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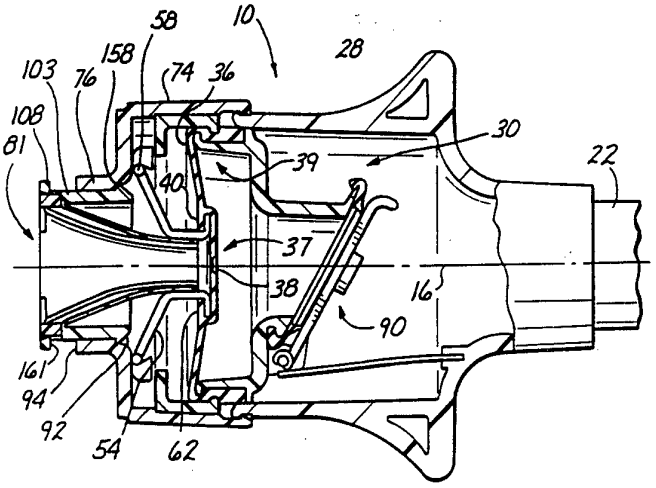
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(54) Title: PROTECTION FOR SEPTUM SEAL OF A TROCAR



(57) Abstract

A trocar (10) having a cannula (22) and housing (28) which define an access channel, is configured to receive a surgical instrument (26). A flexible valve (36) disposed in the channel includes first portions (37) which define an orifice (38) through the valve (36) and second portions (39) which are disposed outwardly of the first portions. The second portions (39) are provided with a greater flexibility so that when the instrument (26) is inserted off axis, the second portions (39) of the valve (38) will deform before the first portions (39) causing the orifice (38) to move without substantial deformation, to the off axis location. Alternatively, levers (54) engaging the first portions (37) of the valve (35) can be pivotally mounted on a floating ring (180) to move the substantially undeformed orifice (38) to the off axis location. An associated method includes the steps of deforming the second portions (30) of the valve (36) without substantially deforming the first portions (37) of the valve (36) to move the orifice (38) into axial alignment with the instrument (26). A mechanism (81) is provided for protecting the valve (36) from instruments having pointed distal tips.

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PROTECTION FOR SEPTUM SEAL OF A TROCAR

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to access devices, such as trocars, and more specifically to access devices including at least one septum valve.

Discussion of the Prior Art

Laparoscopic surgery is conducted through trocars which extend across the abdominal wall and provide channels through which instruments such as scopes, retractors and staplers can be inserted to perform surgery in the abdominal cavity. As a part of this procedure, the abdomen is inflated with an insufflation gas to maintain the abdomen in a distended state. Valves are typically provided in the trocars to form seals around the instruments in order to prevent leakage of this insufflation gas. A variable diameter septum valve is of particular advantage for this purpose as it is able to conform to any size of instrument, regardless of its diameter, without increasing the friction or drag on the instrument. A variable diameter septum valve of this nature is disclosed and claimed by applicant in the parent application Serial No. 07/732,144, filed on July 18, 1992 and entitled Lever Actuated Septum Seal.

Variable diameter seals have a high degree of compliance which is of particular advantage in accommodating different sizes of instruments. However, this compliance can present a problem if a particular instrument is bifurcated or is inserted off center. Under these circumstances, the sharp point of the instrument can localize forces along the side of the valve providing undesirable cupping and perhaps tearing of the seal. This can occur with any septum seal, although the highly compliant variable diameter seals appear to be most susceptible to damage.

The off-axis insertion of an instrument can also be a problem once the instrument extends through the orifice of the septum valve. If this orifice is pulled off-axis, it tends to develop a "cat-eye" which degrades the seal around the instrument and permits for undesirable leakage.

SUMMARY OF THE INVENTION

In accordance with the present invention, a protection mechanism has the configuration of a funnel extending along the axis of the trocar. In one embodiment, this mechanism engages the instrument in an extended position but is movable with the instrument distally axially into close proximity with the septum valve. In this distal position, the mechanism extends between the instrument and at least the outer portions of the seal. In a preferred embodiment, the mechanism actually extends through an aperture in the seal as the instrument passes through an aperture. When forward pressure on the instrument ceases, the elastomeric characteristics of the seal radially compress the protection mechanism and tend to move it rearwardly to its initial proximal position. This movement can be assisted by a slight withdrawal of the instrument if necessary.

With the protection mechanism disposed in the proximal position, the septum valve is free to form a seal with the instrument.

This seal mechanism is effective in trocars having any form of septum valve, although it is particularly valuable where the septum valve is highly compliant as is the case with a variable diameter seal. The lever arms which are normally associated with a variable diameter seal can actually assist in radially spreading the valve during insertion of the instrument, and in returning the mechanism to the proximal position when the instrument has been operatively positioned.

In one aspect the invention includes an access device having an axis extending between the proximal end and an opposing distal end, and properties facilitating introduction into the body of an instrument having a sharp distal tip. The device includes a housing having walls defining a channel and a septum valve disposed across the channel to form a seal with an instrument extending through the channel. The valve includes inner portions defining an aperture and outer portions extending radially outwardly of the inner portions. Means is disposed between the instrument and at least the outer portion of the seal for isolating the seal from the sharp distal tip of the instrument.

The present invention also includes the concept of a floating septum seal which provides for movement of the septum orifice to an off-axis position without deformation. Thus the inner portions which define the orifice are moved substantially intact so that the orifice does not change from its circular configuration as it moves laterally to accommodate the off-axis insertion of an instrument. In

one embodiment, the septum valve is formed with outer portions having a reduced resiliency compared to the that of the inner portions which define the orifice. This encourages the outer portions to deform first pulling the inner portions substantially undeformed to an off-axis position.

In another embodiment, lever actuators are pivotally mounted on a ring which floats in an enlarged annular recess. When an instrument is inserted off-axis, the lateral force on the levers moves the inner portions of the valve laterally but undeformed as the outer portions are stretched.

In another aspect of the invention, a trocar is adapted to form an access channel across a body wall and configured to receive a surgical instrument. The trocar includes a cannula having an axis with a seal housing disposed at the distal end of the cannula and defining with the cannula the access channel. A flexible valve is disposed across the access channel and provided with elastomeric properties for forming a seal with the instrument. First portions of the valve define an orifice which is normally concentric with the axis of the cannula. Second portions of the valve disposed circumferentially outwardly of the first portions facilitate movement of the orifice from a first position generally concentric with the axis of the cannula to a second position generally removed from the axis of the cannula in response to insertion of the instrument along a line removed from the axis of the cannula.

These and other features and advantages of the invention will be more apparent with a discussion of

preferred embodiments and the best mode of the invention, taken in combination with the associated drawings.

DESCRIPTION OF THE DRAWING

Fig. 1 is a side elevation of a trocar assembly operatively positioned to penetrate a tissue barrier;

Fig. 2 is an axial cross-section view of the trocar, showing details of a variable diameter septum valve assembly prior to insertion of a surgical instrument therein;

Fig. 3 is an axial cross-section view similar to that of Fig. 2, showing details of the same embodiment of the trocar valve assembly during insertion of the surgical instrument;

Fig. 4 is a side elevation view of a trocar extending across the abdominal wall and including one embodiment of a seal protection mechanism of the present invention;

Fig. 5 is a side elevation view of a trocar of the prior art illustrating a cupping problem associated with some instruments;

Fig. 6 is an axial cross-section view of a trocar and a further embodiment of the seal protection mechanism of the present invention;

Fig. 7 is an axial cross-section view similar to Fig. 3 illustrating the seal protection mechanism in a distal position as the instrument is being inserted into the trocar;

Fig. 8 is an axial cross-section view illustrating the instrument slightly retracted to return the protection mechanism to a proximal position;

Fig. 9 is an end view of one embodiment of the seal protection mechanism;

Fig. 10 is an axial cross-section view of the seal protection mechanism of Fig. 9;

Fig. 11 is an end view of the seal protection mechanism similar to Fig. 10 but illustrating an instrument extending through the mechanism as illustrated in Fig. 8;

Fig. 12 is a side-view partially in phantom of the trocar and a floating septum valve of the present invention;

Fig. 13 is a radial view taken along lines 13-13 of Fig. 12; and

Fig. 14 is a radial cross-section view similar to Fig. 12 and illustrating the septum valve with its undeformed orifice displaced off-axis.

DESCRIPTION OF PREFERRED EMBODIMENT AND BEST MODE OF THE INVENTION

A surgical trocar is illustrated in Figure 1 and designated generally by the reference numeral 10. The trocar 10 is representative of any elongate access device having a distal end 12 and a proximal end 14. It is

typically configured along a longitudinal axis 16 and is generally circular in radial cross-section.

It is the purpose of the trocar 10 to form a channel through a tissue barrier in order to provide access across the barrier into a body cavity. By way of example, the tissue barrier may include an abdominal wall 18 which defines an abdominal cavity 20. The trocar 10 typically includes an elongate tube or cannula 22 having a cylindrical configuration and a wall thickness which may be on the order of .015 or .030 inches. The cannula 22 has an interior bore or channel 24 which may have a diameter in a range between 5 and 12 millimeters. The trocar 10 is designed to pierce, cut, incise, or otherwise puncture the tissue barrier, such as the abdominal wall 18, and to leave the cannula 22 extending through the incision. An elongate surgical instrument 26 is representative of various cutters, clamps, traction devices, visualization devices, aspirators and irrigators as well as other types of instrument, which have different diameters. In operation, the instrument 26 is positioned through the channel 24 of the trocar 10 and manipulated to perform a particular surgical procedure within the cavity 20.

