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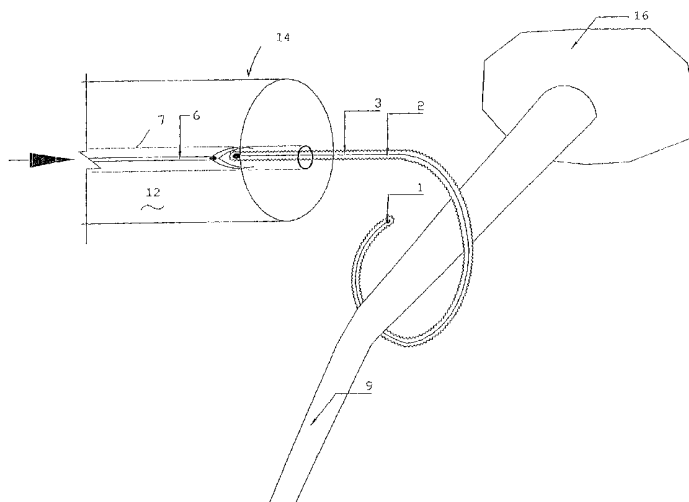
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(54) Title: SHAPE MEMORY DEVICE FOR STRANGULATING PEDUNCULATED POLYPS DURING ENDOSCOPY



(57) **Abstract:** A shape memory device for strangulating pedunculated polyps in endoscopy to prevent bleeding during polypectomy comprises a filament (2) of Nitinol which is electrically insulated from accidental contacts with the metal loop crossed by the current performing the resection due to a non-inflatable tight insulating sheath (3) of latex or, as an alternative, carries a number of microspheres of glass beads (10) suitably distributed all over the length of the filament. Such beads slow also down the strangling loop formation speed. In order to control such speed there is provided a cold water injection inside the tube guiding the device within the channel of the endoscope so as to hit it before its protrusion, thus avoiding that the same filament springs violently when submitted to the temperature of viscera or is caught by the distal end of the guide tube if it bends too early. The shape memory device is pushed by pincers or a second tube coaxial to the guide tube in which the cooling water flows.



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Shape memory device for strangulating pedunculated polyps during endoscopy

The present invention relates to the field of the digestive system endoscopy. More specifically, it concerns an auxiliary device to be used in particular endoscopy techniques such as polypectomy of pedunculated polyps by a metal loop. According to such techniques, a metal loop with a more or less varied circular shape is basically passed under open condition across the head of the polyp until its peduncle is reached. In such position, the loop is tightened round the peduncle and then an electrical current is passed in the metal loop. The final effect is the resection of the polyp peduncle.

The use of such techniques, however, can bring about a lot of problems to date, for the following reasons. The polyp peduncle is provided with a number of arterial, venous, lymphatic vases and nervous filaments.

The greater the polyp peduncle, the larger the size of the vases mentioned above. Upon resection of the peduncle by electrical current having mostly a coagulant effect to the tissues or after combined actions, i.e. resection and coagulation, the vases undergo an occlusion due to the necrosis induced by the current. In order to provide this, the current should be kept at a suitable intensity for a long enough time.

If such effects are not suitable enough to occlude the

arterial vas, the most dangerous consequence is the haemorrhage. Haemorrhage is mainly due to arterial blood and, if it is outstanding, makes the field of endoscopy inaccessible in a very short time.

5 The hindered sight to the endoscopy field also prevents above all the blood spouting stump of the peduncle from being seen. If the emergency endoscopy operation is useless or inapplicable, the problem has to be tackled by the surgeon. It is self-evident that
10 the problem becomes considerable when the haemorrhage due to polypectomy relates to an elderly patient who should face extremely serious surgical risks.

It should be noted that unfortunately the largest polyps provided with peduncles are found in the oldest
15 patients.

The emergency endoscopy operations are partially the same as used for preventing haemorrhages due to polypectomy. The most used ones are adrenaline injection, endoloops, and endoclips. The big problem
20 of blood and coagula still remains, thus making such techniques extremely difficult or even impossible to be carried out, especially with the passing of time and the haemorrhage in progress, if the amount of blood accumulated in the lumen of viscera is even more
25 considerable and the function of the suction channel of the endoscope is reduced because of the presence of coagula which could occlude it upon suction.

Another technique used with bleeding due to polypectomy in progress is to seize again the blood
30 spouting stump by the same loop which has been used

for polypectomy and to hold it tight for five minutes. However, the operator should display great dexterity and be decision-maker to use such technique because it has to be carried out as soon as possible before the
5 stump cannot be seen any longer in the blood and also because the stump tends to retract after an electrical shock. With a significant haemorrhage in progress, the implements are not able to be easily used and require a great operative capability.

10 In order to strangulate a pedunculated polyp in endoscopy and to overcome the above-mentioned problems Italian Patent Application N. RM 2000 A000593 of the same Applicant proposes the use of a material filament provided with thermal memory which is shaped as a loop
15 or the Greek letter α (alpha) and is sheathed under extended, stretched condition in a rigid, straight support sheath which holds it in such condition. The filament recovers the shape of a loop or a letter α when it is removed from the straight support sheath at
20 a predetermined temperature.

As known, some alloys such as a nickel-titanium alloy known under the trade name of Nitinol are provided with a thermal memory, i.e. they are able to take on a programmed shape when exposed to a predetermined
25 temperature.

