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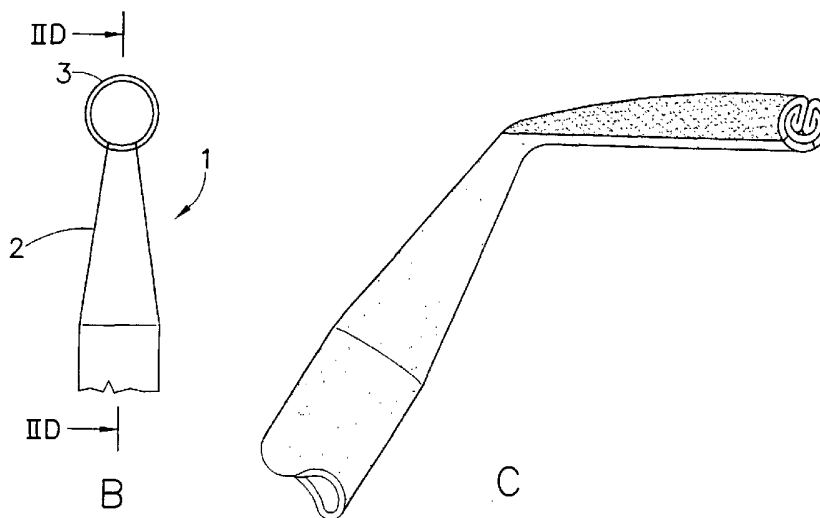
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[Continued on next page]

(54) Title: AORTIC CANNULA



(57) Abstract: The present invention refers to a cannula, in particular aortic. In an embodiment the aortic cannula comprises a tubular tip (1), suitable to be inserted into an aorta, characterised in that said tubular tip (1) comprises at least a first circumferential portion, made up of deformable material (3), and at least a second circumferential portion, made up of non deformable material (2), that extend longitudinally starting from the final end of said tubular tip (1), said second circumferential portion (2) being placed adjacent to the aorta wall, on the same side of the surgically made slit, through which the tubular tip (1) is inserted in the aorta, so that, while a first fluid is introduced into said aorta through said cannula, said portion of deformable material (3) stretches out so as to favour the flow of said first fluid and, while a second fluid is supplied by the heart, said portion of deformable material (3) deforms thus reducing the section of said tubular tip (1) so as to favour the flow of said second fluid.



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"Aortic cannula"

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DESCRIPTION

5 The present invention refers to a cannula, in particular an aortic cannula
utilised in circuits for the extracorporeal treatment of blood or other fluid as
for instance in the circuit for cardiopulmonary bypass during open heart
surgery operations.

10 Aortic cannulae currently available on the market are essentially made
up of ducts, whose end (tip) is inserted in the aorta through a surgically
made slit . The tip of the cannulae is usually rigid and has a small cross
section size as compared with the section of the aorta. The reason of this
small size resides in the need to reduce the occlusion of the lumen of the
aorta caused by the cannula. In fact when the heart starts beating again, a
large sized obstacle in the aorta would cause a remarkable increase in the
15 hydraulic resistance that the heart has to overcome. This could cause an
excessive cardiac work because of the increase in the hydraulic load and it
could possibly lead to heart failure.

20 On the other hand it is not possible to reduce the size of the cross
section of the tip below a certain limit. In fact, when operating at full
regime, the cannula is passed through by the entire blood flow that must be
returned to the patient: by reducing its cross section it is possible to cause
excessive pressure drop, serious mechanical damage to the red cells
(haemolysis), damage of the aortic wall or undesired dislodging of
atheromatous material from the wall of the vessel, effect caused by the
25 kinetic energy of the fluid jet that is injected at a high speed (sand-blasting
effect). Normally, a good compromise between these two requirements is
thought to be obtained by choosing a cannula that occupies the cross section
of the aorta by a portion not greater than 20-30%. For example, in the case
of an adult patient, cannulae with tips having diameters of approximately 6-8
30 millimetres are used.

The aortic cannula is intended for use in extracorporeal treatments requiring blood to be processed at flowrates representing the patient's whole cardiac output, or a large fraction of it. The most frequent such application is cardio-pulmonary bypass (CPB), where the patient's heart pumping function is completely replaced by an external heart-lung machine, to allow surgical access to the non-beating heart. This involves, for example, exchanging blood at up to 6 l/min flowrates in an adult patient. Other applications are left and/or right ventricle circulatory support, extracorporeal membrane oxygenation (ECMO), extracorporeal carbon dioxide removal (ECCO2R), etc., where blood is processed at flowrates representing a large fraction of the patient's cardiac output.