The trocar 10 includes a valve housing 28 which encloses a valve mechanism 30 such as that shown in Figures 2-4. These figures illustrate the trocar 10 at a point in time after it has been inserted through the abdominal wall 18 leaving the cannula 22 to provide access to the abdominal cavity 20.

The valving mechanism 30 includes a septum valve 36, which is preferably molded from an elastomeric material such as C-flex®, a low durometer polymer manufactured by Concept Polymer Technologies. This material is chosen for

its high degree of compliance which makes it particularly adaptable to instruments having different diameters. Of course, other known elastomeric materials could be used instead to accomplish the objectives of the invention.

The valve 36, which is characterized as a septum valve, is deemed to include any valve which has properties for radially compressing against the outer surface of an instrument, such as the instrument 26. Included in this definition without limitation is the valve disclosed and claimed in applicant's U. S. Patent No. 5,127,626, issued on July 7, 1992, and entitled Apparatus for Sealing Around Members Extending Therethrough, which is incorporated herein by reference.

The septum valve 36 includes inner portions 37 which define a central orifice or aperture 38 that is preferably centered about the axis 16 of the trocar 10. The aperture 38 in a relaxed state has a cross-sectional area which, in one embodiment may be substantially zero, and in a different embodiment may be small, but greater than zero. The septum valve 36 also includes outer portions 39 which extend radially outwardly from the inner portions 37.

In the illustrated embodiment, the septum valve 36 also includes an annular flange or lip 40 which is preferably concentric with the aperture 38 and may be disposed in either the inner portions 37 or outer portions 39. The septum valve 36 in the illustrated embodiment also includes seating portions 46 which are clamped between the valve housing 28 and a transition housing 52.

A plurality of levers 54 are disposed outwardly of the elongate axis 16, in such a manner as to define a continuation of the channel 24. In a preferred embodiment,

four such levers 54 are provided, but any number of levers could be employed, with suitable modifications in design.

Each lever 54 can be mounted on a pivot 58 at its proximal end 60, with the pivotal axis being transverse to the elongate axis 16. At least one tooth member 62 can be provided at a distal end 64 of each lever 54. This tooth member 62 is adapted to engage and interlock with the lip 40. In the illustrated embodiment, the lever teeth 62 collectively form a substantially circular tooth member which engages the circular lip 40 about it circumference. Between the pivot point 58 and the tooth member 62, each of the levers 54 extends radially inwardly to define a throat 66 of the channel 24. An open space 68 lies radially outwardly of both the levers 54 and the annular flange or lip 40, within the valve housing 28. This space 68 accommodates outward expansion of the levers 54 and the septum valve 36.

In operation, it may be desired to insert the surgical instrument 26 through the channel 24 and into the body cavity 18. To do so, the instrument 26 is first inserted into the valve housing 28 as shown in Figure 3. The instrument 26 has a particular cross-sectional diameter which may vary according to the type of instrument, but it must be greater than the radial distance separating the levers 54 in order for the levers 54 to be actuated.

As the instrument 26 is pushed into the throat 66 of the channel 24, it pushes the levers 54 radially outwardly, thereby rotating the levers about their respective pivots 58. This moves the tooth members 62 of the lever 54 radially outwardly, as shown by the arrows 67 in Figure 3. The engaging relationship between the lever teeth 62 and the lip 40 expands the lip radially outwardly thereby expanding the diameter of the aperture 38.

The leverage provided by the levers 54 is best illustrated again by reference to Figure 3, where it can be seen that the lever arm for measuring the diameter of the instrument 26 is less than the lever arm for spreading the lip 40. The expansion of the lip 40 in turn stretches the septum 36, causing the radial width of the aperture 38 to be expanded, as shown by the arrows 67. The aperture is preferably expanded to a cross-sectional diameter which is slightly smaller than the cross-sectional diameter of the instrument 26. This will enable the instrument 26 to pass easily through the aperture 8 while the valve 36 engages the instrument with a force sufficient to create a seal. With the valve 36 prestressed by the levers 54, this sealing force will not create significant frictional resistance between the instrument 26 and the septum 38. Such resistance is to be avoided since it not only opposes forward movement of the instrument 26, but also tends to tear the valve 38.

Of particular interest to the present invention is an embodiment illustrated in Figure 4 wherein the trocar 10 is provided with a proximal end cap 74 which can be held in a snap fit relationship with the valve housing 28. This end cap 74 includes an annular flange 76 which extends axially proximally of the trocar 10. This flange 76 is adapted to receive a seal protector 81 which is of particular interest to the present invention.

The protector 81 is movable axially within the flange 76 between a proximal position illustrated in Figure 4 and a distal position discussed in greater detail below. This protector 81 is particularly advantageous when the trocar 10 is used in conjunction with an instrument 26 having sharp points at its distal tip. Such an instrument 26

might include a clip applier having a bifurcated distal end with pointed tips 83.

Use of such an instrument 26 with previous trocars has been particularly damaging to the septum valves of the prior art as can be appreciated with reference to Figure 5. When instruments having pointed tips have been inserted into the trocars of the prior art, the tips have sometimes engaged the septum valve outwardly from the central orifice or aperture. Preferably, the valve would spread radially under these conditions so that the instrument would eventually pass through the central aperture. However, in some cases, the valve 36 has been formed from sufficiently compliant material that it has tended to form a cup such as that shown generally at 85 in Figure 5. When this happens, the localized pressure caused by the insertion forces has typically punctured or torn the septum 36.

Although cupping is most commonly associated with instrument having bifurcated tips, the problem can occur with any type of instrument having a pointed tip. Also, cupping can result with any type of septum valve although the highly compliant variable diameter valves, such as valve 36, previously discussed appear to be most susceptible.

It is the purpose of the seal protector 81 to isolate the outer portions 39 of the septum valve 36 from damaging contact with a pointed instrument tip, such as the tip 83. For the purposes of this discussion the inner portions 37 and outer portions 39 of the valve 36 are separated based on the response of a particular valve 36 to a pointed tip 83. If the tip 83 contacts the valve 36 at a point on the valve 36 where cupping would occur, this point is deemed to be within the outer portions 39. In contradistinction, if the pointed tip 83 of an instrument 26 contacts the valve

36 at a point on the valve which would not produce cupping, that point is deemed to be within the inner portions 37. Thus the inner portions 37 and outer portions 39 will vary for different septum valves 36 depending upon the shape and material of the valve 36 as well as the configuration of the tip 83 of the instrument 26. The compliance of the material forming the valve will be a primary consideration, but other physical characteristics of the valve 36 may also contrtibute to cupping at a particular point on the valve 36.

The invention is illustrated in greater detail in Figure 6 which differs from previously described embodiments in several respects. In the embodiment of Figure 6, the valving mechanism 30 includes not only the septum valve 36 but also a flapper valve 90 which is of no particular interest to the present invention.
Although the levers 54 are illustrated to have a more narrow configuration, they still rotate on the pivots 58 and include the tooth members 62. The septum valve 36 has a different configuration, but it also extends across the channel 24 and includes the inner portions 37 which define the aperture 38 and the outer portions 39 which form a seal with the housing 28. In this detailed view of Figure 6, it is apparent that the annular flange 76 of the end cap 74 includes an inner shoulder and an outer surface 94.

The seal protector 81, which is mounted on the trocar 10 in Figure 6, is shown in an enlarged isolated view in Figure 10. This enlarged view illustrates an embodiment, wherein the seal protector 81 is formed in two sections. A distal section 101 has an outer cylinder 103 and a pair of integral outer leaves 105 and 107. The distal section 101 also includes an integral annular flange 108 which extends radially outwardly and defines with the cylinder 103 a pair of windows 109. The outer leaves 105 and 107

include funnel portions 110 and 112, respectively, which extend radially distally inwardly from the cylinder 103. The leaves 105 and 107 also include distal portions 114 and 116, respectfully, which may also have the configuration of a cylinder.

A proximal section 121 of the seal protector 81 also includes an outer cylinder 123 and a pair of integral inner leaves 125 and 127 (Figure 9). These leaves 125 and 127 are configured similar to the leaves 105 and 107. Thus the inner leaf 125 includes a funnel section 130 and a distal section 132 while the inner leaf 127 includes a funnel section 134 and a distal section 136. These two sections of the seal protector 81, the distal section 101 and the proximal section 121, are intended to be disposed in fixed relationship with the inner leaves 125, 127 disposed inwardly of the outer leaves 105, 107. This fixed relationship between the
distal section 101 and the proximal section 121 can be accomplished by bonding alternatively the outer cylinder 123 of the proximal section 121 can be provided with a pair of snap flanges 145 which are configured to seat in the windows 129.

