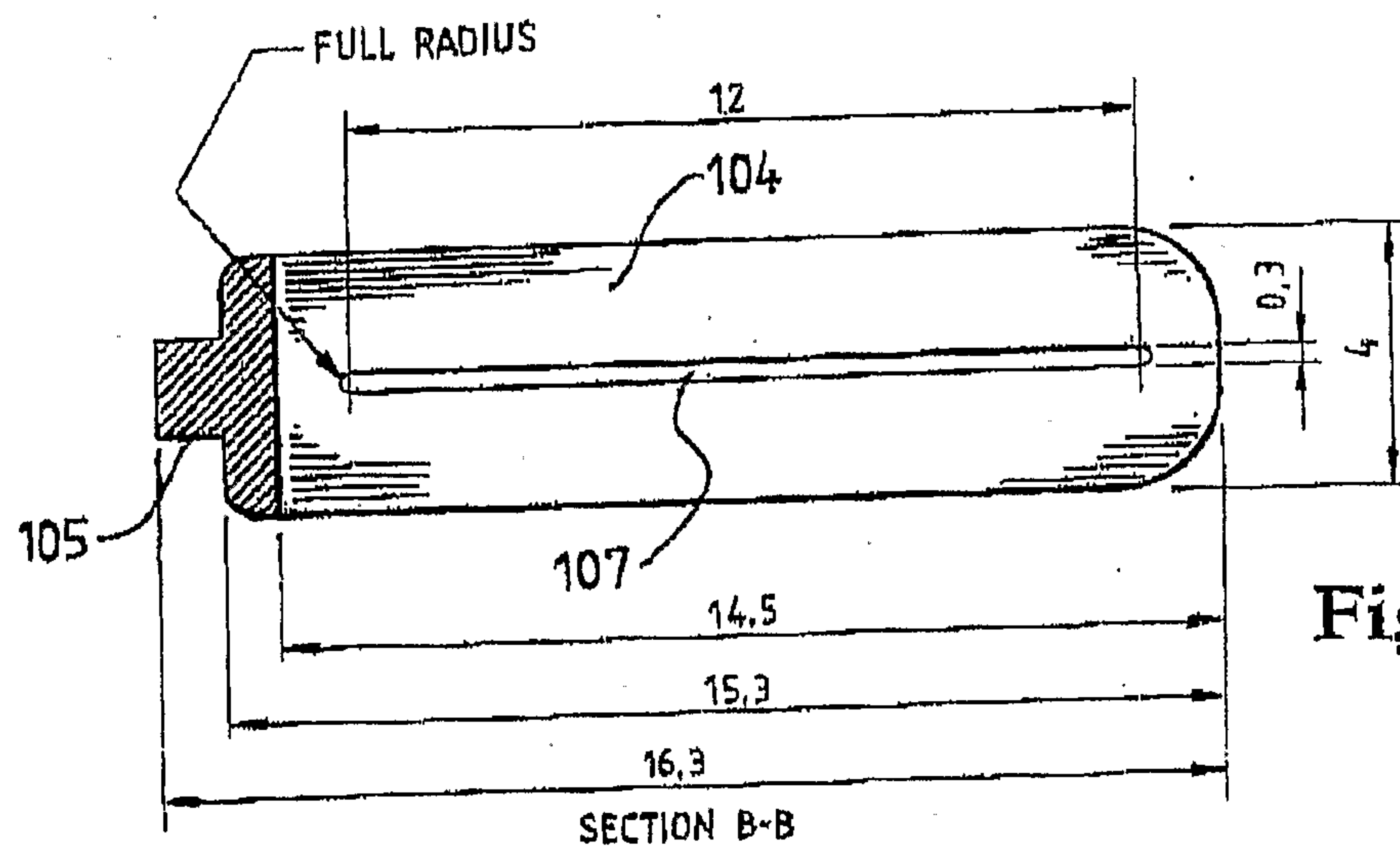


Fig. 16

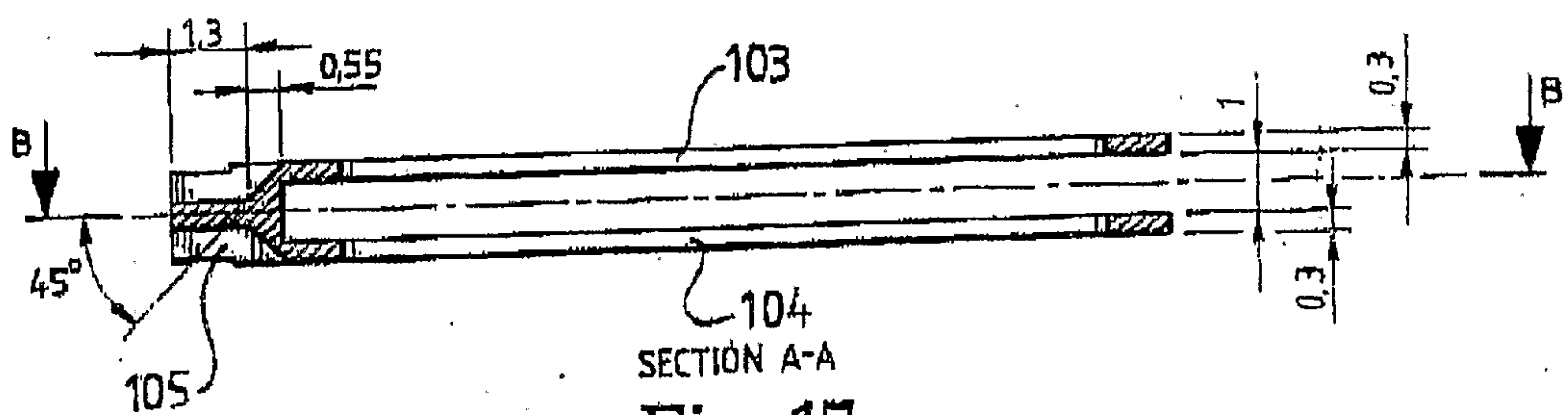


