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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: David Schaffer et al.
 Title: COMPOSITE STASIS VALVE
 Attorney Docket No.: 905.038US1



PATENT APPLICATION TRANSMITTAL

BOX PATENT APPLICATION

Commissioner for Patents
 Washington, D.C. 20231

We are transmitting herewith the following attached items and information (as indicated with an "X"):

- ☒ Return postcard.
- ☒ **NON-PROVISIONAL APPLICATION** from prior Patent Application No. (60/357,937) comprising:
 - ☒ Specification (26 pgs, including claims numbered 1 through 31 and a 1 page Abstract).
 - ☒ Formal Drawing(s) (19 sheets).
 - ☒ Unsigned Combined Declaration and Power of Attorney (4 pgs).
 - ☒ Incorporation by Reference: *The entire disclosure of the prior application, U.S. Provisional Application SN 60/357,937 filed February 19, 2002, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.*
- ☒ Prior application is assigned of record to MedAmicus, Inc. by M. Schaffer and D. Schaffer.
- ☒ Applicant claims small entity status under 37 C.F.R 1.27.

The filing fee (NOT ENCLOSED) will be calculated as follows:

	No. Filed	No. Extra	Rate	Fee
TOTAL CLAIMS	31-20	11	x 9.00 =	\$99.00
INDEPENDENT CLAIMS	5-3	2	x 42.00 =	\$84.00
[] MULTIPLE DEPENDENT CLAIMS PRESENTED				\$0.00
BASIC FEE				\$375.00
TOTAL				\$558.00

THE FILING FEE WILL BE PAID UPON RECEIPT OF THE NOTICE TO FILE MISSING PARTS.

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This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to The Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

COMPOSITE STASIS VALVE

CLAIM OF PRIORITY

5 This application claims priority under 35 U.S.C. 119(e) from U.S. Provisional Application Serial No. 60/357,937 filed February 19, 2002, which application is incorporated herein by reference.

TECHNICAL FIELD AND RELATED APPLICATION

10 This application relates to catheters, in particular to a composite fluid-stasis valve for use with catheters. This application is related to U.S. Patent 5,429,616, which is incorporated by reference herein.

BACKGROUND

15 Fluid stasis mechanisms are commonly used to prevent loss of fluids from the insertion site of a catheter or interventional system. They may range, in complexity, from a simple clamp on a length of tubing to complex valve systems
20 with several moving parts. The most common valves consist of a resilient material in compression within a housing or clamping member. An example of such a valve is patentee's prior U.S. Patent 5,429,616 wherein a length of tubular resilient foam has an occludible lumen.

25 An example of the simplest form is U.S. Patent No. 6,088,889 where a wire clamp is used to occlude a portion of tubing. The resilient material may have a lumen or slit that allows for the passage of an instrument such as a guide wire or catheter.

30 Most of the existing devices require the user to manually open or close the valve by adjusting the compression on the resilient material and subsequently opening or closing the lumen. An example of this configuration is commonly referred to as a Touey-Borst valve. The manual operation of existing valves most often requires a twisting motion or a squeezing motion. In many cases the action requires the use of both hands. In addition, the existing valves often do not prevent

the immediate backflow from within the fluid path as an instrument is inserted or removed.

The existing devices do not perform a complete seal against leakage in the presence of a wide range of instruments or in the presence of multiple instruments.

5 For instance, a single valve element with no instrument in place is generally not optimized for sealing in the presence of an instrument. Often a combination of seals is employed to address these issues, for instance: U.S. Patents 6,083,207 and 6,024,729 employ primary seal portions in combination with “duckbill-valves” or “O” closure valves.

10 Thus, the problems are complex and involve a balance between closing force, opening force, friction, compression and durability. If a valve is inordinately tight, having a closed lumen, it may not allow the insertion of soft, flexible instrumentation such as a “floppy-tip” guidewire, a delicate laser fiber or a soft-tipped catheter. Some catheters, optical fibers and fluid transmission tubes are very
15 delicate and can be damaged by excessive compression or insertion force.

Accordingly, what is needed is a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.

20 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a perspective view of a stasis valve as constructed in accordance with one embodiment.

25 FIG. 2 illustrates a perspective view of a stasis valve as constructed in accordance with one embodiment.

FIG. 3 illustrates an enlarged cut away view of a stasis valve as constructed in accordance with one embodiment.

FIG. 4 illustrates an enlarged cut away view of a stasis valve as constructed in accordance with one embodiment.

30 FIG. 5 illustrates a side cross-sectional view of a seal module as constructed in accordance with one embodiment.

FIG. 6 illustrates an end, cross-sectional view of a seal module chamber as constructed in accordance with one embodiment.

FIG. 7 illustrates a side cross-sectional view of a seal module as constructed in accordance with one embodiment.

5 FIG. 8 illustrates an end, cross-sectional view of a seal module chamber as constructed in accordance with one embodiment.

FIG. 9A illustrates a schematic diagram of a stasis valve as constructed in accordance with one embodiment.

10 FIG. 9B illustrates an enlarged schematic diagram of a stasis valve as constructed in accordance with one embodiment.

FIG. 10A illustrates a schematic diagram of a stasis valve as constructed in accordance with one embodiment.

FIG. 10B illustrates an enlarged schematic diagram of a stasis valve as constructed in accordance with one embodiment.

15 FIG. 11 illustrates a partial cut away view of a detent arrangement inside a housing as constructed in accordance with one embodiment.

FIG. 12 illustrates a side cross-sectional view of seal module with an instrument as constructed in accordance with one embodiment.

20 FIG. 13 illustrates a side cross-sectional view of seal module as constructed in accordance with one embodiment.

FIG. 14 illustrates a side cross-sectional view of seal module as constructed in accordance with one embodiment.

FIG. 15 illustrates a side cross-sectional view of seal module as constructed in accordance with one embodiment.

25 FIG. 16 illustrates an end, cross-sectional view of a seal module chamber as constructed in accordance with one embodiment.

FIG. 17 illustrates an end, cross-sectional view of a seal module chamber as constructed in accordance with one embodiment.

30 FIG. 18 illustrates an end, cross-sectional view of a seal module chamber as constructed in accordance with one embodiment.

FIG. 19 illustrates an end, cross-sectional view of a seal module chamber as constructed in accordance with one embodiment.

FIG. 20 illustrates a perspective view of a seal module as constructed in accordance with one embodiment.

5 FIG. 21 illustrates a perspective view of a seal module as constructed in accordance with one embodiment.

FIG. 22 illustrates a perspective view of a seal module as constructed in accordance with one embodiment.

10 FIG. 23 illustrates a cross-sectional view of a seal module as constructed in accordance with one embodiment.

FIG. 24 illustrates a cross-sectional view of a seal module as constructed in accordance with one embodiment.

FIG. 25 illustrates a cross-sectional view of a seal module as constructed in accordance with one embodiment.

15 FIG. 26 illustrates a cross-sectional view of a seal module as constructed in accordance with one embodiment.

FIG. 27 illustrates a perspective view of a stasis valve and external mechanism assembly in accordance with one embodiment.

20 FIG. 28 illustrates a sectional view of a seal module in accordance with one embodiment.

FIG. 29 illustrates a sectional view of a seal module in accordance with one embodiment.

FIG. 30 illustrates a perspective view of a seal valve as constructed in accordance with one embodiment.

25 FIG. 31 illustrates a transparent perspective view of a housing and a seal valve as constructed in accordance with one embodiment.

FIG. 32 illustrates a cross-sectional view of a seal valve as constructed in accordance with one embodiment.

30 FIG. 33 illustrates a transparent perspective view of a housing and a seal valve as constructed in accordance with one embodiment.

FIG. 34 illustrates a cross-sectional view of a seal valve as constructed in accordance with one embodiment.

DETAILED DESCRIPTION

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In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the scope of the invention. Therefore, the following detailed description is not to be taken in a limiting sense, and the scope of the invention is defined by the appended claims and their equivalents.

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With reference to the drawings, FIGS. 1-4 illustrate a composite fluid stasis valve 10 with a housing 20, a proximal end 30, and a distal end 40. In one embodiment, the housing 20 comprises a hollow rectangular structure having a first end-wall 21, a second end-wall 22, a first side-wall 23, a second side-wall 24, a bottom or floor 25, and a top or lid 26. A hollow interior wall 11 of the housing 20 is sized and configured to hold and control a composite seal module 100, a portion of an actuator 50, and an actuating member 55.

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The first end-wall 21 of the housing 20 is fitted with a connecting member 35 sized and configured to attach in fluid communication to a fluid delivery supply or a body passage such as a blood vessel. The connecting member 35 is a common male thread "Luer" type fitting or a common "slit-fit" tube connector or the like. The second end-wall 22 of the housing 20 is sized and configured to receive an inserted instrument, catheter or guide wire through a receiving member 45.

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The actuator 50, in one option, includes an actuator flange 57 exterior to the interior wall 11 about the second side wall 24 of the housing 20. In one option, a second stationary member 65 is positioned in the interior wall 11 of the first side wall 23 of the housing 20 distal to the actuating member 55. In one example, the second stationary member 65 is part of the interior wall 11 of the first side wall 23

of the housing 20 or in another example, the second stationary member 65 is inserted into the bottom 25 of the housing 20 as a separate piece.

The stasis valve 10 includes the seal module 100 enclosed in the housing 20 such that the seal module 100 is proximally connected to the connecting member 35 and distally connected to the receiving member 45. The receiving member 45 is, in one option, configured to connect to a fluid or gas delivery system or device such as a syringe, intravenous system or the like. The top edge 18 of the second side wall 24 of the housing 20 forms a guide support for moving the actuating member 55 which, in one option, includes an extension 52. The top 26 of the housing 20 provides an opposing support member for the moving actuator 50. As the actuator flange 57 is depressed, the actuator 50 moves across along the top edge 18 of the second side wall 24 toward the interior wall 11 of the first side wall 23 of the housing 20. The actuating member 55 of the actuator 50 depresses and at least partially collapses, a portion of the seal module 100. The collapsed portion of the seal module 100 forms a seal 200 preventing fluid and/or gasses communication between the connecting member 35 and the receiving member 45.

The actuator 50 is adapted to slide from a first position to a second position. In the first position the actuator 50 is, in one option, disposed and held against a portion of the seal module 100 which depresses and at least partially collapses, for example, the central portion 110 of the containment structure 160 by a compressive force 67 from a resilient member (e.g., by a spring 210). In one position, the containment structure 160 has a normally closed position (i.e., the lumen remains sealed until a user depresses the actuator 50). In the second position, the actuator 50 is disposed away from a portion of the seal module 100 by a compressive force 67 (e.g. by depressing the actuator flange 57) thus allowing, for example, the central portion 110 of the containment structure 160 to retract to an unsealed configuration.

A seal module 100, in one option, extends between the first end-wall 21 of the housing 20 and the second end-wall 22 of the housing 20 and is in fluid communication with the connecting member 35 and the receiving member 45. The seal module 100 comprises an elongate tubular structure 101 having a central portion 110, a first end portion 120, and a second end portion 140. The central

portion 110 is sized and configured to hold a plurality of sealing members including a first seal member 170, a second seal member 180, and a third central seal member 165. It should be noted that one or more of the first seal member 170, the second seal member 180, and the third central seal member 165 can be formed of the various materials, and/or having the various properties, discussed throughout this application. In one option, the seal module 100 includes the first seal member 170 fixed at a proximal end 115 of the seal module 100, a second seal member 180 fixed at a distal end 117 of the seal module 100, and a third central seal member 165 extending between the first and the second seal members 170, 180. The plurality of seal members 165, 170 and 180 have an internal diameter sized to allow the passage of fluids or gases therethrough.

In one embodiment, the first end portion 120 includes a distal end 121 that axially communicates with the central portion 110 of the containment structure 160 within the hollow interior wall 11 of the housing 20 and axially communicates with the connecting member 35 exterior to the housing 20. The first end portion 120 includes, in one option, a first diameter substantially smaller than the diameter of the central portion 110. The second end portion 140, in one option, includes a distal end 141 that axially communicates with the central portion 110 of the containment structure 160 within the hollow interior wall 11 of the housing 20 and axially communicates with the receiving member 45 exterior to the housing 20. The second end portion 140 includes a second diameter that is substantially smaller than the diameter of the central portion 110. An amount of compressive force 67 is applied to the actuator flange 57 of the actuator 50 by the user causing the actuator 50 to slide across along the top edge 18 of the second side wall 24. As the actuator 50 slides across along the top edge 18 of the second side wall 24, the actuating member 55 is forced against the outer wall 27 of the seal module 100.

In another embodiment, the actuator 50 is adapted to slide from a first position to a second position. In the first position the actuator 50 is disposed and held against a portion of the seal module 100 which depresses and at least partially collapses, for example, the central portion 110 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210) creating a seal 200 preventing gas

and/or fluid from passing therethrough. In the second position, the actuator 50 is disposed away from a portion of the seal module 100 by a compressive force 67 (e.g. by depressing the actuator flange 57) thus allowing, for example, the central portion 110 of the containment structure 160 to retract to an uncollapsed configuration. When there is no longer a compressive force 67 (e.g. by releasing the actuator flange 57), the actuator 50 reengages the portion of the seal module 100 and at least partially collapses, for example, the central portion 110 of the containment structure 160.

With reference to FIGS. 5-22, the seal module 100, in one embodiment, includes a flexible, elongate tubular structure 101 having an outer wall 27 which includes a material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. The outer wall 27 is formed so as to have a large diameter in the central portion 110 and a reduced diameter at the first end portion 120 and the second end portion 140 of the seal module 100. A first abutment 111 and a second abutment 112 are formed by the diameter reduction of the elongate tubular structure 101. The first abutment 111 forms a stop or seat for a first seal member 170 and the second abutment 112 forms a stop or seat for a second seal member 180. A third central seal member 165 is placed between the first seal member 170 and the second seal member 180 and in fluid communication therewith. The third central seal member 165 includes a highly deformable, non-compressible material 166 (e.g., plastic). The third central seal member 165 is sized and configured to maintain an open lumen 193 when no compressive force 67 is applied.

When the actuating member 55 is, in one option, forcibly pushed against the central portion of the seal module 100, the compressive force 67 of the actuating member 55 against the outer wall 27 of the containment structure 160 inwardly depresses or collapses the third central seal member 165 of the containment structure 160 as the actuator 50 progresses toward the first side wall 23 of the housing 20. The third central seal member 165 is, in one option, depressed to the point where the containment structure 160 of the seal module 100 slows or stops the flow of fluid (e.g., blood) from communicating between the connecting member 35

and the receiving member 45 of the stasis valve 10. This creates a seal 200 between the orifices 171, 181 of the lumen 191, 190. The stationary member 65 (see Fig. 4) further assists the depression of the outer wall 27 of the containment structure 160 on an opposing side as the actuating member 55 progresses toward the first side wall 23 of the housing 20.