The outer leaves 105 and 107 are separated by a radial slot 141 which permits these leaves to be individually moved in opposite directions as the instrument 26 is inserted. In a similar manner, the inner leaves 125 and 127 are separated by a radial slot 143 which is disposed transverse, perpendicular in a preferred embodiment, to the slot 141.

The seal protector 81 is preferably molded from a strong, tough material. In a particular embodiment, characteristics facilitating formation of a living hinge or

a lubricious surface may also be of interest. Based on these considerations, materials such as high density polyethylene, Hytrel (a trademark of DuPont), and Valox (a trademark of General Electric) might be considered. The Valox material was chosen for a preferred embodiment.

Depending on the flexibility of the respective leaves 105, 107, 125, and 127, it may be desirable to extend the respective slots 141 and 143 circumferentially along the line which joins the respective leaf to its associated cylinder 103, 123. In Figure 9 an extension of the slot 141 is designated by the reference numeral 147; an extension of the slot 143 is designated by the reference numeral 149. With the provision of these circumferential slot extensions 147, 149, the leaves 105, 107 and 125, 127 are free to pivot on the remainder of the circumferential structure which functions as a living hinge.

These living hinges are best illustrated in Figure 11 and designated by the reference numerals 152 and 154 for the respective leaves 105 and 107. This end view of Figure 11 also illustrates the configuration of the seal protector 81 with the instrument 26 inserted. The accommodating separation of the respective leaves 105, 107 and 125, 127 is apparent from this view.

The seal protector 81 disclosed in these Figures 9-11 is illustrated in Figure 6 mounted to the proximal end of the trocar 10. As illustrated, the protector 81 is preferably mounted co-axially with the aperture 38 with the leaves 105, 107 and 125, 127 functioning as a funnel to guide the instrument 26 toward the aperture 38. In this location, the protector 81 in a preferred embodiment is movable axially between a proximal position, illustrated in Figure 6, and a distal position illustrated in Figure 7.

These respective positions are defined by interlocking parts of the protector 81 and the annular flange 76 of the end cap 74.

In one embodiment, the cylinder 103 is provided with an annular snap ring having a proximally facing shoulder 158. The cylinder 108 has a distally facing surface 161. In this case, the protector 81 is preferably mounted with the cylinder 103 disposed in sliding engagement with the annular flange 76. The shoulder 158 and surface 161 are separated an axial distance greater than the axial length of the flange 76. This permits the protector 81 to move axially between the proximal and distal positions. In the proximal position, illustrated in Figure 6, further proximal movement of the protector 81 is prevented by contact between the shoulder 92 on the flange 76 and the shoulder 158 on the cylinder 103. In the distal position, illustrated in Figure 7, further distal movement of the protector 81 is prevented by contact between the surface 161 of the flange 108 and the surface 94 of the flange 76.

In operation, the instrument 26 is inserted into the funnel formed by the protector 81. As the instrument contacts the inner leaves 125, 127, it moves the protector 81 to the distal position. In this location, the leaves extend between the pointed points 83 of the instrument 26 and the outer portions 39 of the septum valve 36. In a particular embodiment, the distal sections 114, 116 and 132, 136 may actually contact the proximal side of the septum valve 36 although this is not required by the present invention. Nevertheless, this contact is encouraged as it permits the protector 81 to actually engage the septum valve 36. Then as the instrument 26 is further inserted and the leaves 105, 107 and 125, 127 expand radially outwardly, they will also spread the inner

portions 37 of the valve 36, thereby enlarging the aperture 38.

In the embodiment illustrated in Figure 7, the distal sections 114, 116 and 132, 136 of the leaves actually extend into the aperture 38 in the distal position. This insures that the aperture 38 is spread at least as far as the leaves of the protector 81. In this case, the protector 81 extends between the instrument 26 and all portions of the septum valve 36.

Once the instrument 26 is in place, it is important that the valve 36 be permitted to engage the outer surface of the instrument in order to form the desired seal and prevent the escape of insufflation gasses. In a particular embodiment, this will require that the seal protector 81 be separated from the septum valve 36 for example by returning the protector 81 to the proximal position.

This movement of the protector 81 from the distal position to the proximal position may occur automatically when the instrument is in place and the protector 81 is no longer subjected to insertion forces. In such an embodiment, the automatic return of the protector 81 would result from the elastomeric forces of the septum valve 36 which compress the leaves 105, 107 and 125, 127 radially inwardly. This compression may result from contact between the valve 36 and the leaves, or contact between the levers 54 and the leaves.

In order to facilitate this movement of the protector 81 from the distal position to the proximal position, it may be advantageous to withdraw the instrument 26 slightly to produce a force on the leaves 105, 107 and 125 and 127 in the proximal direction. This movement of the protector

81 to the proximal position is illustrated in Figure 8 where the feature of automatic retraction is enhanced by the slight movement of the instrument 26 in the direction of arrow 163.

There are many variations on this concept of seal protection which will be apparent to those skilled in the art. Certainly different materials could be used for the protector 81 which could also be formed from more than the two sections 101 and 121. An embodiment including a different number of the leaves 105, 107 and 125, 127 may offer certain advantages in other configurations. It is also particularly advantageous if the protector 81 can protect the valve 36 during insertion of the instrument 26, but also permit the valve 36 to form a seal with the instrument when it has achieved its ultimate position. While these features may be available in an embodiment providing for axial movement of the protector 81, such movement may not be required in other embodiments of the invention.

The septum valve 36, illustrated in Figure 2 and 3, is of particular interest due to the floating characteristics provided by the outer portion 39. These characteristics are further described with reference to Figure 12. In this figure both the cannula 22 and the housing 28, are illustrated along with the septum valve 36. The annular lip 40 which defines the central orifice of 38, and the seating portion 46 which circumferentially attaches the septum 36 to the housing 28, are also shown in this view. In the radial cross section of Figure 12, the letter "A" designates a point on the lip 48 which defines the orifice 38. The reference letter "B" designates a point on the seating portion 46.

The instrument 26 is also illustrated in Figure 12 but with its axis 170 offset from the normal axis 96 of the orifice 38, as well as the axis 16a of the cannula 22. This offset of the instrument 26 is also shown in the radial cross section view of Figure 13. From this view it will be apparent that the function of the floating outer portions 39 of the septum 36 is based primarily on the configuration of the septum between the orifice 38 and the seating portion 46. This region is further defined as the region between the reference points "A" and "B" in the axial view of Figure 12, and the region A-B between the reference circles "A" and "B" in the radial view of Figure 13.

Within this region A-B, the outer portions 39 have a resiliency which is reduced relative to that of the inner portions 37. In general this means that the outer portions 39 offer less resistance to movement in a radial direction than do the inner portions 37 which define the orifice 38. As a practical matter, this difference in the resiliency of the inner portons 37 and the outer portions 39 means that an instrument, such as the instrument 26, which is inserted off-axis as illustrated in Figures 12 and 13, will tend to deflect the outer portions 39 before it deflects the inner portions 37. In a particular embodiment, the reduced resiliency of the outer portions 39 may be characterized as a higher elasticity or higher flexibility than that of the inner portions 37. The result to be greatly appreciated is that the inner portions 37 can move off-axis without deforming the orifice 38. In this off-axis location, the orifice 38 maintains its generally circular configuration without producing the "cat-eye" effect which would result

otherwise in a leak between the instrument 26 and the septum 36.

As used herein the term "off-axis", when applied to the instrument 26, means that the axis 94 of the instrument 26 is removed from the axis 16 of the cannula 22. When the term is applied to the septum 36, it means that the axis 96 of the orifice 38 is removed from the axis 16a of the cannula 22.

The region A-B, which has a reduced resiliency relative to the lip 40, can be embodied in many different forms. For example, the septum 36 can be formed with different rings of material, one ring for the inner portions 37 and another ring for the outer portions 39. In such an embodiment (not shown) the ring associated with the outer portion 39 can be formed from a material having increased elastomeric properties relative to the material forming the ring of the inner portions 37.

In the form illustrated in Figures 12 and 13, the reduced resiliency of the outer portion 39 is provided by an excess of material between the circles "A" and "B". This excess of material enables the inner portions 37 to easily move off axis without deforming the associated orifice 38.

This excess of material in the region A-B can best be defined with reference to Figure 12. In this figure, the excess of material in the region A-B is illustrated by the septum 36a having a radial length between the reference points "A" and "B", which is greater than the radial distance between the points "A" and "B". When there is an

excess of material, the ratio of this radial length to radial distance is greater than one. While this excess of material will generally be disposed in a uniform circular configuration around the orifice 38, the reduced resiliency could vary around the circumference of the septum 36 in order to encourage off-axis movement of the orifice 38a in a particular direction.

In a further embodiment, the region A-B of reduced resiliency could also be formed by a reduction in the thickness of the septum 36a. With a reduced thickness of material, the region A-B would be more easily stretched than the inner portion 37. The same effect would result, namely the inner portion 37 would move off-axis without significantly deforming the orifice 38.