Thus a filament of Nitinol which is programmed to take on the shape of an alpha loop at the temperature in the colon can take on a straight shape if it is brought to low temperature, i.e. about zero degree,
30 while it recovers the shape of a loop or a letter α

(alpha) when it is removed from its rigid, straight support sheath in the intestine at the peduncle to be strangulated.

5 The Patent Application mentioned above provides that the filament of Nitinol is included in a tubular closed sheath which is able to follow the shape changes in the same filament and can be blown up pneumatically by inflating air through a sclerosis needle to allow the operator to hold the peduncle
10 tighter when the latter is restrained by the loop in order to ensure a perfect strangling.

The modality of use provides that the inflatable tubular sheath containing the filament of Nitinol is inserted into the channel of the endoscope through the
15 distal ostium so as to be applied to the sclerosis needle after having been extracted from its rigid sheath when the endoscope is still outside the human body. This allows tearing of sheath of elastic material to be avoided notwithstanding its insertion
20 along the whole length of the endoscope channel.

Once the endoscope is inserted into the human body and the polyp peduncle to be strangulated is reached, the tubular sheath can be extracted outside the channel by the sclerosis needle so that the filament of Nitinol
25 being free of any obstacle in the environment at the temperature of the colon takes on the original programmed alpha shape again going round the peduncle.

In practice, however, such device does not give the desired results and shows a number of drawbacks that
30 makes its use quite impracticable.

A first drawback relates to the strangling function: this is bound to the formation of an air chamber round the filament of Nitinol which should compress the peduncle. However, this is not the case because the
5 inflated tubular sheath tends always to slide either upwards or downwards, thus making useless the pressure on the polyp peduncle which should conversely be fixed and constant. When strangling seldom begins, the pressure is never constant. It is sometimes sufficient
10 to stretch slightly the polyp when the latter is seized by the loop for polypectomy to cause the inflated tubular sheath to slide either upwards or downwards along the axis of the polyp peduncle, thus making the operation useless.

15 In case of shortly pedunculated polyps, the inflation of the air chamber surrounding the filament of Nitinol creates many problems for the next positioning of the metal loop for polypectomy.

A second drawback consists in that it is impossible to
20 control the speed at which the filament forms the alpha loop.

In the described device no means for reducing the speed at which the filament of Nitinol forms the alpha loop is provided. This implies that it is very easy
25 for the shape memory device to get out of touch with the needle when the loop is wound round the peduncle at excessive speed.

A third drawback consists in that the loop of Nitinol of the preceding Patent Application should be wound
30 first round the polyp peduncle and then the pneumatic

air chamber is inflated to strangulate the peduncle. This is, therefore, a two-step operation.

A fourth drawback consists in that the operator has to put the needle in the pneumatic sheath surrounding the filament of Nitinol and to position the whole at the distal end of the endoscope before the latter is put into the human body.

This preliminary rather complex step is followed by the operative step. Also in this case the operator should carry out two-step operations with evident loss of time.

In any case, both for the operations to be carried out and its construction characteristics, the inflatable sheath does not give any sufficient guarantee of providing a valid, effective electrical insulation for the filament of Nitinol in case of an accidental contact with the metal loop in the step of the peduncle resection.

The present invention seeks to overcome all of the problems described above by using a shape memory device having the following peculiar characteristics:

- a) the device consists of a filament of Nitinol provided with electrically insulated means able to avoid the danger that the same filament can transmit the current flowing in the metal loop during polypectomy to the wall of the intestine when the resection of the peduncle is carried out;
- b) said device can be put into the endoscope after having found the position of the peduncle to be cut

without the need to extract the endoscope from the body of the patient because of the combination of a guide tube put into said endoscope up to its distal end and a means controlled by the operator and able to push the shape memory device from the proximal to distal ends of said guide tube causing the latter to protrude from the endoscope;

5

c) the use of said guide tube and said means allows even more than one shape memory device to be positioned after one another near the distal end;

10

d) a means for controlling the loop formation speed and grading the protrusion of each loop head from the distal ostium of the endoscope is provided;

15

e) the strangling is only carried out by the filament of Nitinol which preferably is so shaped as to form a loop of three millimetres. If it is larger, the width of the loop is reduced by microspheres or glass beads described thereafter.

20

In particular, according to a preferred embodiment of the invention, the device consists of a filament of Nitinol which is coated by a non-inflatable tight latex sheath having only an insulation function to avoid the danger that the same filament can accidentally transmit the current flowing in the metal loop performing the resection to the wall of the intestine during polypectomy; said sheath may also be provided with microholes for an easier heat exchange.

25

In order to control the loop formation speed in the environment of viscera two ways are possible:

30

e) injecting cold water so as to hit the filament of

Nitinol before its protrusion, thus avoiding that the same filament springs violently when submitted to the temperature of viscera or is caught by the distal end of the guide tube if it bends too early;

5 f) threading a number of microspheres or beads of glass or other suitable insulating material properly distributed all over the length of the Nitinol filament so as to slow down the protrusion of the device from the guide tube. Such beads slow down the
10 filament winding speed as well as have the function of ensuring the filament insulation from an accidental contact with the metal loop crossed by the current performing the polypectomy. The beads can then be provided, as an alternative, to the insulating latex
15 sheath or can be applied above the same sheath.

To sum up, according to the invention there can be provided three different embodiments of the Nitinol filament: filament having only the insulating sheath; filament having only beads; filament having the
20 insulating sheath and the beads; and two preferred expelling systems: using common biopsy pincers seizing the proximal end of the shape memory device and controlling its protrusion from the guide tube; or using a thrust tube when the devices placed in the
25 guide tube are more than one.