In all these applications, the patient is surgically prepared to provide direct access to central arterial vessels. In CPB the aortic cannula is usually placed in the ascending aorta, immediately downstream of the aortic valve orifice.

The tip length is normally kept as short as possible in order to limit the mentioned hydraulic hindrance downstream of the heart. For example, for an adult patient, the tip length is normally in the range 1 to 5 cm.

Diametric and longitudinal dimensions are decreased, with respect to the adult dimensions, according to the patient size, e.g. in the cases of newborn or pediatric patients.

The tip can have different configurations. The most widely used cannulae are the ones with a straight beveled tip or with a curved tip.

A particular solution of tip is the one described in US patent 5,616,137 that describes a tip made of a flexible material having helical slits along its walls and a cap that partially or totally blocks the outflow hole. When the pressure of the fluid inside the cannula increases the slits get open and the fluid's outflow speed decreases.

US patent 5,868,717 discloses a partially collapsible dual lumen catheter related to fluid exchange therapies, such as hemodialysis or

therapeutic apheresis. The catheter is intended for vascular access through relatively peripheral vessels. The dual lumen catheter has one lumen wall able to collapse against the other lumen in response to external, physiological body pressure when the catheter is in a latency phase, i.e.,
5 when it is not in use.

In view of the state of the art herein described, a scope of the present invention is to provide a tip with better performances as compared with the ones of the tips of the known art.

According to the present invention, these and other scopes are attained
10 by means of an aortic cannula comprising a tubular tip, suitable to be inserted into an aorta, characterised in that said tubular tip comprises at least a first circumferential portion, made up of deformable material, and at least a second circumferential portion, made up of non deformable material, that extend longitudinally starting from the final end of said tubular tip, said
15 second circumferential portion being placed adjacent to the aorta wall, on the same side of the surgically made slit, through which the tubular tip (1) is inserted in the aorta, so that, while a first fluid is input into said aorta through said cannula, said portion of deformable material stretches out so as to favour the flow of said first fluid and, while a second fluid is supplied by
20 the heart, said portion of deformable material gets deformed thus reducing the section of said tubular tip so as to favour the flow of said second fluid.

Owing to the present invention it is possible to provide a cannula having a tip that can vary its geometry on the bases of the fluid mechanics requirements. In particular, such cannula guarantees to infuse high flow rates
25 without causing high kinetic energy jets, since it makes available a passage section that is comparable to the one of the natural aorta, without even producing excessive resistance on behalf of the heart during the weaning transient (restart of the heart), owing to the deformability of the tip wall. These peculiarities allow overcoming one of the main technological limits
30 that current state of the art devices suffer from, that is the fact of not being

optimised neither for regime operating conditions, nor for the operating conditions during the transitory.

In particular, when it is the extracorporeal circuit that delivers all, or the preponderant part, of the blood flow rate, the tip is stretched out up to
5 occupying a large part of the aortic section available (approximately 80%-90%), thus considerably reducing the disadvantages due to the reduced section. When instead it is also or only the heart that pumps blood to the patient the wall collapses up until occupying a negligible section of the aorta (approximately 5%-20%), thus reducing in this way the hydraulic resistance
10 opposed to the cardiac pumping.

The characteristics and the advantages of the present invention will become evident from the following detailed description of an embodiment thereof, that is illustrated as a non-limiting example in the enclosed drawings, in which:

15 Figure 1A is a schematic layout of an embodiment of a tip, in one of the possible positions of installation, according to the present invention;

Figure 1B is a schematic layout of the front view in Figure 1A;

Figure 1C is a schematic perspective layout of Figure 1A;

20 Figure 2A is a schematic layout of an embodiment of the tip, in position of maximum expansion, according to the present invention;

Figure 2B is a schematic layout of the front view of Figure 2A;

Figure 2C is a schematic perspective layout of Figure 2A;

Figure 2D is a schematic layout in section taken along the plane of line IID in Figure 2B;

25 Figure 3A is a schematic layout of an embodiment of a tip, in position of minimum expansion, according to the present invention;

Figure 3B is a schematic layout of the front view of Figure 3A;

Figure 3C is a schematic perspective layout of Figure 3A;

30 Figure 4 is a schematic layout of a section of the final portion of the tip, in position of maximum expansion, according to another embodiment.