As the orifice 38 moves off-axis as illustrated in Figure 14, the region A-B of reduced resiliency functions in two manners. That portion of the region A-B which is disposed in the direction of orifice movement, shown by an arrow 180, is placed in compression. In an embodiment providing an excess of material, this compression at the arrow 180 tends to gather the material thereby offering no resistance to the movement of the orifice 38. At the same time, that portion of the region A-B which is disposed away from the direction of orifice movement, shown by an arrow 182, is placed in tension. In an embodiment providing an excess of material, this tension at the arrow 182 merely tends to unfold the material thereby offering substantially no resistance to movement of the inner portions 37 and the associated orifice 38.

The concept of a floating seal is also included in the embodiment of Figure 6. In this case, the levers 54 which actuate the septum valve 36 are pivotally attached to a floating ring 180 at the pivots 58. This ring 180 has a diameter which is less than that of an annular recess 182 within which it is free to float.

If the instrument 26 is inserted off-axis, as illustrated in Figure 12, it contacts the side of the seal protector 81 which transfers that off-axis force to the levers 54. Since the levers 54 float with the ring 180, they tend to move off-axis carrying the inner portions 37 of the septum valve 36 with them. This stretches the outer portions 39 which are away from the direction of movement and compresses the outer portions 39 which are in the direction of the movement. During this process, the inner portions 37 which are supported on the tooth members 62 of the levers 54 are entirely isolated from the off-axis, deflection forces. This isolation automatically occurs with the floating characteristics of the ring 180. Again in this embodiment, the resiliency of the outer portions 39 is less than that of the inner portions 37 because of the force isolation provided by the levers 54. This same concept of a floating ring would also be present in an embodiment which did not include the seal protector 81. Thus in the absence of a seal protector 81, the instrument would immediately contact the levers 54 supported on the ring 180 and thereby provide the desired deformation of the outer portions 38 without deforming the inner portions 37.

Again the advantages of a floating septum seal are apparent in these embodiments where an instrument, such as the instrument 26, which is inserted off-axis, is

accommodated without deformation of the inner portions 37 which define the orifice 38. As a result, the orifice 38 moves off-axis toward the instrument 26 without deformation. Even in this off-axis position, the orifice 38 maintains a configuration which optimizes the seal characteristics with the instrument without generating the cat-eye effect.

This concept of a floating septum seal can be embodied in many forms all providing for the undeformed movement of the orifice 38 away from the axis 96 of the trocar 10. Several of these embodiments have been disclosed herein, but many others will now be apparent to those skilled in the art. Given these wide variations within the scope of this concept, one is cautioned not to restrict the invention to the embodiments which have been specifically disclosed and illustrated, but rather encouraged to determine the scope of the invention only with reference to the following claims.

TROCAR WITH FLOATING SEPTUM SEAL AND PROTECTION THEREFOR

CLAIMS

1. An access device having an axis extending between a proximal end and an opposing distal end, and properties for facilitating introduction into the body of an instrument having a pointed distal tip, the device comprising:

a housing having walls defining a channel extending through the device;

a valve disposed in the housing across the channel and adapted to form a seal around the instrument when the instrument is inserted into the channel;

the valve including inner portions defining an aperture to receive the instrument and outer portions extending radially outwardly of the inner portions; and

means carried by the housing is positioned to be disposed between the instrument and at least the outer portion of the seal for isolating the seal from the pointed distal tip during insertion of the instrument.

2. The device recited in Claim 1 wherein the isolating means includes:

at least one leaf of material disposed in juxtaposition to the valve and positioned to engage the pointed distal tip of the instrument upon insertion of the instrument into the channel, the material of the leaf having a compliance less than that of the valve in order to distribute the insertion forces and prevent tearing of the valve.

3. The device recited in Claim 1 wherein:

the isolation means is movable with the instrument between a distal position wherein the isolation means extends between the instrument and at least the outer portion of the valve, and a proximal position removed from the distal isolation means is displaced from the valve and the valve is free to form a seal around the instrument.

4. The device recited in Claim 3 wherein the isolation means in the first position is disposed to extend through the hole in the valve.

5. The device recited in Claim 1 wherein the isolation means includes a plurality of leaves overlapping to form an expandable funnel.

6. The device recited in Claim 5 wherein the funnel is axially movable with the instrument from a proximal position to a distal position in proximity to the hole in the valve.

7. An access device having an axis extending between a proximal end and a distal end, and properties for facilitating the introduction into the body of an instrument having a pointed distal tip, the device comprising:

a housing having walls defining a channel through the device;

a septum valve disposed in the housing across the channel and adapted to form a seal around the instrument when the instrument is inserted into the channel;

inner portions of the valve defining an aperture to receive the instrument;

outer portions of the valve extending radially outwardly of the inner portions; and

means disposed between the instrument and at least the outer portion of the valve for funneling the pointed distal tip of the instrument toward the hole in the septum valve.

8. The device recited in Claim 7 wherein the funneling means comprises:

a plurality of leaves forming a funnel having a relatively large proximal end and a relatively narrow distal end extending into proximity with the hole in the septum valve.

9. The device recited in Claim 8 wherein the funnel comprises at least two opposing leaf pairs that are connected and radially offset in overlapping relationship.

10. The device recited in Claim 8 wherein the funnel is axially movable with the instrument from a proximal position to a distal position wherein the distal end of the funnel is disposed in proximity with the hole in the septum valve.

11. The device recited in Claim 10 wherein the distal end of the funnel in the distal position extends through the hole in the septum valve.

12. The device recited in Claim 7 wherein:

the valve has a proximal face;

the funneling means is movable between a proximal position and a distal position; and

the funneling means in the distal position contacts the proximal face of the valve to distribute insertion forces across the proximal face of the valve.

13. A trocar adapted to facilitate introduction into a body of an instrument having a pointed distal tip, the trocar having an axis extending between a proximal end and a distal end and further comprising:

a housing having walls defining a channel through the trocar;

a septum valve disposed in the housing across the channel and adapted to form a seal around the instrument when the instrument is inserted into the channel;

the valve including lip portions defining a hole to receive the instrument, and outer portions extending radially outwardly of the lip portions;

means disposed proximally of the valve for prestressing the valve in response to insertion of the instrument into the trocar, the prestressing means enlarging the hole of the valve prior to introduction of the instrument through the valve; and

means for funneling the instrument toward the prestressed hole to avoid substantial contact between the valve and the instrument as the instrument passes through the hole.

14. The trocar recited in Claim 13 wherein the funneling means includes a funnel having an enlarged proximal end and a narrow distal end, the funnel being movable axially between a proximal position and a distal position wherein the distal end of the funnel is disposed in proximity to the valve and concentric with the prestressed hole.

15. The trocar recited in Claim 14 wherein the funnel is disposed radially inwardly of the means for prestressing the valve.

16. The trocar recited in Claim 14 wherein the funnel comprises a plurality of overlapping leaves and the funnel is radially expandable to accommodate different diameters of the instrument.

17. The trocar recited in Claim 13 wherein the septum valve has a proximal face;

the insertion of the instrument into the trocar creates insertion forces on the valve; and

the funneling means is disposed in contact with the proximal face of the valve to distribute insertion forces across the proximal face of the valve.

18. A trocar adapted to form an access channel across a body wall, and configured to receive a surgical instrument, the trocar comprising:

a cannula having an axis extending between a proximal end and a distal end of the trocar;

a seal housing disposed at the distal end of the cannula and forming with the cannula the access channel of the trocar;

a flexible valve disposed relative to the housing and across the access channel, the valve having elastomeric properties for forming a seal with the instrument when the instrument is disposed in the access channel;

first portions of the valve defining an orifice which is normally concentric with the axis of the cannula, the first portions being sized and configured to receive the instrument and form the seal with an outer surface of the instrument; and

second portions of the valve disposed circumferentially outwardly of the first portions of the valve for facilitating movement of the orifice from a first position generally concentric with the axis of the cannula to a second position generally removed from the axis of the cannula, in response to insertion of the instrument along a line removed from the axis of the cannula.

19. The trocar recited in Claim 18 wherein:

the first portions of the valve have a first resiliency which tends to deform the orifice when the instrument is inserted off-axis;

the second portions of the valve have a second resiliency which tends to move the first portions of the valve off-axis in response to the instrument being inserted off-axis; and

the resiliency of the second portions of the valve being greater than the resiliency of the first portions of the valve so that the orifice tends to move off-axis without substantial deformation, in response to the instrument being inserted off-axis.

20. The trocar recited in Claim 18 wherein the first portions of the valve have a first radial length to radial distance ratio;

the second portions of the valve have a second radial length to radial distance ratio; and

the second ratio is greater than the first ratio.

21. The trocar recited in Claim 20 wherein the second portions of the valve have a bellows configuration.

22. A trocar adapted to form an access channel across a body wall, the channel being sized and configured to receive a surgical instrument having a first axis, the trocar comprising:

a cannula having a second axis extending between a proximal end and a distal end of the trocar;

a seal housing disposed at the distal end of the cannula and forming with the cannula the access channel of the trocar;

a flexible valve disposed relative to the housing and across the access channel, the valve having elastomeric properties for forming a seal with the instrument when the instrument is disposed in the access channel;

portions of the valve defining and orifice having a third axis which is normally aligned with the second axis of the cannula, the valve portions being sized and configured to receive the instrument and form the seal with the outer surface of the instrument; and

means disposed circumferentially outwardly of the valve portion and responsive to the instrument being inserted with the first axis non-aligned with the second axis of the cannula, for moving the valve portions so that the third axis of the orifice is substantially aligned with the first axis of the instrument.