Further features and advantages of the invention will be more readily apparent from the following detailed description with reference to the accompanying
30 drawings that show some preferred embodiments thereof

only by way of a not limiting example.

In the drawings:

5 Fig. 1 is a general view of the shape memory loop in the original shape, i.e. in the form of a loop, according to a first embodiment consisting of a filament of Nitinol carrying a sphere at each end within a tubular sheath;

10 Fig. 2 shows the same loop of Fig. 1 in straight shape;

15 Fig. 3 shows a portion of the loop of Fig. 2 in enlarged scale, with the sheath provided with microholes;

20 Figs. 4 and 5 show a second embodiment in the original loop structure and straight structure, respectively, where microspheres or beads of glass or similar material are threaded by the filament without sheath;

25 Figs. 6 and 7 show a third embodiment still in the original loop structure and straight structure, respectively, with the filament provided both with the sheath and microspheres or beads;

Fig. 8 shows schematically a first thrust means to be used when several loops are present in the endoscope after one another;

Fig. 9 shows a second embodiment of the thrust means to be used in case only one loop is employed;

Fig. 10 shows the filament of Nitinol at the beginning
5 of the loop formation round the polyp peduncle;

Fig. 11 shows the filament of Nitinol with an already closed loop.

10 With reference to the Figures, according to a first embodiment of the invention, the shape memory device consists of a filament 2 of Nitinol fastened at its ends to a couple of beads or bulges 1 placed within a sheath 3 preferably of rubber latex having only the
15 function of insulating electrically such filament.

As can be seen in Fig. 3, sheath 3 is provided with microholes 4 ensuring a correct thermal exchange with the outside and allowing a faster adaptation of filament 2 to the intraluminal temperature.

20 Figs. 3 and 4 show a second embodiment. In this case, a plurality of microspheres or beads 10 of insulating material having a much larger diameter than the filament but lower than the lumen of the guide tube sliding in the channel of the colonoscope are threaded
25 by filament 2. Preferably, microspheres 10 are of glass, a material having the advantage of being non-conductive.

A third embodiment collecting the characteristics of the preceding embodiments is shown in Figs. 6 and 7.

30 As can be seen in such Figures, the microspheres or

beads are threaded by the sheath surrounding the filament of Nitinol.

As mentioned above, once filament of Nitinol 2 is programmed to take on the shape of the Greek small letter alpha at the temperature of colon, it can be formed before use, i.e. outside the human body, to a straight shape by submitting it to a low temperature.

Under such conditions it is possible to insert the filament with the straight shape into a guide tube 7 with suitable diameter so as to allow it to pass easily through channel 12 of a colonoscope or another endoscope 14.

As can be seen in Fig. 10, once endoscope 14 reaches peduncle 9 of polyp 16, the operator has only to push filament 2 with the programmed loop toward the output of channel 12 of endoscope 14 by a suitable thrust means that can be either common biopsy pincers 6 able to seize the proximal end of the loop, as can be seen in Fig. 9, or another tube 5 coaxial to channel 7 but with lower diameter, as shown in Fig. 8.

As the loop pushed by the operator projects from guide tube 7 containing and forcing it to the straight shape, the loop in the intestine will take on the alpha shape to which it has been programmed, and will engage the polyp peduncle in such a movement so as to strangulate it (Fig. 10).

When the loop of Nitinol projects from guide tube 7 and begins to bend, it is conveniently guided by the movements both of endoscope and pincers 6 that hold it tight. The loop of Nitinol will surround the peduncle

and grip it, thus blocking the hematic flow in irreversible manner (Fig. 11).

As mentioned above, tube 7 containing the loop of Nitinol with the straight shape in its distal length can include another tube 5 coaxial thereto and acting as pusher instead of pincers 6. Such tube 5 which is empty is provided at its distal end with suitable means for pushing such shape memory device and is pushed together with tube 7 along channel 12 of the endoscope.

The use of tube 5 as thrust means is necessary when the shape memory devices are more than one located after one another in the last few centimetres of length of tube 7, as can be seen in Fig. 8, in order to engage as many peduncles. Actually, the use of pincers allows only one device to be guided until it protrudes from guide tube 7.

It should be appreciated that such tube 5 also allows both the shape memory devices to be pushed and cold water to be injected so that the same shape memory devices do not bend in tube 7, thus avoiding problems due to the protrusion of the same guide tube 7.

It should be noted to this purpose that such glass beads slow down the winding speed.

Conversely, if there is only one shape memory device, even if the latter tends to bend in the guide tube containing the same, the thrust exerted by biopsy pincers is strong enough to bring it outside the tube toward the peduncle round which it will be wound automatically. Biopsy pincers are obviously inserted

into the same guide tube and hold the end of the loop of Nitinol provided with beads in its straight shape tight between their arms.

5 The loop strangulating the peduncle has a variety of sizes. The diameter of the loop varies relative to the size of the peduncle to be strangulated. The minimum diameter of the loop is 3 mm because a peduncle smaller than 3 mm hardly bleeds when it is cut by a loop for polypectomy.

10 The desired size can however be reached by either shaping the Nitinol loop in that way or, if it is believed suitable for technical reasons, by shaping the loop in a larger manner and contracting it by using glass beads 1 which are compatible with the diameter of the channel containing the same.

15 When a system of dual coaxial tubes 5-7 is used to push the shape memory device, glass microspheres 1, besides being stacked in the length of Nitinol filament which will then form the loop, should also be positioned in the minimum number of three along the two wings of the loop so that they are not expelled too quickly from the distal ostium of the endoscope, thus slowing down the winding speed.

