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(71) Applicant *(for all designated States except US)*: **ID-TECH LIMITED** [GB/GB]; 53 Linden way, Darras Hall, Ponteland, Newcastle Upon Tyne NE20 9JE (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BYRNE, Phillip, Owen** [GB/GB]; 48 Whaggs Lane, Whickham, Tyne & Wear NE16 4PQ (GB). **INGHAM, Harry, Raymond** [GB/GB]; 53 Linden way, Darras Hall, Ponteland, Newcastle Upon Tyne NE20 9JE (GB). **ATTRIDGE, Penelope, Rosemary** [GB/GB]; 18 The Avenue, St Margarets, Twickenham TW1 1RY (GB).

(74) Agent: **VINSOME, Rex, Martin**; Urquhart-Dykes & Lord LLP, St Nicholas Chambers, Amen Corner, Newcastle Upon Tyne, NE1 1PE (GB).

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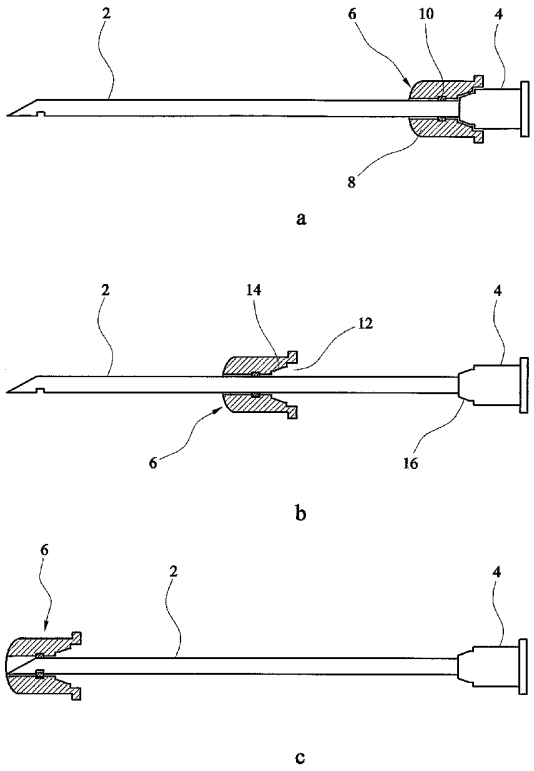
(54) Title: SAFETY APPARATUS FOR HYPODERMIC NEEDLE



(57) Abstract: A safety apparatus (6) for a hypodermic needle (2) is disclosed. The needle has an elongate hollow shaft and a tip for penetrating tissue. The safety apparatus comprises a housing (8) adapted to be slidably mounted on the shaft and to be slidable between a first position (Figure 1a) allowing access to the tip and a second position (Figure 1c) preventing access to the tip, and a circlip (10) for locking the housing in the second position relative to the shaft.

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Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Safety Apparatus for Hypodermic Needle

The present invention relates to a safety apparatus for a hypodermic needle and relates particularly, but not exclusively, to a syringe having a hypodermic needle incorporating such an apparatus.

Medical staff, patients and members of the general public are at risk from needle stick injuries in which a person is inadvertently pricked by a contaminated hypodermic needle of a used syringe. Such injuries can result in the victim being infected with diseases such as AIDS, hepatitis or other diseases, which are transmitted by bodily fluids.

Preferred embodiments of the present invention seek to provide a solution to the above problem.

According to an aspect of the present invention there is provided a safety apparatus for a hypodermic needle, wherein the needle has an elongate hollow shaft and a tip for penetrating tissue, the safety apparatus comprising:-

a cover member adapted to be slidably mounted on said shaft and to be slidable between a first position allowing access to said tip and a second position preventing access to said tip; and

locking means for locking the cover member in said second position relative to said shaft and comprising at least one engaging member slidable relative to said cover member and adapted to engage at least one slot formed in said hollow shaft.

This provides the advantage that the hypodermic needle can be used as normal when the cover member is positioned in the

first position, and when the needle has been used, for example after a patient has been injected the cover member can be slid along the needle until it reaches its respective second position covering the blade (tip) of the needle and the engaging member slides into the slot formed through the needle barrel such that the cover member locks into position. This prevents other persons from being inadvertently pricked by the used needle and therefore prevents exposure to infectious diseases from needle stick injuries. By using a slot formed through the needle shaft, this provides the advantage that the slot can be easily and inexpensively manufactured in a standard needle by cutting out or grinding away a part of the needle barrel, without the need for high manufacturing accuracies.

An edge of said slot adjacent the outer surface of said needle may comprise a first bevelled surface to assist at least one said engaging member to move into said slot when the cover member moves into the second position.

This provides the advantage of helping the engaging member to fall into the slot and engage with the slot when the cover member is slid over the slot.

An edge of said slot may comprise a second bevelled surface to prevent said engaging member being removed from said slot when the cover member is in the second position.

This provides the advantage of helping to prevent the engaging member becoming detached from the slot and the cover member moving from the second position.

