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(54) Title: SEAL FOR A SURGICAL INSTRUMENT

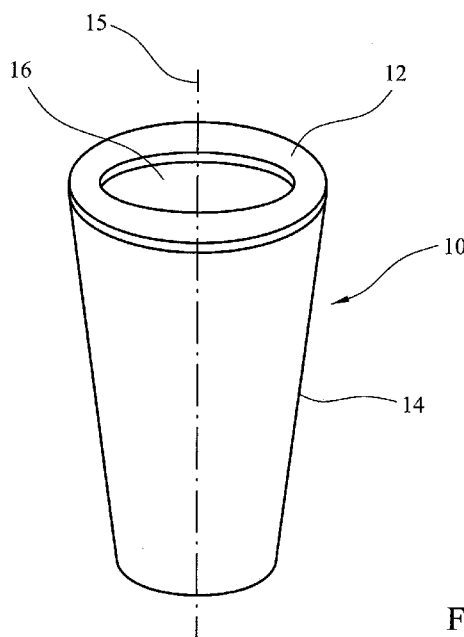


FIG. 2

(57) Abstract: A seal is provided for sealing an opening in a pressurised body cavity from the atmosphere. The seal comprises a flexible annular member and a flexible tubular member. The flexible tubular member extends from the annular member, has a first end and a second end and defines a lumen between the first end and the second end. The flexible tubular member is configured such that the lumen is closed in the absence of an internal force within the lumen.

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SEAL FOR A SURGICAL INSTRUMENT

The present invention relates to a seal for a surgical instrument, an in particular to a seal for sealing a shaft of a surgical instrument between a pressurised human or animal body
5 cavity and the atmosphere.

During minimally invasive surgical procedures the body cavity in which the procedure takes place is often insufflated. The insufflation causes the body cavity to be at a higher pressure than the external atmosphere. There is therefore a need to seal instruments
10 inserted into the body cavity at the interface between the body cavity and the outside atmosphere (typically the abdominal wall) to prevent loss of the insufflation gas.

Seals for use with minimally invasive surgical instruments are known. One example is the system sold under the trade name Yelloport, which is commercially available from
15 Surgical Innovations Ltd. The Yelloport system provides a trocar system with a seal. A typical seal 2 used in the Yelloport system is depicted in Figure 1. The seal 2 comprises an annular sealing member 4. Adjacent the annular sealing member 4 are two flaps 6. The flaps 6 are manufactured from a resilient material. When an instrument is not present in the seal the resilience of the flaps 6 presses them together. This creates a seal that prevents
20 insufflation gas from escaping.

When an instrument is inserted into the seal 2, it passes first through the seal 2 which forms a seal against the shaft of the instrument. As the instrument is inserted further it acts against the flaps 6 to open them and enter the body cavity. The seal 2 then prevents the
25 insufflation gas from escaping, not the flaps 6.

In order to provide sufficient resilience to form a gas-tight seal in the absence of a surgical instrument the flaps 6 are formed of a material with relatively high Shore hardness, for example a Shore hardness of 50 to 71. In addition a reasonably large amount of material
30 must be used to provide sufficient sealing in the absence of an instrument. The flaps 6 must also define a slit larger than the diameter of the instrument, so that they can be opened by inserting an instrument. These factors combine to require an increase in the size of the

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seal. It would be desirable for the seal to be smaller, particularly for use in systems where multiple instruments enter a body cavity through a single incision. The high resilience required also increases the friction on the shaft of the instrument during insertion and removal.

5

Accordingly the present invention provides a seal comprising an annular sealing member and a flexible tubular member extending from the annular sealing member. The flexible tubular member is configured to be substantially closed to the passage of gas through the seal in the absence of an internal force. Surprisingly, a flexible tubular member can still
10 form an effective valve against the passage of gas through the seal when an instrument is not present to open the tubular member. When an instrument is present the annular sealing member forms a seal on the shaft of the instrument. The tubular shape of the flexible tubular member enables the size of the seal can be reduced compared to prior art seals using flaps. A further advantage is reduced friction on insertion and removal of the
15 instrument.