In one embodiment, the first seal member 170 has an orifice 171 of a selected diameter 194 that corresponds, for example, to a range of instruments used within the seal module 100. The second seal member 180 includes the orifice 181 that corresponds to a range of inserted instruments. The first seal member 170 provides a fluid/gas tight seal around and upon an instrument within a selected range of diameters 194, such as a catheter, guidewire, needle or fiber, inserted within the orifice 171 of the first seal member 170. The second seal member 180 is sized and configured to provide containment for the third central seal member 165. The orifice 181 of the second seal member 180 is, in one option, substantially the same as the orifice 171 of the first seal member 170 and provides a backup or secondary seal in the event that the first seal member 170 becomes damaged.

The first and second seal members 170 and 180 include elastomeric materials, such as rubber or silicone, and are essentially septums sized and configured to seal against gas or fluid pressure around an instrument. The first and second septum seal members 170 and 180, allow smooth and accurate movement of instruments since there is no additional compressive force or load required to complete the seal. In one option, a relatively high durometer material is used as the septum material for the first and second seal members 170 and 180 because it provides a low frictional coefficient against most inserted instruments while providing a competent seal. In another embodiment, one or more of the first, second, and third seal members 170, 180, and 165 includes self-lubricating, lubricious or coated septum materials. Such materials include specialty silicones, natural latex, various synthetic rubbers or elastomeric compounds of polyurethane, vinyl or the like. The low friction nature of the first and second seal members 170, 180 is in contrast to the highly deformable and compliant nature of the third central seal member 165.

The third central seal member 165 includes an elongated tubular structure 101 sized and configured to fit into the tubular containment structure 160 between the first seal member 170 and the second seal member 180. The lumen 193 of the third central seal member 165 is, in one option, slightly larger than the orifice 171 of the second seal member 180 so that an inserted instrument 260 need not contact the luminal surface.

In one embodiment, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. Materials 166 include modified vinyl, silicone, polyurethane or a combination thereof. The basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked modifiers. Such materials are commonly available as "C-Flex" or "Kraton" in the range of 5 to 15 (shore A), as examples. The shore hardness of the material 166 is, in another option, in the range of between 15-20 shore on the "00" scale. This provides a material 166 that is extremely soft and compliant and intrinsically "sticky". An extremely low shore hardness of the third central seal member 165 material 166 allows the third central seal member 165 to be easily compressed upon itself or upon an inserted instrument. For illustrative purposes only, the nature of the material 166 of the third central seal member 165 can be compared to a gelatinous substance. The material 166 exhibits a "self-closing" nature in that it sticks occlusively to itself forming a nearly fluid/gas tight seal under very light compression.

With particular reference to FIGS. 10A, 10B, 16-19, the highly compliant third central seal member 165 seals around a variety of profile shapes 192 and diameters 194 of the lumen 193 when at least one side of compressive force 67 is exerted upon the central region 195 with respect to the central portion 110 of the containment structure 160. The compressive load may be supplied by a movable, sliding or hinged, actuator 50 that maintains a compressive load upon the third central seal member 165 under the influence of a spring 210 or other resilient material. The spring 210 provides a compressive load between the actuating member 55 of the actuator 50 and the stationary member 65 positioned in the interior wall 11 of the housing 20.

With reference to FIGS. 9A, 9B, 10A, 10B, 11, the compressive load upon the third central seal member 165 is, in one option, selectively relieved by moving the movable actuator 50 so as to compress the spring 210 and subsequently enlarge the distance between the actuating member 55 of the actuator 50 and the stationary member 65 positioned in the interior wall 11 of the housing 20. A “hold-open” or “hold-closed” feature is, in one option, a latching or detent arrangement 250. An operator can choose to have the lumen of the composite seal remain substantially open, allowing gas or fluid flow in either direction. The operator can subsequently “squeeze” or otherwise operate the actuator 50 to the following sequential position of the detent arrangement 250 thereby allowing the spring 210 to fully compress the third central seal member 165. For example, the action of “hold and release” is repeated as the actuator 50 is urged from one extreme position to another extreme position within the detent arrangement 250. The detent arrangement 250 includes, but is not limited to, a series of ramps and slides that move the sliding actuator 50 through a path.

In another embodiment, the actuator 50 includes an extension configured to be urged up an incline ramp 251 and into a depression 252 where it finds a neutral resting place under the return force of the compression spring 210. Upon further urging forward, the extension 52 of the actuator 50 is forced against an angular wall 253 that forces the extension of the actuator 50 to one side, over a ledge 255, and into a return incline ramp 256. The neutral bias of the actuator 50 is to position the extension so as to move up the first incline ramp 251 upon subsequent or further actuation of the actuator 50.

FIGS. 12-15 illustrate the use of a seal module 100 that requires no compressive load for use in sealing the stasis valve 10 closed. The non-compressive embodiment may include a second seal member 180 in a fixed position within the containment structure 160 toward the distal end 117 of the containment structure 160, a first seal member 170 in a sliding relationship within the containment structure 160, and a third central seal member 165 comprised of a highly deformable material 166. The first seal member 170 includes an elastomeric seal that is movable within the containment structure 160 in response to a retrograde flow 270.

The first seal member 170 includes a length that maintains axial alignment within the containment structure 160 which, in one option, includes an orifice 181 that is significantly smaller than the lumen 193, 191 size of the other seal members 165, 180. The region adjacent to the small orifice 181 includes a thin cross-section to
 5 reduce entry force, friction and restriction. In another option, the seal module 100 includes a first seal member 170 with a first diameter, a second seal member 180 with a second diameter, and a third seal member 165 with a third diameter, the third diameter of the third seal member 165 being greater than at least one of the first diameter and the second diameter.

10 The seal module 100 includes, in one option, the first seal member 170 having a first material, the second seal member 180 having a second material, and the third seal member 165 having a third material, wherein at least one of the first material of the first seal member 170 and the second material of the second seal member 180 is different than the third material of the third seal member 165. The
 15 first material of the first seal member 170 and the second material of the second seal member 180 can have a lower friction than the third material of the third seal member 165. The second seal member 180 includes an elastomeric seal that is fixed within the containment structure 160 so that it does not move within the seal module 100. The second seal member 180 has a length that keeps it axially stable within the
 20 containment structure 160 and an orifice 171 that represents the designated lumen 191 size of the instrument 260.

The back pressure from the retrograde flow 270 forces the first seal member 170 toward the third central seal member 165 in the containment structure 160. As the first seal member 170 moves distally, or toward the second seal member 180
 25 under the influence of the pressure from the gas or fluid, the third central seal member 165 is compressed. However, since the material 166 of the third central seal member 165 is essentially non-compressible, the lumen 193 of the third central seal member 165 collapses upon itself circumferentially. The material 166 of the third central seal member 165 is sufficiently soft and compliant to deform under the
 30 movement of the first seal member 170. In one option, at least one of the first and the second materials have a higher durometer than the third material. As long as

there is backpressure against the first seal member 170, a gas or fluid tight seal is maintained.

In one embodiment, instrument 260, for example, a catheter or guidewire is inserted into the valve antegrade, for example, in the distal end 117 of the containment structure 160 while the lumen 193, 190, and 191 of the seal members 165, 170, and 180, are in an open configuration. The instrument 260 frictionally engages the lumen 190 of the first seal member 170 and forces it distally away from the second seal member 180 and the third central seal member 165. The first seal member 170 forms a seal against the instrument 260. The back pressure from the retrograde flow 270 against the first seal member 170 forces the first seal member 170 toward the distal end 117 of the containment structure 160 compressing the third central seal member 165 and collapsing it circumferentially against the instrument 260 forming a second, complete seal.

In another embodiment, instrument 260, for example, a catheter or guidewire is inserted into the valve antegrade, for example, in the distal end 117 of the containment structure 160 while the lumen 193 of the third central seal member 165 is in a closed configuration. The instrument 260 frictionally engages the lumen 190 of the first seal member 170 and forces it distally away from the second seal member 180 and the closed third central seal member 165. The first seal member 170 forms a seal against the instrument 260. The back pressure from the retrograde flow 270 against the first seal member 170 forces the first seal member 170 toward the distal end 117 of the containment structure 160 compressing the third central seal member 165 and collapsing it circumferentially against the instrument 260 forming a second, complete seal.

In yet another embodiment, two or more instruments 260 are inserted into the valve antegrade, for example, in the distal end 117 of the containment structure 160 while the lumen 193, 190, and 191 of the seal members 165, 170, and 180, are in an open configuration, or in another option, while the lumen 193 of the third central seal member 165 in a closed configuration. The instruments 260 frictionally engage the lumen 190 of the first seal member 170 and forces it distally away from the second seal member 180 and the third central seal member 165. The first seal

member 170 forms a seal against the instruments 260. The back pressure from the retrograde flow 270 against the first seal member 170 forces the first seal member 170 toward the distal end 117 of the containment structure 160 compressing the third central seal member 165 and collapsing it circumferentially against the instruments 260 forming a second, complete seal. The material 166 of the third central seal member 165 is so compliant that it forms a seal around the instruments 260 even if the instruments 260 are irregularly shaped.

An pressure from the antegrade flow 272 repositions the first seal member 170 toward the proximal end 115 of the containment structure 160 and subsequently opens the stasis valve 10 while preventing back-flow or leakage. While this arrangement may not be as friction-less as the other embodiments using an actuator 50, it may offer the advantages of "hands-free" operation.

With reference to FIGS. 23-29, the stasis valve 10 includes the seal module 100 enclosed in the housing 20 where, in one option, the seal module 100 includes the first seal member 170 at the proximal end 115 of the containment structure 160, a second seal member 180 at the distal end 117 of the containment structure 160, and a third central seal member 165 extending between the first and the second seal members 170, 180. The plurality of seal members 165, 170 and 180 have an internal diameter sized to allow the passage of fluids or gases. A support member 168 includes a woven or braided material 166 configured to fit over the first seal member 170 and over the third central seal member 165. The support member 168 is capable of retractionably collapsing with a compressive side-load by opposing protrusions, for example, the actuating member 55 and the stationary member 65. In one option, the support member 168 is compressible under a side-load but not elongatable. In one example, this is accomplished by a biased weaving or tubular braiding of rigid material. An example of such a construction is the shielding found on certain electronic wire components. A tubular braided or woven rigid material exhibits the characteristics of an elasometric material and yet is not, itself, elastic.

The actuator 50 is adapted to move from a first position to a second position. In the first position the actuator is, in one option, disposed and held against a portion of the seal module 100 depressing or collapsing, for example, an off-center portion

109 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210). In the second position, the actuator 50 is disposed away from a portion of the seal module by a compressive force 67 (e.g. by depressing the actuator flange 57) thus allowing, for example, the off-center portion 109 of the containment structure 5 160 to retract to an uncollapsed configuration.

In the first position, the actuator 50 is, in another option, disposed and held against a portion of the seal module 100 which depresses and at least partially collapses, for example, the central portion 110 of the containment structure 160 by a compressive force 67 (e.g. by a spring 210). In the second position, the actuator 50 10 is disposed away from a portion of the seal module 100 by a compressive force 67 (e.g. by depressing the actuator flange 57) thus allowing, for example, the central portion 110 of the containment structure 160 to retract to an uncollapsed configuration.

In one embodiment, the first seal member 170 is fixed in a position at the 15 proximal end 115 of the central portion 110 of the seal module 100. The first abutment 111 forms a stop or seat for a first seal member 170. The braided or woven support member 168 is connected to the first seal member 170 and attached to or formed into the wall of the third central seal member 165. The third central seal member 165 is thus not permitted to migrate under a backpressure load into the 20 distal orifice 181 of the second seal member 180 and occlude said orifice 171. In one example, a compressive side-load is applied to the third central seal member 165. In another example, a compressive side-load is applied by opposing protrusions, for example, actuator 50 and stationary member 65, under a spring 210 load. Under this influence, the material 166 of the third central seal member 165 is 25 not allowed to extrude longitudinally to an area 182 due to the linear limit of the braided or woven support member 168.

Now referring to FIG. 27, the seal module 100 is, in one option, used without the housing 20 or the containment structure 160. The seal module 100 includes an elongate tubular structure 101 having a central portion 110 with a 30 proximal end 30 and a distal end 40. In one option, a compressive or occlusive side load or "squeezing" is supplied by a separate tool or device, such as a clamp 300,

forceps, hemostat or a combination thereof, or additionally occluded by bending or finger pressure. The third central seal 165 is, in one option, closed off from the central lumen 193 of the seal module 100 in the instance where a plurality of instruments 260 are within said lumen 193. The highly occlusive nature of the material 166 of the third central seal member 165 allows it to conform to the interstices adjacent to the instruments. For instance, a guidewire and catheter may be placed into the same lumen 193 for extension into a body passage rather than have two or more separate insertion sites into the same vessel or passage.

FIGS. 30-34 illustrate one embodiment of the stasis valve 10 including a seal module 100 having a lumen sized to allow the passage of fluids or gases. The seal module 100 includes a containment structure 160 with a proximal end 115 and a distal end 117. The seal module 100 is formed of one or more seal members, as discussed above. In another option, the seal module 100 and/or any of its respective seal members can be formed of one or more materials, including their relative properties, as discussed above.

In one option, two circular actuators 50 are at least partially circumferentially disposed about a portion of the seal module 100 movable from a first position to a second position on opposing sides of the housing 20. The actuators 50 each include an actuating member 55 which, in one option, is U-shaped. The outer wall 262 of the housing 20 and the inner flange wall 265 of the housing 20 provides opposing support for two resilient members 267 (e.g. spring 210) disposed within the actuating member 55. The resilient members 267 include a proximal end 269 and a distal end 271 where the proximal end 269 of the resilient members 267 abut the inner flange wall 265 of the housing 20 and the distal end 271 of the resilient members 267 each abut the proximal end 273 of an actuator button 261. In one option, the actuators 50 are configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second position.

In the first position the actuating members 55 of the actuators 50 are, in one option, disposed and at least partially circumferentially disposed about the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108

of the containment structure 160 by a compressive force 67 (e.g. by a spring 210). The lumen 193 of the third seal member 165 is at least partially collapsed by the compressive force 67. In the second position, the actuators 50 are disposed away from the portion 108 of the seal module 100 by a compressive force 67 (e.g. by
5 depressing the distal end 275 of the actuator button 261). As each actuator button 261 is depressed, each actuator 50 slides along the cylindrical interior wall 11 of the housing 20. The proximal end 273 of each actuator button 261 compresses the distal end 271 of each resilient member 267 which in turn, the proximal end 269 of each resilient member 267 compresses against the inner flange wall 265 of the
10 housing 20. Such movement allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough. As the actuator 50 is disposed away from the portion 108 of the seal module 100, the lumen 193 of the third seal member 165
15 is able to retract in an unsealed configuration.

