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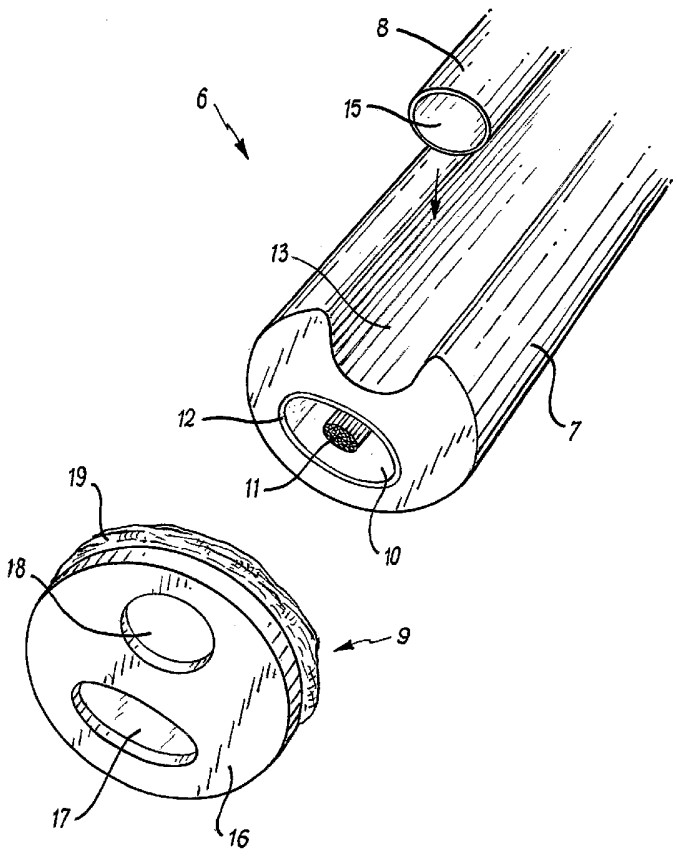
(54) Title: FLEXIBLE FIBREOPTIC ENDOSCOPE



(57) Abstract: A flexible fibreoptic endoscope suitable for medical procedures is described. The endoscope includes a flexible shaft with an associated, disposable, instrumentation conduit and a fibreoptic illumination chamber that runs the length of the endoscope. A disposable sheath is attached to a distal end of the endoscope. The diposable sheath comprises a translucent window to permit the required illumination and an aperture to allow for the passage of one or more medical instruments. The combination of the disposable instrumentation conduit and the sheath acts to significantly reduce the risk of patient infection and cross-contamination.

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Flexible Fibreoptic Endoscope

The present invention relates to fibreoptic endoscopes and in particular to a flexible fibreoptic endoscope whose design significantly reduces the sterilisation requirements on the device.

Flexible fibreoptic endoscopes (or fibrescopes) are frequently used within the medical field for a range of medical procedures e.g. gastroscopy, bronchoscopy, laryngoscopy, colonoscopy, cystoscopy. A typical fibreoptic endoscope 1 employed in the prior art is presented in Figure 1. The fibreoptic endoscope 1 comprises a flexible shaft 2 that completely encloses a number of fibreoptic image transmitting illumination fibres 3, and a lens 4. In most fibreoptic endoscopes 1 there is also at least one hollow conduit 5 contained within the flexible shaft 2 through which surgical instruments can be passed.

Fibreoptic endoscopes are expensive to manufacture and therefore are used in the course of their lifetime for a number of medical procedures carried out on a number of

different patients. The repeated employment of fibreoptic endoscopes places a strict requirement for stringent sterilisation of the device between medical procedures due to the existence of bacterial endospores.

Traditionally, medical equipment is sterilised at high temperatures. The equipment is commonly sterilised in a steam autoclave under a combination of high temperature and pressure. While such sterilisation methods are very effective for more durable medical instruments, more sensitive medical instruments, such as fibreoptic endoscope, can be damaged or have their useful lifetimes severely curtailed due to such harsh sterilisation processes. Furthermore, fibreoptic endoscopes (as described above) present particular problems in that these devices typically comprise numerous exterior crevices and interior lumens which can harbour microbes and are thus difficult to clean and sterilise using such techniques.

Alternative methods for sterilising sensitive medical instruments have thus been developed. These include the employment of a fast acting, low corrosivity sterilant. However, such processes are typically expensive, involve large reprocessing times and employ sterilants that can be both toxic and non biodegradable.

