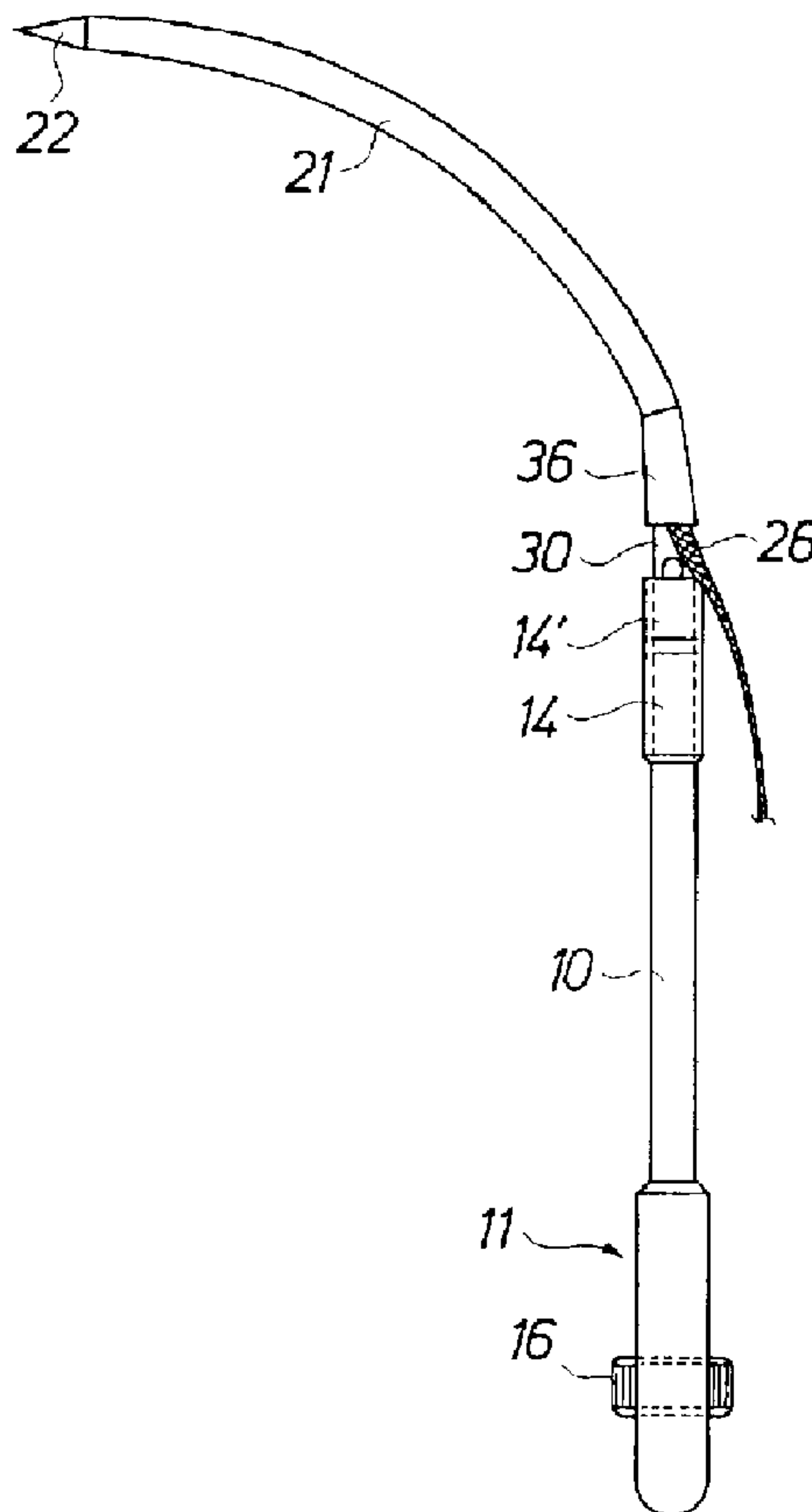




(86) Date de dépôt PCT/PCT Filing Date: 1996/10/08
 (87) Date publication PCT/PCT Publication Date: 1997/04/17
 (45) Date de délivrance/Issue Date: 2005/03/08
 (85) Entrée phase nationale/National Entry: 1998/03/04
 (86) N° demande PCT/PCT Application No.: SE 1996/001269
 (87) N° publication PCT/PCT Publication No.: 1997/013465
 (30) Priorité/Priority: 1995/10/09 (9503512-7) SE

(51) Cl.Int.⁶/Int.Cl.⁶ A61B 17/04
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(54) Titre : INSTRUMENT CHIRURGICAL DE TRAITEMENT DE L'INCONTINENCE URINAIRE CHEZ LA FEMME
 (54) Title: SURGICAL INSTRUMENT FOR TREATING FEMALE URINARY INCONTINENCE



(57) **Abrégé/Abstract:**

A surgical instrument for treating female urinary incontinence comprises a shank (10) having a handle (11) at one end thereof, and two curved needle-like elements (21A, 21B) which can be connected one at the time with the shank at the other end thereof to form a curved end portion of the shank and are attached at one end thereof each with one end of a netting (26) which is intended to be implanted into the body and is covered by a thin plastic sheath (34).