Figures 1A and 1B are schematic layouts of an embodiment of a tip of a cannula (not shown) according to the present invention. The tip 1 in this embodiment is of the type having a curve, at point 4, so as to facilitate its introduction in the aorta as also to withhold the tip in place during operation.
5 The tip axes upstream and downstream of point 4 form an angle comprised between 90° (tip at right angle) and 180° (rectilinear tip), preferably between 120° and 150° .

In this embodiment, the tip 1 is made up of a body 2 made of a substantially rigid first material and a body 3 made of a substantially
10 deformable second material.

The bodies 2 and 3 consist of distinct portions of the circumference of the final end of the tip 1 that extend longitudinally from the final end of the tip 1 for a pre-established length, typically up to the curvature point 4.

In this embodiment, the rigid body 2, in the zone downstream of point 4,
15 as compared with the circumference of the tip 1 has a size comprised between approximately 0 and 50 % and preferably smaller than approximately 15%, and it is located on the internal side of the curvature of the tip, fixed to the completely rigid body 2 upstream of point 4. It has the functions to keep the cannula in its position during operation, to guarantee a
20 correct positioning, and to allow its installation. The deformable body 3 takes the majority of the circumference of the tip, comprised between approximately 50 and 100% and preferably greater than approximately 85 %, and it gives it the property to modify the section according to the fluid
25 dynamic requirements.

In Figures 1A, 1B and 1C the deformable body 3 is folded over onto
25 itself thus occupying the smallest possible space so that it can be introduced in the aorta without major problems.

In the 2A figures, 2B, 2C and 2D the deformable body 3 is stretched and
it has a maximum cross section.

30 In Figures 3A, 3B and 3C the deformable body 3 is collapsed and it has

a minimum cross section.

The tip 1, in the portion downstream of point 4, when the deformable body 3 is stretched as in Figures 2, is preferably made up of a substantially conical tubular duct, in such a way so as to increase the cross section
5 available for the flow of the blood infused into the aorta, therefore to reduce the outflow speed avoiding the formation of a high energy jet, thus diminishing the shear stress within the fluid and the forces that the fluid transmits to the wall of the vessel.

The substantially conical portion of Figure 2, downstream of point 4,
10 has an opening angle such that when the blood flow is delivered by the cannula 1, its final end occupies a considerable portion of the section of the aorta. In the preferred configuration, this portion is greater than approximately 80%, as opposed to the 20-30% portion typically occupied by the cannulae of the state of the art: in this way the average output speed of
15 the fluid from the cannula is reduced by approximately 3-4 times and the kinetic energy associated to the flow by approximately 9-16 times.

In Figure 3 the deformable body 3 is shown as collapsed when the blood flow is delivered also by the heart, it occupies a negligible section of the aorta, approximately 5%-20%, thus reducing in this way the hydraulic
20 resistance against cardiac pumping.

The opening or the collapse of the cannula tip are respectively determined by the fact that a fluid flow coming from the extracorporeal circuit pushes, by virtue of its kinetic energy, onto the inner surface of the deformable body or, vice versa, a fluid flow caused by the ventricular
25 ejection pushes onto the outer surface of the deformable body. Such changes in shape of the deformable body are therefore due to a dynamic phenomenon caused by the movement of the fluid, rather than to static pressure differences only.

The tip is placed in the aorta in such way that the fluid flow coming
30 from the extracorporeal circuit or from the natural heart only interact with

the tip's deformable body. The rigid body does not interfere with such interaction, however it constitutes the means for the correct cannula placement.

Advantageously, the cannula placement in the vessel is unequivocally
5 determined by the fact that the circumferential rigid portion, that is also rigid in the axial direction, is adjacent to the aorta wall, on the same side of the slit, made surgically, through which the tubular tip is inserted in the aorta, occupying a reduced or negligible percentage of the aortic lumen section. Consequently, the circumferential deformable portion, when operating and
10 therefore in its expanded state, occupies a substantial percentage of the aorta section, extending itself inside said aorta section towards the side opposite to the slit entry of the tubular tip in the aorta, that is towards the axis of the aorta. In the preferred embodiment, the operator determines from the outside the correct positioning on the fact that the circumferential rigid
15 portion constitutes the continuation of the external body of the cannula on the internal bending side of the tubular tip. In a possible tubular rectilinear tip configuration, the correct position can be determined by some proper marker placed on the external body of the cannula.