More recently the discovery of the existence of prions has lead to even more stringent requirements being placed on the sterilisation process. Prions are cellular glyco-proteins which are responsible for diseases such as varient Creutzfeldt-Jakob Disease (vCJD) and Bovine Spongieform Encephalitis (BSE). They have been found in

large quantities in tissues such as tonsils, other lymphoid tissue and in the bowel (particularly the appendix). They bind readily to the surfaces of metal and plastic objects without losing their infectivity, and they are known to be resistant to the normal sterilisation procedures described above. Thus, it is not possible to be certain that the employment of these sterilisation procedures will render the fibreoptic endoscope 1 sterilised to a sufficient level so as to reduce the effects of cross contamination between patients. The hollow tube 5 in particular is known to those skilled in the art to be a source of cross contamination as this feature tends to be extremely difficult to sterilise and/or monitor.

It would therefore be desirable to provide a flexible fibreoptic endoscope that obviates or at least mitigates one or more of the sterilisation drawbacks associated with the prior art.

According to a first aspect of the present invention there is provided a fibreoptic endoscope comprising a flexible shaft, one or more instrumentation conduits that locates with the flexible shaft so as to form a combined assembly and a disposable sheath suitable for attachment to a distal end of the combined assembly.

Most preferably the disposable sheath comprises an end cap and a flexible sheath.

Optionally the end cap comprises a substantially circular cross section. Alternatively, the end cap comprises a substantially crescent shaped cross section.

Preferably the end cap further comprises one or more exit apertures so that when the end cap is attached to the combined assembly the exit apertures locates with a distal ends of the one or more instrumentation conduits.

Most preferably the end cap further comprises a lens cover that provides a transparent physical barrier for the distal end of the combined assembly.

Optionally the end cap comprises one or more sockets suitable for receiving the one or more instrumentation conduits.

Preferably the flexible sheath comprises a polyurethane material, for example Tactylon®.

Optionally the flexible shaft comprises one or more channels located on an outer surface of the shaft and extending longitudinally along the length of the shaft and at least one internal shaft conduit. Alternatively the flexible shaft comprises a standard fibreoptic endoscope.

Most preferably a plurality of fibreoptic image transmitting illumination fibres and a lens are housed within the internal conduit.

Most preferably the one or more instrumentation conduits comprises an off axis instrument entrance conduit.

Optionally the one or more instrumentation conduits comprises a cylindrical tube suitable for locating within

the one or more channels of the flexible shaft so that the combined assembly has a substantially circular cross section.

Alternatively the one or more instrumentation conduits comprises a flexible body having a substantially crescent shaped cross-section so that the combined assembly has a substantially circular cross section.

According to a second aspect of the present there is provided a method of assembling a fibreoptic endoscope comprising the steps of:

1) Locating one or more instrumentation conduits with a flexible shaft so as to form a combined assembly;
2) Attaching a disposable sheath to a distal end of the combined assembly; and
3) Expanding the disposable sheath so as to provide the combined assembly with a physical barrier.

Example embodiments of the present invention will now be described with reference to the following figures:

Figure 1 presents a schematic representation of a standard fibreoptic endoscope as described in the prior art;

Figure 2 presents an exploded view of a fibreoptic endoscope in accordance with an aspect of the present invention;

Figure 3 presents a schematic representation of the fibreoptic endoscope of Figure 2;

Figure 4 presents a schematic representation of the fibreoptic endoscope of Figure 2 in conjunction with a standard fibreoptic endoscope adapter; and

Figure 5 presents an alternative embodiment of the fibreoptic endoscope suitable for retro fitting with the standard fibreoptic endoscope presented in Figure 1.

Referring to Figure 2 an exploded view of a fibreoptic endoscope 6 in accordance with an aspect of the present invention is presented. The fibreoptic endoscope 6 comprises a flexible shaft 7, an instrumentation tube 8 and a disposable sheath 9.

The flexible shaft 7 comprises a shaft conduit 10 that extends internally along its length and which is employed to house a plurality of flexible fibre optic image transmitting illumination fibres 11. At the distal end of the shaft conduit 10 is located a lens 12 employed to focus the light provided by the illumination fibres 11.

In a first embodiment the flexible shaft 7 further comprises a channel 13 located on its outer surface and extending longitudinally along its length. The channel is suitable for receiving the instrumentation tube 8 that is of a substantially circular cross section.