23. The trocar recited in Claim 22 wherein the moving means comprises second portions of the valve disposed circumferentially outwardly of the first portions of the valve, the second portions having characteristics for aligning the third axis of the orifice with the second axis of the cannula without substantial deformation of the orifice.

24. The trocar recited in Claim 23 further comprising:

means responsive to the first axis of the instrument being non-aligned with the second axis of the cannula, for moving the valve portions toward a position wherein the third axis of the orifice is aligned with the first axis of the instrument prior to contact between the instrument and the valve.

25. The trocar recited in Claim 24 wherein portions of the housing define an annular recess and the trocar further comprises:

a lever mechanism disposed proximally of the valve and having a fourth axis generally aligned with the third axis of the orifice;

the lever mechanism being floatingly supported in the annular recess of the housing; whereby

insertion of the instrument through the lever mechanism substantially aligns the fourth axis of the lever mechanism and the third axis of the orifice with the first axis of the instrument.

26. A method for forming a seal around an instrument introduced off-axis through an access device, includes the steps of:

providing a valve in the access device, the valve having an axis and including first portions defining an aperture sized and configured to receive the instrument, and second portions having a greater flexibility than the first portions;

inserting the instrument into the access device;

contacting the valve with the instrument at a location off-axis relative to the aperture;

pushing the instrument through the aperture to form the seal around the instrument; and

during the pushing step deforming the second portions of the valve, without substantially deforming the first portions of the valve to move the aperture into axial alignment with the instrument.

27. The method recited in Claim 26 wherein the providing step includes the step of forming the second portions of the valve with an excess of material, and the deforming step includes the step of gathering the excess of material on the side of the instrument away from the aperture to displace the first portions of the valve into axial alignment with the instrument.

28. The method recited in Claim 27 wherein the forming step includes the step of forming the second portions of the valve in a bellows configuration.

29. The method recited in Claim 27 wherein the providing step includes the steps of:

forming the first portions of the valve with a first elastomeric material;

forming the second portions of the valve with a second elastomeric material having a greater elasticity than the first elastomeric material.

30. The method recited in Claim 26 wherein the providing step includes the steps of:

providing the valve in the form of a septum with the first portions defining the aperture and the second portions extending outwardly of the first portions;

providing the first portions with a first thickness;

providing the second portions with a second thickness less than the first thickness in order to increase the flexibility of the second portions relative to the first portions.

31. A trocar adapted to form an access channel across a body wall and configured to receive a surgical instrument, the trocar comprising:

a cannula having an axis;

a housing disposed relative to the cannula and defining with the cannula the access channel of the trocar, the housing having an annular recess with a first diameter;

a ring disposed in the recess and having a second diameter;

a flexible valve disposed relative to the housing and across the access channel, the valve having an orifice and elastomeric properties for forming a seal with the instrument when the instrument is disposed in the access channel;

a plurality of levers connected to the ring and engaging the valve in proximity to the orifice;

the second diameter of the ring being less than the first diameter of the recess so that the ring and levers are free to float radially of the access of the cannula; whereby

movement of the ring and levers cause the orifice to move without substantial deformation from the access of the cannula.

32. The trocar recited in Claim 31 wherein the levers engage the valve outward of the orifice.

33. The trocar recited in Claim 32 wherein the levers are pivotally mounted on the ring.

34. The trocar recited in Claim 31 wherein the annular recess is defined in a radial plane substantially perpendicular to the axis of the cannula.

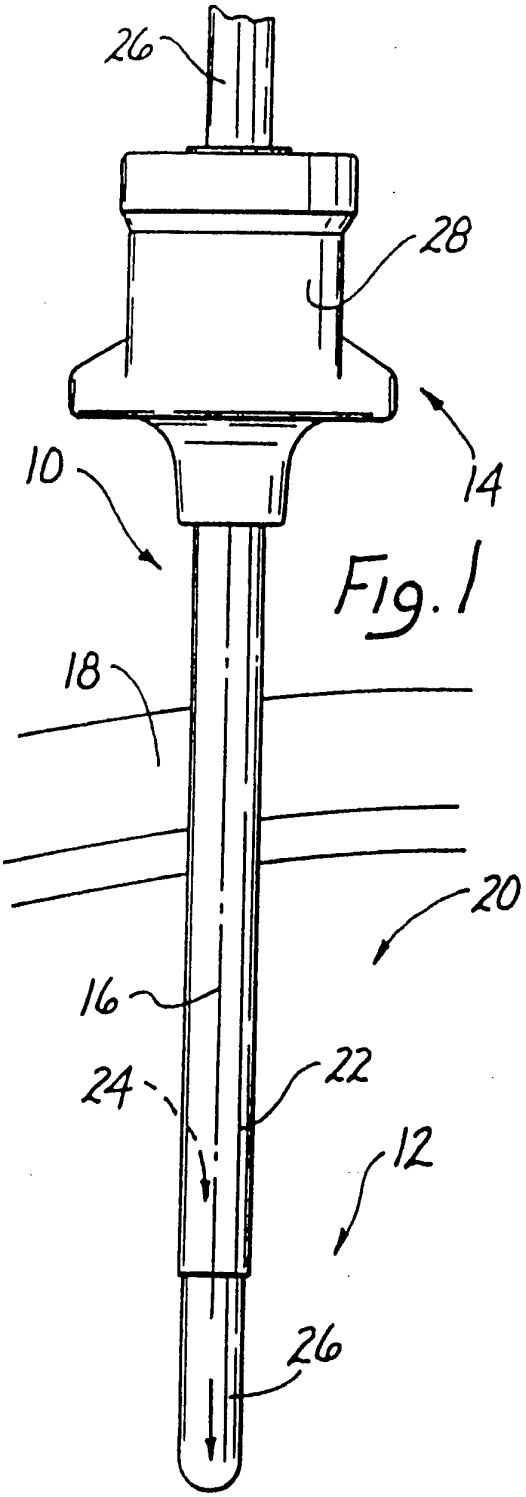


Fig. 1

Fig. 2

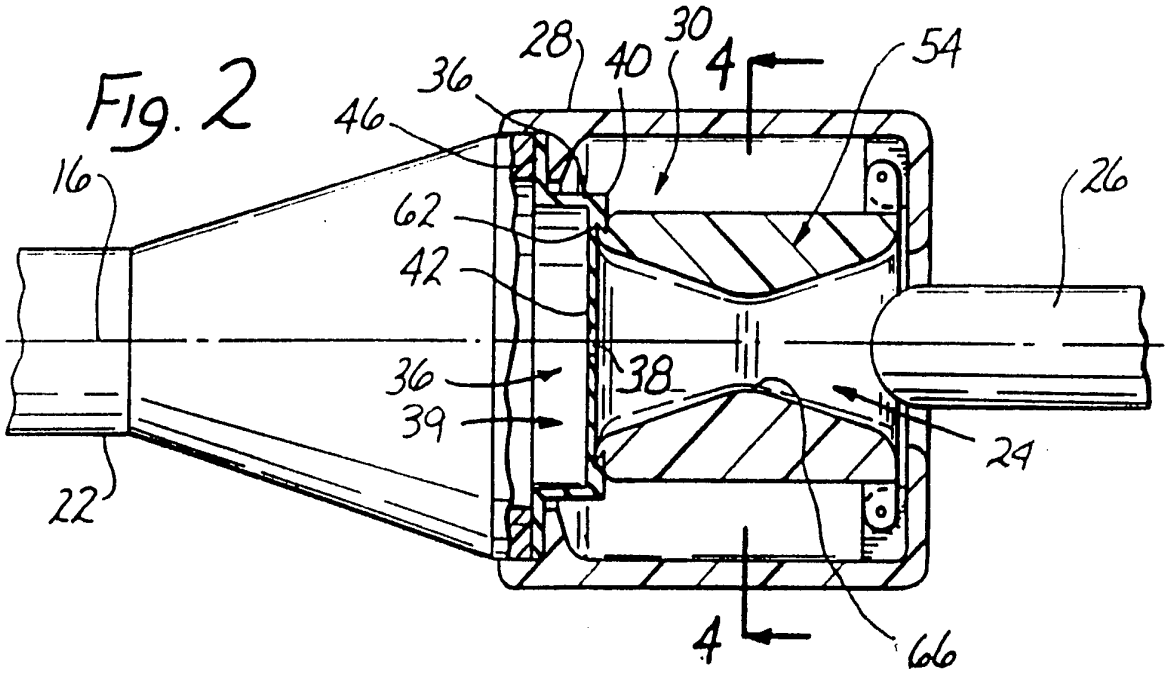
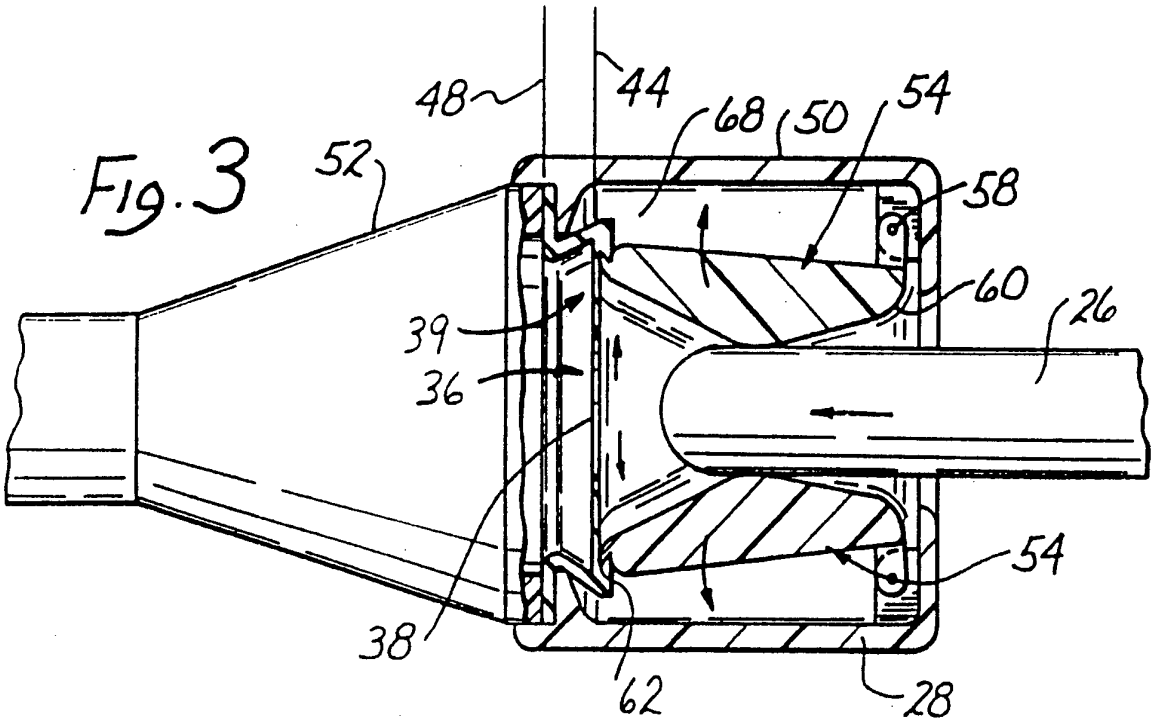