In the preferred embodiment, the tip 1 has a wall made up of two parts,
20 a rigid one 2 and a deformable one 3. However a plurality of rigid and deformable modules can be provided along the perimeter of the section, as for instance several rigid modules interconnected to each other by deformable modules. Or a completely deformable tip can be provided, thus giving to an external element the function of keeping the cannula in position.

25 The tip 1, and in particular the deformable body 3 has preferably a substantially conical shape but it can also have a substantially cylindrical shape. The cross section of the tip 1 has preferably round shape but it can also have another shape as for example an elliptic shape.

The relative relationships between surface occupied by the rigid wall
30 and by the deformable wall, the opening of the cone, the inclination angle of

the tip and the relative radii of curvature are parameters that are subject to possible variations during the stage of optimisation of the device and may possibly vary with the size of the patient, in fact by its own nature, aortic cannulae are produced in different sizes as a function of the size of the patients which they are destined to.

The portion of the cannula external to the aorta can have any configuration among the ones that are normally used. In particular, it could either provide or not specific accessories suitable to the anchorage of the aorta, for the prevention of possible disadvantages such as kinking of the external tube, etc.

In the preferred embodiment, the tip 1 of the cannula is made of a resilient and flexible polymer material. The different rigidity of the parts of the tip are given by means of addition of additive to the polymer and by maintaining the relative thickness of the two parts unchanged, as in Figures 1, 2 and 3, or as an alternative, by means of variations in the thickness of the wall as it can be seen in Figure 4, that represents a schematic layout of a section of the final portion, downstream of point 4, of the tip 1 in a maximum expansion position.

Instead of the polymer material, it is possible to use a metal as for instance a very flexible one, in this case too the different rigidity would be given by means of variations of the thickness.

As an alternative it is possible to use a relatively rigid material (as for instance a metal) with a relatively flexible material (as for instance, a polymer), and binding the rigid part to the flexible one by means of gluing or welding, or to make the rigid part, onto which a layer of flexible material is superimposed, or also to make the flexible part with one or more stiffening inserts drowned into it.

The system of installation provides that at the time of packaging the deformable body 3 is collapsed or is refolded onto itself, as in Figure 1, so as to occupy the smallest possible space, and it is kept in such position by

appropriate means that will be better specified later, up until the moment in which the surgeon, after having introduced the cannula in the aorta activates it.

5 One packaging method is the one by which the cannula lumen is put in depression and its proximal section gets closed by a watertight plug, in such a way that the entire deformable wall of the tip stays completely collapsed, as in Figures 1, up to the moment in which the surgeon, after having introduced the cannula in the aorta, increases the pressure inside the deformable body 3 by removing the aforesaid plug.

10 As an alternative, it is possible to use a semi-rigid containing sheath that gets removed by the surgeon after its installation. Or to use one or more suture stitches as a system for holding the deformable body 3, bound by means of slipknots, either prepared during the packaging stage or by the surgeon during surgery. Or yet maintaining the deformable body 3 collapsed through gluing by means of soluble and highly bio-compatible glues
15 (starches and sugars), that dissolve in the blood shortly after the installation. Or to maintain the deformable body 3 collapsed owing to characteristic property of the material that it is made of, as for instance, using a shape memory material a rigid cannula could be made that is collapsed at room
20 temperature and that at operating temperature becomes deformable and patent again. Or yet to use active systems that are controlled from the outside.

In the preferred embodiment, the behaviour of the deformable tip is completely passive, that is the deformation is guided exclusively by the fluid
25 flow pushing on its inner or outer surfaces.

The possibility to adopt active systems is not excluded. Active systems due to characteristics of the materials themselves, as for instance: the use of activable materials, that is that they change their mechanical properties according to an external stimulus (for example: polymer conductors
30 activated by means of application of electric potential), the use of materials

whose mechanical characteristics vary considerably when a critical value of temperature is exceeded (for example: shape memory polymers or alloys). Systems activated from the outside, as for instance activation by mechanics: bars, rods, etc., magnetic or electromagnetic activation.

5 The cannula herein described especially for aortic use, can also be used for others applications as for instance for ventricular assistance with or without counter-pulsation, other circulatory support treatments such as ECMO or ECCO2R.