The instrumentation tube 8 comprises an instrument entrance conduit 14, located off axis, and an exit aperture 15 at the distal end of the hollow tube 8. The instrumentation tube 8 is of sufficient rigidity so as to

prevent its inward collapse. Therefore, the instrumentation tube 8 provides an isolated passage for surgical instruments to be passed via the entrance conduit 14 to the exit aperture 15.

The disposable sheath 9 comprises a solid end cap 16 which contains a translucent perspex (or similar material) lens cover 17, an aperture 18 and a flexible sheath 19. The flexible sheath 19 is attached to the solid end cap 16 and comprises a latex-free polyurethane material (for example Tactylon®) and is normally stored in a rolled up position.

In an alternative embodiment (not shown) the solid end cap 1 is cresent shaped rather than circular in cross section.

The fibreoptic endoscope 6 is assembled by locating the instrumentation tube 8 within the channel 13. When so located the combination of the instrumentation tube 8 and the flexible shaft 7 provide an assembly that exhibits a substantially circular cross section, as shown in Figure 3. The solid end cap 16 is attached to the distal end of the assembly so that the lens cover 17 protects the lens 12 while the aperture 18 locates in front of the exit aperture 15 of the hollow tube 8. The solid end cap 16 fits tightly over the distal end of the combined hollow tube 8 and flexible shaft 7 assembly so that it does not become displaced during any subsequent medical procedure. Thereafter, the flexible sheath 19 is unrolled such that it covers the length of the combined hollow tube 8 and the flexible shaft 7 assembly.

For use in medical procedures the fibreoptic endoscope 6 is simply required to be connected at its proximal end to a standard fibreoptic endoscope adapter 20, as shown in Figure 4. Therefore, with the present design the entrance conduit 21 of the adapter 22 is rendered redundant.

In an alternative embodiment the instrumentation tube 8 is further secured to the flexible shaft 7 by temporary fixing means (not shown). The temporary fixing means comprise either ties or adhesive tape. In a further alternative the instrumentation tube 8 is further secured by fixing it to the solid end cap 16. This can be achieved by employing an adhesive, tape or by forming a threaded end on the hollow tube 8 suitable for screwing into a threaded socket formed on the inside surface of the solid end cap 16.

Figure 5 presents a further alternative embodiment of the fibreoptic endoscope 22 suitable for retro fitting with the fibreoptic endoscope 1 presented in Figure 1. In this embodiment the instrumentation tube 8 comprises a crescent shaped flexible body 23 that is employed to locate around the fibreoptic endoscope 1, as shown. A disposable sheath 9 is then connected to the distel end of the device as described above so that when the flexible sheath is unrolled there is provided a physical barrier for the instrumentation tube 8 and flexible fibreoptic endoscope 1 assembly.

In a further alternative embodiment (not shown) the fibreoptic endoscope 6 comprises two or more

instrumentation tubes to allow additional surgical instruments to be passed along the length of the device.

The employment of the flexible sheath 19 provides the flexible fibreoptic endoscopes 6 with a physical barrier so as to minimise the contact of the device with human tissue and so reducing the opportunity of contamination by bacterial endospores, prions and the like. After use the disposable sheath 9 and the instrumentation tube 8 can be removed and disposed of, as appropriate. In order to reuse the fibreoptic endoscope a new uncontaminated disposable sheaths 9 and instrumentation tube 8 can then be employed. Furthermore, by employing the entrance conduit 14 the sterilisation requirements on the adapter 20 are also reduced.

The fibreoptic endoscope exhibits significant advantages over those systems described in the prior art. The incorporation of the disposable sheath and the instrumentation tube provide a cheap and simple way of significantly reducing the sterilisation requirements on these devices. Furthermore, the employment of the crescent shaped flexible body allows the device to be retro fitted with existing fibreoptic endoscopes. As the opportunity of contact with human tissue is significantly reduced the chances of cross contamination between patients on which the endoscope is employed are similarly reduced.

The foregoing description of the invention has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the precise form disclosed. The described

embodiments were chosen and described in order to best explain the principles of the invention and its practical application to thereby enable others skilled in the art to best utilise the invention in various embodiments and with various modifications as are suited to the particular use contemplated. Therefore, further modifications or improvements may be incorporated without departing from the scope of the invention as defined by the appended claims.