In another embodiment, the stasis valve 10 includes a containment structure 160 with a proximal end 115 and a distal end 117 with only one actuators 50 disposed against a portion of the seal module 100 movable from a first position to a second position. The actuator 50 includes an actuating member 55 which, in one
20 option, is U-shaped. The outer wall 262 of the housing 20 and the inner flange wall 265 of the housing 20 provide an opposing support for the resilient member 267 (e.g. spring 210) disposed within the actuating member 55. The resilient member 267 includes a proximal end 269 and a distal end 271 where the proximal end 269 of the resilient member 267 abuts the inner flange wall 265 of the housing 20 and the
25 distal end 271 of the resilient member 267 is disposed against the proximal end 273 of an actuator button 261.

In one option, the actuator 50 is configured cylindrically to slide along the cylindrical interior wall 11 of the housing 20 from a first position to a second
30 position. In the first position the actuating member 55 of the actuator 50 is, in one option, disposed and held against the portion 108 of the seal module 100 depressing and at least partially collapsing a portion 108 of the containment structure 160 by a

compressive force 67 (e.g. by a spring 210). In the second position, the actuator 50 is disposed away from the portion 108 of the seal module 100 by a compressive force 67 (e.g. by depressing the distal end 275 of the actuator button 261).

As the actuator button 261 is depressed, the actuator 50 slides along the
 5 cylindrical interior wall 11 of the housing 20. The proximal end 273 of the actuator button 261 compresses the distal end 271 of the resilient member 267 which in turn, the proximal end 269 of the resilient member 267 compresses against the inner flange wall 265 of the housing 20. Such movement allows the engaged actuating member 55 to forcibly disengage the outer wall 27 of the seal module 100 allowing
 10 the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.

The actuating member 55 and/or the actuating button 261 in one option includes aluminum. In another option, the actuating member 55 and the actuating button 261 include plastic. The housing 20, in one option, is made of ABS plastic.
 15 In one option, the third central seal member 165 includes material 166 that is highly elastic, deformable, compliant and yet virtually non-compressible. Materials 166 include modified vinyl, silicone, polyurethane or a combination thereof. The basic materials are, in one option, modified by compounding them with waxes and/or oils or un-cross-linked modifiers. Such materials are commonly available as "C-Flex"
 20 or "Kraton" in the range of 5 to 15 (shore A), as examples. The shore hardness of the material 166 is, in another option, in the range of between 15-20 shore on the "00" scale.

The stasis valve 10, in one option, is made from machining pre-existing amounts of metals and/or plastics. For example, The actuating member 55 and the
 25 actuating button 261 is machined from aluminum. In another example, the actuating member 55 and the actuating button 261 are machined from plastic where the housing 20, in one option, is machined from ABS plastic. In another example, the housing 20, actuator button 261, the connecting member 35 and a cap 276 are injection molded utilizing the various material outlined above.

30 In an example where the stasis valve 10 includes two actuators 50, the stasis valve 10 is assembled by inserting the actuator button 261 and resilient member 267

(e.g., spring 210) into one side of the housing 20. The actuator button 261 and resilient member 267 (e.g., spring 210) are inserted into an opposing side of the housing 20. Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50.

5 Each actuator button is released and the cap 276 secured to the housing 20, for example, with an adhesive. Further, the connecting member 35 is snapped onto the housing. The materials used and the assembly thereof of the stasis valve 10 as described herein can include any of the earlier disclosed embodiments or a combination thereof.

10 It is to be understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reading and understanding the above description. It should be noted that embodiments or portions thereof discussed in different portions of the description or referred to in different drawings can be combined to form additional embodiments
15 of the invention. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

We claim:

1. A valve comprising:
a seal module having a lumen sized to allow the passage of fluids or gases,
5 the seal module having a proximal end and a distal end;
a resilient member disposed against an actuator; and
the actuator disposed against a portion of the seal module, the actuator
movable from a first position to a second position, in the first position the actuator is
disposed against the portion of the seal module collapsing the lumen between the
10 proximal end and the distal end of the seal module creating a seal, in the second
position the actuator is disposed away from the portion of the seal module by a force
allowing the lumen to return to an unsealed configuration.
2. The valve as recited in claim 1, wherein the actuator is disposed away from
15 the portion of the seal module by a compressive force.
3. The valve as recited in claim 1, wherein the seal module is enclosed in a
housing.
- 20 4. The valve as recited in claim 1, wherein the resilient member is a spring.
5. The valve as recited in claim 1, further comprising at least one detent, the
detent retaining a lumen of the seal module in at least one of a closed position or an
open position.
25
6. The valve as recited in claim 1, wherein the actuator includes an extension
configured to slidably engage into a first incline ramp extending from an interior
wall of a housing and an angular wall with a depression having a ledge extending
therebetween, where the extension of the actuator is further configured to engage
30 over the ledge of the depression and into a second incline ramp.

7. The valve as recited in claim 1, wherein the seal module is collapsible by the actuator and by an opposing protrusion.
8. The valve as recited in claim 1, wherein the actuator includes an actuating member having a U-shaped configuration.
9. The valve as recited in claim 1, having two actuators disposed on opposing sides of a housing.
10. A valve comprising:
a seal module having a plurality of seal members including a first seal member, a second seal member, and a third seal member extending between the first and the second seal members, the plurality of seal members each having a lumen sized to allow the passage of fluids or gases; and
the first seal member having a first material, the second seal member having a second material, and the third seal member having a third material, wherein at least one of the first material of the first seal member and the second material of the second seal member is different than the third material of the third seal member.
11. The valve as recited in claim 10, wherein the first seal member is disposed in a sliding relationship with a proximal end of the seal module, the second seal member is disposed against a distal end of the seal module, and the third seal member extends between the first and the second seal members, the third seal member collapsible under pressure from the first seal member.
12. The seal module as recited in claim 10, wherein at least one of the first and the second materials have a higher durometer than the third material.
13. The seal module as recited in claim 10, wherein the first seal member has a first diameter, the second seal member has a second diameter, and the third seal

member has a third diameter, the third diameter of the third seal member is greater than at least one of the first diameter and the second diameter.

14. The seal module as recited in claim 10, wherein at least one of the first
5 material of the first seal member and the second material of the second seal member has a lower friction than the third material of the third seal member.

15. The valve as recited in claim 10, further comprising a support member fitted
10 over the first and the third seal members.

16. The valve as recited in claim 15, wherein the support member includes a
woven material, a braided material, or a combination thereof.

17. A valve comprising:
15 a seal module having a lumen sized to allow the passage of fluids or gases, the seal module having a proximal end and a distal end;
one or more resilient members disposed against one or more actuators; and
the one or more actuators disposed against a portion of the seal module, the
one or more actuators movable from a first position to a second position, in the first
20 position the one or more actuators are at least partially circumferentially disposed about the portion of the seal module collapsing the lumen between the proximal end and the distal end of the seal module creating a seal, in the second position the one or more actuators are circumferentially disposed away from the portion of the seal module allowing the lumen to return to an unsealed configuration.

25 18. The valve as recited in claim 17, wherein the one or more actuators each include an actuating member having a U-shaped configuration.

19. The valve as recited in claim 17, wherein the one or more resilient members
30 is a spring.

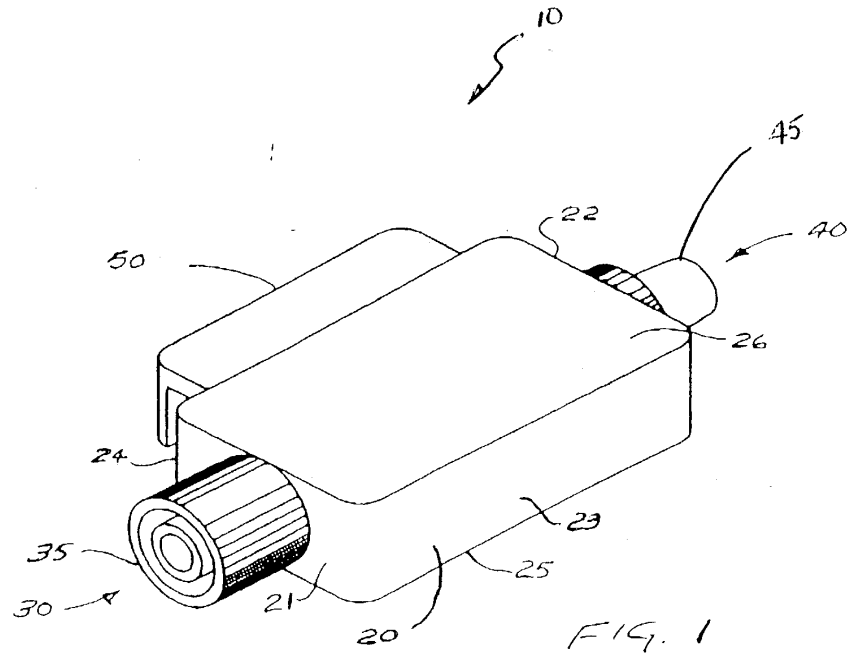
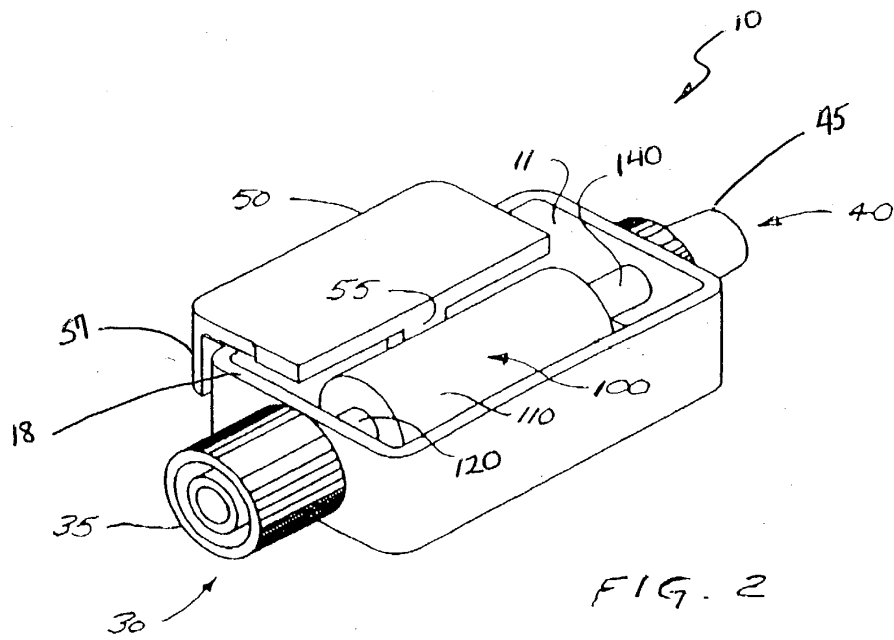
20. The valve as recited in claim 17, wherein the one or more actuators are disposed on opposing sides of a housing.
21. The valve as recited in claim 17, wherein each of the one or more actuators
5 is disposed away from the portion of the seal module by a compressive force.
22. A method comprising:
providing a seal module having a plurality of seal members including a first
seal member with a first lumen in a sliding relationship with a proximal end of the
10 seal module;
disposing a second seal member with a second lumen against a distal end of
the seal module;
disposing a third deformable seal member with a third lumen between the
first and the second seal members, the plurality of seal members sized to allow the
15 passage of fluids or gases;
urging the first seal member toward the second seal member where the
deformable third seal member is compressed; and
collapsing the third seal member creating a seal of at least a portion of the
third lumen of the third seal member.
20
23. The method as recited in claim 22, wherein sealing the module includes
sliding the first seal member disposed against a proximal end of the seal module
toward the second seal member disposed against the distal end of the seal module
and collapsing the third seal member extending between the first and the second seal
25 members.
24. The method as recited in claim 22, further comprising disposing an
instrument through a first diameter of the first seal member, a second diameter of
the second seal member, and a third diameter of the third seal member sealing at
30 least the first seal member to the instrument.