Fig. 17

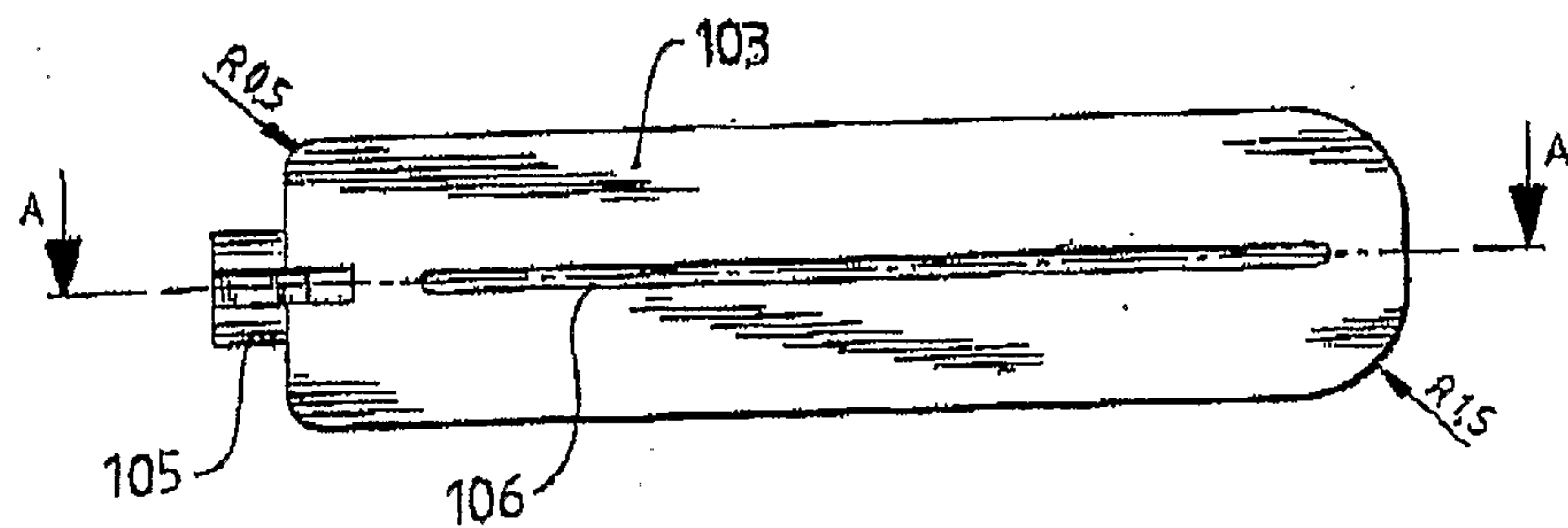


Fig. 18