CLAIMS

1. A fibreoptic endoscope comprising a flexible shaft, one or more instrumentation conduits that locates with the flexible shaft so as to form a combined assembly and a disposable sheath suitable for attachment to a distal end of the combined assembly.

2. A fibreoptic endoscope as claimed in Claim 1, wherein the disposable sheath comprises an end cap and a flexible sheath.

3. A fibreoptic endoscope as claimed in Claim 2, wherein the end cap comprises a substantially circular cross section.

4. A fibreoptic endoscope as claimed in Claim 2, wherein the end cap comprises a substantially crescent shaped cross section.

5. A fibreoptic endoscope as claimed in any of Claims 2 to 4, wherein the end cap further comprises one or more exit apertures so that when the end cap is attached to the combined assembly the one or more exit apertures locate with distal ends of the one or more instrumentation conduits.

6. A fibreoptic endoscope as claimed in any of Claims 2 to 5, wherein the end cap further comprises a lens cover that provides a transparent physical barrier for the distal end of the combined assembly.

7. A fibreoptic endoscope as claimed in any of Claims 2 to 6, wherein the end cap comprises one or more sockets suitable for receiving the one or more instrumentation tubes.

8. A fibreoptic endoscope as claimed in any of the previous claims, wherein the flexible sheath comprises a polyurethane material.

9. A fibreoptic endoscope as claimed in Claim 8 wherein the flexible sheath comprises Tactylon®.

10. A fibreoptic endoscope as claimed in any of the previous claims, wherein the flexible shaft comprises one or more channels located on an outer surface of the shaft and extending longitudinally along the length of the shaft and at least one internal shaft conduit.

11. A fibreoptic endoscope as claimed in any of the previous Claims, wherein the flexible shaft comprises a standard fibreoptic endoscope.

12. A fibreoptic endoscope as claimed in Claim 10 or Claim 11, wherein a plurality of fibreoptic image transmitting illumination fibres and a lens are housed within the at least one internal shaft conduit.

13. A fibreoptic endoscope as claimed in any of the previous claims, wherein one or more of the instrumentation conduits comprise an off axis instrument entrance conduit.

14. A fibreoptic endoscope as claimed in Claim 10, wherein the one or more instrumentation conduits comprises a cylindrical tube suitable for locating within the one or more channels of the flexible shaft so that the combined assembly has a substantially circular cross section.

15. A fibreoptic endoscope as claimed in Claim 11, wherein the one or more instrumentation conduits comprises a flexible body having a substantially crescent shaped cross-section so that the combined assembly has a substantially circular cross section.

16. A method of assembling a fibreoptic endoscope, comprising the steps of:

1) Locating one or more instrumentation conduits with a flexible shaft so as to form a combined assembly;
2) Attaching a disposable sheath to a distal end of the combined assembly; and
3) Expanding the disposable sheath so as to provide the combined assembly with a physical barrier.