10 The present invention therefore provides a cannula with variable geometry that as far as the geometry of the duct external to the aorta is concerned, is equivalent to a conventional cannula. Its peculiarity instead consists in having a tip whose wall is deformable for a considerable portion of its circumference so that its shape varies spontaneously the size of its section is considerably reduced when fluid flow pushes onto the outer tip
15 surfaces. In this way, the geometry of the duct that makes up the tip is suitable to all possible fluid mechanics conditions of operation.

CLAIMS

1. Aortic cannula comprising a tubular tip (1), suitable to be inserted into an aorta, characterised in that said tubular tip (1) comprises at least a first circumferential portion, made up of deformable material (3), and at least a second circumferential portion, made up of non deformable material (2), that extend longitudinally starting from the final end of said tubular tip (1), said second circumferential portion (2) being placed adjacent to the aorta wall, on the same side of the surgically made slit, through which the tubular tip (1) is inserted in the aorta, so that, while a first fluid is introduced into said aorta through said cannula, said portion of deformable material (3) stretches out so as to favour the flow of said first fluid and, while a second fluid is supplied by the heart, said portion of deformable material (3) deforms thus reducing the section of said tubular tip (1) so as to favour the flow of said second fluid.
2. Aortic cannula according to claim 1 characterised in that said deformable circumferential portion (3) has a size comprised between 50 and 100% as compared with the circumference of said tubular tip (1), and preferably greater than 85%.
3. Aortic cannula according to claim 1 characterised in that it comprises at least one circumferential portion that extends longitudinally and made up of non deformable material (2) that has a size comprised between 0 and 50% as compared with the circumference of said tubular tip (1), and preferably smaller than 15%.
4. Aortic cannula according to claim 1 characterised in that said tubular tip (1) has substantially conical shape with the larger section at the final end of said tubular tip (1).
5. Aortic cannula according to claim 1 characterised in that said tubular tip (1) has substantially cylindrical shape.
6. Aortic cannula according to claim 1 characterised in that said deformable material (3) and said non deformable material (2) are made of

the same material with different thickness.

7. Aortic cannula according to claim 1 characterised in that said deformable material (3) and said non deformable material (2) are made of material having substantially the same thickness but different rigidity.

5 8. Aortic cannula according to claim 1 characterised in that said deformable material (3) and said non deformable material (2) are made up of different materials having different rigidity.

9. Aortic cannula according to claim 1 characterised in that said tip (1) in position of installation before being inserted in the aorta has said
10 deformable material (3) refolded onto itself, so as to occupy the smallest possible space.

10. Aortic cannula according to claim 9 characterised in that said deformable material (3) refolded onto itself is kept in such position by means of a containing sheath.

15 11. Aortic cannula according to claim 9 characterised in that said deformable material (3) refolded onto itself is kept in such position by means of a soluble and bio-compatible glue.

12. Aortic cannula according to claim 9 characterised in that said deformable material (3) refolded onto itself is kept in such position by
20 means of depression.

13. Aortic cannula according to claim 9 characterised in that said deformable material (3) refolded onto itself is kept in such position by means of suture stitches held by slipknots.

25 14. Aortic cannula according to claim 1 characterised in that said tubular tip (1) is of the type having a bend, said second circumferential portion (2) being placed on the internal bending side of said tubular tip (1).