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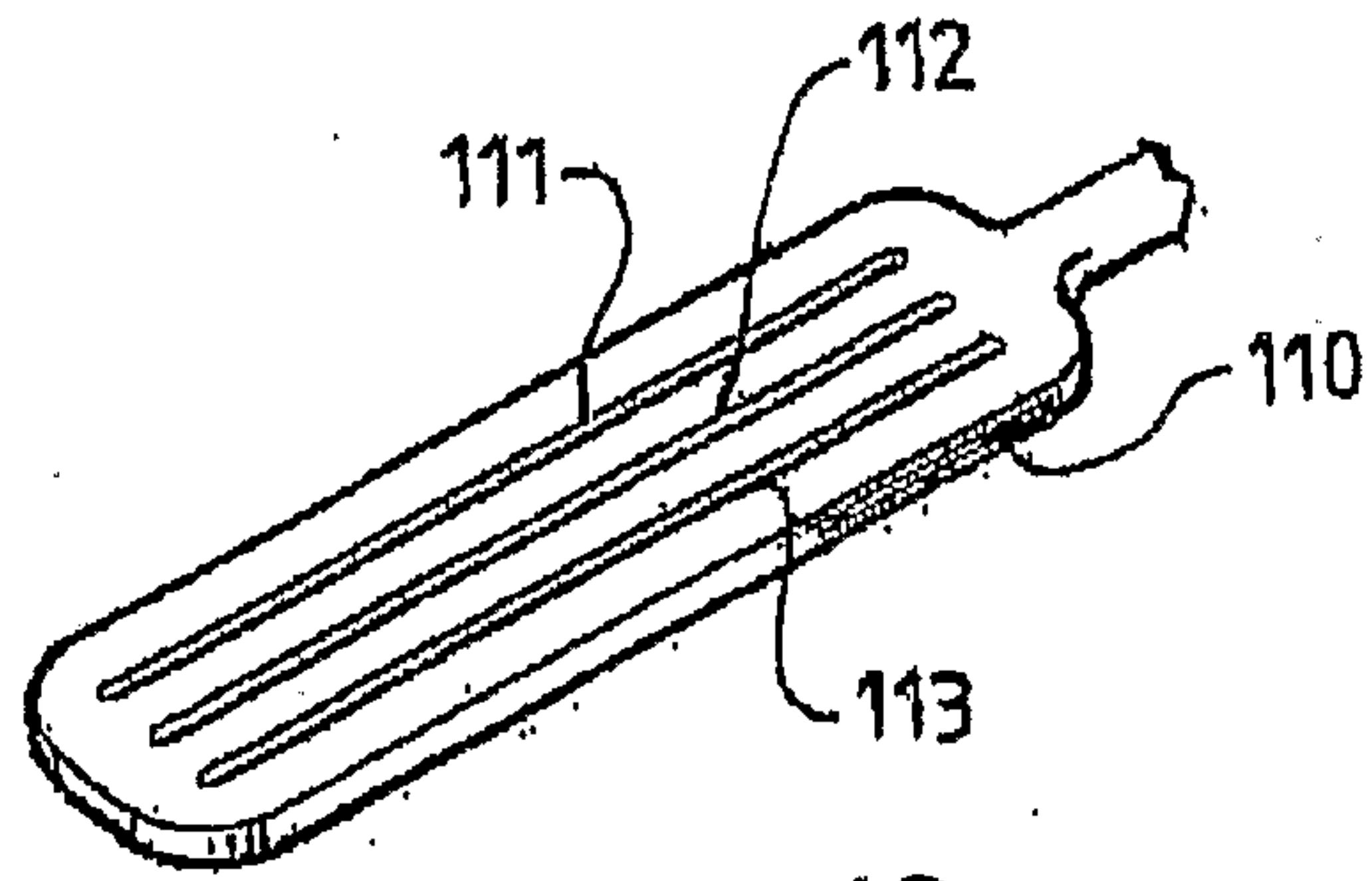