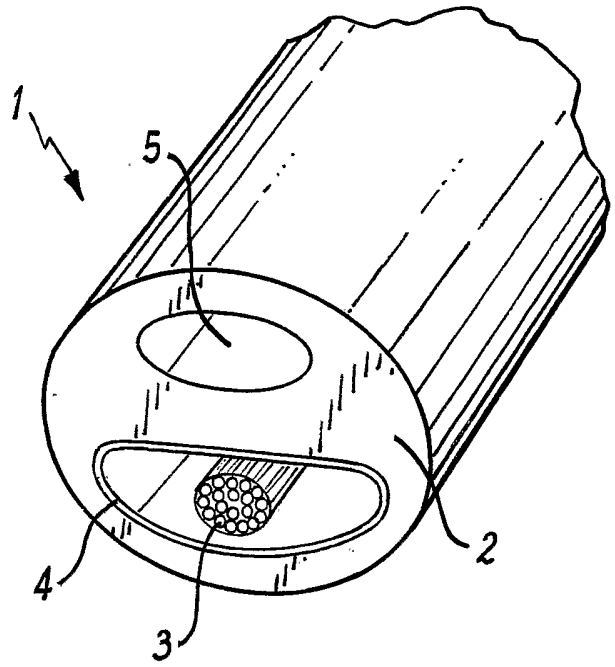

FIG. 1

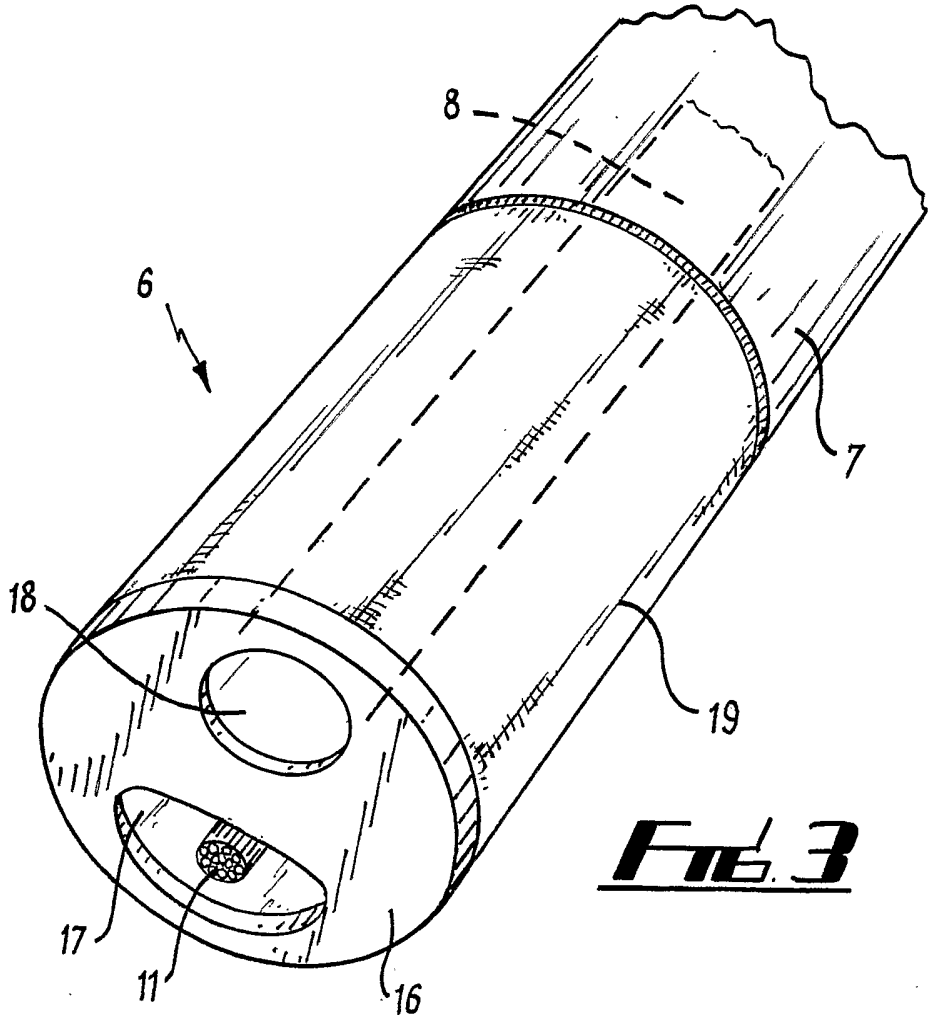

FIG. 3

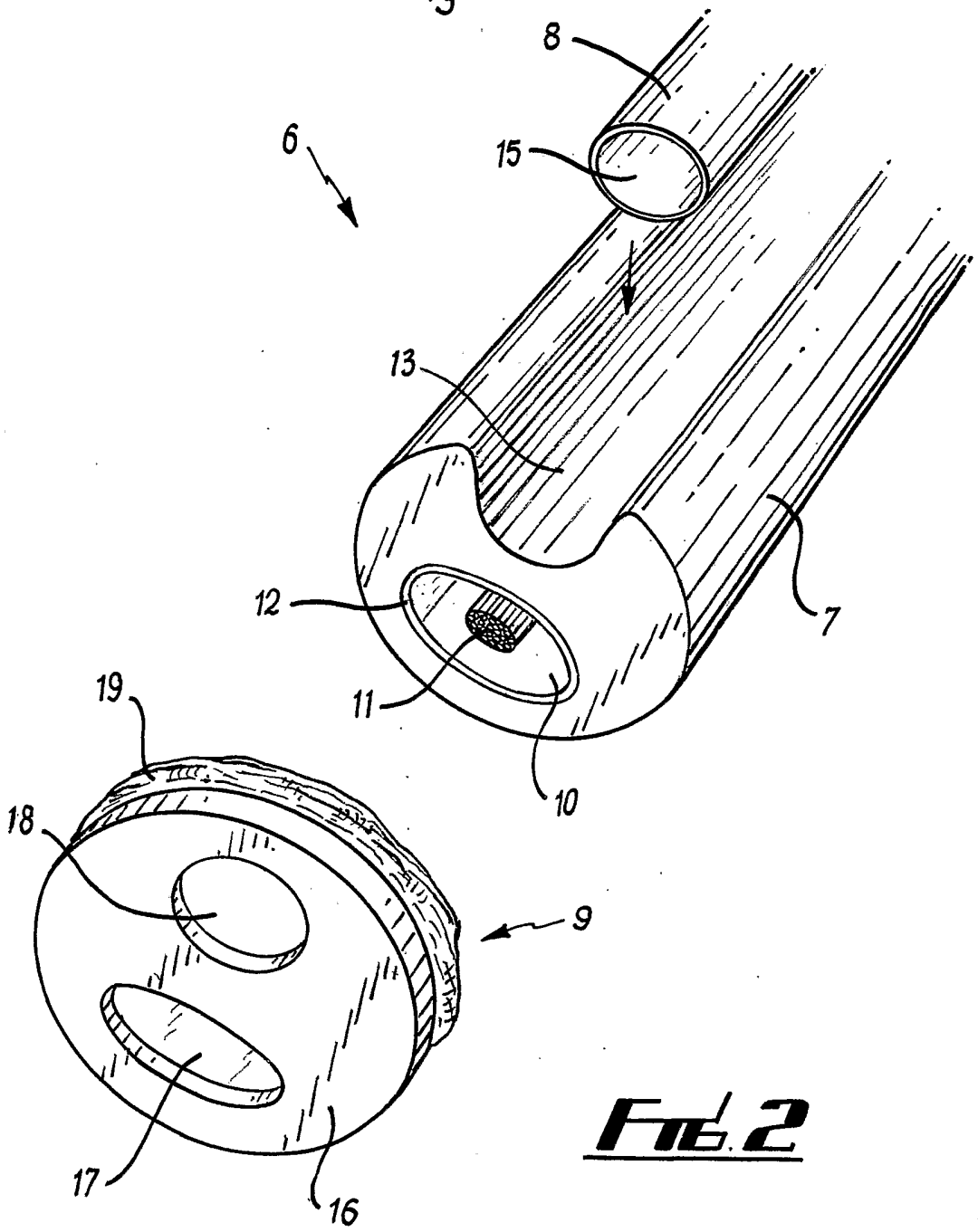

FIG. 2

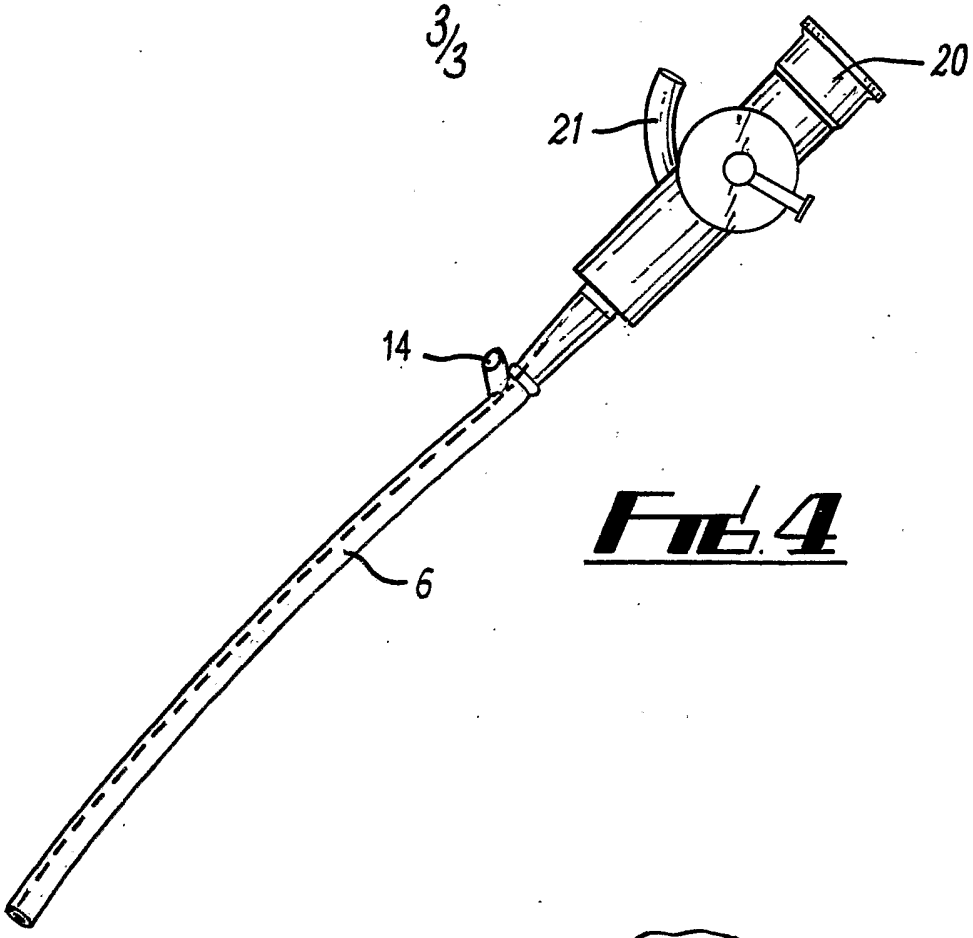

FIG. 4

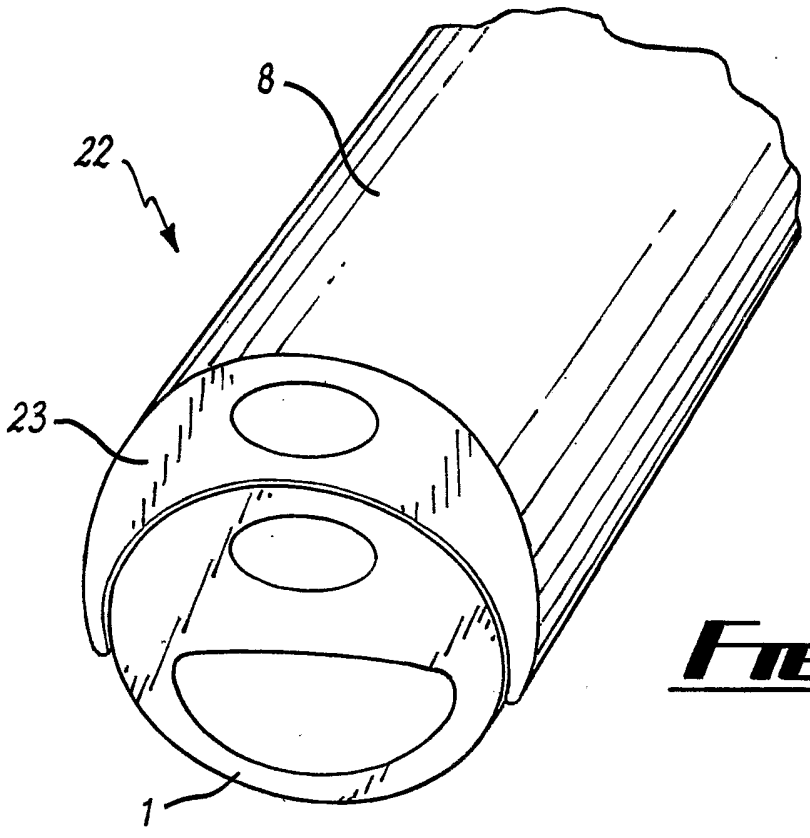

FIG. 5

INTERNATIONAL SEARCH REPORT

PCT/GB2004/003317

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B1/00

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 A61B

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	US 4 646 722 A (OPIE ERIC A ET AL) 3 March 1987 (1987-03-03) column 4, line 66 - column 5, line 15 column 6, line 14 - column 7, line 19; figures 1-3	1-7, 10-14,16
X	US 2002/013511 A1 (AILINGER ROBERT ET AL) 31 January 2002 (2002-01-31) paragraphs '0003!, '0004!, '0030!, '0032!, '0034!, '0035!; claim 31	1-3,5,6, 8,9
X	US 5 489 256 A (ADAIR EDWIN L) 6 February 1996 (1996-02-06) column 10, line 10 - column 11, line 14; claim 16; figures 26-32	1,11,15

☐ 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

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

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"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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Date of the actual completion of the international search	Date of mailing of the international search report
16 December 2004	29/12/2004

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

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