20 Conversely, when a thrust tube 5 is used, it is convenient that one of the two ends of the loop is longer than the other one so that it does not spring with excessive speed and get lost in the lumen of the intestine, since it is not held by pincers but only slowed down in its winding by a cold water flow.

Claims

1. A shape memory device for strangulating pedunculated polyps in endoscopy, comprising a material filament provided with a shape memory that can be thermally programmed and is able to recover the programmed shape of a loop so as to strangulate the peduncle of the polyp upon reaching a predetermined temperature, characterized in that it consists of a filament of Nitinol provided with electrically insulated means able to avoid the danger that the same filament can transmit the current flowing in the metal loop performing the resection of the peduncle to the wall of the intestine during polypectomy; said device being able to be put and shifted into the endoscope already inserted in the patient's body so as to be positioned round the peduncle to be cut without the need to extract the endoscope from the patient's body, because of the use of:

a tube guiding the shape memory device in its straight shape and being able to pass within the channel of said endoscope to reach the distal end thereof; and means controlled by the operator and able to push the shape memory device from the proximal to distal ends of said guide tube causing the latter to protrude from the endoscope.

25

2. The shape memory device for strangulating pedunculated polyps in endoscopy according to claim 1, characterized in that a means for controlling the loop

formation speed and grading the protrusion of each loop head from the lumen of the guide tube is provided.

5 3. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that the device consists of a filament of Nitinol which is coated by a non-inflatable tight latex sheath having only an
10 insulation function to avoid the danger that the same filament can accidentally transmit the current flowing in the metal loop performing the resection to the wall of the intestine during polypectomy; said sheath being also provided with microholes for an easier heat
15 exchange.

4. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that a number of
20 microspheres or glass beads are suitably distributed all over the length of the Nitinol filament so as to slow down the filament winding speed as well as ensure the filament insulation from an accidental contact with the metal loop crossed by the current performing
25 the polypectomy.

5. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that the strangling
30 is carried out only by the filament of Nitinol without

any air chamber.

5 6. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that said filament of Nitinol is preferably shaped so as to form a loop of 3 millimetre diameter and, if it is larger, the width of the loop is reduced by microspheres or glass beads threaded by said filament.

10

7. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that biopsy pincers inserted into the guide tube are used to push the shape memory device out of the guide tube and the endoscope.

15

8. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that a bead or a bulge is fastened to either end of the filament of Nitinol to help the grip of the biopsy pincers.

20

9. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that an inner tube coaxial to the guide tube is provided as thrust means.

25

10. The shape memory device for strangulating pedunculated polyps in endoscopy according to the

30

preceding claims, characterized in that in order to control the loop formation speed in the viscera there is provided a cold water injection so as to hit the filament of Nitinol before its protrusion from the guide tube, thus avoiding that the same filament springs violently when submitted to the temperature of viscera or is caught by the distal end of the guide tube if it bends too early.

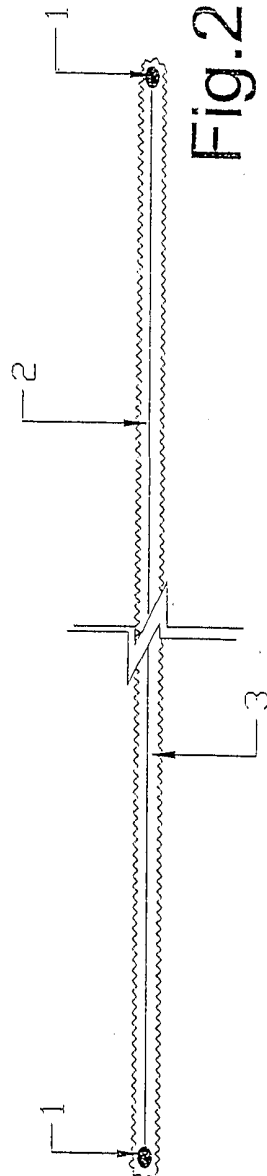
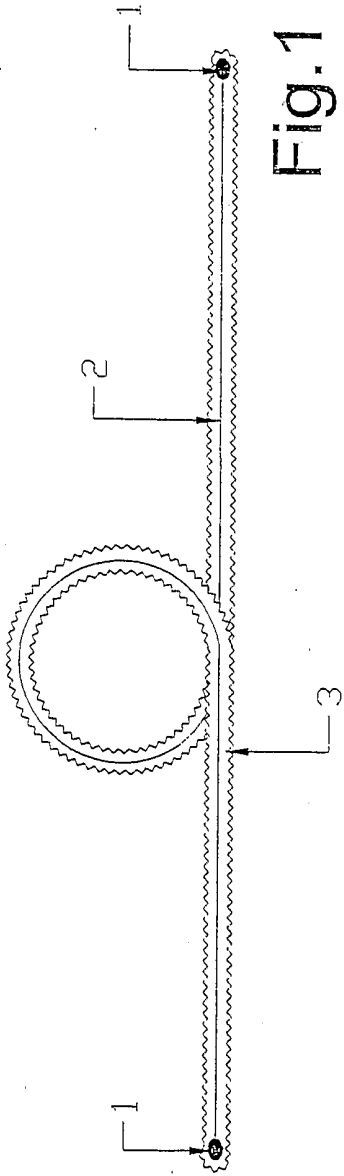
10 11. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that the cold water injection is carried out by said thrust tube which is empty.

15 12. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that the beads are applied above the latex sheath which is tight to the filament of Nitinol.