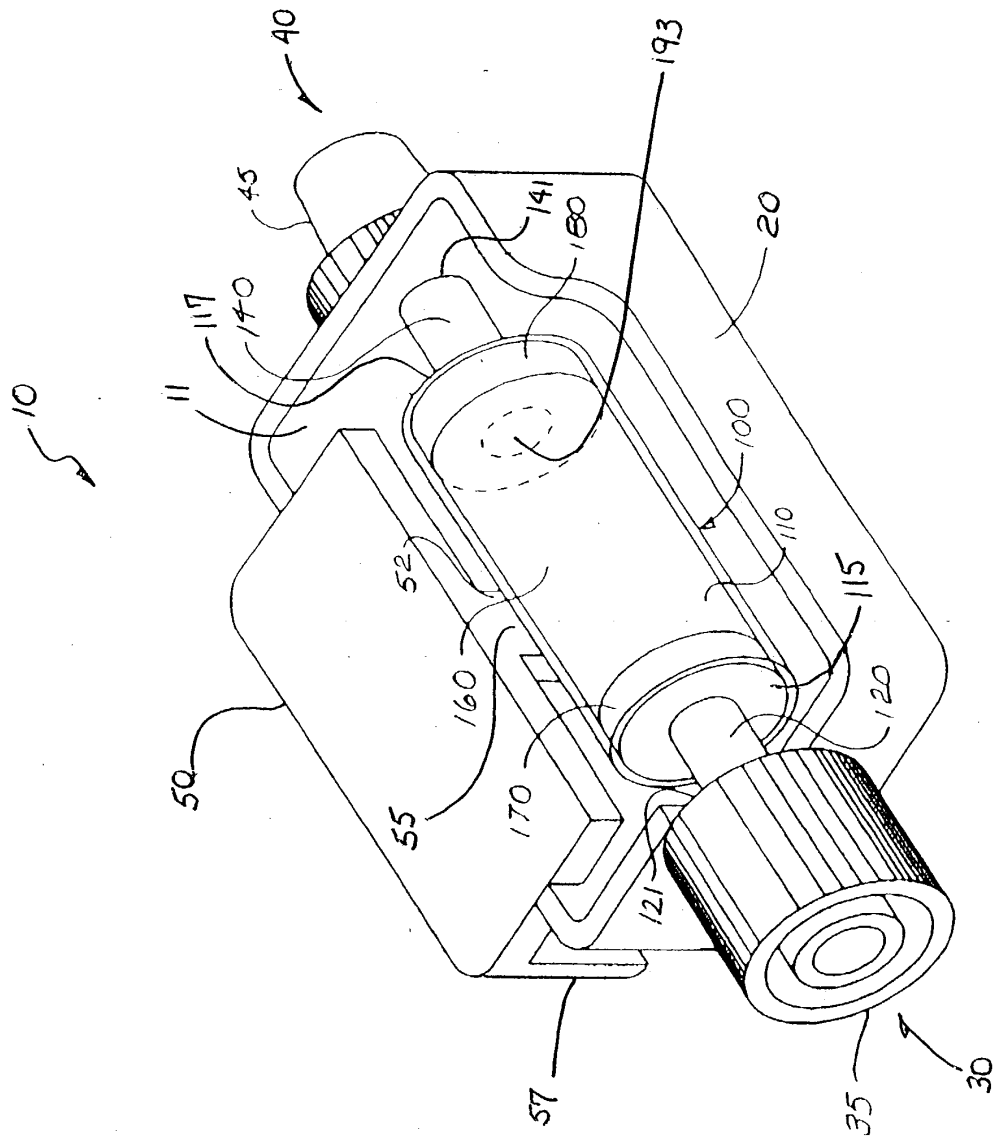
25. The method as recited in claim 22, including moving an actuator along an incline ramp of an interior wall of a housing and into a depression, disposing the actuator under the force of a compression spring, urging the actuator against an angular wall, pushing the actuator to one side over a ledge, and disposing the actuator into a return incline ramp.
26. A method comprising:
forming a seal module having a lumen sized to allow the passage of fluids or gases;
disposing an actuator against a portion of the seal module with a resilient material, the actuator movable from a first position to a second position;
collapsing the lumen between a proximal end and a distal end of the seal module creating a seal; and
moving the actuator away from the portion of the seal module in the second position allowing the lumen to return to an unsealed configuration.
27. The method as recited in claim 26, wherein moving the actuator away from the portion of the seal module includes moving the actuator by a compressive force.
28. The method as recited in claim 26, wherein collapsing the seal module includes depressing the seal module with the actuator and an opposing protrusion.
29. The method as recited in claim 26, wherein collapsing the seal module includes depressing the seal module with two opposing actuators.
30. The method as recited in claim 26, further comprising moving at least one detent, and retaining the lumen of the seal module in at least one of a closed position or an open position.
31. The method as recited in claim 26, including moving an extension of the actuator along an incline ramp of an interior wall of a housing and into a depression,

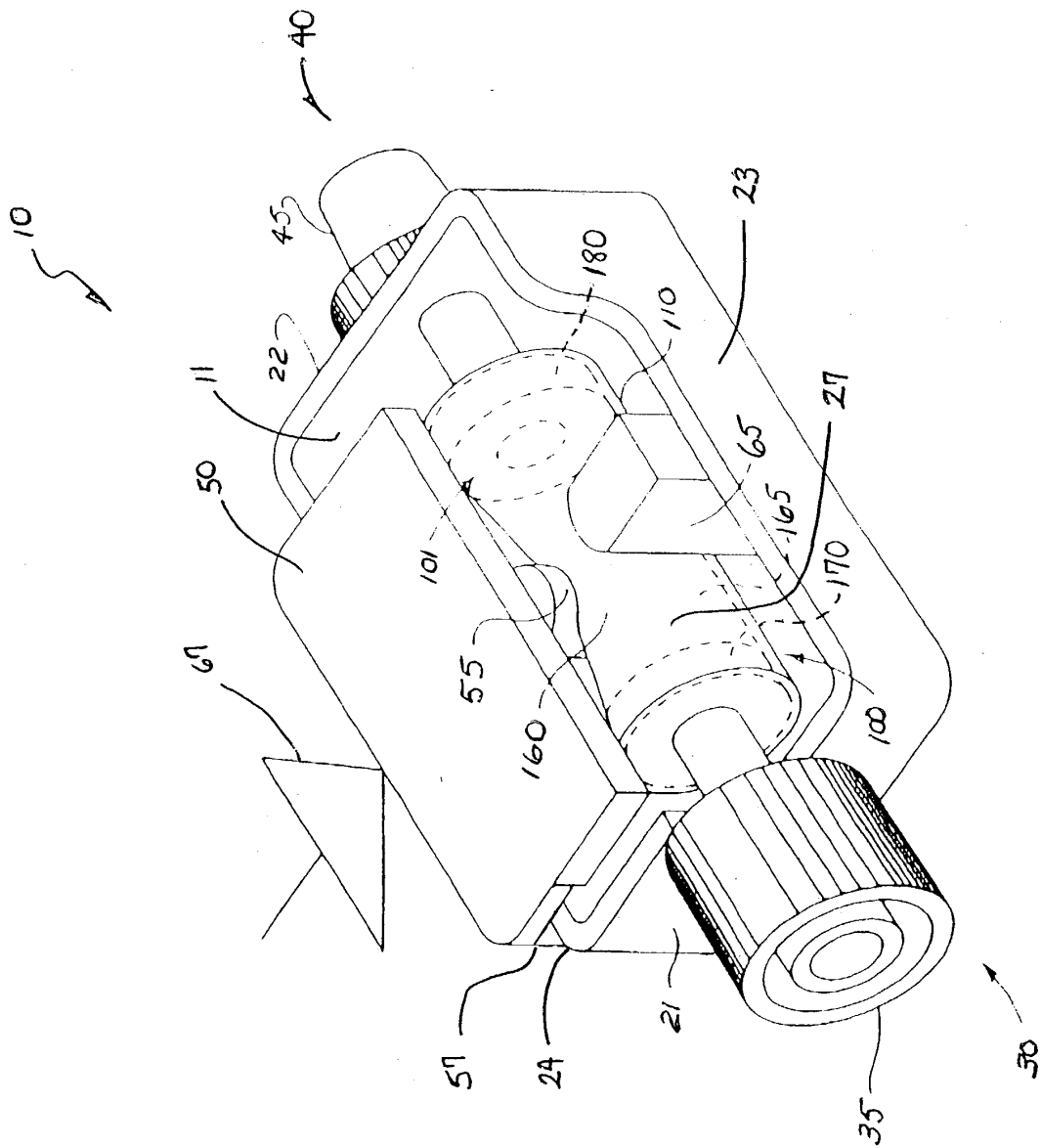
disposing the extension under the force of a compression spring, urging the extension against an angular wall, pushing the extension to one side over a ledge, and disposing the extension into a return incline ramp.

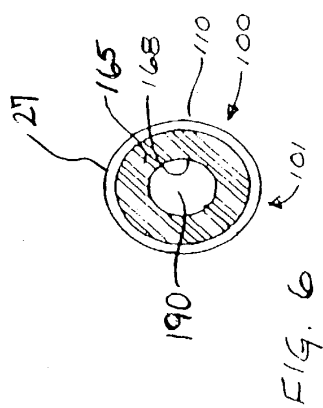
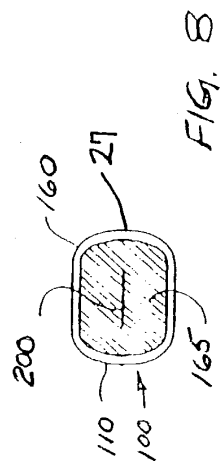
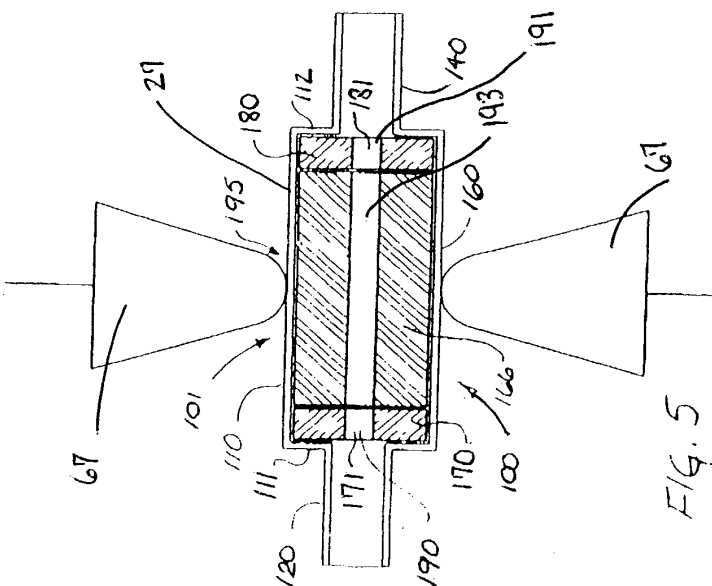
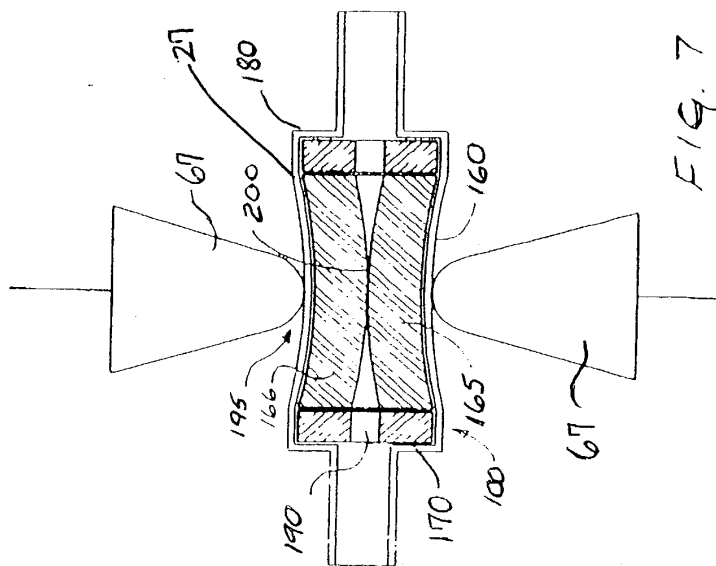
ABSTRACT

A valve for blocking the flow of gas or fluid with or without an instrument in place within the gas/fluid path. The valve includes a seal module having a proximal end and a distal end with a lumen sized to allow the passage of fluids or
5 gases.