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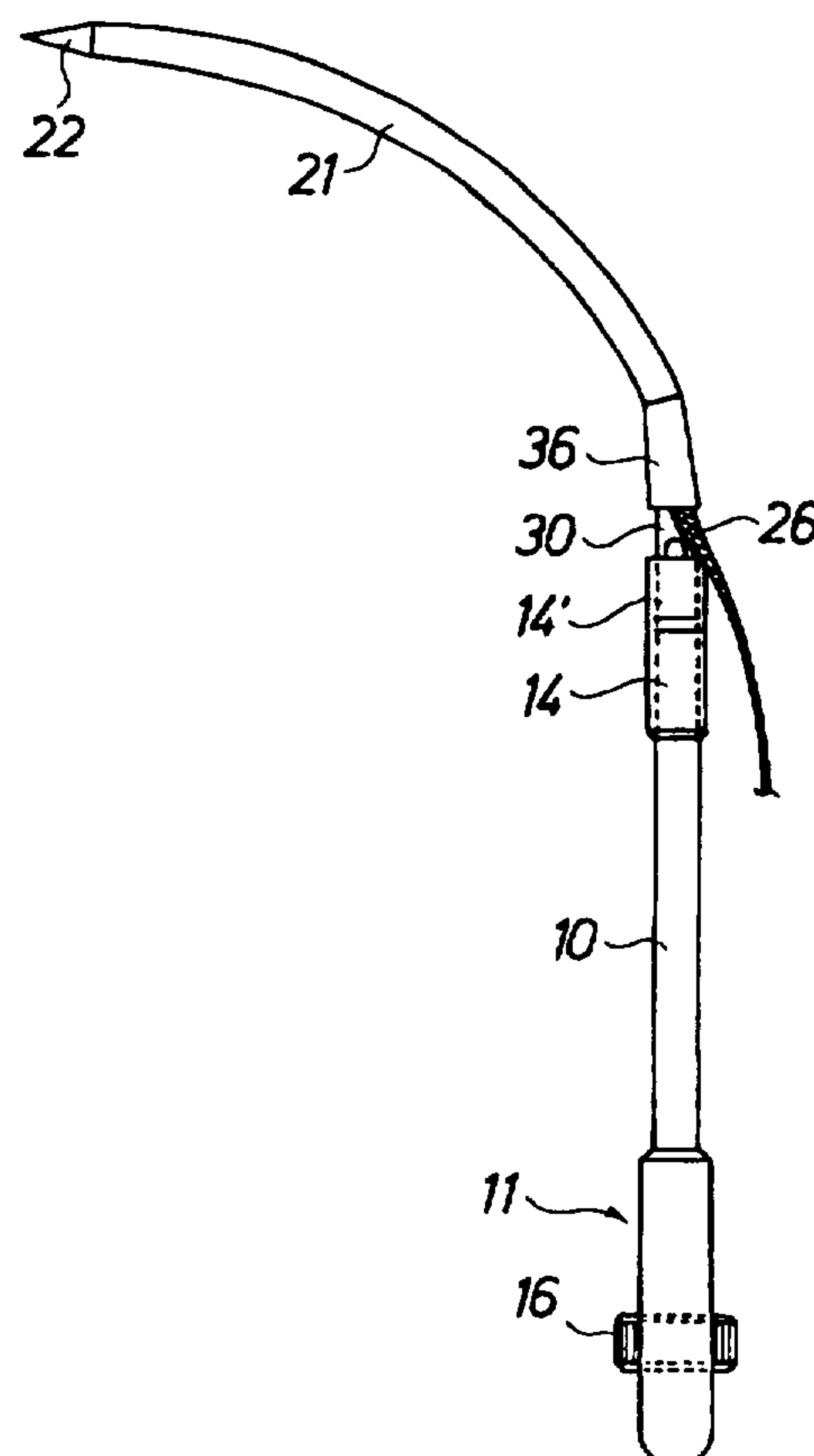
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁶ : A61B 17/04</p>	<p>A1</p>	<p>(11) International Publication Number: WO 97/13465</p> <p>(43) International Publication Date: 17 April 1997 (17.04.97)</p>
<p>(21) International Application Number: PCT/SE96/01269</p> <p>(22) International Filing Date: 8 October 1996 (08.10.96)</p> <p>(30) Priority Data: 9503512-7 9 October 1995 (09.10.95) SE</p> <p>(71) Applicant (for all designated States except US): MEDSCAND MEDICAL AB [SE/SE]; P.O. Box 20047, S-200 74 Malmö (SE).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): ULMSTEN, Ulf [SE/SE]; Ridvägen 18 D, S-182 35 Danderyd (SE).</p> <p>(74) Agents: STRÖM, Tore et al.; Ström & Gulliksson AB, P.O. Box 4188, S-203 13 Malmö (SE).</p>		<p>(81) Designated States: AU, CA, CN, JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: SURGICAL INSTRUMENT FOR TREATING FEMALE URINARY INCONTINENCE

(57) Abstract

A surgical instrument for treating female urinary incontinence comprises a shank (10) having a handle (11) at one end thereof, and two curved needle-like elements (21A, 21B) which can be connected one at the time with the shank at the other end thereof to form a curved end portion of the shank and are attached at one end thereof each with one end of a netting (26) which is intended to be implanted into the body and is covered by a thin plastic sheath (34).