According to a first aspect of the present invention, there is provided a seal for sealing an opening in a pressurised body cavity from the atmosphere, the seal comprising:

a flexible annular member; and

20

a flexible tubular member extending from to the annular member, the flexible tubular member having a first end and a second end and defining a lumen therebetween;

wherein the flexible tubular member is configured such that the lumen is closed in the absence of an internal force within the lumen

25

The flexible tubular member is configured so that the lumen is closed in the absence of a surgical instrument, which will provide an internal force to open the lumen as it is inserted. This forms a seal against gas escaping through the seal when no instrument is present.

Closure of the lumen can be accomplished in various ways, some of which are described in more detail below. In one embodiment the flexible tubular member is sufficiently flexible
30 that the higher pressure around the walls of the flexible hollow member cause it close under the pressure.

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In use with a surgical instrument, the flexible annular member provides a seal around a shaft of the instrument.

The flexible tubular member can be affixed directly to the flexible annular member. In other embodiments, such as embodiments where the seal is in a housing, it may be spaced apart from the flexible annular member, provided that the lumen follows on from the opening.

Preferably, the flexible hollow member comprises a material with a Shore hardness less than 50, more preferably less than 5. The flexible hollow member may have a thickness less than 1mm, more preferably, less than 0.15 mm.

In some embodiments, the flexible tubular member may have a frustoconical shape. The reference to a frustoconical shape should be interpreted broadly to include all forms which are generally conical or pyramid-like with a cross-sectional area decreasing along an axis. A frustoconical portion may not have smooth sides, for example the sides may include creases or pleats providing the overall cross sectional area decreases along an axis. The frustoconical shape can assist in closure of the lumen in the absence of an internal force.

In one embodiment, the valve further comprises a gas inlet port adapted for connection to a source of pressurised gas, and wherein the gas inlet port is configured to divert inflowing gas towards the outside of the flexible tubular member thereby increasing air pressure outside the lumen of the flexible tubular member. The gas inlet port can therefore provide a source of additional pressure to cause the lumen of the flexible tubular member to close.

In another embodiment, the flexible tubular member comprises a shape memory material and is shaped such that in the absence of an internal force acting outwardly on the walls of the lumen, the lumen is closed, preventing flow of gas through the lumen. This can be achieved in various ways. For example, in one embodiment a material with a preformed shape in which the lumen is closed can be used, such as a shape which is configured to roll up at the second or distal end. Various materials can be used, including shape memory polymers.

In other embodiments, the seal may further comprise a housing. The annular member is mounted at a first end of the housing. Preferably, the second end of the flexible tubular member is mounted at a second end of the housing. In this embodiment the flexible
5 tubular member is not attached directly to the annular member.

Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

- 10 Figure 1 is a diagrammatic representation of a prior art seal;
Figure 2 is a diagrammatic representation of a seal according to an embodiment of the present invention;
Figures 3A and 3B are cross sections showing diagrammatic representations of the operation of the seal of Figure 2 both with and without a surgical instrument present;
15 Figure 4 is a diagrammatic representation of a perspective view of the seal of Figure 2 without a surgical instrument present;
Figure 5 is a diagrammatic representation of a cross section of another embodiment of the present invention;
Figure 6 is a diagrammatic representation of a perspective view of a further embodiment of
20 the invention;
Figure 7 is a diagrammatic representation of a perspective view of another embodiment of the invention.

Figure 2 depicts perspective view of a seal 10 according to an embodiment of the present
25 invention shown with an open lumen for clarity. The seal 10 comprises a flexible annular member 12 and flexible hollow member 14 extending from the flexible annular member 12.

The flexible annular member 12 has an inner surface which defines an opening 16 with a
30 diameter slightly smaller than the shaft of a surgical instrument. Typical surgical instrument shaft diameters include 5mm, 10mm, 12mm and 16mm. The seal 10 can be formed in a number of different sizes and the appropriate size selected.

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Extending from and attached to the flexible annular member 12 is the flexible tubular member 14. The flexible tubular member 14 has a frustoconical shape in this embodiment. The frustoconical shape defines an internal diameter that decreases along axis 15.

5 Optionally, this can enable part of the flexible tubular member 14 to have a diameter smaller than the diameter of the instrument shaft so that a second seal can be formed with the instrument shaft. This second seal is not essential to the invention.