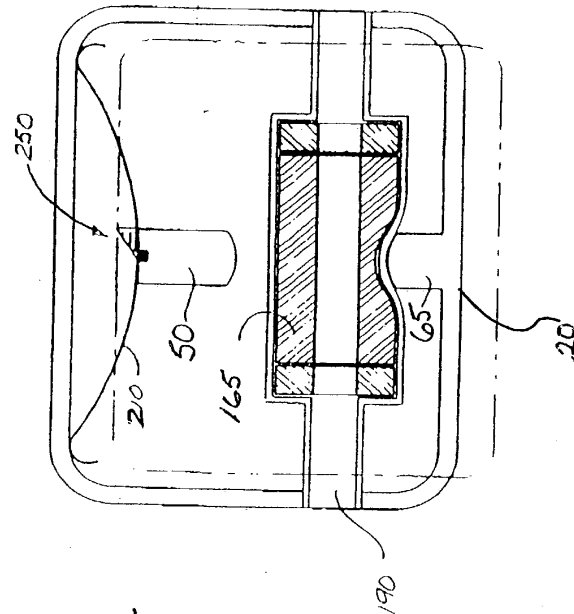


FIG. 9A

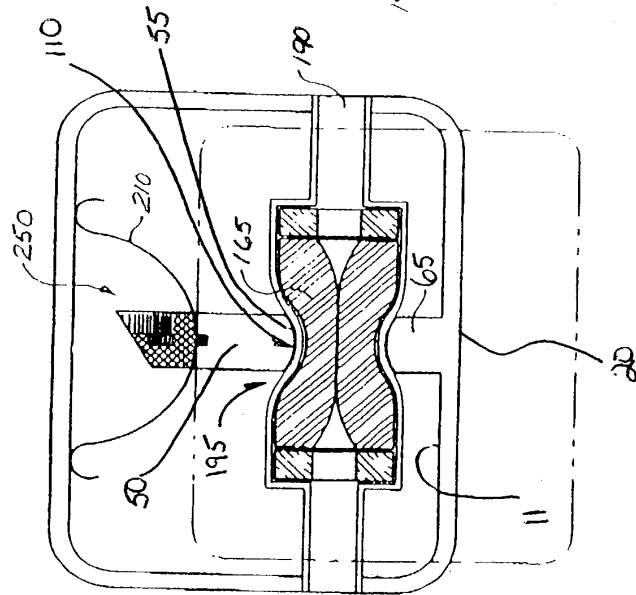


FIG. 10A

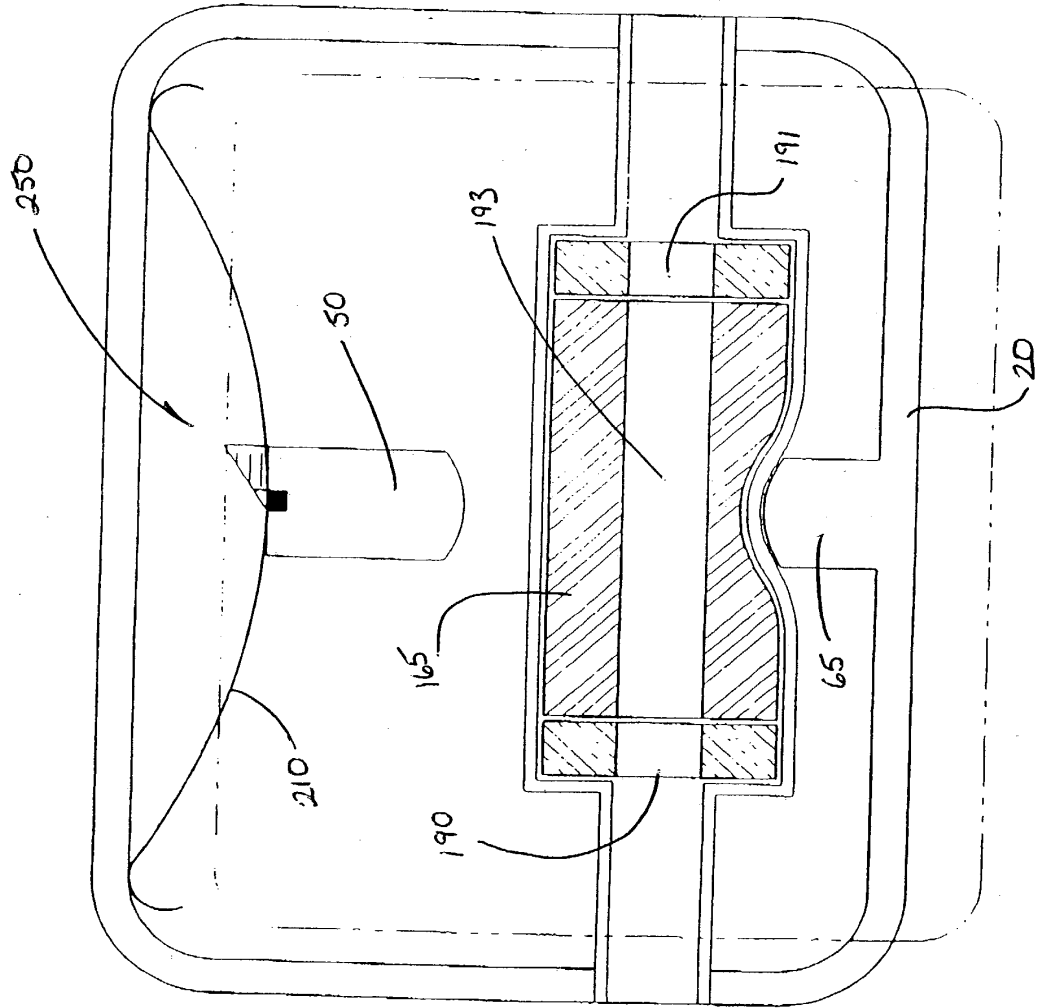
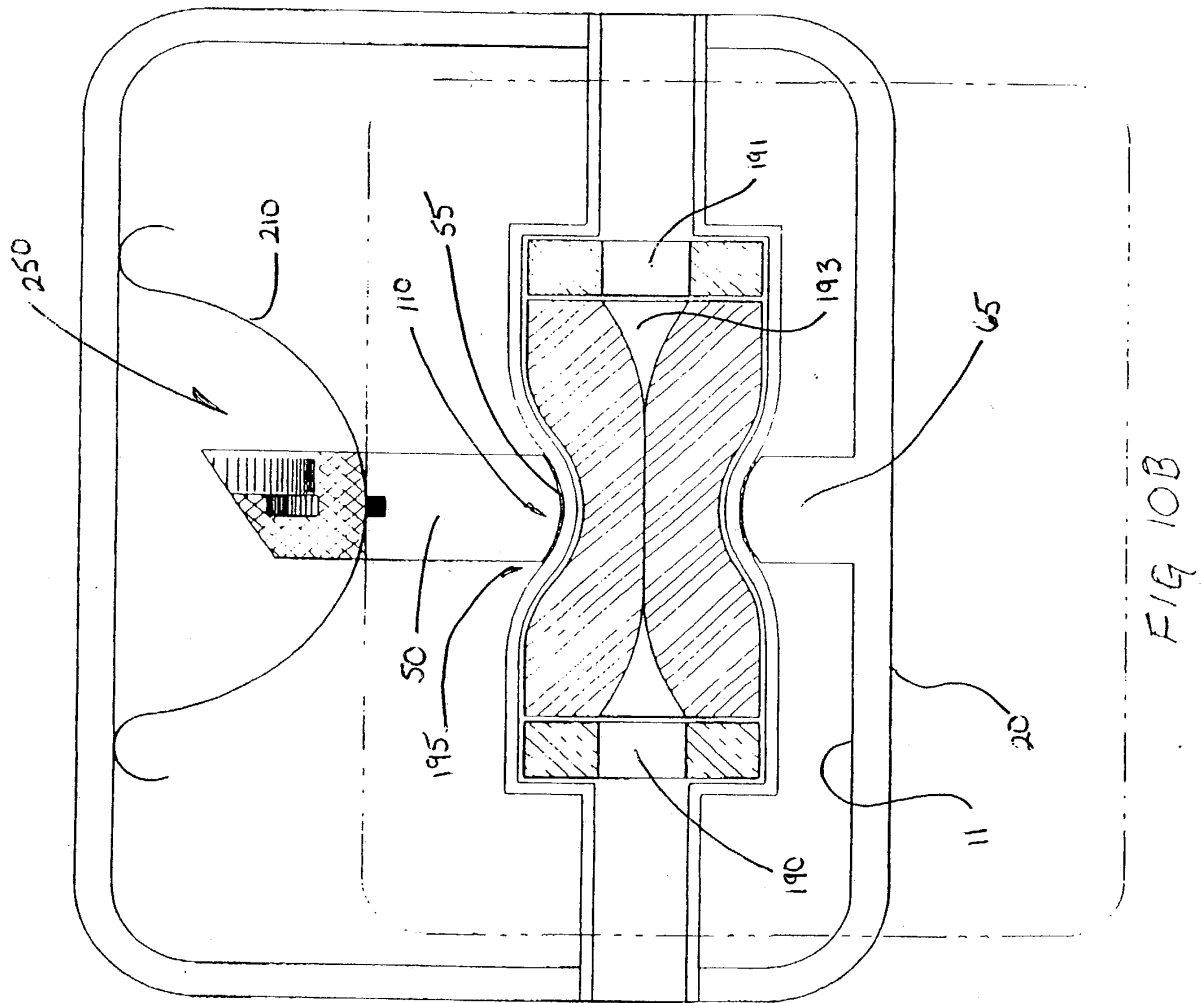


FIG. 9



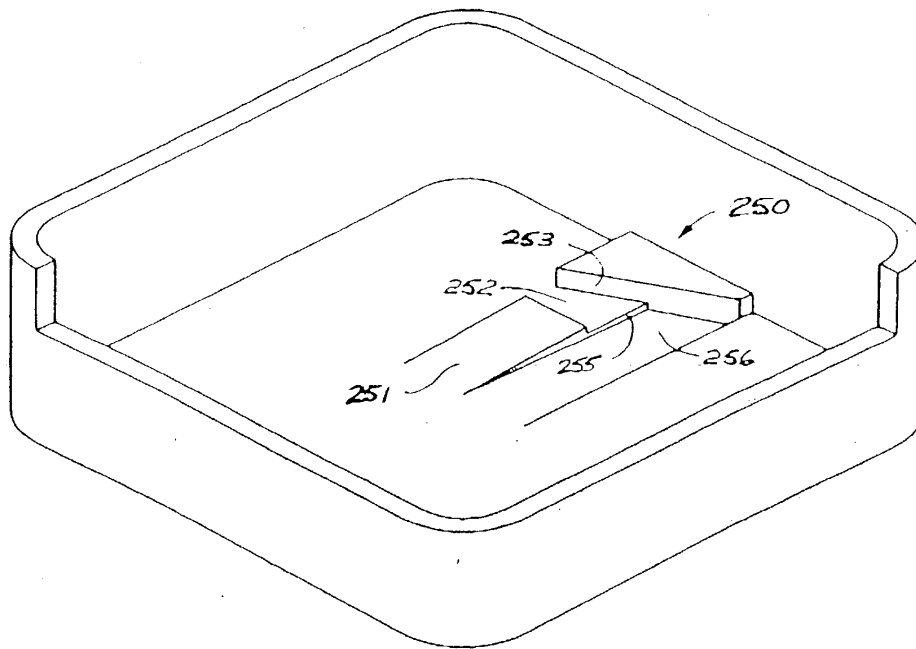
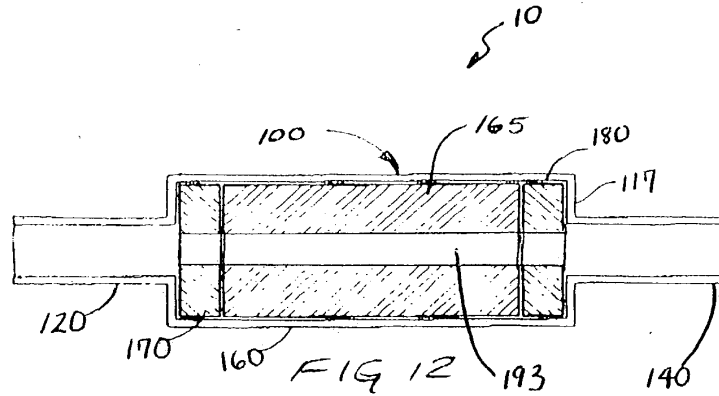
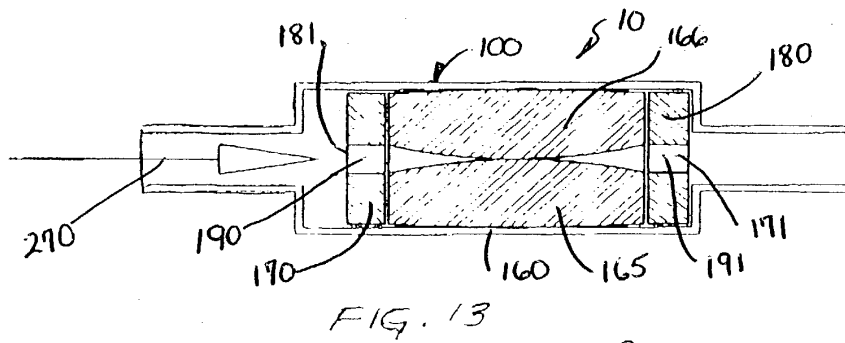
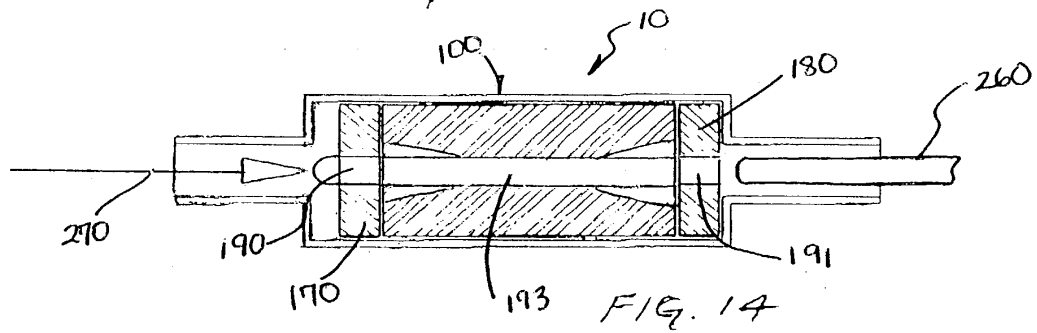
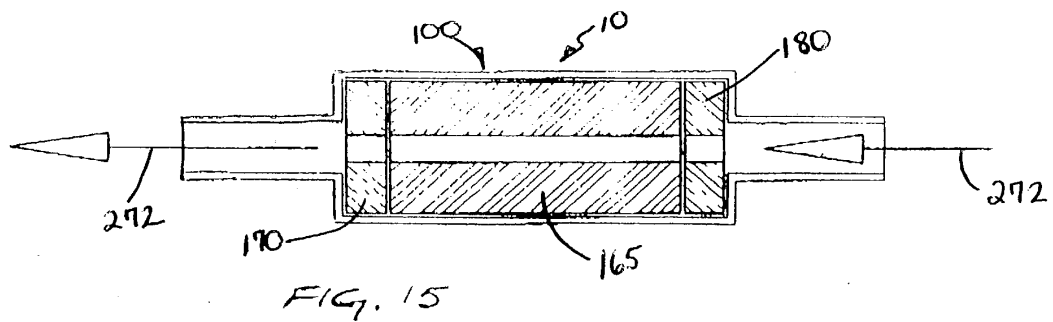


FIG. 11



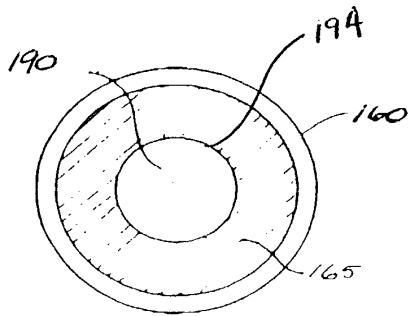


FIG. 16

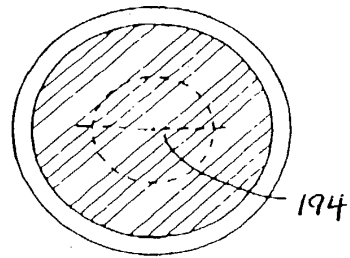


FIG. 17

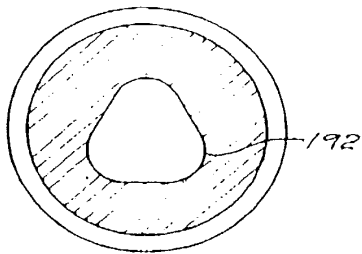


FIG. 18

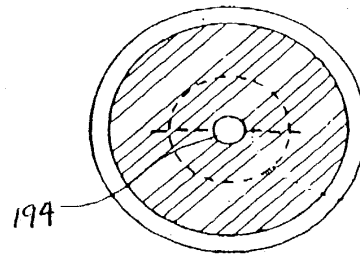


FIG. 19

FIG. 20

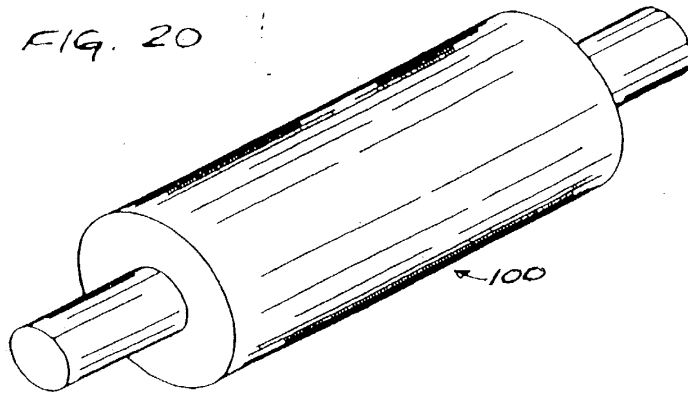
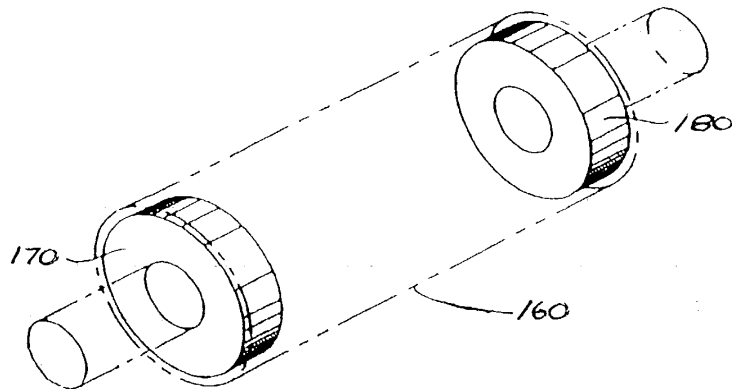