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Surgical instrument for treating female urinary incontinence

The invention relates to a surgical instrument for treating female urinary incontinence, of the type described in WO-9003766, comprising a shank having a handle at one end thereof, and a curved needle-like element which is constructed to be connected with the shank to form a curved portion.

Document WO-9606567 discloses a surgical incontinence device that allows for alleviating female urinary incontinence while restoring continence by attaching two curved needle to a tape that is intended to be permanently implanted into the tissue between the vaginal wall and the abdominal wall of a patient, thus strengthening the tissue required to restore the urinary incontinence. The surgical instrument according to the present application is an improvement over this instrument, where the tape comprises a netting enclosed by a thin plastic sheath such that insertion is facilitated while avoiding irritation or damage of body tissue.

In accordance with one aspect of the present invention, there is provided a surgical instrument for treating female urinary incontinence, comprising a shank having a proximal end and a distal end, a handle at the proximal end of said shank, a tape to be implanted into the body as a loop around urethra, said tape including a netting enclosed by a sheath that can be withdrawn from the tape after the tape is inserted within the body, two curved needles, each having a proximal end and a distal end, wherein the proximal end of each needle is connected to an end of the tape, and means on said shank and each of said needles for exchangeable connection of the proximal end of the needles one at a time to the distal end of the shank to

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form an extension of the shank as a curved end portion thereof.

In accordance with a further aspect of the present invention, there is provided a surgical instrument for
5 treating female urinary incontinence, comprising a shank having a proximal end and a distal end, a handle at the proximal end of said shank, a tape to be implanted into the body as a loop around urethra, said tape including a netting enclosed by a sheath that can be withdrawn from the tape
10 after the tape is inserted within the body, a curved needle, having a proximal end and a distal end, wherein the proximal end of the needle is connected to an end of the tape, and means on said shank and said needle for exchangeable connection of the proximal end of the needle to the distal
15 end of the shank to form an extension of the shank as a curved end portion thereof.

The invention will be explained in more detail with reference to the accompanying drawings which disclose the surgical instrument according to the invention and
20 wherein:

FIG. 1 is a side view of the surgical instrument according to the invention,

FIG. 2 is a plan view of the surgical instrument,

FIG. 3 is an exploded side view of one of the
25 needles and tape and shrinkage hose to be connected with said needle,

FIG. 4 is a side view of the needle in FIG. 3 with the tape connected therewith,

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FIG. 5 is an enlarged fragmentary axial cross sectional view of a coupling of the instrument for connecting an exchangeable needle thereof, and

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FIG 6 is a side view of two needles and a tape inter-connecting said needles.

In the following description the same reference numerals have been used as in WO-9606567 for corresponding
5 details of the instrument.

The surgical instrument comprises a cylindrical tubular shank 10 having at one end thereof a handle 11. At the other end of the shank there is a socket 14. A cylindrical shaft 15 is rotatably mounted in the shank and can be rotated manually by means of a knob 16 mounted to one end of the shaft. The other end of the shaft forms a cylindrical portion 17, FIG 5, of smaller outside diameter than the shaft, which joins a portion 18 having external threads, a smooth end portion 19 of further reduced diameter joining the threaded portion 18, end portion 19 forming a guide pin at said other end of the shaft. Portions 18 and 19 are received in the portion of socket 14 projecting from the shank. The surgical instrument as described so far is in agreement with the instrument disclosed
20 in WO-9606567 except that the end portion 14' of socket 14 is flattened from opposite sides (cfr FIGS 1 and 2), so that the cross section of said end portion is non-circular.

The surgical instrument also includes an exchangeable
25 and disposable needle 21 which at one end thereof is attached to the shank at one end of the needle and extends over substantially a quarter of a circle to the other, free end thereof in order to follow substantially the profile of the pubis between the vagina and the abdominal wall. The
30 needle has uniform circular cross section and has a smooth, preferably polished outside surface. At the free end thereof the needle forms a point 22 by being terminated by a conical portion.

For attachment of needle 21 to shank 10 the needle
35 forms at said one end thereof a straight portion 30 which

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is cylindrical but has milled flat faces 31 over that part of said portion 30, extending from the adjacent end of the needle, which shall be received by socket portion 14'. The needle should be oriented in a predetermined rotational position in relation to the shank, and more particularly it should project at right angles to the plane of handle 11. This rotational position is secured by the non-circular shape of socket portion 14' and the end portion of the needle having the flat faces 31, which fits into socket portion 14'. The end portion of the needle having the flat faces 31 joins the body of the needle over a conical portion 32, which tapers towards a shoulder 33.