Fig. 19

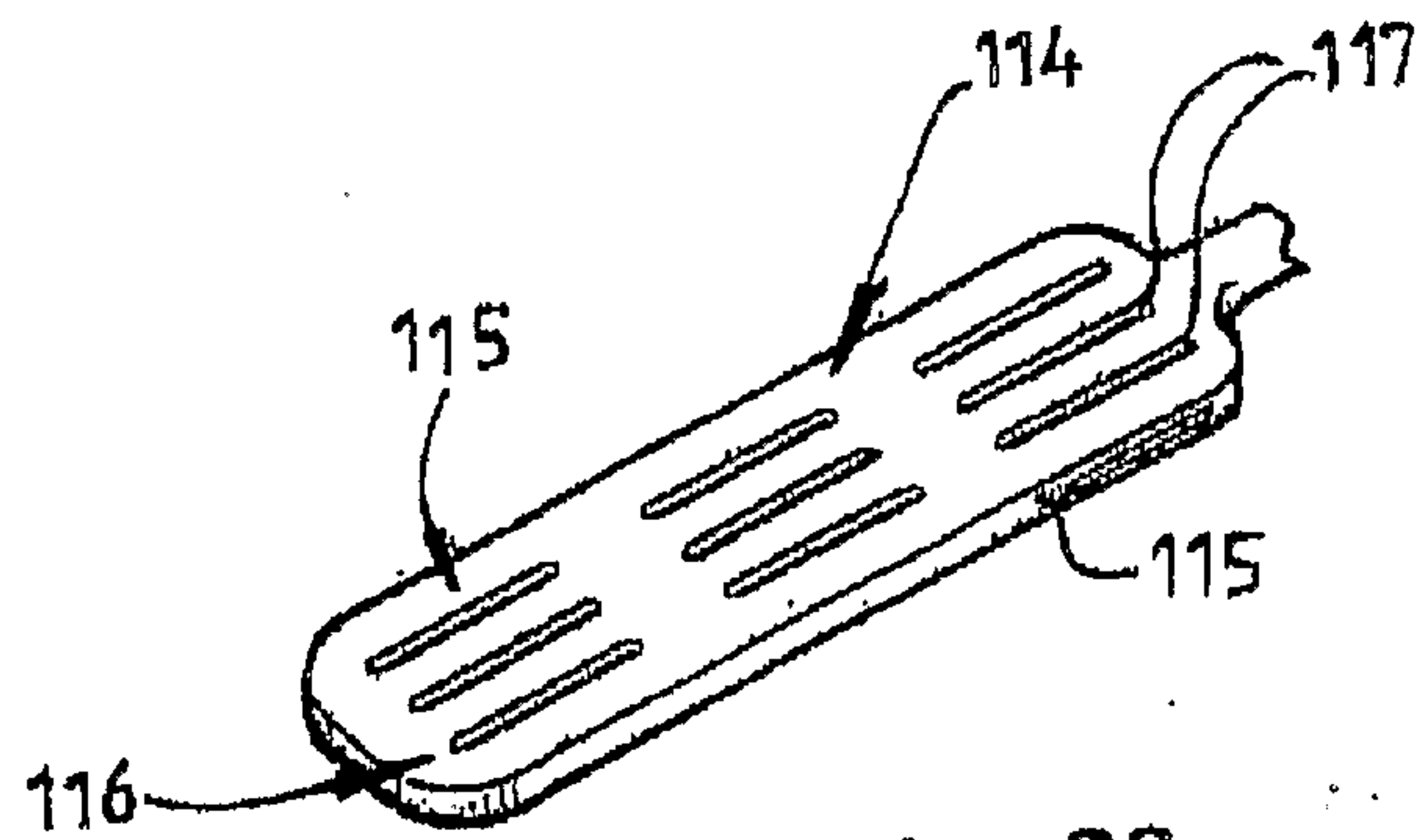


Fig. 20