FIG. 21

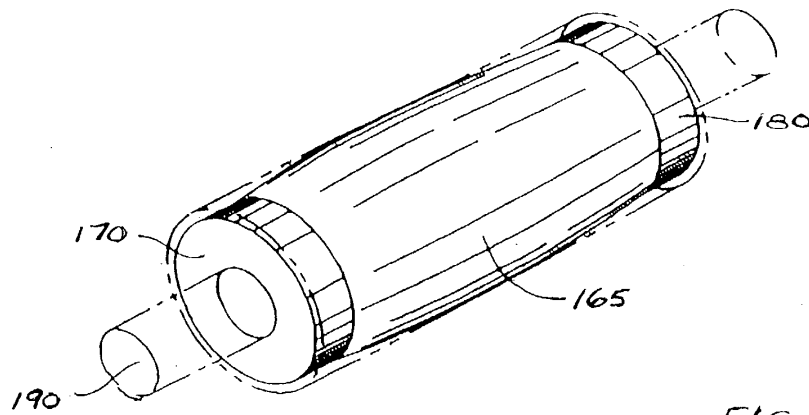


FIG. 22

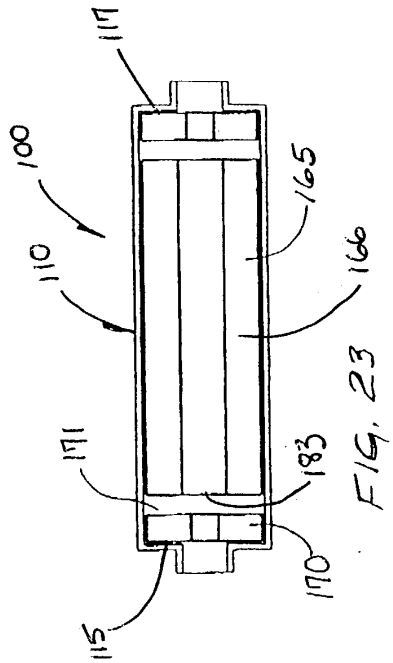


FIG. 25

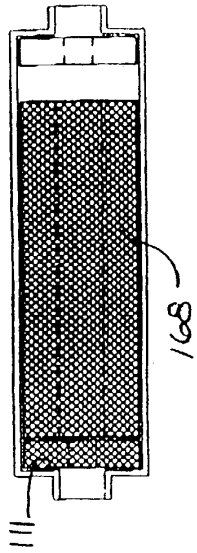
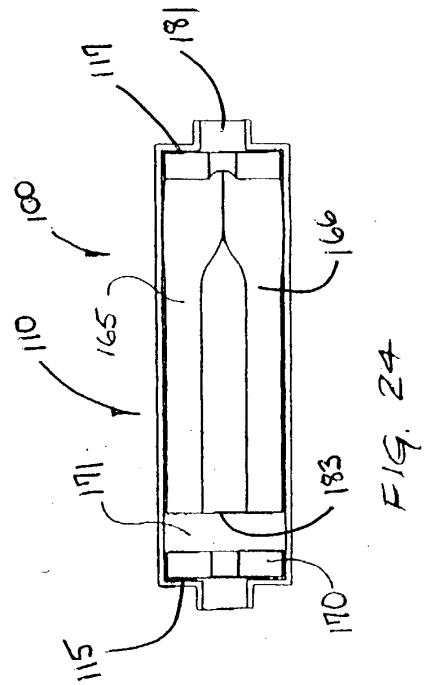
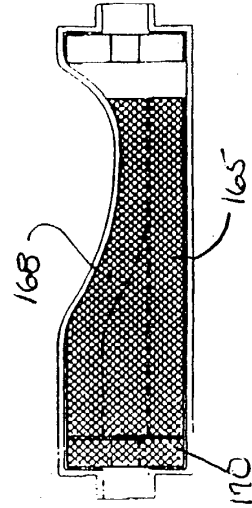


FIG. 26



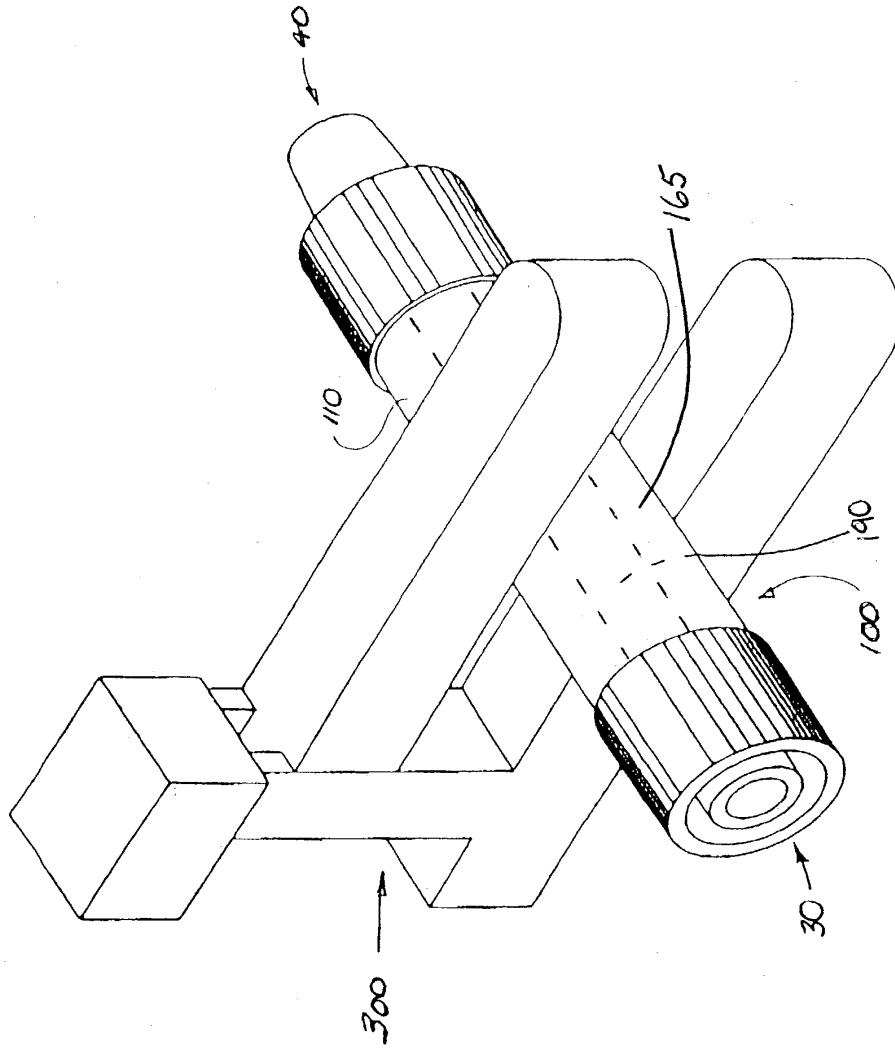


FIG. 27

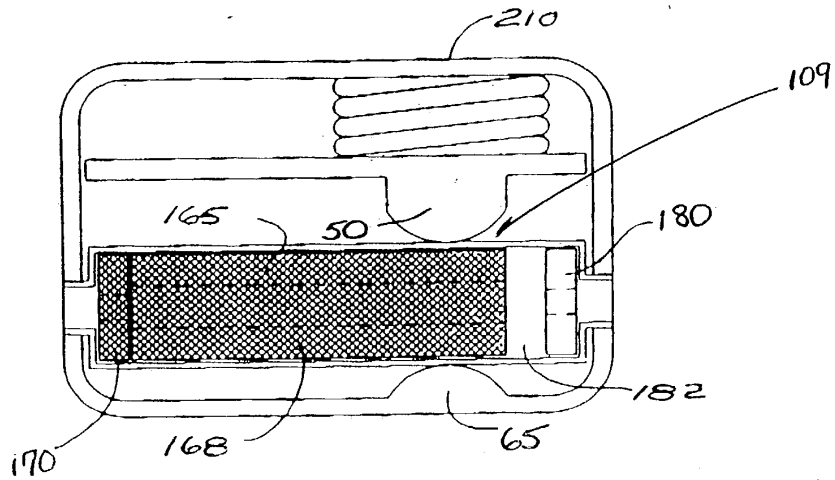


FIG. 28

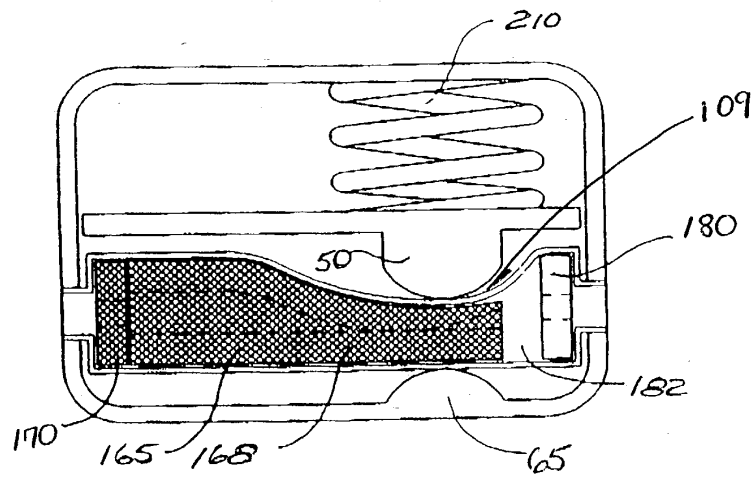
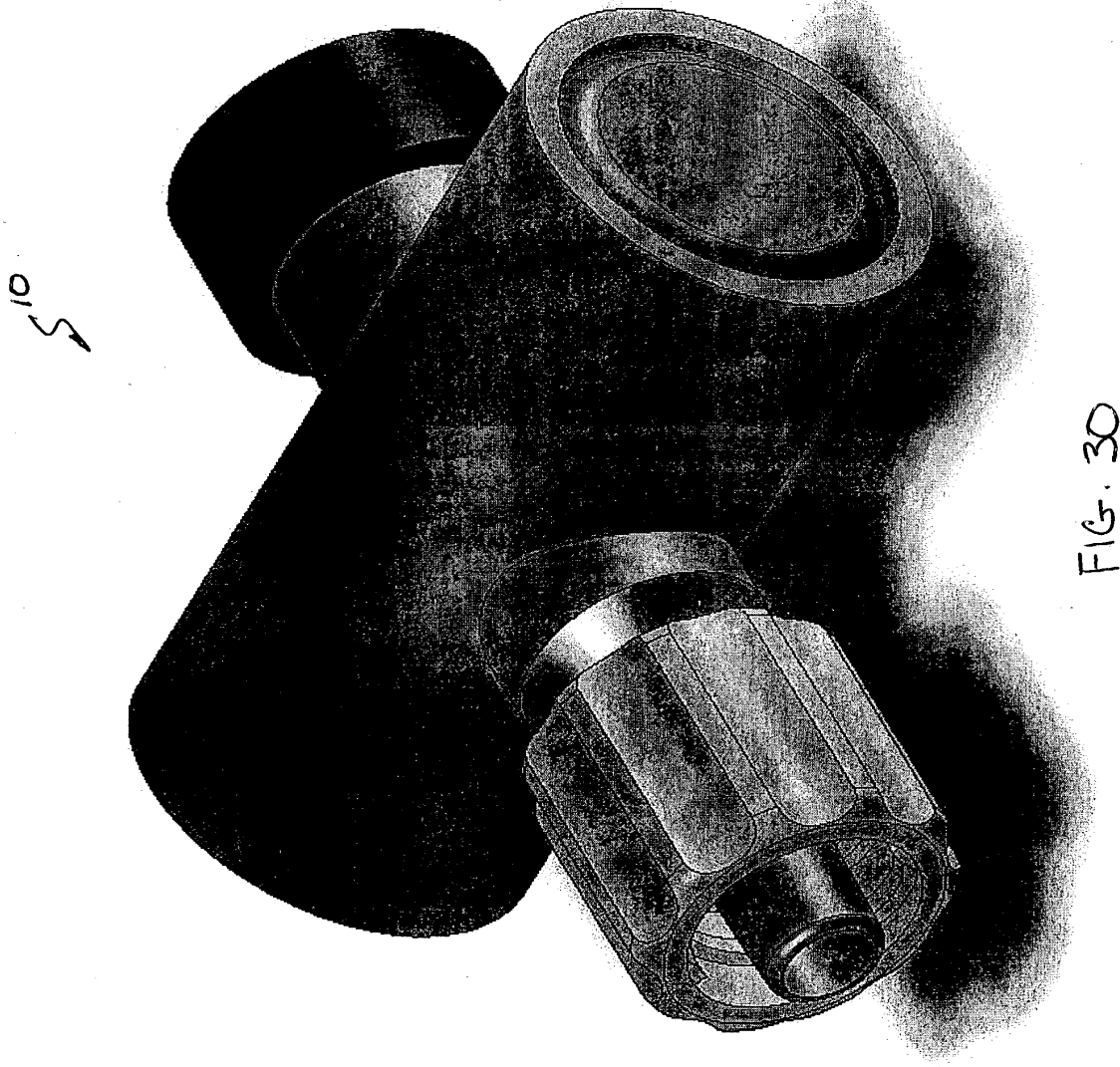
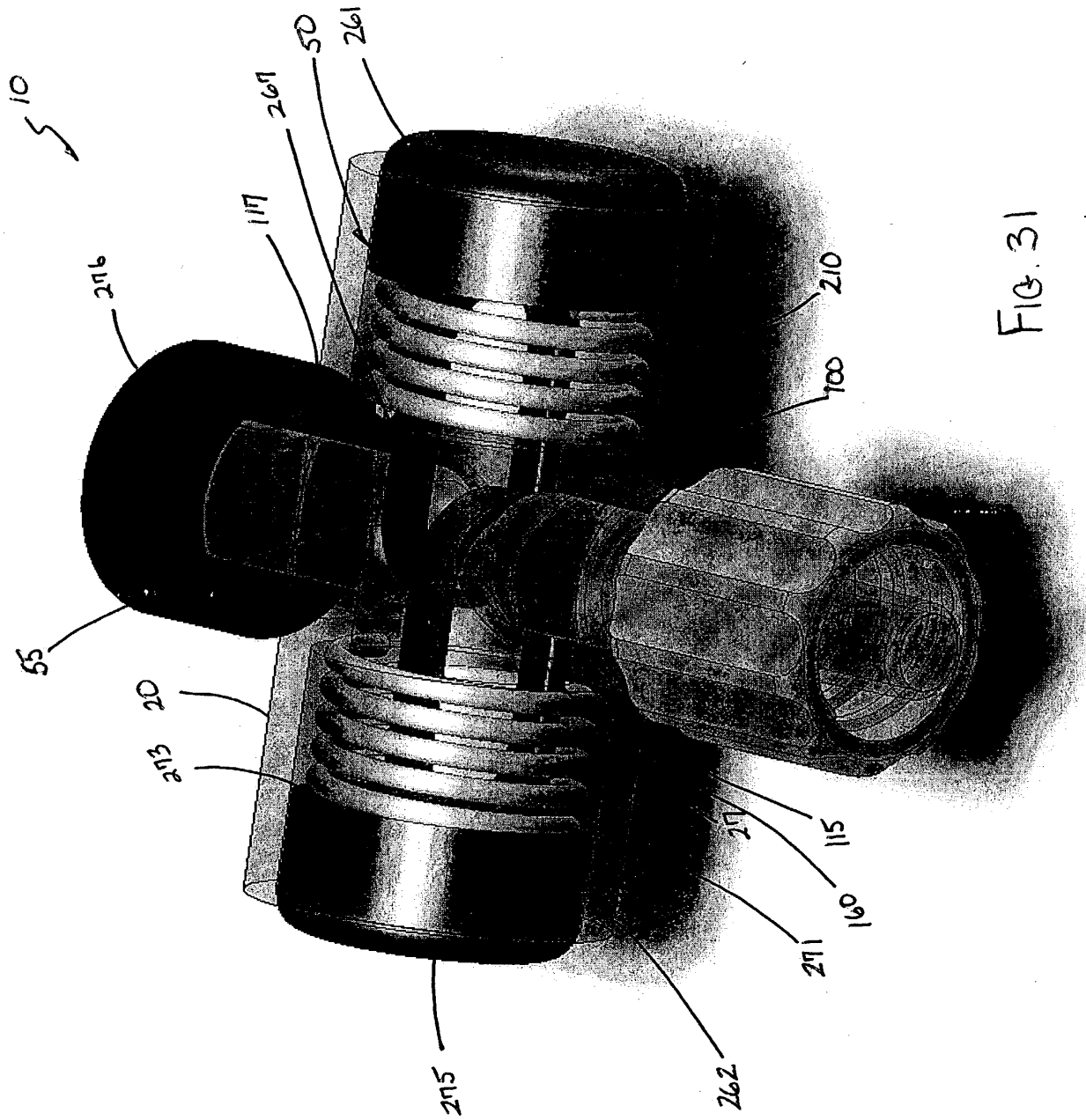