An axial blind hole extends from the end surface of the needle said hole having a threaded portion 23 and inwardly thereof a narrower, cylindrical portion 24. Guide pin 19 is dimensioned to be guidingly received by said latter portion when the threaded portion 18 for attaching needle 21 to the rest of the surgical instrument is screwed into threaded portion 23 of the blind hole by rotating shaft 15 by manual rotation of knob 16, the end surfaces of the shank and the needle being pressed against each other. Also this attachment is in agreement with that described in WO-9606567.

When the method as described in WO-9606567 is practised two needles 21A and 21B, FIG. 6 of the embodiment described shall be connected one at each end of a tape 26. According to the present invention the tape of the preferred embodiment comprises a mesh or netting forming openings of the order of 1 mm. A suitable material for the tape is PROLENE®, a knitted polypropylene mesh having a thickness of 0,7 mm manufactured by Ethicon, Inc., Somerville, New Jersey, USA. This material is approved by FDA in USA for implantation into the human body. The netting (tape) preferably has a width of approximately 10 mm and is enclosed in a thin polyethylene sheath 34 which in

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flattened condition has substantially the same width as the tape although a difference in width is shown in FIG 2 in order to make the provision of the sheath more clear. The length of the netting should be approximately 400 mm. The netting and the sheath are interconnected by means of two rows 35 of stitching. The end portion of the sheath is attached to the conical portion 32 of the needle by means of a suitable strong glue, and the interconnection of the needle and sheath is covered by a shrink hose 36 of rubber which extends from the shoulder 33 over the conical portion 32 and partly over the cylindrical end portion 30 of the needle. The shrink hose is substantially flush with the surface of the needle at the shoulder. By this arrangement the netting is securely attached to the needle.

The purpose of sheath 34 is above all to facilitate the insertion of the netting in the manner described in WO-9606567 i e when the netting is pulled at the ends thereof from the vaginal wall to the abdominal skin and to avoid that rough edges of the netting irritate or damage the body tissue.

When the tape has been positioned in the correct position as a sling around the urethra the polyethylene sheath shall be removed, and in order to facilitate the removal the sheath should be perforated at the longitudinal center thereof as indicated by a dot-and-dash line 37 in FIG. 6, so that the two halves of the sheath can be withdrawn from the body by pulling at the respective outer ends thereof the halves being separated at the perforation under the influence of the pulling force.

The purpose of the polyethylene sheath is also to protect the netting during attachment to the needles and during handling before and during insertion into the body.

The longitudinal center of the tape and sheath should be indicated by a visible colour mark 38, FIG. 6 so that the surgeon readily can see when the netting is sym-

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metrically located with reference to urethra during the surgery.

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CLAIMS:

1. A surgical instrument for treating female urinary incontinence, comprising

a shank having a proximal end and a distal end,

5 a handle at the proximal end of said shank,

a tape to be implanted into the body as a loop around urethra, said tape including a netting enclosed by a sheath that can be withdrawn from the tape after the tape is inserted within the body,

10 two curved needles, each having a proximal end and a distal end, wherein the proximal end of each needle is connected to an end of the tape, and

means on said shank and each of said needles for exchangeable connection of the proximal end of the needles
15 one at a time to the distal end of the shank to form an extension of the shank as a curved end portion thereof.

2. The surgical instrument according claim 1 wherein the netting is made of polypropylene.

3. The surgical instrument according to claim 1 or 2
20 wherein said sheath is made of polyethylene.

4. The surgical instrument according to any one of claims 1 to 3 wherein said sheath has a perforation line at a longitudinal center thereof.

5. The surgical instrument according to any one of
25 claims 1 to 4, wherein the netting and the sheath are interconnected by stitching.

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6. The surgical instrument according to any one of claims 1 to 5, wherein the netting and the sheath are connected to the needle by gluing to a conical portion at said proximal end of each of said needle.

5 7. The surgical instrument according to claim 6 further comprising a shrink hose covering said netting and said sheath at the site of attachment thereof.

8. The surgical instrument according to claim 7, wherein one end of the shrink hose abuts a shoulder distal
10 to said conical portion and has its outside surface substantially at the level of the surface of each of said needle at said shoulder.

9. The surgical instrument according to any one of claims 1 to 8 wherein a visible marking is provided on the
15 sheath at a longitudinal center thereof.

10. A surgical instrument for treating female urinary incontinence, comprising

a shank having a proximal end and a distal end,

a handle at the proximal end of said shank,

20 a tape to be implanted into the body as a loop around urethra, said tape including a netting enclosed by a sheath that can be withdrawn from the tape after the tape is inserted within the body,

25 a curved needle, having a proximal end and a distal end, wherein the proximal end of the needle is connected to an end of the tape, and

means on said shank and said needle for exchangeable connection of the proximal end of the needle to

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the distal end of the shank to form an extension of the shank as a curved end portion thereof.

11. The surgical instrument according claim 10 wherein the netting is made of polypropylene.

5 12. The surgical instrument according to claim 10 or 11 wherein said sheath is made of polyethylene.

13. The surgical instrument according to any one of claims 10 to 12 wherein said sheath has a perforation line at a longitudinal center thereof.