20 13. The shape memory device for strangulating pedunculated polyps in endoscopy according to the preceding claims, characterized in that one of the two ends of the shape memory device is longer than the other one so that it does not spring with excessive speed and get lost in the lumen of the intestine, since it is not held by pincers but only slowed down by the cold water flow controlling the temperature thereof.

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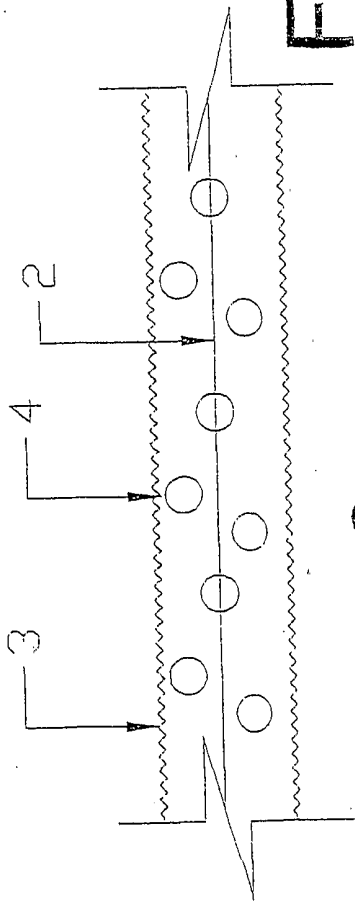