FIG. 29





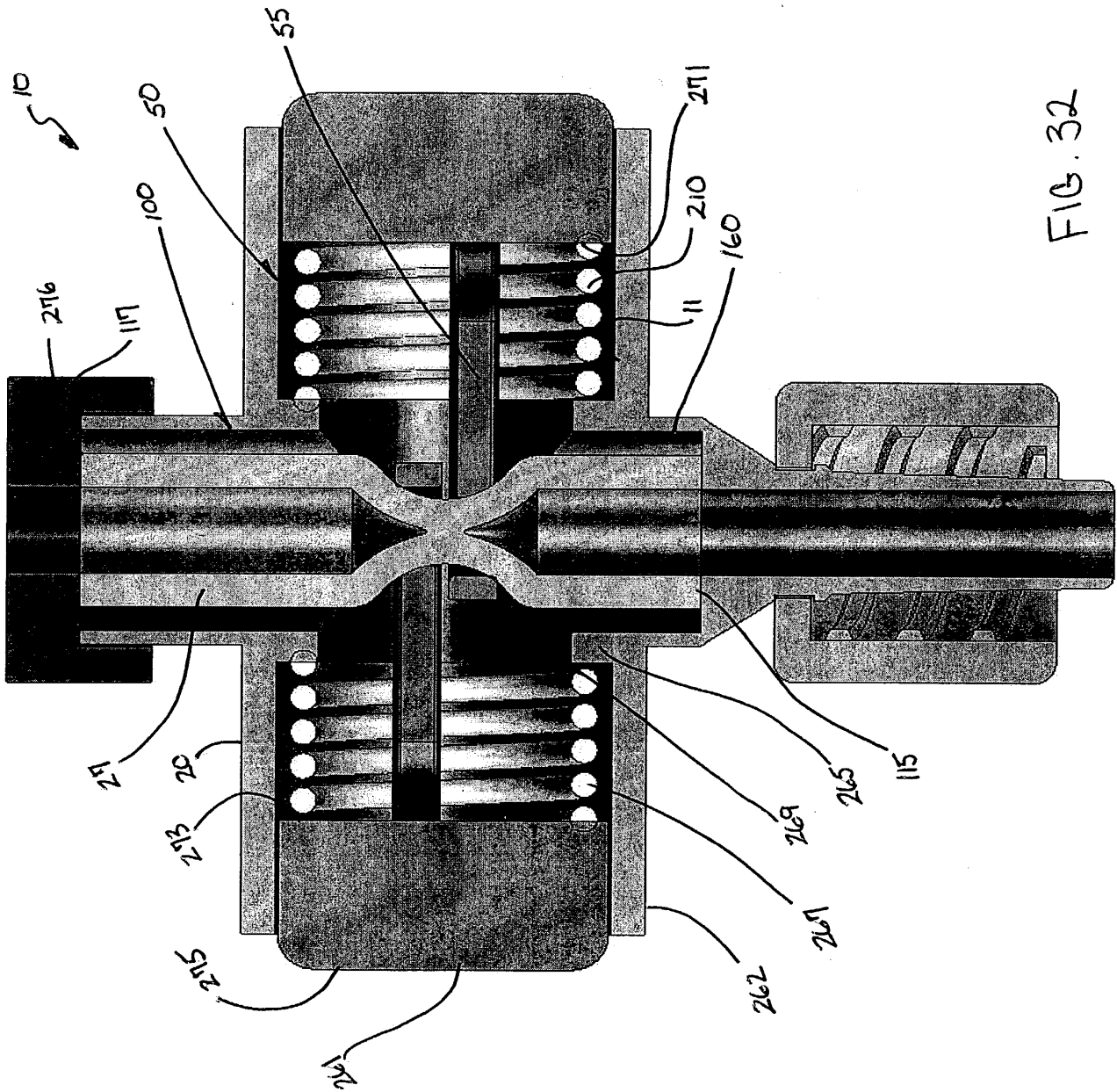
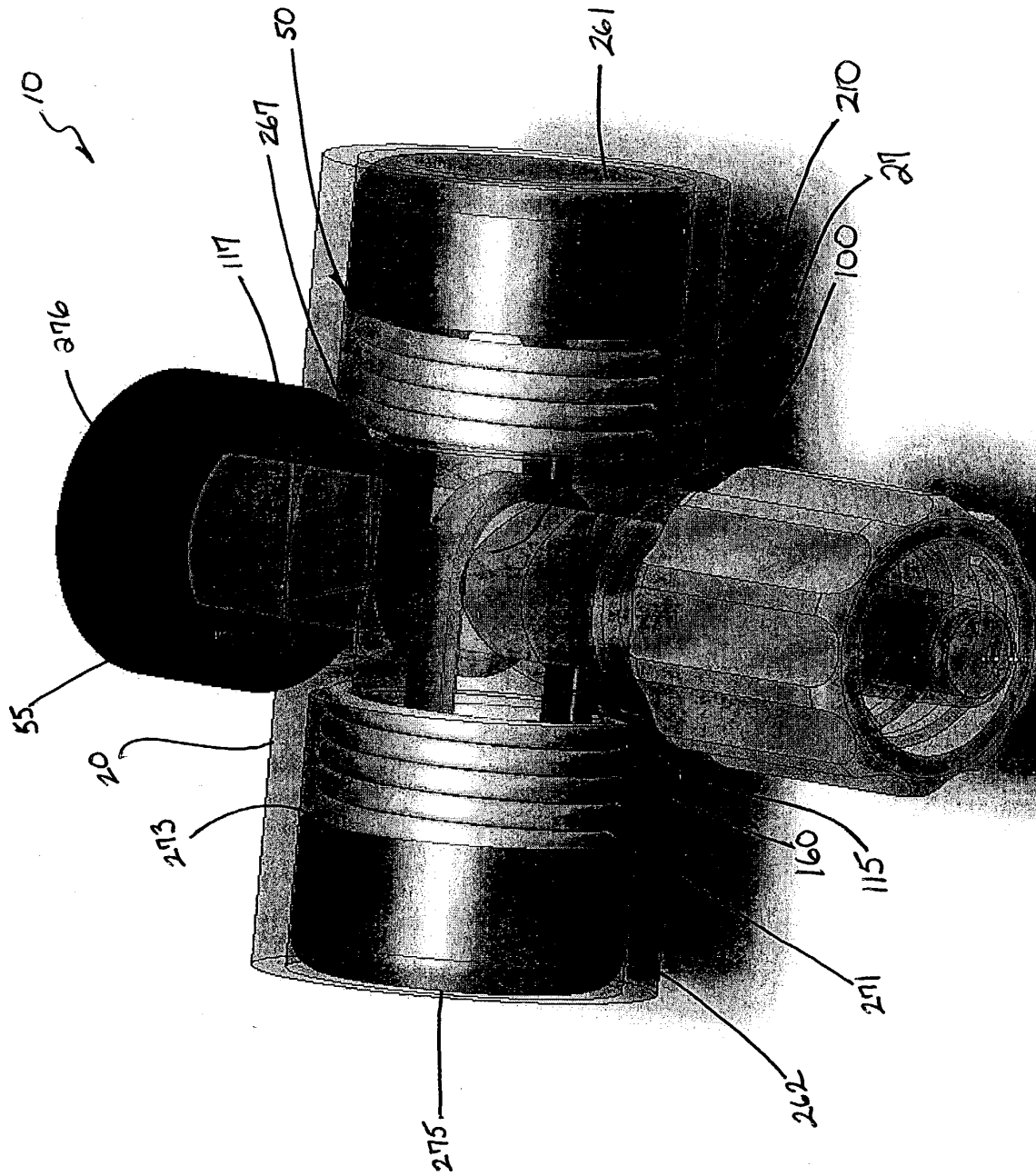
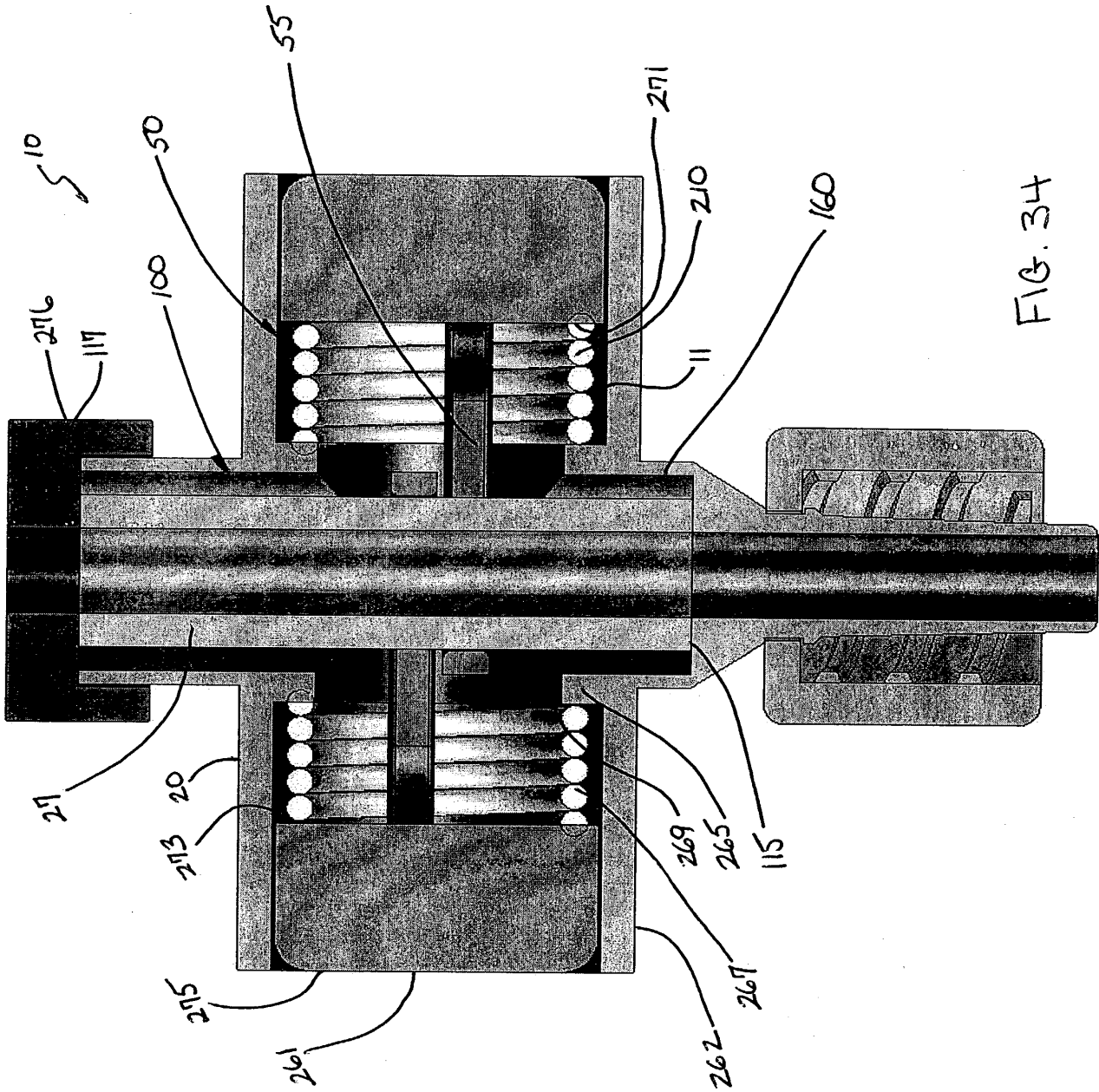


FIG. 32





SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application**COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: COMPOSITE STASIS VALVE.

The specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. § 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Number
60/357937

Filing Date
February 19, 2002

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

No such claim for priority is being made at this time.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

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Black, David W	Reg. No. 42,331	Kluth, Daniel J	Reg. No. 32,146	Peacock, Gregg A	Reg. No. 45,001
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Greaves, John N	Reg. No. 40,362	Mehrle, Joseph P	Reg. No. 45,535	Viksnins, Ann S	Reg. No. 37,748
Haack, John L	Reg. No. 36,154	Muller, Mark V	Reg. No. 37,509	Woessner, Warren D	Reg. No. 30,440

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:

P.O. Box 2938, Minneapolis, MN 55402
Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 1 : **David Schaffer**
 Citizenship: **United States of America**
 Post Office Address: **5949 Northwest 125th Avenue**
Coral Springs, FL 33076

Residence: **Coral Springs, FL**

Signature: _____ Date: _____
 David Schaffer

Full Name of joint inventor number 2 : **Michael Schaffer**
 Citizenship: **United States of America**
 Post Office Address: **5949 Northwest 125th Avenue**
Coral Springs, FL 33076

Residence: **Coral Springs, FL**

Signature: _____ Date: _____
 Michael Schaffer

☒ Additional inventors are being named on separately numbered sheets, attached hereto.