At least one said engaging member may be a circlip adapted to be received in a respective recess in the cover member.

In a preferred embodiment, at least one said slot has a respective depth greater than half the thickness of the portion of the circlip located in said slot in a direction transverse to the longitudinal axis of the needle, to prevent said circlip being removed from said slot.

This provides the advantage of more secure engagement between the circlip and that slot, to prevent the cover member being moved once it has been locked in the covering position.

Said cover member may comprise at least one arm member resiliently biased against said shaft in use, wherein a respective engaging member is provided adjacent a engaging member is provided adjacent a distal end of at least one said arm member.

At least one said engaging member may be formed from a harder material than the corresponding said arm member.

Said cover member may further comprise an absorbent material for absorbing fluid disposed on said shaft.

This provides the advantage that any fluid, such as blood from a patient, is absorbed by the cover member thus cleaning the shaft and reducing the risk of spreading infection.

Said cover member may further comprise at least one reservoir for collecting fluids disposed on said shaft.

This also provides the advantage of removing any fluid disposed on the shaft of the used hypodermic needle.

According another aspect of the present invention, there is provided a syringe comprising a hollow barrel, a needle

having an elongate hollow shaft and a tip for penetrating tissue, and a safety apparatus as defined above.

In a preferred embodiment, at least one said slot is formed on said shaft adjacent said tip.

In a preferred embodiment, at least one said slot is wider in an axial direction of the shaft than the corresponding said engaging member.

This provides the advantage of increasing the likelihood that the engaging member will engage with the recess and lock the cover member into the second position.

Preferred embodiments of the present invention will now be described, by way of example only and not in any limitative sense, with reference to the accompanying drawings in which:-

Figure 1a is a cross sectional view of a hypodermic needle of a syringe with a capping assembly of a first embodiment of the present invention shown in a parked position;

Figure 1b shows the needle of Figure 1a with the capping assembly in an intermediate position between the parked position and a covering position;

Figure 1c shows the needle of Figures 1a and 1b with the capping assembly locked into the covering position;

Figure 2 is a side view of a needle of a syringe having a slot formed therein;

Figure 3 is a top view of the tip of the needle of Figure 2;

Figure 4 is a side view of the tip of Figures 2 and 3 with the capping assembly of Figure 1 slidably disposed thereon;

Figure 5 is a side view of the tip of Figures 2 to 4 with the capping assembly of Figure 4 locked into the covering position;

Figure 6 is a side view of the needle tip and capping assembly of Figure 4 showing the reservoir of the capping assembly;

Figure 7 is a cross sectional view of a needle tip with a capping assembly of a second embodiment of the invention disposed thereon;

Figure 8 shows a second embodiment of the slot formed in the needle comprising an outer bevel;

Figure 9 shows a third embodiment of the slot comprising an inner bevel; and

Figure 10 shows a fourth embodiment of the slot comprising both an inner and outer bevel.

Referring to Figures 1a to 1c a syringe comprises a hypodermic needle 2 connected to a syringe barrel (not shown) by a luer hub 4. A capping assembly shown generally by 6 comprises a housing 8 formed from durable plastics material with a circlip, manufactured from a suitable material, usually metallic 10 received in an aperture 13 (Figure 4). The capping assembly 6 is slidable along needle 2.

Figure 1a shows the capping assembly in the parked position. The housing 8 comprises a recess 12 having a tapered surface 14. The front surface of luer hub 4 comprises a

corresponding tapered projection 16 such that when the capping assembly 6 is in the parked position as shown in Figure 1a the rear surface of the capping assembly 6 sits flush on the front surface 16 of luer hub 4.

Referring to Figures 2 and 3, needle 2 comprises a blade 18 for penetrating the surface of the skin of a patient (not shown). A slot 20 is also formed adjacent blade 18. The slot passes through the needle 2 and can be easily machined in an existing standard hypodermic needles during fabrication without the need for high manufacturing accuracy. Slot 20 is formed such that it is generally orthogonal to the needles primary axis and may penetrate to the lumen of the needle. It has a greater width than circlip 10, to ensure that circlip 10 does not pass over slot 20. The slot 20 is also formed with sufficient thickness that when circlip 10 is located in slot 20, more that half of the thickness of the portion of the circlip engaging the slot is located in the slot 20. This prevents circlip 10 being removed from slot 20. Blade 18 comprises a generally oval shaped aperture 22 for permitting the flow of fluid into a patient when the plunger (not shown) of the syringe is depressed.

Referring to Figures 4 and 5, the operation of capping assembly 6 will now be described.

After the needle 2 has been used to inject a patient, capping assembly 6 can be slid along needle 2 (as shown moving from Figure 1a through to Figure 1c) until circlip 10 is located over slot 20. Circlip 10 is an annular spring which when in the position shown in Figure 4 inwardly biases itself against the surface of needle 2. When the capping assembly is slid along needle 2 into the position shown in Figure 5 where the circlip 10 is aligned with slot 20, the inward biasing force of circlip 10 causes it to snap into place in slot 20. As

slot 20 is only formed on one side of needle 2, and a portion 10b of circlip 10 remains in capping assembly aperture 13 then the capping assembly 6 is locked in place over the blade 18 of needle 2 such that access to blade 18 is prevented. Once the capping assembly 6 is locked into position, it is impossible to remove the capping assembly without applying sufficient force to damage the capping assembly 6 or needle 2.