In this embodiment the flexible annular member 12 is made of Silicone or TPE and the
10 flexible tubular member 14 is made of Ripstop Nylon or Polythene, with a Shore Hardness of 5 or less. The flexible tubular member is 0.15 mm or less thick.

In use, the seal 10 of this embodiment will be combined with other components of a port system to provide a seal between a pressurised body cavity and the outside atmosphere.

15 For example the seal of the invention may be used with the Yelloport system. The operation of the seal will now be explained with reference to Figures 3A and 3B.

Figure 3A depicts the seal 10 with a shaft 18 of a surgical instrument in place. It can be seen how the flexible annular member 12 forms a first seal on the shaft 18, and the flexible
20 tubular member 14 forms an optional second seal on the shaft 18.

Figure 3B depicts how the seal 10 prevents gas escaping from the pressurised body cavity. The action of pressure on the outside of the flexible tubular member 14 causes it to collapse, closing the lumen within it so that gas cannot pass through the flexible hollow
25 member 14. Figure 4 is a perspective view of the seal in this closed state.

Figure 5 depicts another embodiment of a seal 20 according to the present invention. It shows a diagrammatic cross section of the seal 20 with a shaft 21 of a surgical instrument in place. The construction is the same as the first except as described below. In this
30 embodiment the flexible tubular member 22 is not directly attached to the flexible annular member 24. This embodiment further comprises a housing 26, which to which both the flexible annular member 24 and the flexible tubular member 22 are attached.

In this embodiment both first and second ends of the flexible tubular member 22 are attached to the housing 26. In order for the second end to be attached to the housing 26 the flexible tubular member comprises an additional portion as well as the frustoconical
5 portion of reducing diameter.

So that the flexible tubular member can still close under the action of air pressure additional material must be provided given that both first and second ends are attached to the housing and held open. This additional material is depicted by the undulations in the
10 flexible tubular member 22 visible in Figure 5 and may be provided by pleating or folding the flexible tubular member 22.

Figure 6 depicts a diagrammatic representation of a further embodiment of the invention, which is the same as the first except as described below. Here the flexible tubular member
15 28 is formed into a shape which closes the lumen in the flexible tubular member 28. When no shaft is present the material properties of the flexible tubular member 28 cause it to assume a closed shape, such as the partially rolled up shape shown in Figure 6. When a surgical instrument shaft is present in the seal, the flexibility of the flexible tubular member 28 causes it to unroll and the lumen to open.

20

Figure 7 depicts a diagrammatic representation of a further embodiment of the invention, which is the same as the first except as described below. In this embodiment the flexible tubular member 30 defines a tube of substantially constant diameter. As depicted in Figure
7 the tubular member 30 is shown in an open position for clarity. However, the tubular
25 member 30 of this embodiment is configured to close in the absence of an internal force using any of the methods described in conjunction with other embodiments.

In other embodiments (not illustrated) the seal may further comprise a port for a gas supply. The gas flow through the port can be configured to increase the air pressure
30 around the outside of the flexible tubular member, assisting its closure.

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Thus, the present invention provides a seal which can have a reduced profile because of the use of a flexible tubular member. This can still form an effective seal and allows the use of material with a lower Shore hardness and consequent smaller size of the seal. An additional advantage is reduced friction during inserting and removal of a surgical
5 instrument.

CLAIMS

1. A seal for sealing an opening in a pressurised body cavity from the atmosphere,
5 the seal comprising:
a flexible annular member; and
a flexible tubular member extending from the flexible annular member, the
flexible tubular member having a first end and a second end and defining a lumen
therebetween;
10 wherein the flexible tubular member is configured such that the lumen is closed in
the absence of an internal force within the lumen.
2. A seal according to claim 1, wherein the flexible tubular member comprises a
material with a Shore Hardness less than 5.
15
3. A seal according to claim 1 or 2, wherein the flexible tubular member has a
thickness less than 0.15 mm.
4. A seal according to claim 1, 2 or 3, wherein the flexible tubular member has a
20 frustoconical shape.
5. A seal according to any one of the preceding claims, wherein the valve further
comprises a gas inlet port adapted for connection to a source of pressurised gas, and
wherein the gas inlet port is configured to divert inflowing gas towards the outside of the
25 flexible tubular member thereby increasing air pressure outside the lumen of the flexible
tubular member.
6. A seal according to any one of the preceding claims, wherein the flexible tubular
member comprises a shape memory material and is shaped such that in the absence of an
30 internal force acting outwardly on the walls of the lumen, the lumen is closed, preventing
flow of gas through the lumen.