10 14. The surgical instrument according to any one of claims 10 to 13, wherein the netting and the sheath are interconnected by stitching.

15 15. The surgical instrument according to any one of claims 10 to 14, wherein the netting and the sheath are connected to the needle by gluing to a conical portion at said proximal end of said needle.

16. The surgical instrument according to claim 15 further comprising a shrink hose covering said netting and said sheath at the site of attachment thereof.

20 17. The surgical instrument according to claim 16, wherein one end of the shrink hose abuts a shoulder distal to said conical portion and has its outside surface substantially at the level of the surface of said needle at said shoulder.

25 18. The surgical instrument according to any one of claims 10 to 17 wherein a visible marking is provided on the sheath at a longitudinal center thereof.

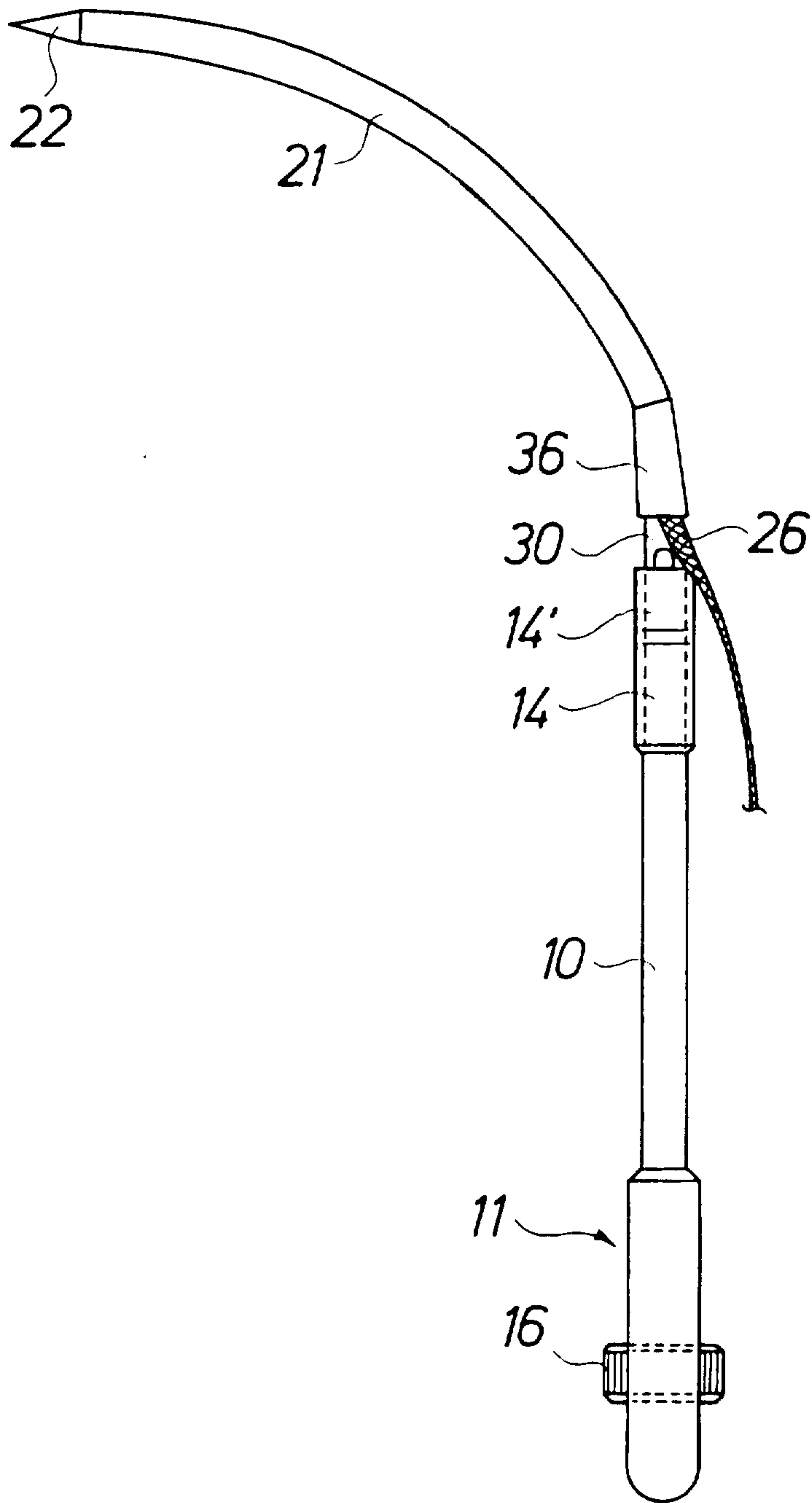


FIG. 1

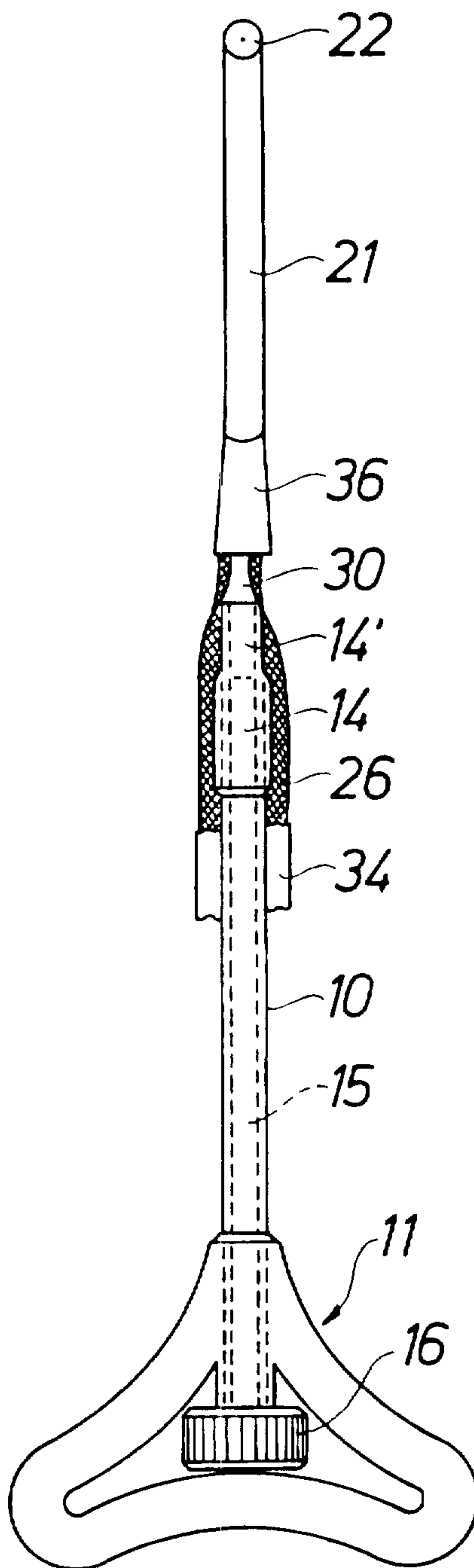


FIG. 2

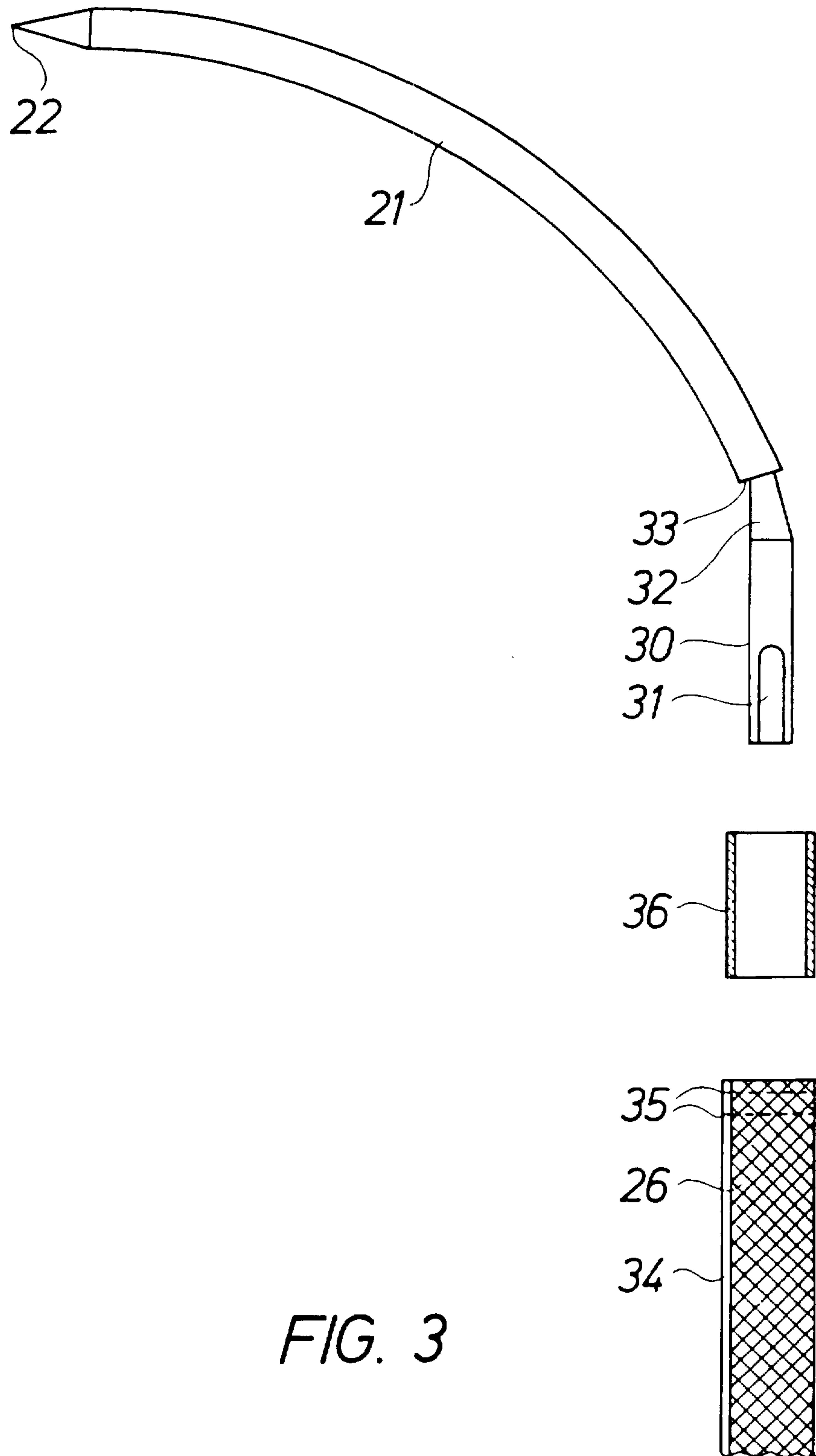
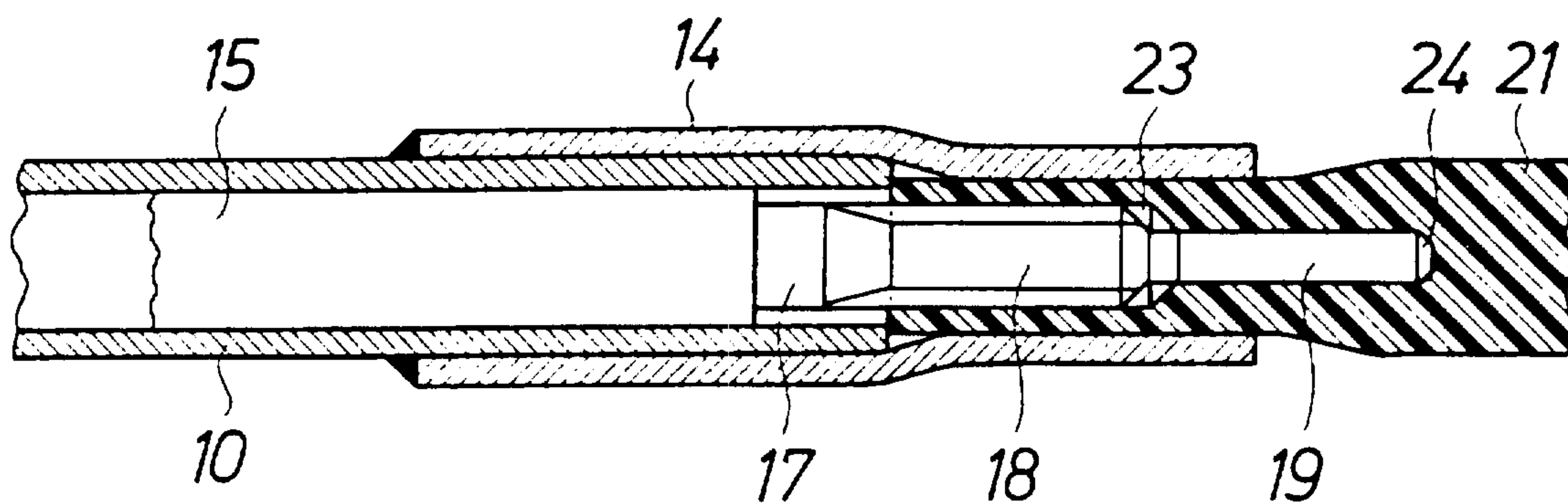
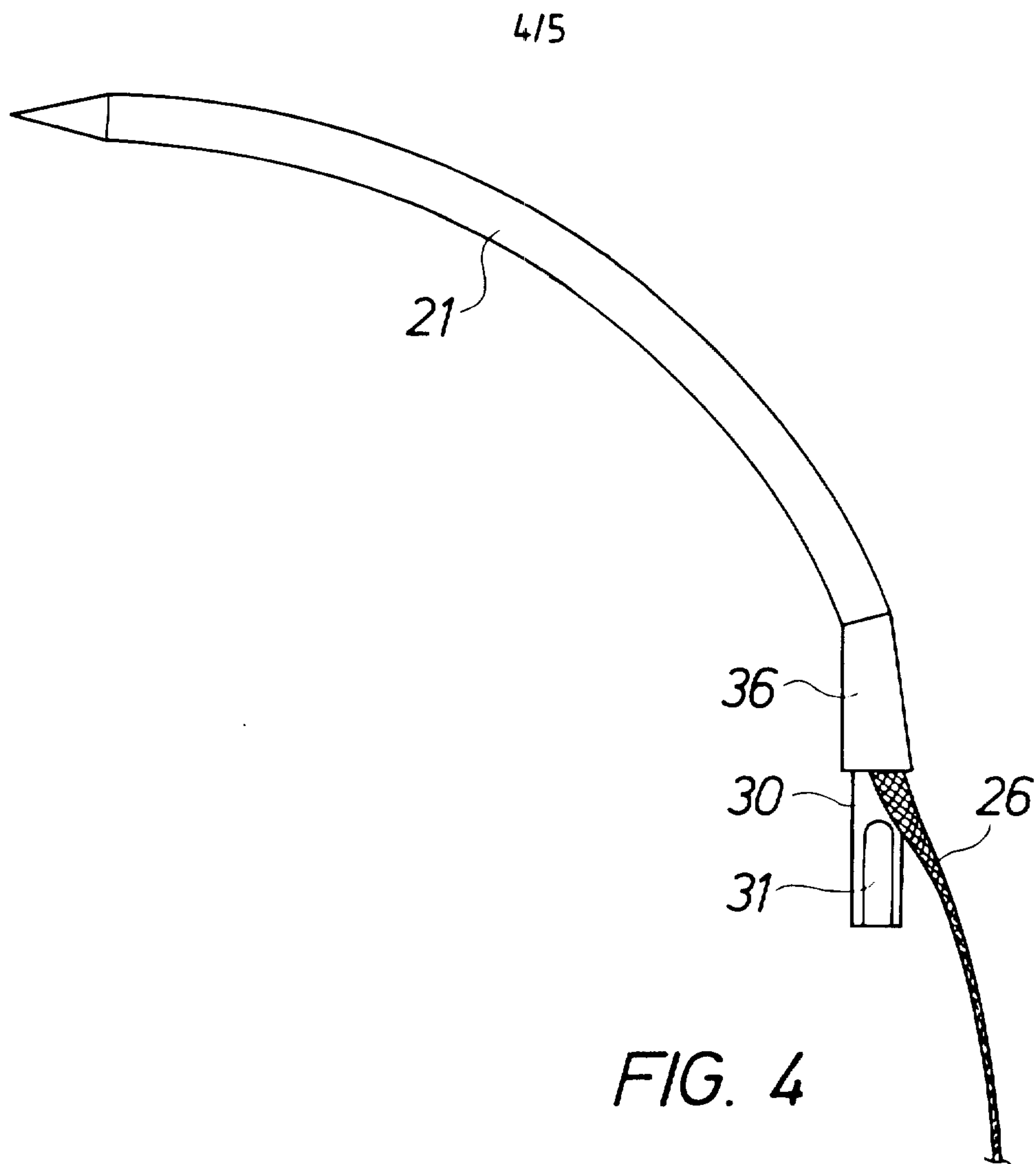