Figure 8 shows a second embodiment of slot 30 having a bevel 32. Bevel 32 is angled to help the circlip 10 move into slot 30 as the capping assembly 6 passes over slot 30.

Figure 9 shows a third embodiment of slot 34 having an undercut 36 formed in the forward edge of the slot 34. The undercut 36 helps retain circlip 10 in slot 34. Referring to Figure 10, a fourth embodiment of slot 38 has both a bevel 32 and undercut 36.

Referring to Figure 6, the capping assembly 6 may further comprise a reservoir 24 formed in aperture 13. When the capping assembly 6 is slid along needle 2 any fluid disposed on the surface of used needle 2 will be trapped by circlip 10 and gathered up in reservoir 24. This results in the surface of needle 2 being cleaned of bodily fluids and further reduces the risk of infection. Alternatively, an absorbent material (not shown) may be disposed in reservoir 24 to absorb fluids disposed on the surface of needle 2.

Referring to Figure 7, a second embodiment of the capping assembly is shown with parts common to the embodiment of Figures 1 to 6 shown by like reference numerals but increased by 100.

A capping assembly shown generally as 106 is mounted on a hypodermic needle 102 having a recess 120 formed thereon. Capping assembly 106 comprises a plurality of resilient arms 124 each having an engaging portion 126 formed on the end thereof. The engaging portions 126 are formed from a substantially harder material than the arms 124. Arms 124 are formed such that the engaging portions 126 are biased radially inwardly against the surface of needle 102. It can be seen therefore that when capping assembly 106 is slid along needle 102 until engaging portions 126 are located over slot 120, the arm 124 will force engaging portion 126 into the slot 120 thus locking the capping assembly 106 in place over the blade 118 of needle 102.

It will be appreciated by persons skilled in the art that the above embodiment has been described by way of example only and not in any limitative sense, and that various alterations and modifications are possible without departure from the scope of the invention as defined by the appended claims. For example, the capping assembly above has been described in connection with the hypodermic needle of a syringe. It could also be applied to other types of hypodermic needles such as those used on catheter assemblies.

CLAIMS

1. A safety apparatus for a hypodermic needle, wherein the needle has an elongate hollow shaft and a tip for penetrating tissue, the safety apparatus comprising:-

a cover member adapted to be slidably mounted on said shaft and to be slidable between a first position allowing access to said tip and a second position preventing access to said tip; and

locking means for locking the cover member in said second position relative to said shaft and comprising at least one engaging member slidable relative to said cover member and adapted to engage at least one slot formed in said hollow shaft.

2. An apparatus according to claim 1; wherein an edge of said slot adjacent the outer surface of said needle comprises a first bevelled surface to assist at least one said engaging member to move into said slot when the cover member moves into the second position.

3. An apparatus according to claim 1 or 2, wherein an edge of said slot comprises a second bevelled surface to prevent said engaging member being removed from said slot when the cover member is in the second position.

4. An apparatus according to any one of the preceding claims, wherein at least one said engaging member is a circlip adapted to be received in a respective recess in the cover member.

5. An apparatus according to claim 4, wherein at least one said slot has a respective depth greater than half the

thickness of the portion of the circlip located in said slot in a direction transverse to the longitudinal axis of the needle, to prevent said circlip being removed from said slot.

6. An apparatus according to any one of claims 1 to 3, wherein said cover member comprises at least one arm member resiliently biased against said shaft in use, wherein a respective engaging member is provided adjacent a distal end of at least one said arm member.

7. An apparatus according to claim 6, wherein at least one said engaging member is formed from a harder material than the corresponding said arm member.

8. An apparatus according to any one of the preceding claims, wherein said cover member further comprises an absorbent material for absorbing fluid disposed on said shaft.

9. An apparatus according to any one of the preceding claims, wherein said cover member further comprises at least one reservoir for collecting fluid disposed on said shaft.

10. A safety apparatus for a hypodermic needle, the needle comprising an elongate hollow shaft and a tip for penetrating tissue, the apparatus substantially as hereinbefore described with reference to the accompanying drawings.

11. A syringe comprising a hollow barrel, a needle having an elongate hollow shaft and a tip for penetrating tissue, and a safety apparatus according to any one of the preceding claims.

12. A syringe according to any one of claims 2 to 7 and claim 11, wherein at least one said slot is formed in said shaft adjacent said tip.

13. A syringe according to claim 12, wherein at least one said slot is wider in an axial direction of the shaft than the corresponding said engaging member.