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Fig. 3


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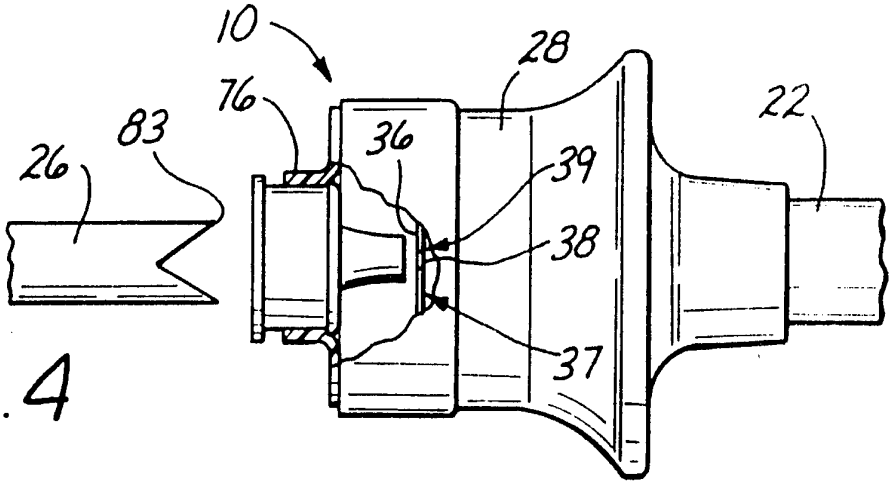