FIG. 3



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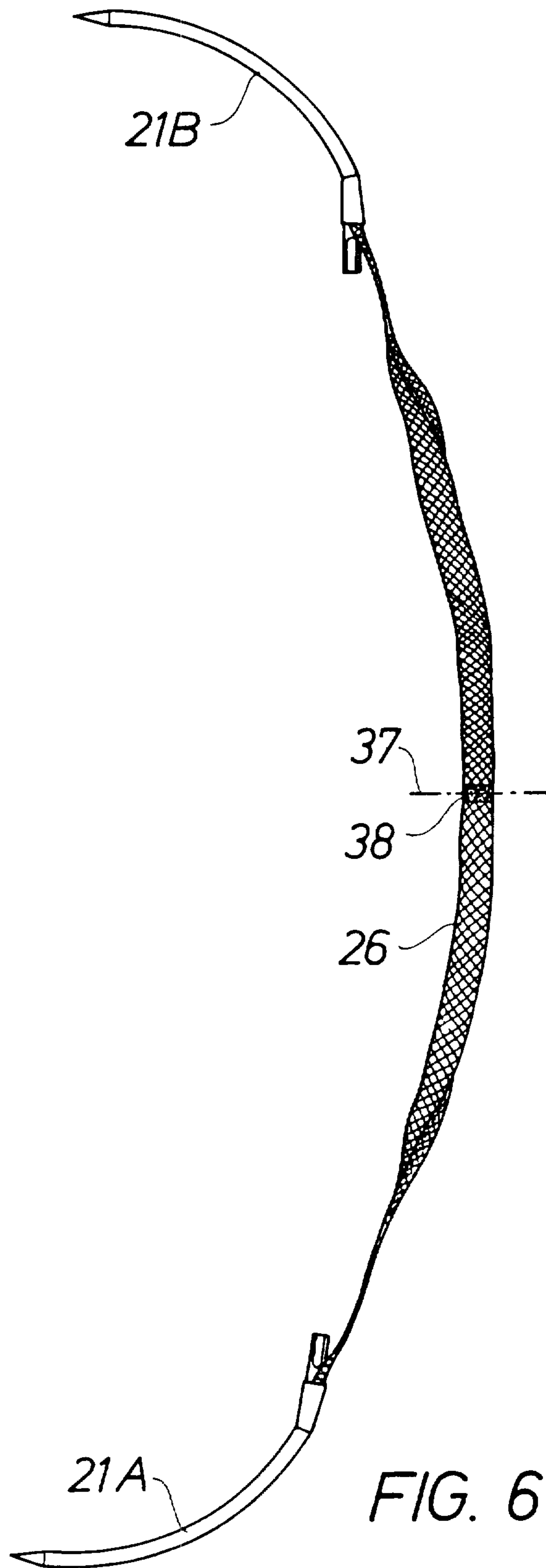


FIG. 6