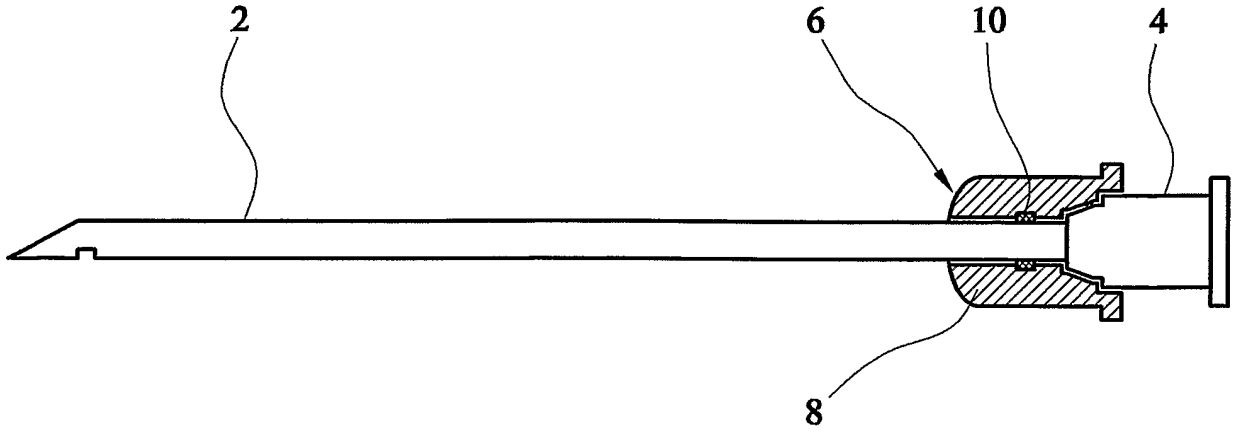

FIG. 1a

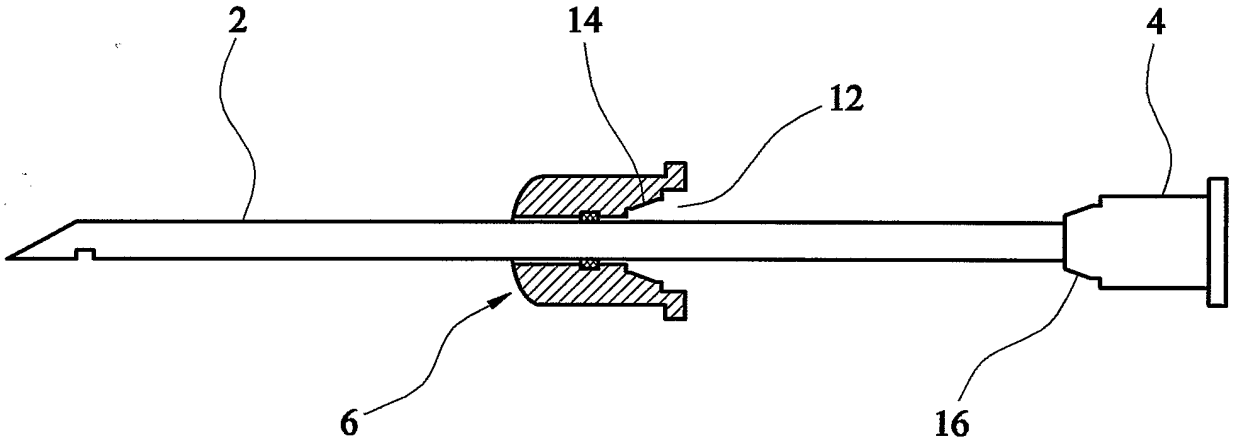

FIG. 1b

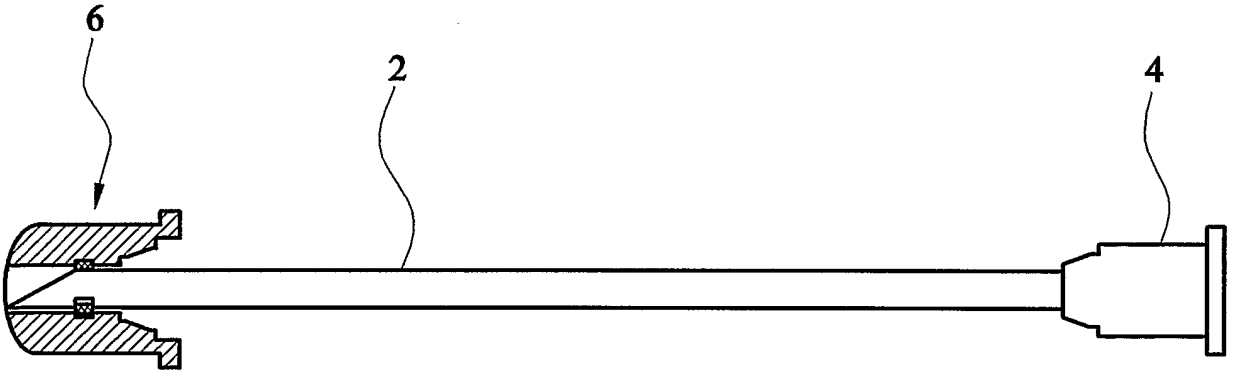

FIG. 1c

FIG. 2

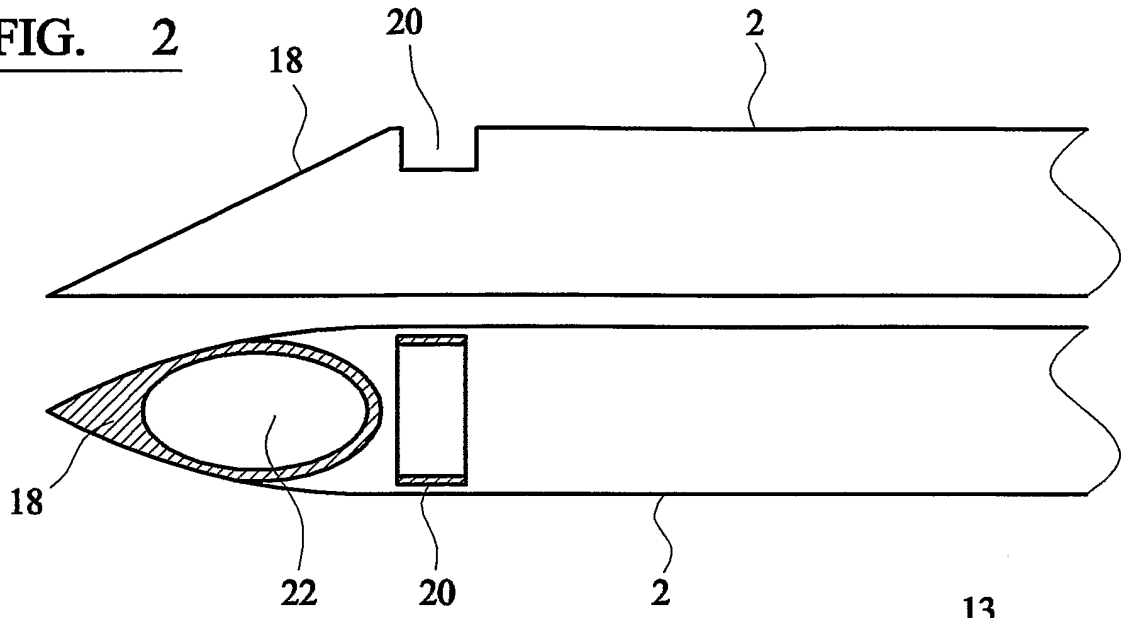

FIG. 3

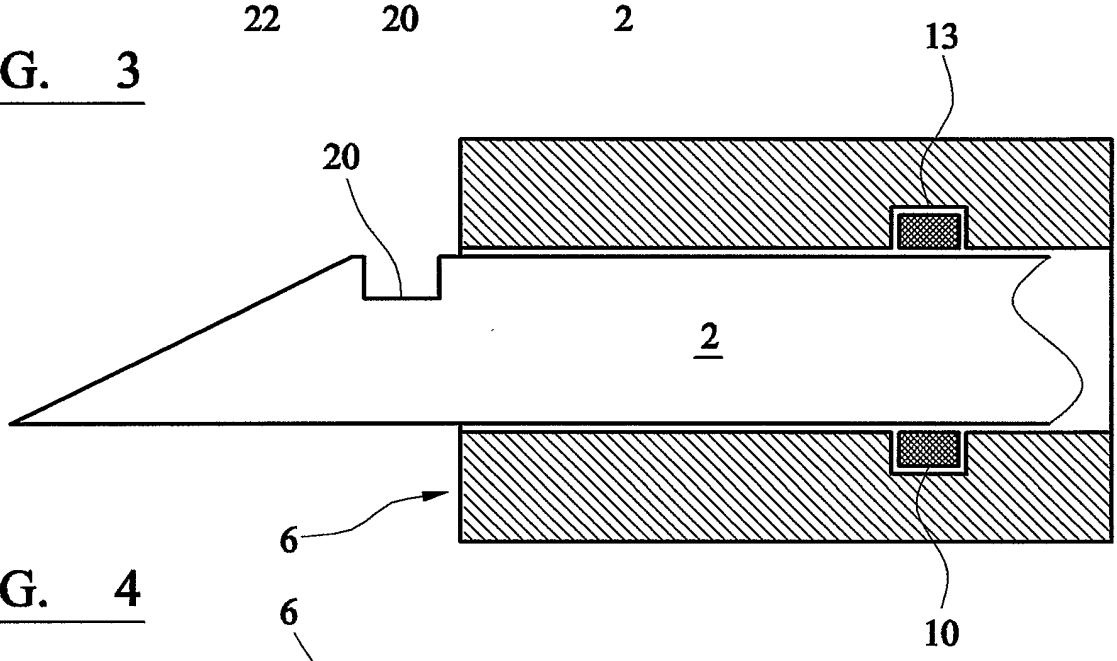

FIG. 4

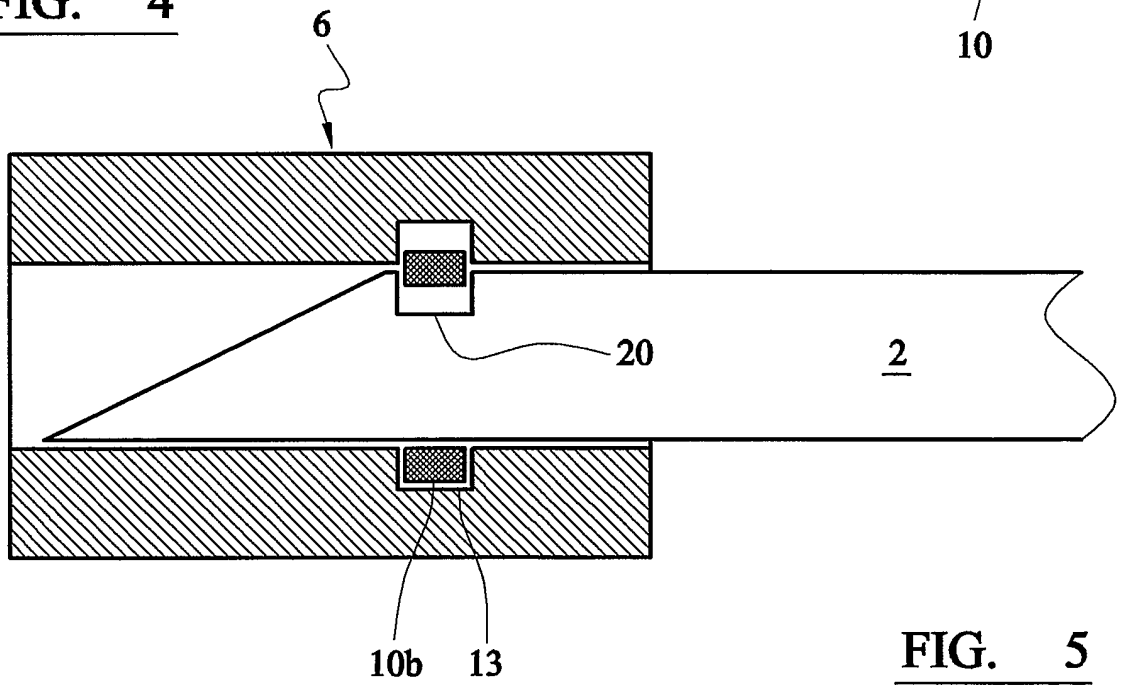

FIG. 5

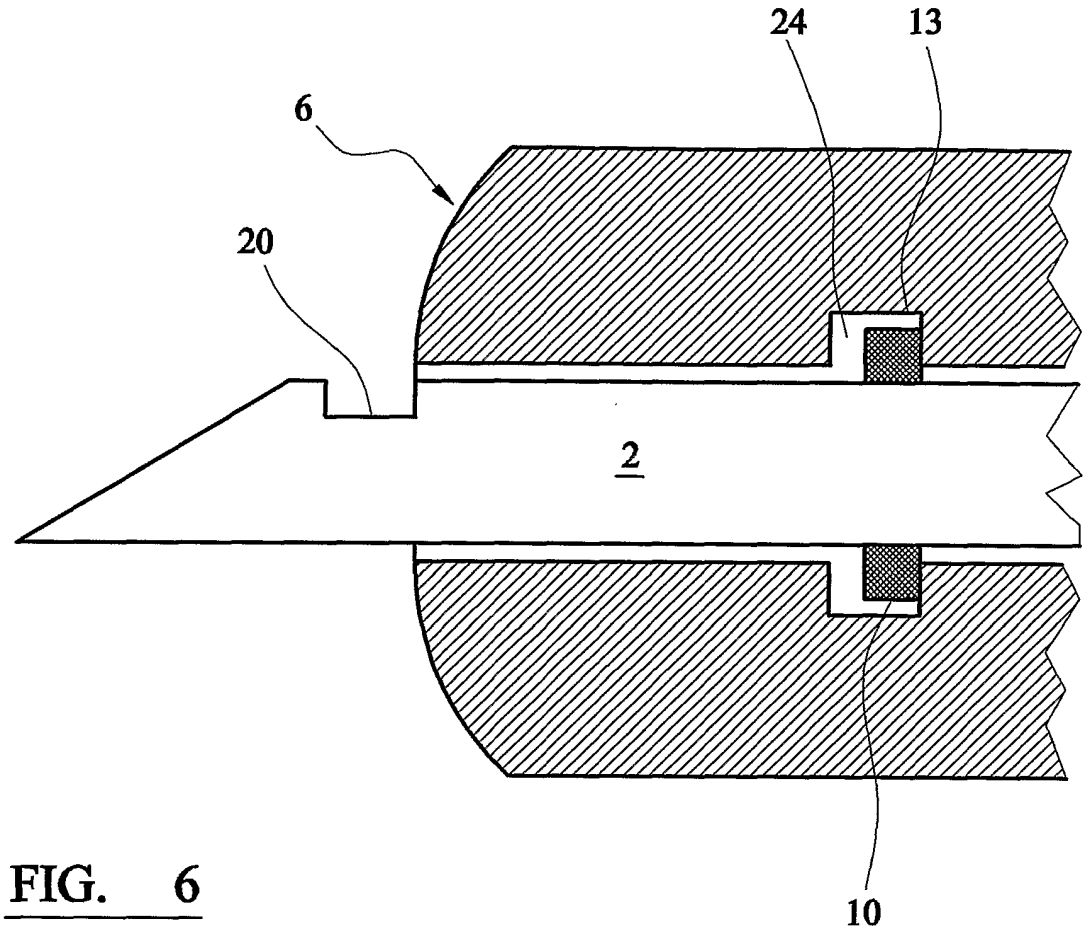

FIG. 6

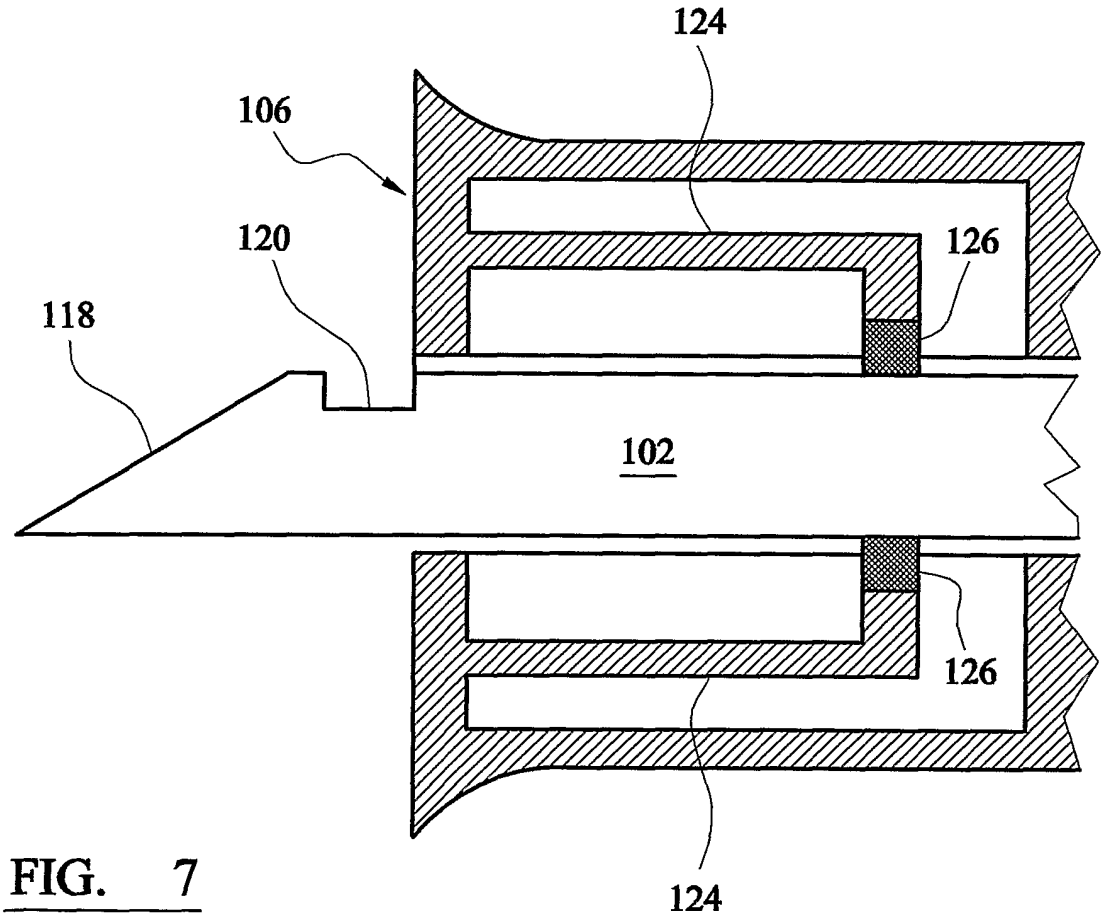

FIG. 7