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7. A seal according to claim 6, wherein the flexible tubular member is configured to partially roll up at its distal end.

8. A seal according to any one of the preceding claims, further comprising a housing
5 and wherein the annular member is mounted at a first end of the housing and the second
end of the flexible tubular member is mounted at a second end of the housing.

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FIG. 1

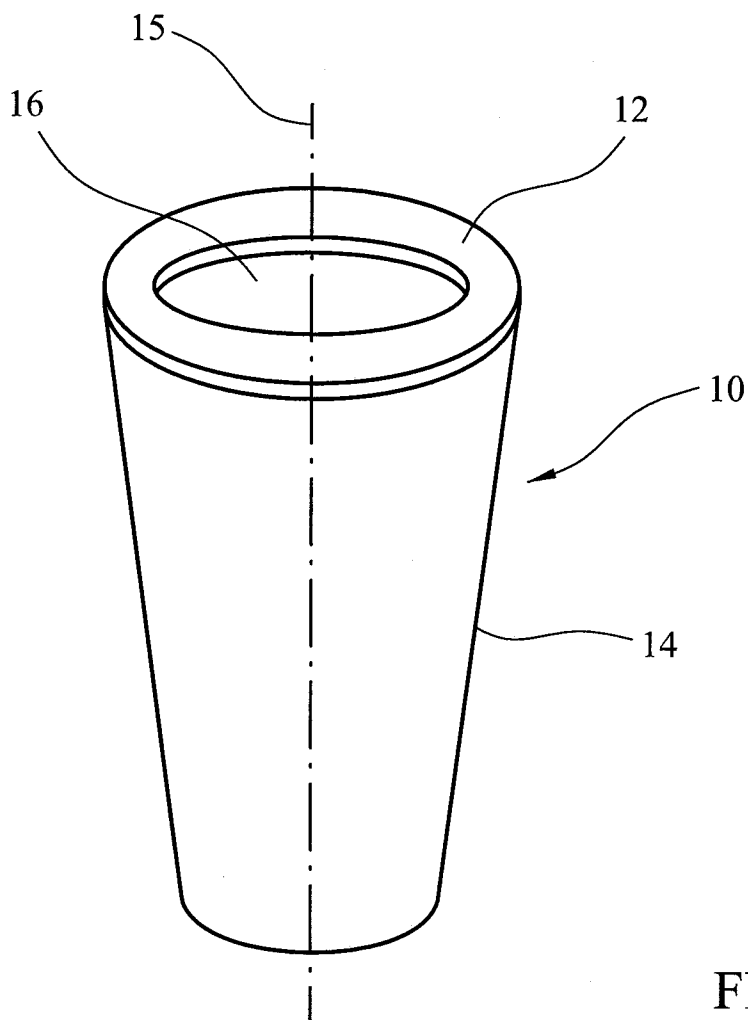
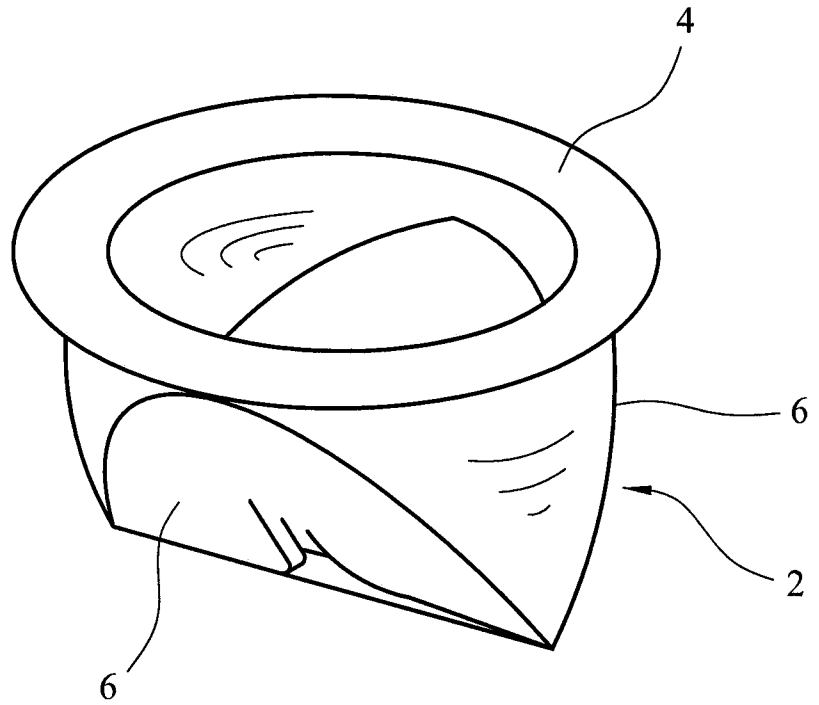