Fig. 3

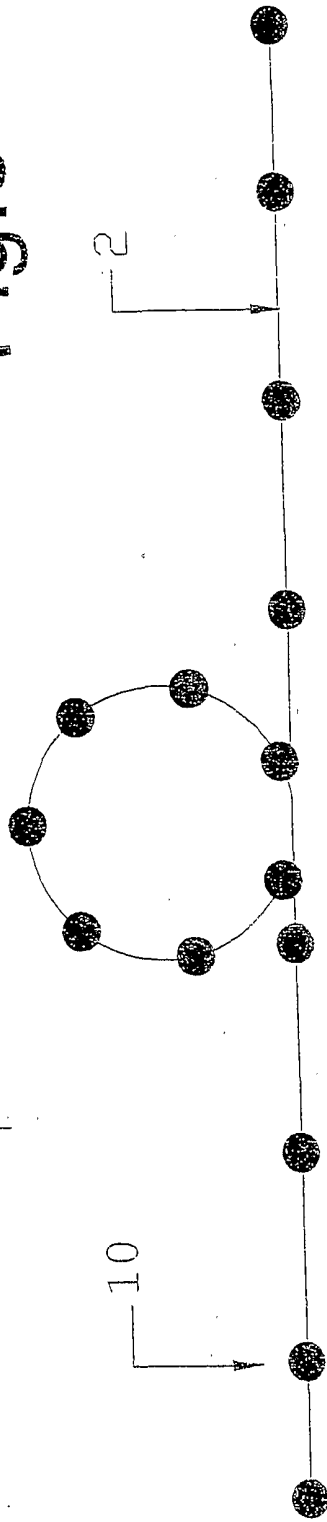


Fig. 4

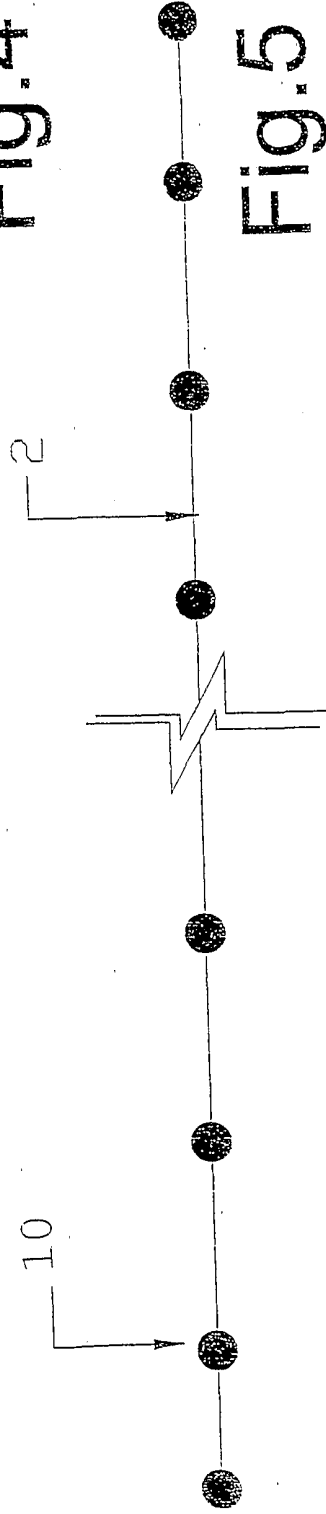


Fig. 5

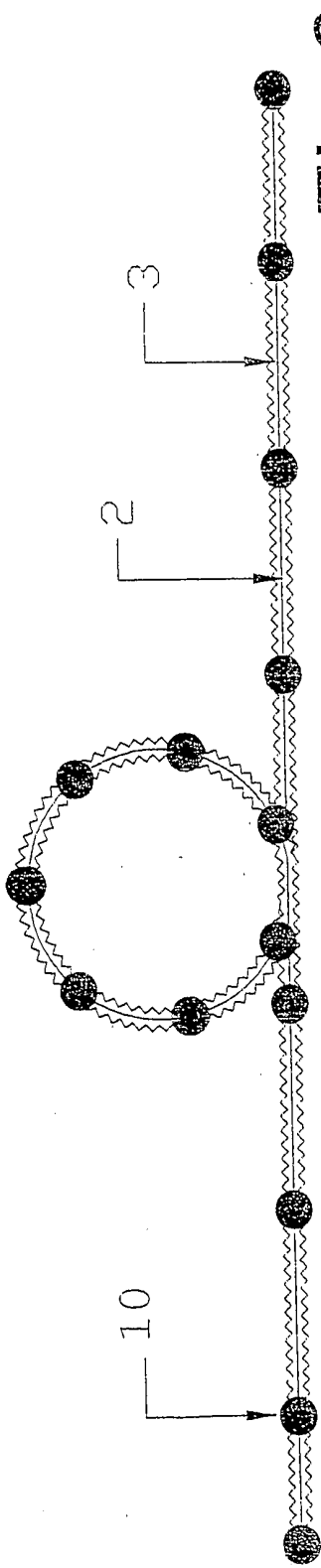


Fig. 6

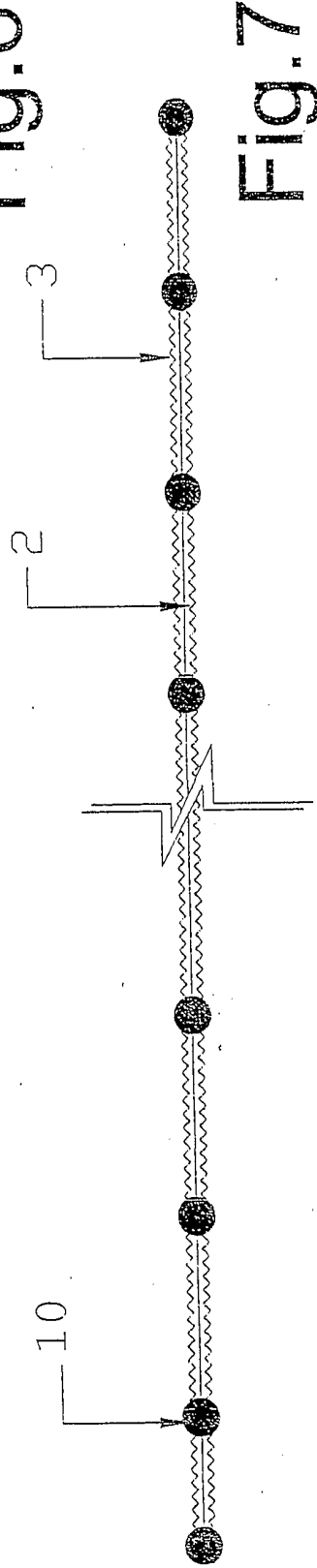


Fig. 7

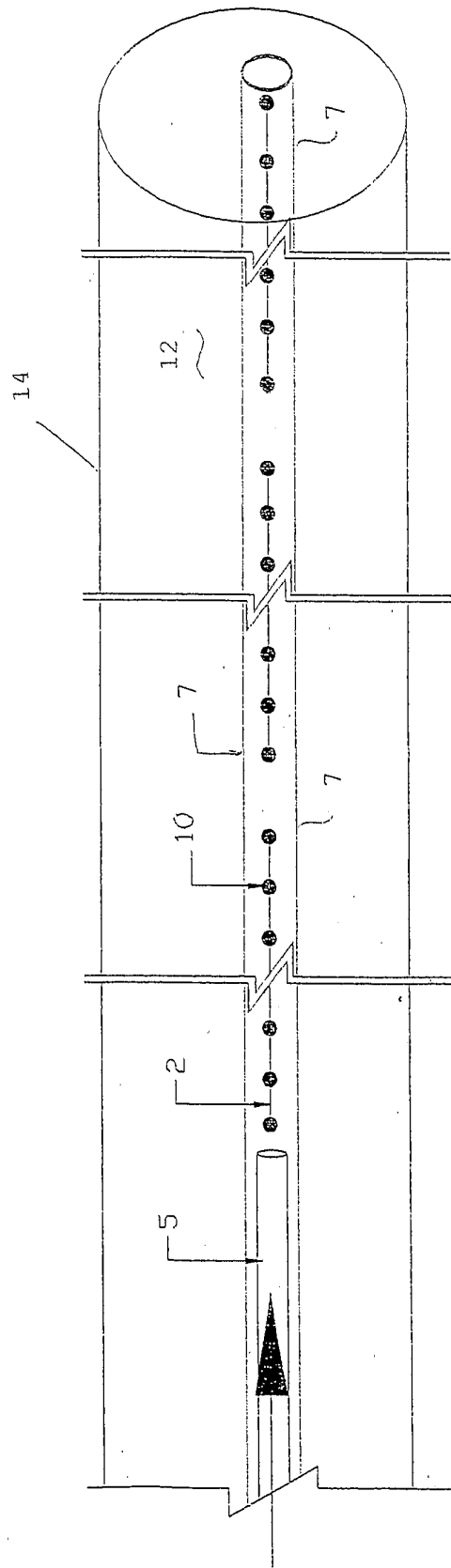


Fig.8

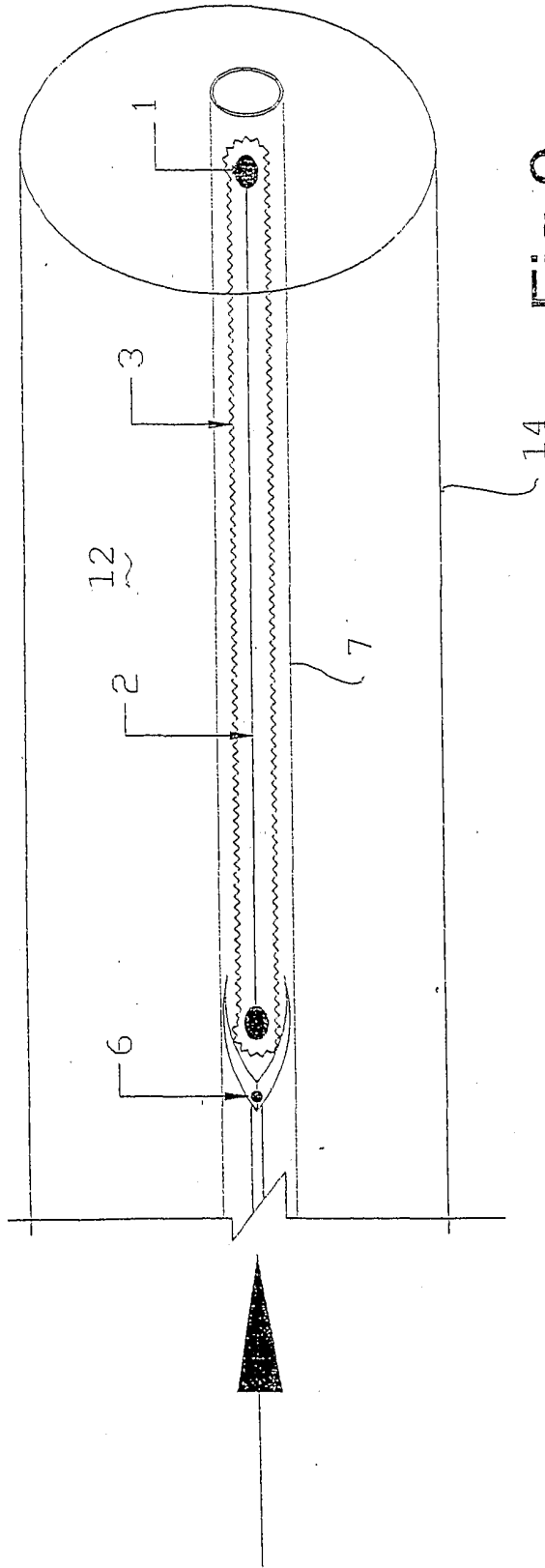


Fig.9

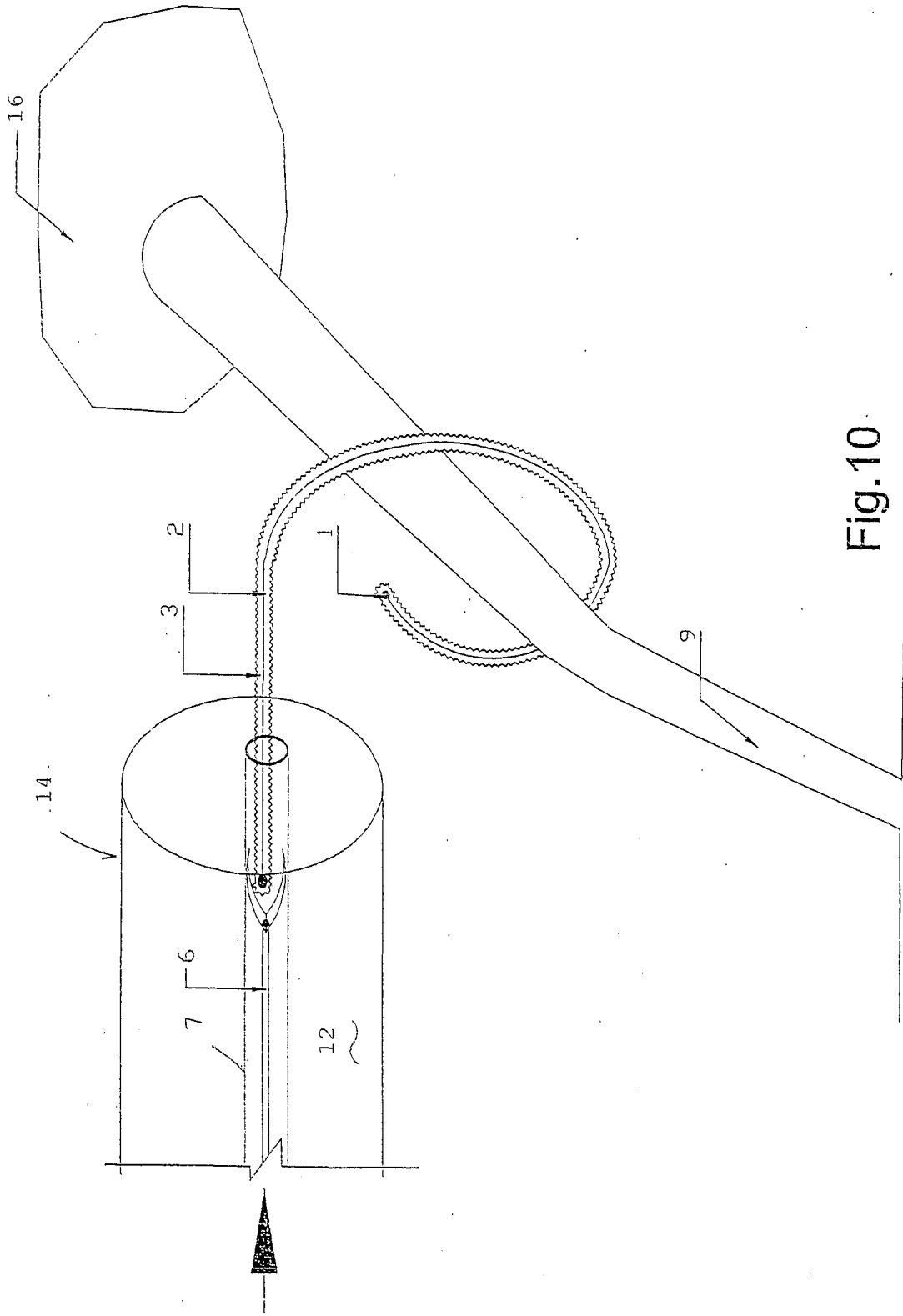


Fig.10

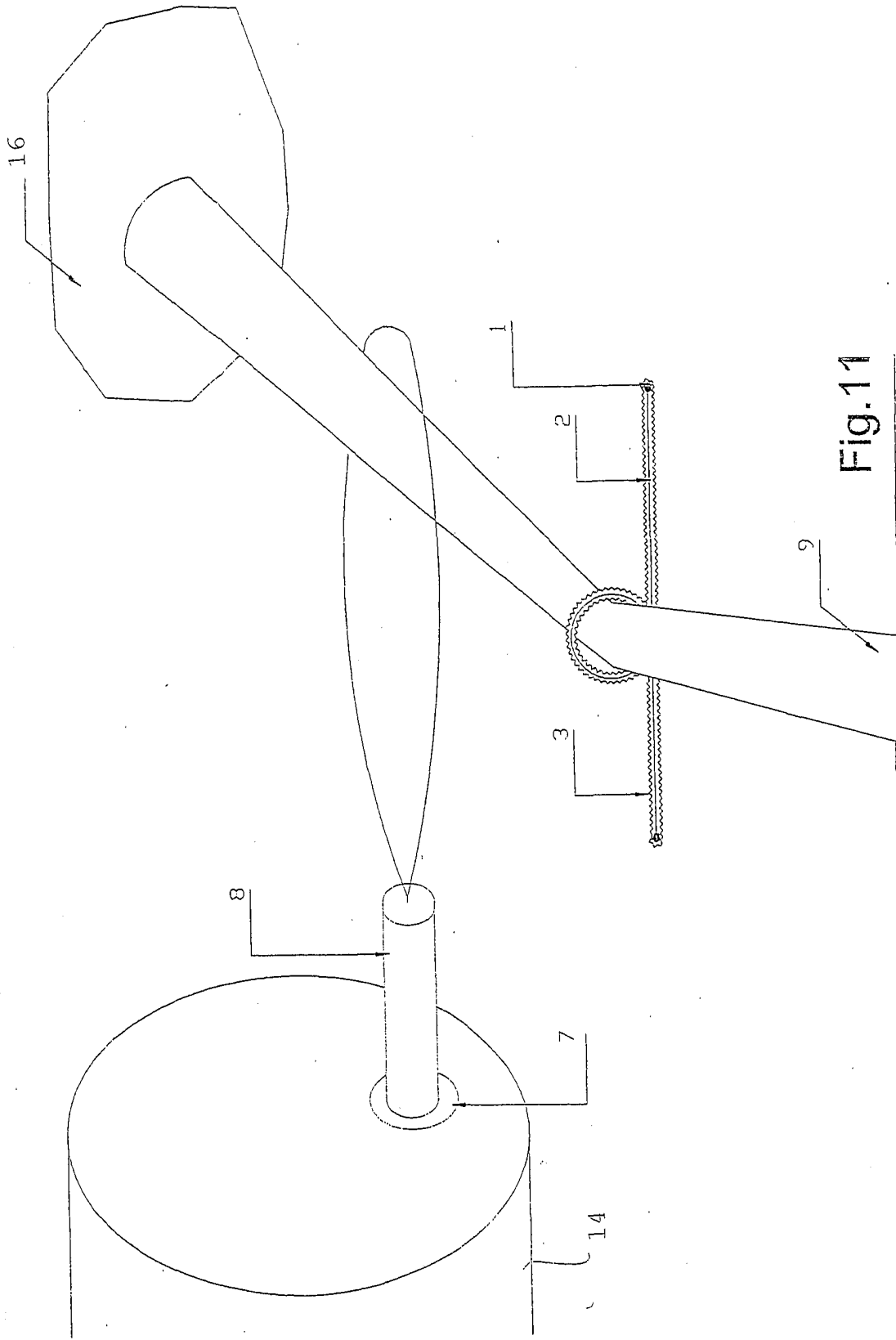


Fig.11

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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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)
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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)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 00 53107 A (AVELLANET FRANCISCO J ; GEN SCIENCE & TECHNOLOGY CORP (US)) 14 September 2000 (2000-09-14) page 1, paragraphs 2,3 page 2, paragraph 1 -page 4, paragraph 1 page 5, paragraph 4 -page 8, paragraph 1	1
A	figures 2-7	2-13
Y	US 6 080 160 A (CHEN JAMES C ET AL) 27 June 2000 (2000-06-27) column 7, line 10 -column 8, line 34 column 8, line 27-34 column 9, line 44-49 figure 1	1
A		3,10,11
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 12553 A (CHANGUS JAMES E ;CORBITT JOHN D (US)) 10 April 1997 (1997-04-10) page 6, last paragraph figures 1,2,5 -----	1

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 Information on patent family members

In International Application No
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