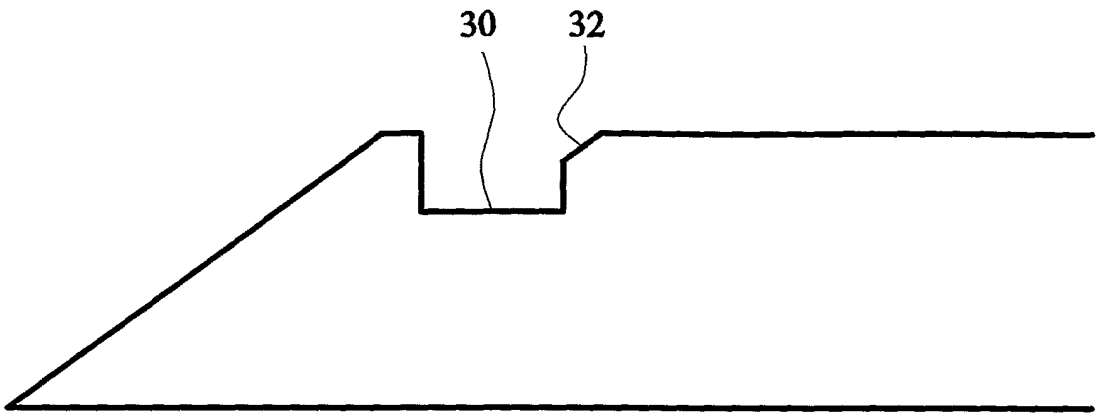

FIG. 8

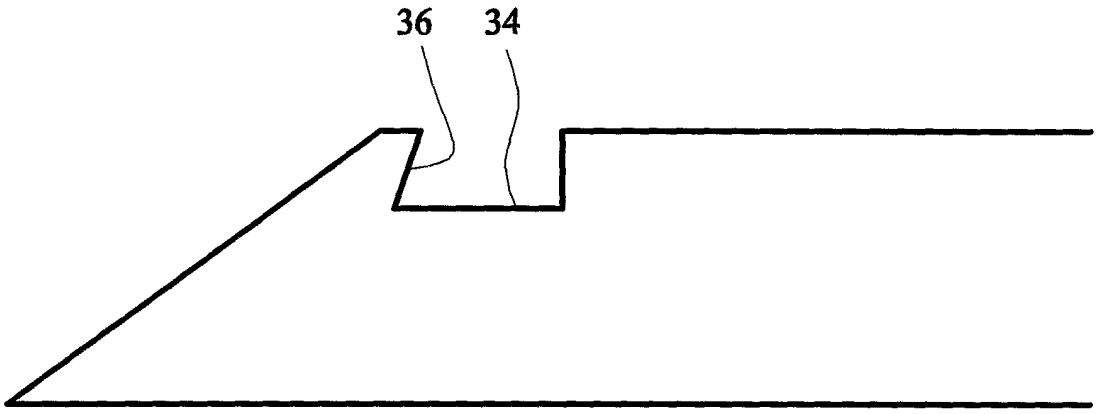

FIG. 9

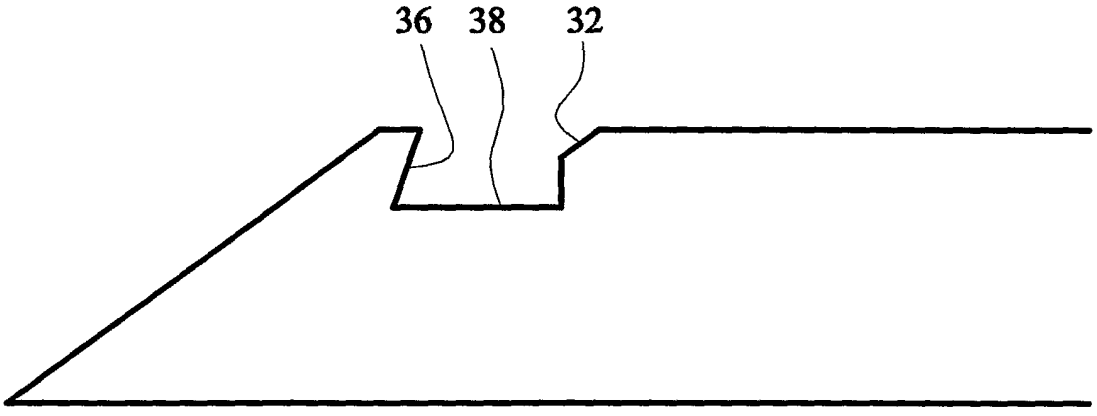

FIG. 10

INTERNATIONAL SEARCH REPORT

Int ›nal Application No
P iB2005/000276

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/32

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, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 1 291 035 A (ETHICON ENDO-SURGERY, INC) 12 March 2003 (2003-03-12) figures 1-13	1,4-7, 11-13 2,3,8,9
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Y	US 5 658 255 A (ISHAK ET AL) 19 August 1997 (1997-08-19) abstract; figures 1,4A-4B	2,3

-/--

[X] Further documents are listed in the continuation of box C.

[X] 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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
13 May 2005	31/05/2005
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Björklund, A

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International Application No
PC.. ..32005/000276

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 053 017 A (CHAMUEL ET AL) 1 October 1991 (1991-10-01) column 5, lines 34-68; figures 8,9	8,9
A	US 5 498 243 A (VALLELUNGA ET AL) 12 March 1996 (1996-03-12) figures 5-12	5

INTERNATIONAL SEARCH REPORT

ational application No.
PCT/GB2005/000276

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 10
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 10

Claim 10 does not fulfill the requirements of Rule 6.2(a) PCT and is therefore not sufficiently clear (Article 6 PCT) to allow a meaningful search.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Int onal Application No
PC.. GB2005/000276

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