FIG. 2

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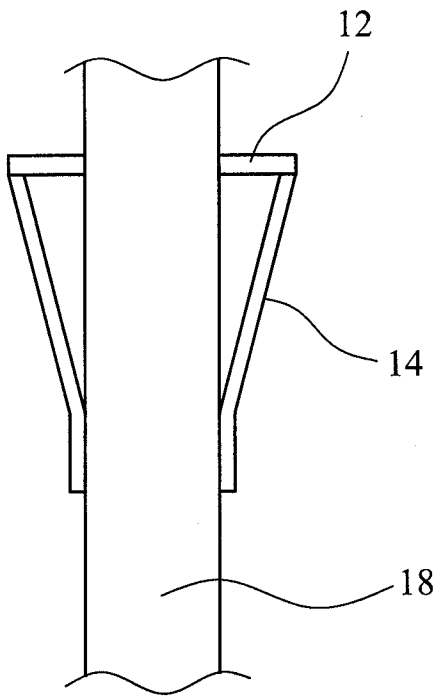


FIG. 3A

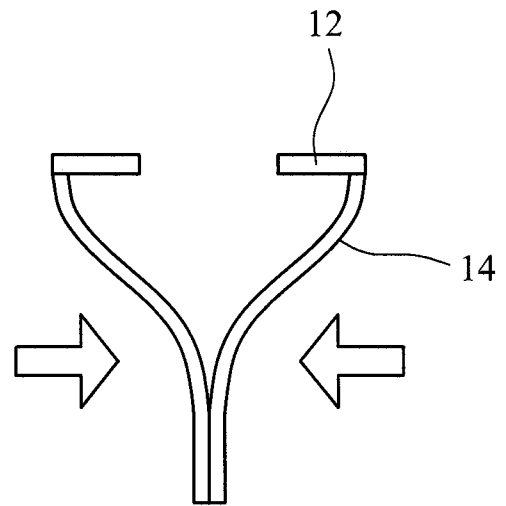


FIG. 3B

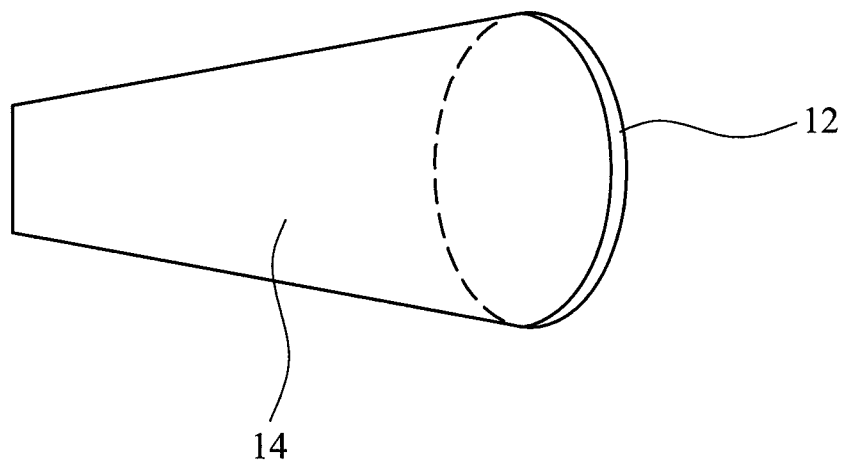


FIG. 4

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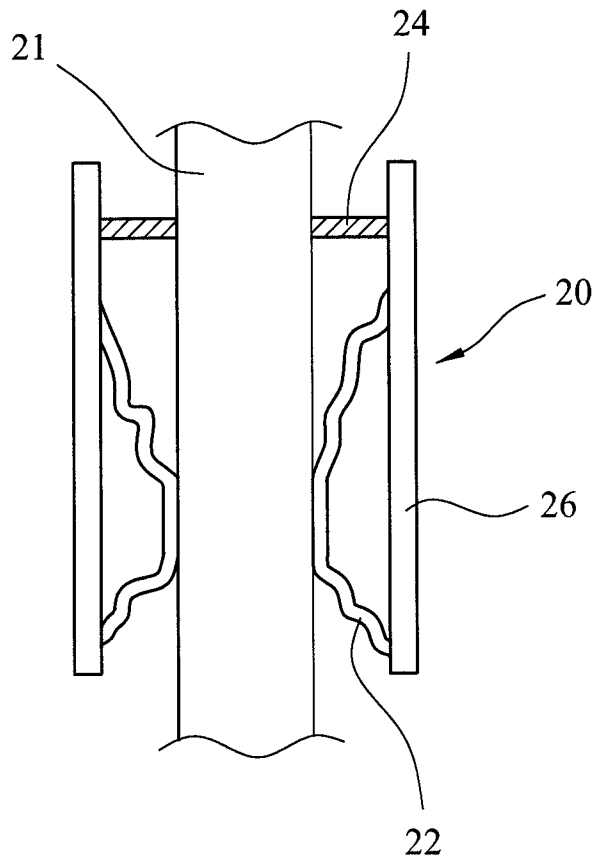


FIG. 5

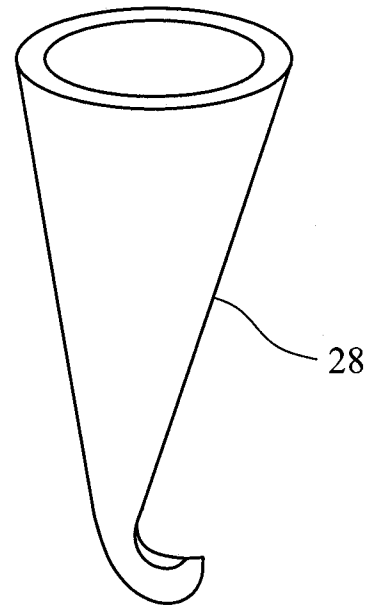


FIG. 6

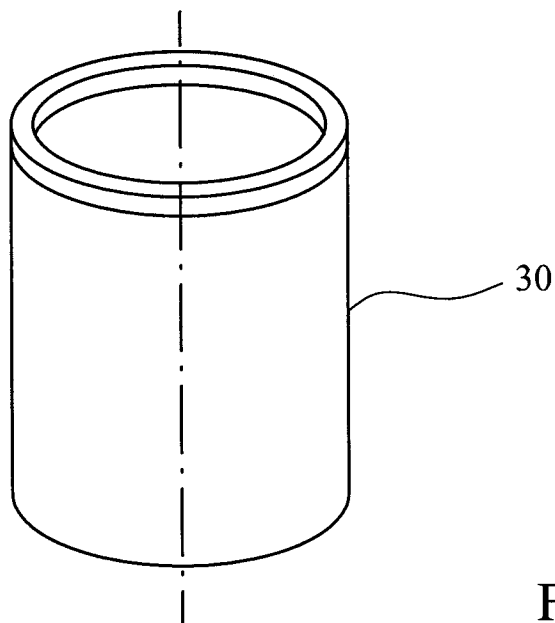


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2011/050913

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/34
ADD.

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)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 2008/171988 A1 (BLANCO ERNESTO E [US]) 17 July 2008 (2008-07-17) figures 5,13	1-4,8
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X	US 5 662 615 A (BLAKE III JOSEPH W [US]) 2 September 1997 (1997-09-02) figures 4-6	1-3,8
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Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"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

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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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Information on patent family members

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