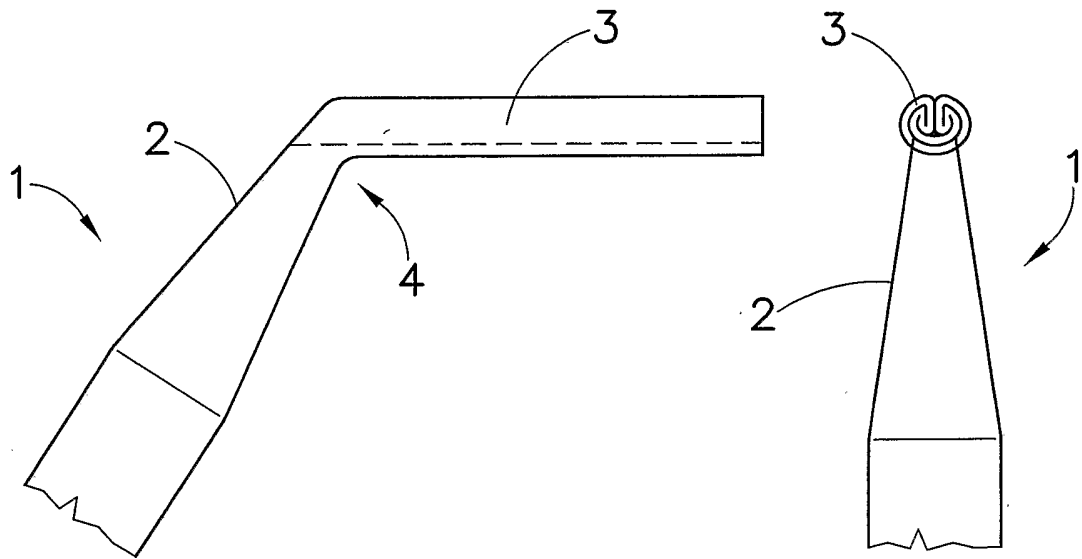


FIG. 1A

FIG. 1B

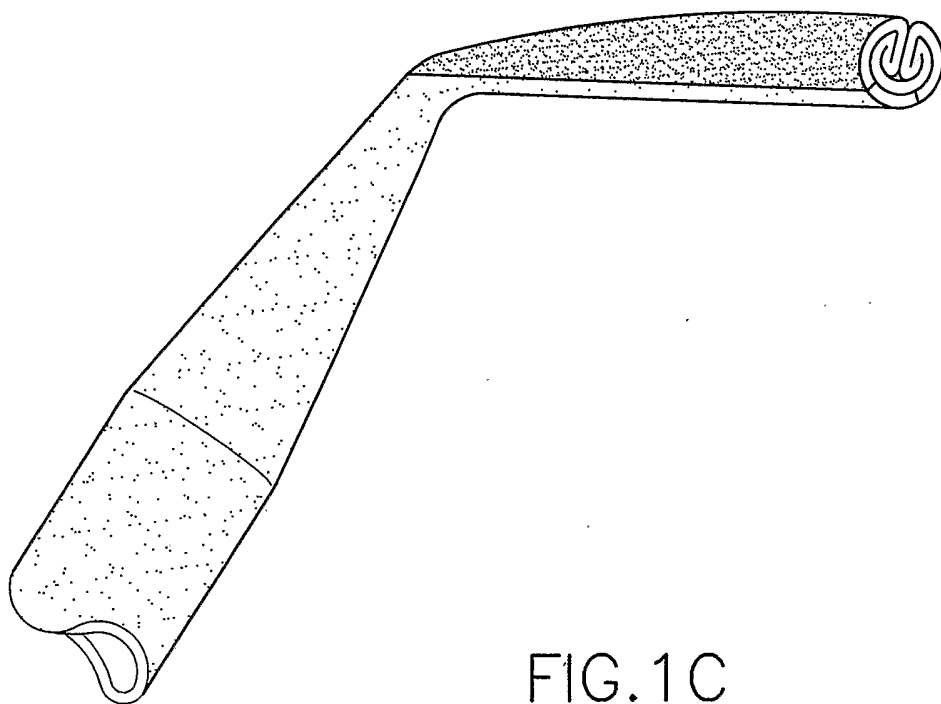


FIG. 1C

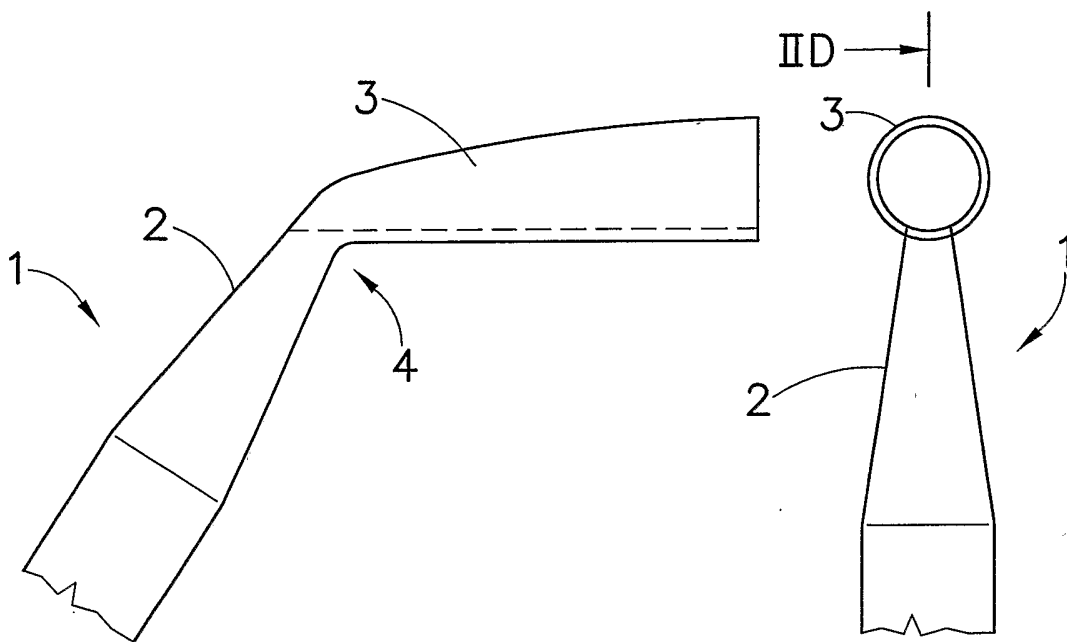


FIG. 2A

II-D
FIG. 2B

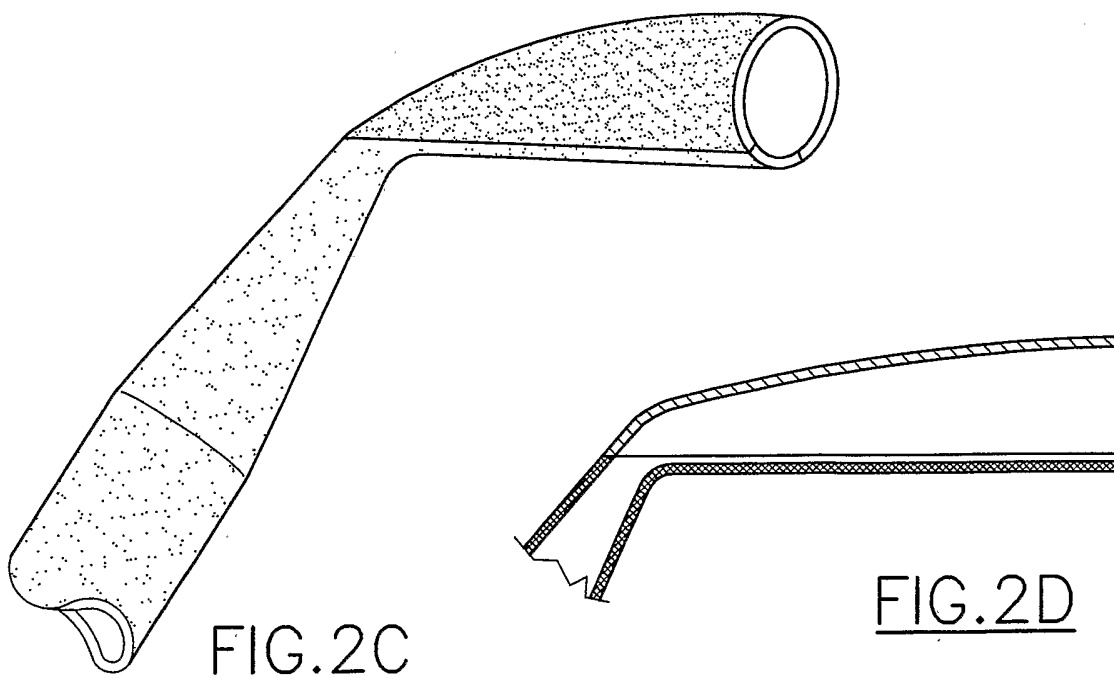


FIG. 2C

FIG. 2D

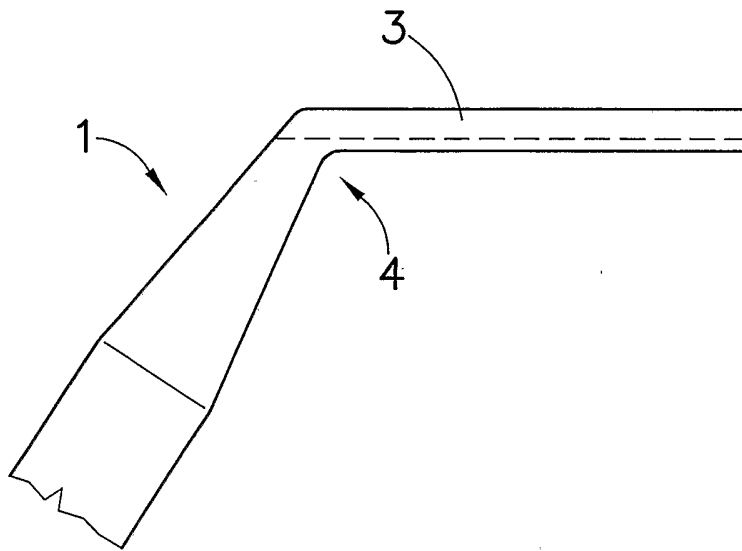


FIG. 3A

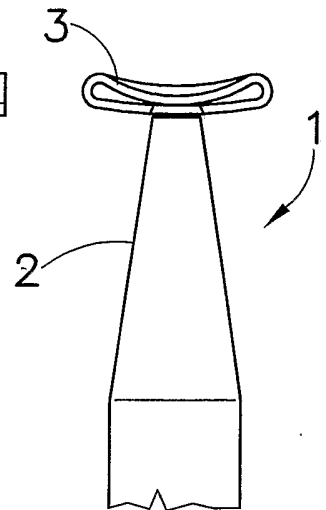


FIG. 3B

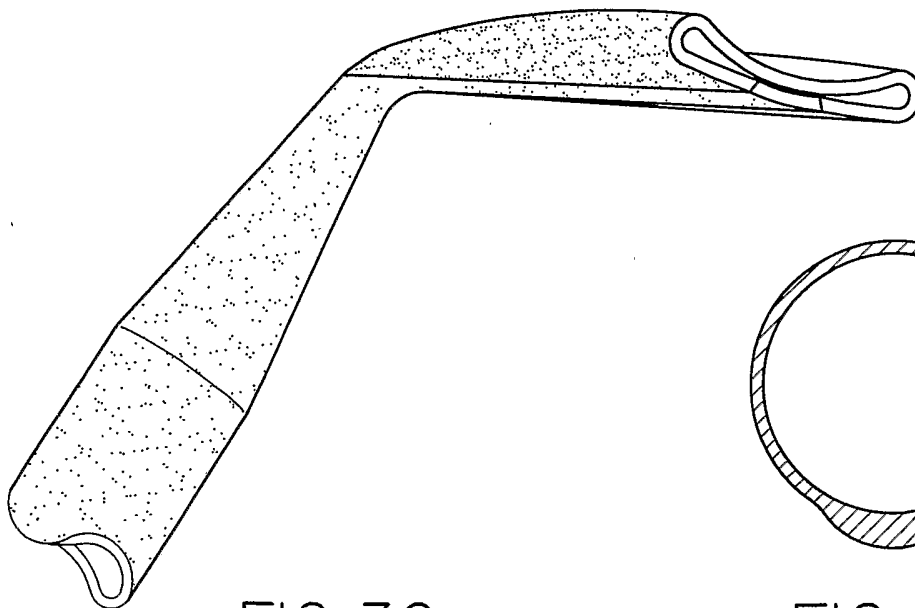


FIG. 3C

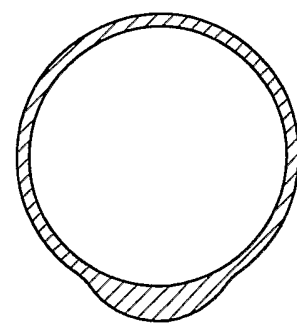


FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/12532

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 406 656 A (RICHARDS RONNIE D ET AL) 27 September 1983 (1983-09-27) column 3, line 21-42; figures 1-13 column 4, line 50 -column 5, line 18 column 5, line 33-47 column 6, line 23-46 ---	1-3,5,6, 8-10,12, 14
X	US 4 738 666 A (FUQUA CLARK R) 19 April 1988 (1988-04-19) column 3, line 28-60; figures 1-6 column 4, line 36-60 column 5, line 18-25 column 6, line 7-14 ---	1-3,5,6, 9,10
X	US 1 596 754 A (MOSHELLE JUDSON D) 17 August 1926 (1926-08-17) column 1, line 25-42; figures 1-9 ---	1-3,5,6
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Further documents are listed in the continuation of box C. Patent family members are listed in annex.

° Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
E earlier document but published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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INTERNATIONAL SEARCH REPORT

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	EP 0 618 059 A (CORDIS EUROP) 5 October 1994 (1994-10-05) column 2, line 30-42; figures 2-5 -----	6-8
A	US 5 084 033 A (O'NEILL WILLIAM G ET AL) 28 January 1992 (1992-01-28) column 3, line 3-42; figures 1-4 -----	14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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