Fig. 4

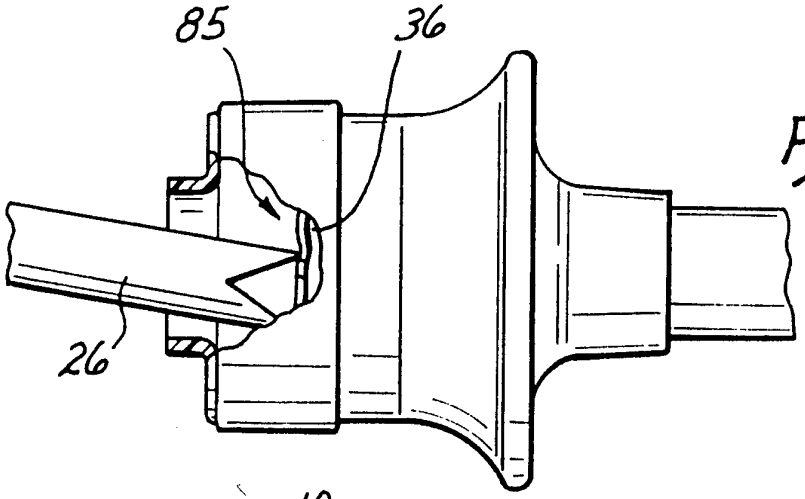


Fig. 5
PRIOR ART

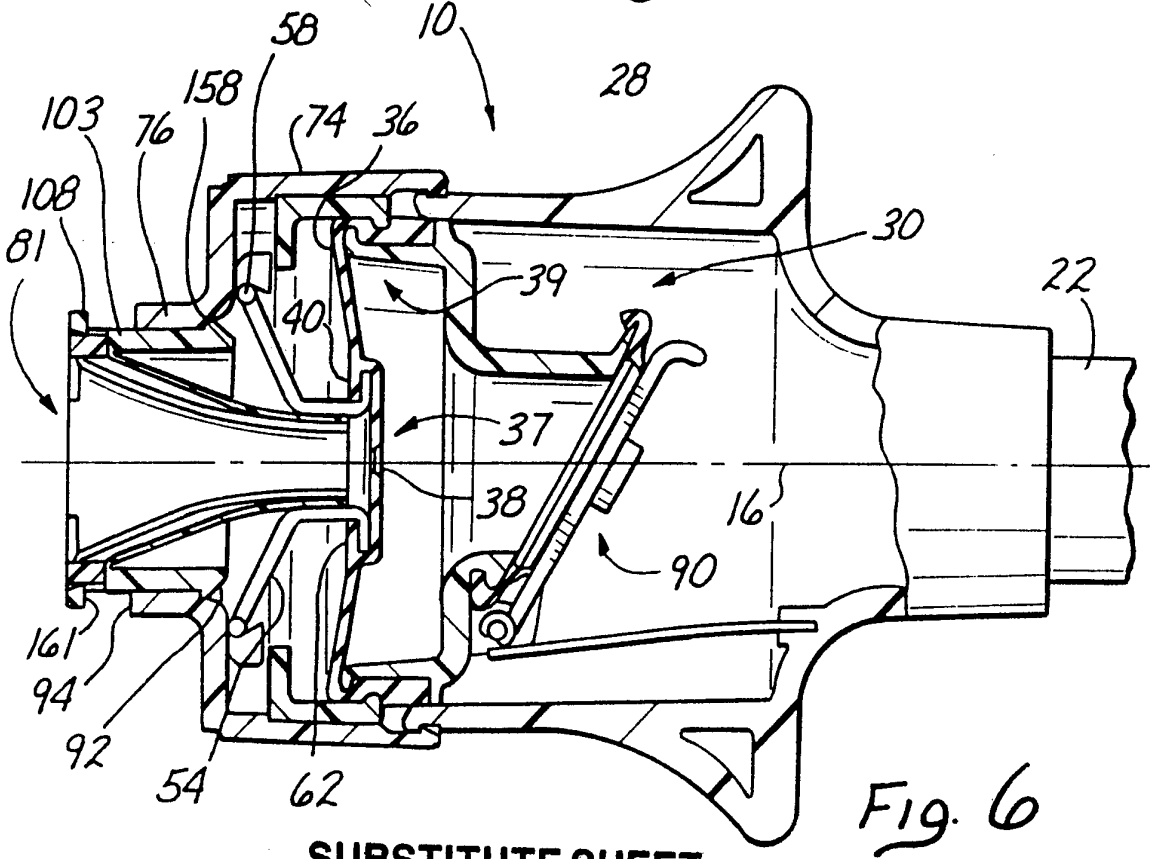


Fig. 6

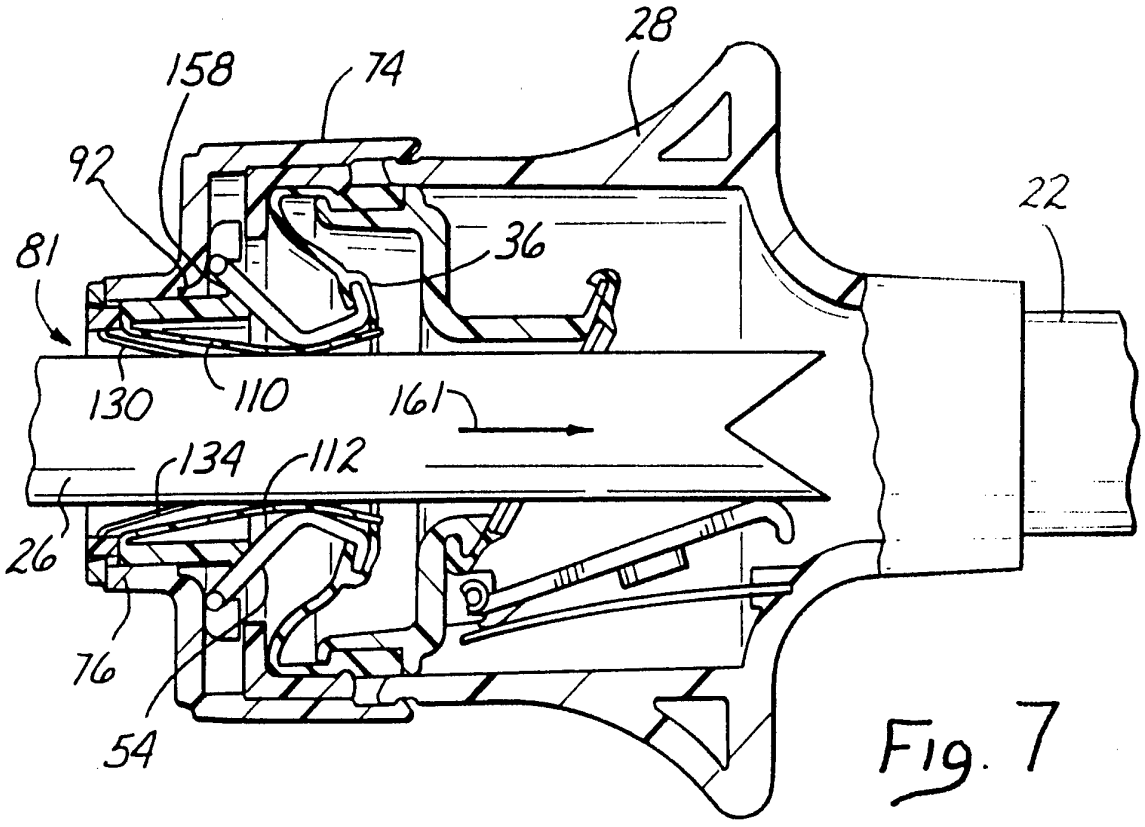

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Fig. 7

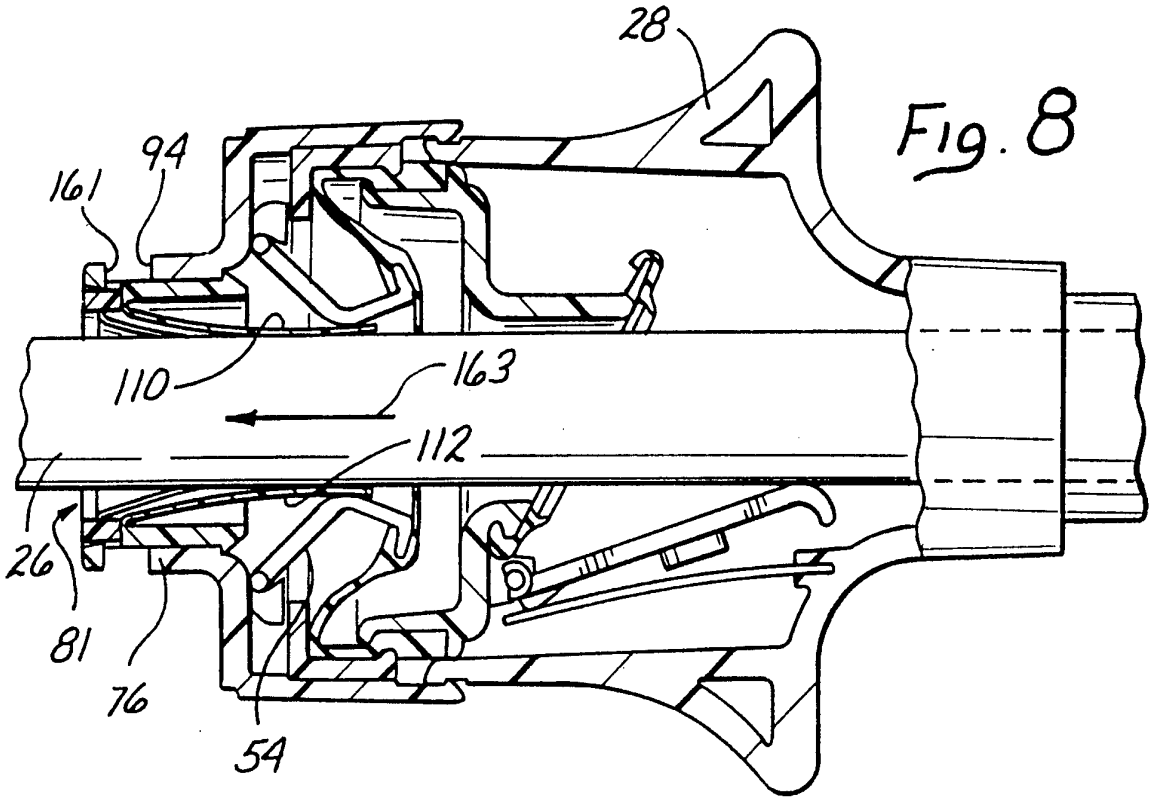

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Fig. 8

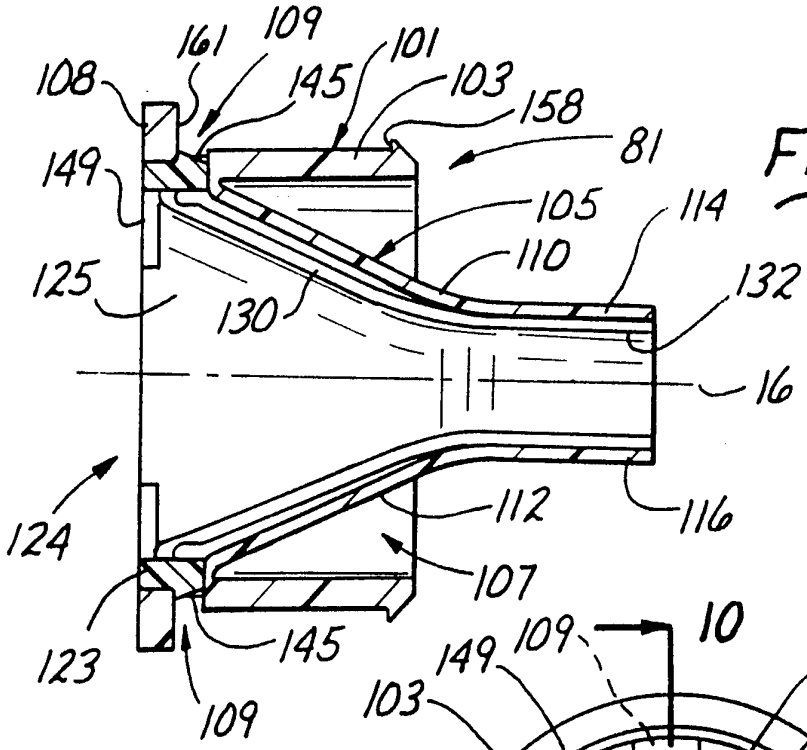


Fig. 10

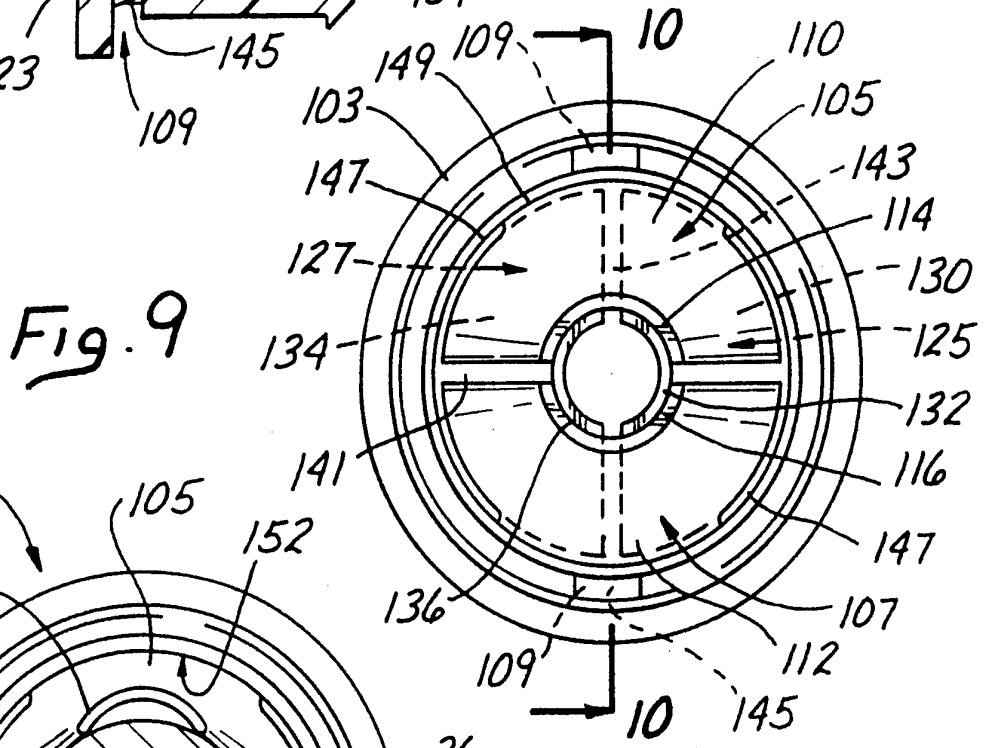


Fig. 9

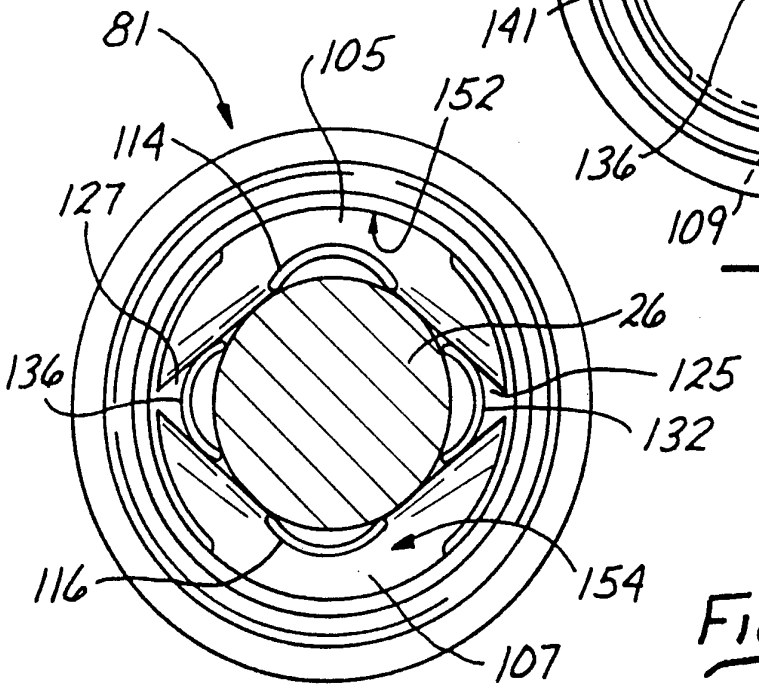
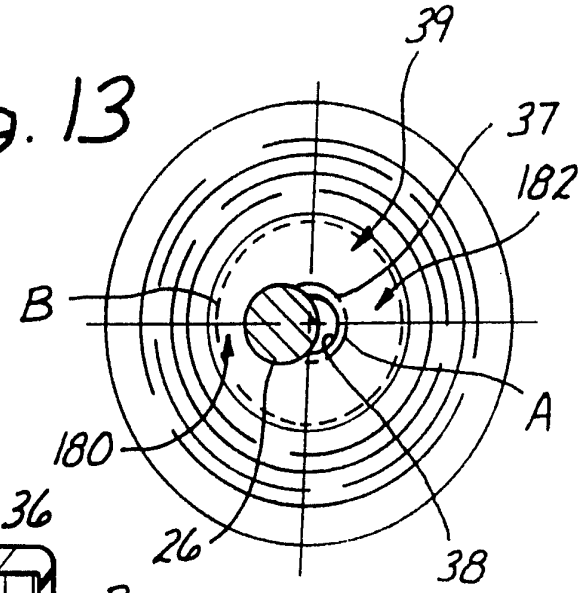


Fig. 11

Fig. 13



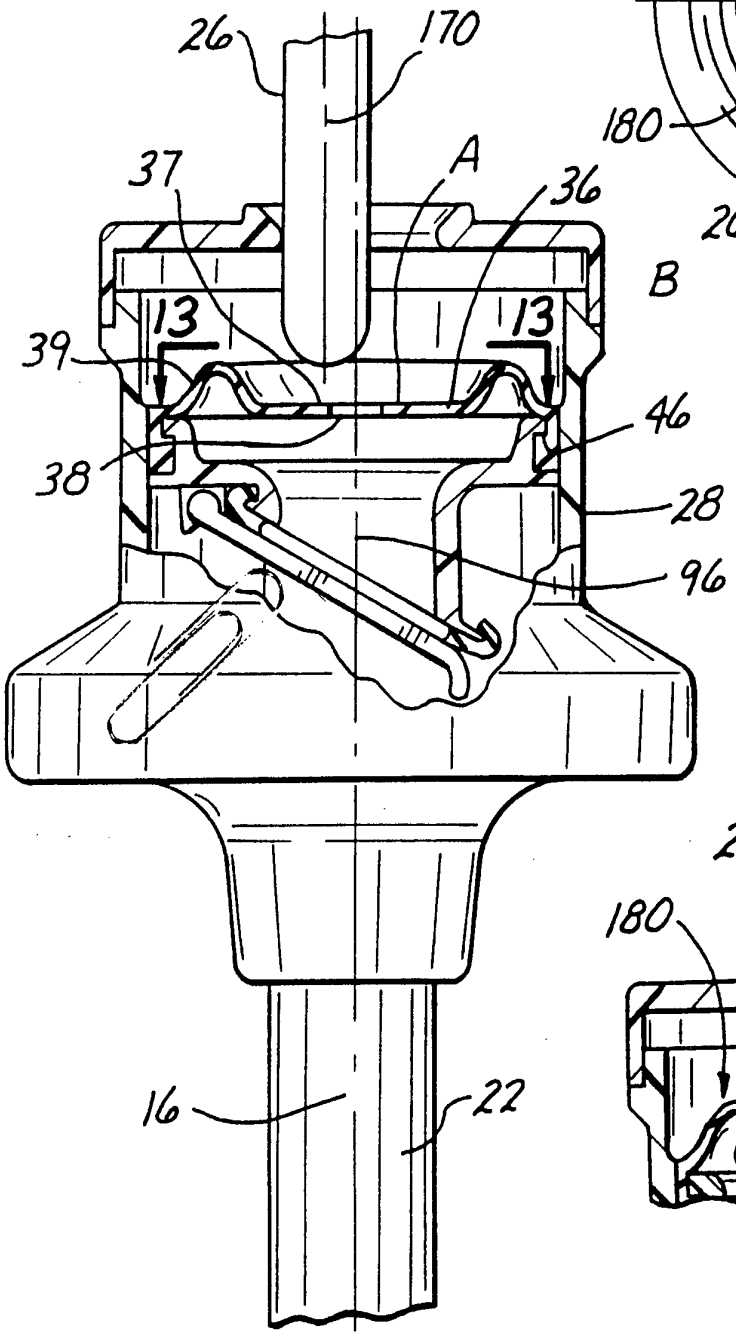


Fig. 12

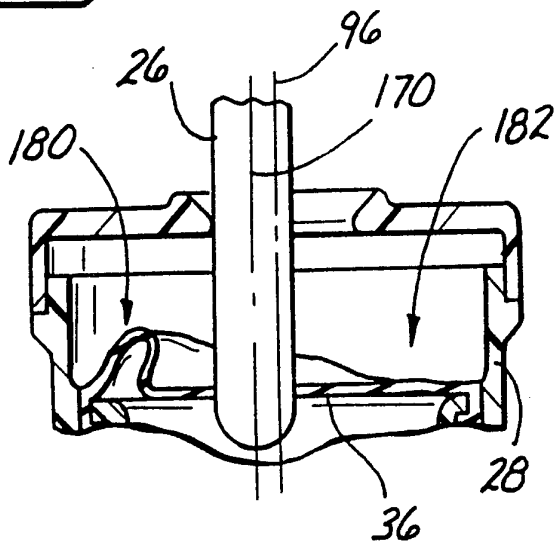


Fig. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/09067

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 5/178
US CL :604/167

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)

U.S. : 604/167, 256

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

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US, A, 5,180,373 (GREEN ET AL.) 19 JANUARY 1993, WHOLE DOCUMENT.	
A,P	US, A, 5,197,955 (STEPHANS ET AL.) 30 MARCH 1993, WHOLE DOCUMENT.	
X	US, A, 4,842,591 (LUTHER) 27 JUNE 1989, WHOLE DOCUMENT.	1-3, 7
X	US, A, 4,960,412 (FINK) 02 OCTOBER 1990, WHOLE DOCUMENT.	1-3, 7
Y	US, A, 4,758,225 (COX ET AL.) 19 JULY 1988, WHOLE DOCUMENT.	4-14, 16-17
Y	US, A, 4,240,411 (HOSONO) 23 DECEMBER 1980, WHOLE DOCUMENT.	4-14, 16-17

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

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"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
20 DECEMBER 1993	FEB 07 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer FOR PAUL HIRSCH
Facsimile No. NOT APPLICABLE	Telephone No. (703) 308-0858

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/09067

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,127,626 (HILAL ET AL.) 07 JULY 1992	
A	US, A, 4,929,235 (MERRY ET AL.) 29 MAY 1990.	
A	US, A, 4,917,668 (HAINOL) 17 APRIL 1990.	