Attorney Docket No.: 905.038US1
Serial No. not assigned
Filing Date: not assigned

Page 3 of 4

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 3 : **Brian Fischer**
Citizenship: **United States of America**
Post Office Address: **3139 Colfax Avenue South**
Minneapolis, MN 55408

Residence: **Minneapolis, MN**

Signature: _____ Date: _____
 Brian Fischer

Full Name of inventor :
Citizenship:
Post Office Address:

Residence:

Signature: _____ Date: _____

Full Name of inventor :
Citizenship:
Post Office Address:

Residence:

Signature: _____ Date: _____

Full Name of inventor :
Citizenship:
Post Office Address:

Residence:

Signature: _____ Date: _____

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

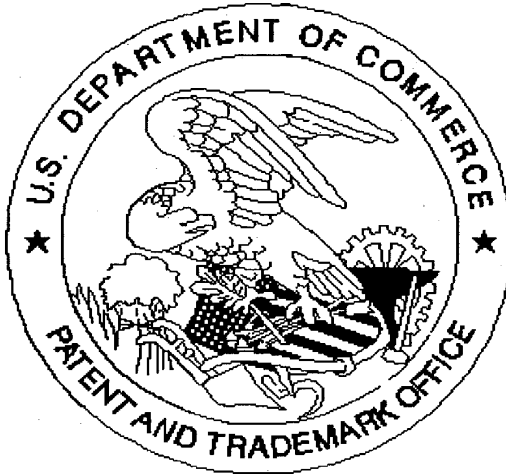
A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

United States Patent & Trademark Office
Office of Initial Patent Examination -- Scanning Division



Application deficiencies found during scanning:

☐ Page(s) _____ of _____ were not present
for scanning. (Document title)

☐ Page(s) _____ of _____ were not
present
for scanning. (Document title)

☐ *Scanned copy is best available. Some drawings are dark*

Special Instructions for Evidence Copy Box Identification

Documents in this patent application scanned prior to the scan date of this document may not have a box number present in the database. The documents are in the same box as this paper. If the patent application documents that do not have a box number are stored in more than one box, a copy of this form is placed in each box. Check the database box number for each copy of this form to identify all of the evidence copy box numbers for documents that do not have a box number.

☒

The documents stored in this box are original application papers scanned and endorsed by PACR and imported into IFW.

☐

The documents stored in this box were scanned into the IFW prototype for GAU 1634, 2827, or 2834.

Indexer, place an X in only one box above to indicate the documents placed in this box that were previously scanned in PACR or IFW and will not be scanned again.

PATENT APPLICATION FEE DETERMINATION RECORD

Effective January 1, 2003

Application or Docket Number

103 7190

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	31	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	31 minus 20 = *	11
INDEPENDENT CLAIMS	5 minus 3 = *	2
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
Independent	*	Minus	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

1 10 17 22 26

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
Independent	*	Minus	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
Independent	*	Minus	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	\$375
X\$ 9=	99
X42=	89
+140=	
TOTAL	558

RATE	FEE
BASIC FEE	\$750
X\$18=	
X84=	
+280=	
TOTAL	

SMALL ENTITY

OR OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	



Commissioner for Patents
Washington, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/371,190	02/19/2003	David Schaffer	905.038US1

Schwegman, Lundberg,
Woessner & Kluth, P.A.
P.O. Box 2938
Minneapolis, MN 55402

CONFIRMATION NO. 9260

FORMALITIES LETTER



OC00000009849218

Date Mailed: 04/16/2003

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$ 375 to complete the basic filing fee for a small entity.
- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121 are required. The drawings submitted are not acceptable because:
 - The drawings have a line quality that is too light to be reproduced (weight of all lines and letters must be heavy enough to permit adequate reproduction) or text that is illegible (reference characters, sheet numbers, and view numbers must be plain and legible) see 37 CFR 1.84(l) and (p)(1)); See Figure(s) 9A, 9B, 10A, 10B and 26.

Items Required To Avoid Processing Delays:

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

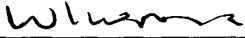
- Additional claim fees of **\$183** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$623** for a Small Entity

- **\$375** Statutory basic filing fee.
- **\$65** Late oath or declaration Surcharge.
- Total additional claim fee(s) for this application is **\$183**
 - **\$99** for **11** total claims over 20 .
 - **\$84** for **2** independent claims over 3 .

*A copy of this notice **MUST** be returned with the reply.*



Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#3

MR \$

Applicant: David Schaffer et al.

Title: COMPOSITE STASIS VALVE

Docket No.: 905.038US1

Filed: February 19, 2003

Examiner: Unknown

Serial No.: 10/371,190

Due Date: June 16, 2003

Group Art Unit: 3763

Mail Stop Missing Parts
Commissioner for Patents
P.O.Box 1450
Alexandria, VA 22313-1450

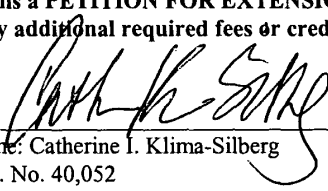
We are transmitting herewith the attached:

- ☒ A return postcard.
- ☒ A check in the amount of \$65.00 to cover the small entity surcharge.
- ☒ A check in the amount of \$375.00 to cover the Basic Filing Fee and Additional Claims Fee.
- ☒ Communication Re: Missing Parts (1 pg.).
- ☒ A signed Combined Declaration and Power of Attorney (4 pgs.).
- ☒ Notice to File Missing Parts (2pgs.).
- ☒ Communication Re: Corrected Application Papers (1 pg.).
- ☒ Formal Drawings(19 pgs).

Applicant claims small entity status under 37 C.F.R. 1.27.

If not provided for in a separate paper filed herewith, please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional required fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938, Minneapolis, MN 55402 612-359-3276

By: 
Name: Catherine I. Klima-Silberg
Reg. No. 40,052
CIK:CMG:mjm

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Attn: Mail Stop Missing Parts, Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450, on this 16th day of June, 2003

MEREDITH MESCHER
Name

Meredith Mescher
Signature



10/371190

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Schaffer et al.

Examiner: Unknown

Serial No.: 10/371,190

Group Art Unit: 3763

Filed: February 19, 2003

Docket: 905.038US1

Title: COMPOSITE STASIS VALVE

COMMUNICATION RE: MISSING PARTS

Mail Stop Missing Parts
Commissioner for Patents
P.O.Box 1450
Alexandria, VA 22313-1450

In response to the "Notice to File Missing Parts" (see enclosed copy), we submit the Combined Declaration and Power of Attorney a check in the amount of \$65.00 to cover the Small entity surcharge and a check in the amount of \$375.00 to cover the small entity basic filing fee and additional claims fee.

Applicants assume the application is now in proper order and in condition for examination. Please direct any inquiries to the undersigned attorney at 612-359-3276.

If necessary, please charge any additional fees or credit overpayment to Deposit Account 19-0743.

Respectfully submitted,

David Schaffer et al.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
612-359-3276

Date June 9, 2003

By

Catherine I. Klima-Silberg

Reg. No. 40,052

CIK:CMG:mjm

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Attn: Mail Stop Missing Parts, Commissioner for Patents, P.O.Box 1450, Alexandria, VA 22313-1450, on this 10 day of June, 2003

MEREDITH MESCHER
Name

Meredith Mescher
Signature



Serial 10/371190

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Schaffer et al. Examiner: Unknown
Serial No.: 10/371,190 Group Art Unit: 3763
Filed: February 19, 2003 Docket: 905.038US1
Title: COMPOSITE STASIS VALVE

COMMUNICATION RE: CORRECTED APPLICATION PAPERS

Mail Stop Missing Parts
Commissioner for Patents
P.O.Box 1450
Alexandria, VA 22313-1450

In response to the "Notice to File Corrected Application Papers" (see enclosed copy), enclosed are 19 pages of formal drawings for the above-identified application.

Applicants assume the application is now in proper order and in condition for examination. Please direct any inquiries to the undersigned attorney at 612-359-3276.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

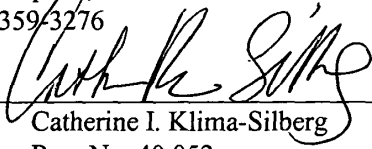
DAVID SCHAFFER et al.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
612-359-3276

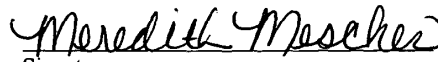
Date June 9, 2003

By


Catherine I. Klima-Silberg
Reg. No. 40,052
CIK:CMG:mjm

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Attn: Mail Stop Missing Parts, Commissioner for Patents, Alexandria, VA 22313-1450, on this 16th day of June, 2003.

MEREDITH MESCHER
Name


Signature



UNITED STATES
PATENT AND
TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/371,190	02/19/2003	David Schaffer	905.038US1

CONFIRMATION NO. 9260

Schwegman, Lundberg,
Woessner & Kluth, P.A.
P.O. Box 2938
Minneapolis, MN 55402

FORMALITIES LETTER



OC000000009849218

Date Mailed: 04/16/2003

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

06/19/2003 MBERHE 00000042 10371190

Filing Date Granted

01 FC:2001	375.00	OP
02 FC:2202	99.00	OP
03 FC:2201	84.00	OP
04 FC:2051	65.00	OP

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

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Applicant must submit \$ 375 to complete the basic filing fee for a small entity.
- The oath or declaration is unsigned.
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The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

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 - The drawings have a line quality that is too light to be reproduced (weight of all lines and letters must be heavy enough to permit adequate reproduction) or text that is illegible (reference characters, sheet numbers, and view numbers must be plain and legible) see 37 CFR 1.84(l) and (p)(1)); See Figure(s) 9A, 9B, 10A, 10B and 26.

Items Required To Avoid Processing Delays:

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

PORTFOLIO I.P.

APR 21 2003

RECEIVED

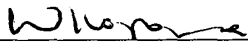
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- Total additional claim fee(s) for this application is **\$183**
 - **\$99** for **11** total claims over 20 .
 - **\$84** for **2** independent claims over 3 .

*A copy of this notice **MUST** be returned with the reply.*



Customer Service Center
Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **COMPOSITE STASIS VALVE**.

The specification of which was filed on February 19, 2003 as application serial no. 10/371,190.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. § 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Number
60/357937

Filing Date
February 19, 2002

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

No such claim for priority is being made at this time.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Anglin, J. M	Reg. No. 24,916	Harris, Robert J	Reg. No. 37,346	Nelson, A. J	Reg. No. 28,650
Arora, Suneel	Reg. No. 42,267	Jackson Huebsch, Katharine A	Reg. No. 47,670	Nielsen, Walter W	Reg. No. 25,539
Beekman, Marvin L	Reg. No. 38,377	Jurkovich, Patti J	Reg. No. 44,813	Padys, Danny J	Reg. No. 35,635
Bianchi, Timothy E	Reg. No. 39,610	Kalis, Janal M	Reg. No. 37,650	Parker, J. K	Reg. No. 33,024
Billion, Richard E	Reg. No. 32,836	Klima-Silberg, Catherine I	Reg. No. 40,052	Peacock, Gregg A	Reg. No. 45,001
Black, David W	Reg. No. 42,331	Kluth, Daniel J	Reg. No. 32,146	Perdok, Monique M	Reg. No. 42,989
Brennan, Thomas F	Reg. No. 35,075	Lacy, Rodney L	Reg. No. 41,136	Peret, Andrew R	Reg. No. 41,246
Chadwick, Robin A	Reg. No. 36,477	Lemaire, Charles A	Reg. No. 36,198	Peterson, David C	Reg. No. 47,857
Clark, Barbara J	Reg. No. 38,107	Lundberg, Steven W	Reg. No. 30,568	Prout, William F	Reg. No. 33,995
Clise, Timothy B	Reg. No. 40,957	Lundberg, Steven W	Reg. No. 30,568	Puckett, Craig L	Reg. No. 43,023
Cochran, David R	Reg. No. 46,632	Maki, Peter C	Reg. No. 42,832	Schumm, Sherry W	Reg. No. 39,422
Dahl, John M	Reg. No. 44,639	Malen, Peter L	Reg. No. 44,894	Schwegman, Micheal L	Reg. No. 25,816
DeLizio, Andrew	Reg. No. 52,806	Mates, Robert E	Reg. No. 35,271	Speier, Gary J	Reg. No. 45,458
Drake, Eduardo E	Reg. No. 40,594	McCrackin, Ann M	Reg. No. 42,858	Steffey, Charles E	Reg. No. 25,179
Embretson, Janet E	Reg. No. 39,665	McGough, Kevin J	Reg. No. 31,279	Stordal, Leif T	Reg. No. 46,251
Forrest, Bradley A	Reg. No. 30,837	McTavish, Hugh E	Reg. No. 48,341	Terry, Kathleen R	Reg. No. 31,884
Gorrie, Gregory J	Reg. No. 36,530	Mehrl, Joseph P	Reg. No. 45,535	Tong, Viet V	Reg. No. 45,416
Gortych, Joseph E	Reg. No. 41,791	Muller, Mark V	Reg. No. 37,509	Viksins, Ann S	Reg. No. 37,748
Greaves, John N	Reg. No. 40,362	Nama, Prakash	Reg. No. 44,255	Woessner, Warren D	Reg. No. 30,440

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:
P.O. Box 2938, Minneapolis, MN 55402
Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 1 : **David Schaffer**
Citizenship: **United States of America**
Post Office Address: **5949 Northwest 125th Avenue**
Coral Springs, FL 33076

Residence: **Coral Springs, FL**

Signature: David Schaffer
David Schaffer

Date: 6-04-03

Full Name of joint inventor number 2 : **Michael Schaffer**
Citizenship: **United States of America**
Post Office Address: **5949 Northwest 125th Avenue**
Coral Springs, FL 33076

Residence: **Coral Springs, FL**

Signature: Michael Schaffer
Michael Schaffer

Date: 6.02.03

☒ Additional inventors are being named on separately numbered sheets, attached hereto.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 3 : **Brian Fischer**
Citizenship: **United States of America**
Post Office Address: **3139 Colfax Avenue South**
Minneapolis, MN 55408

Residence: **Minneapolis, MN**

Signature: Brian Fischer
Brian Fischer

Date: 5/27/03

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

1/19

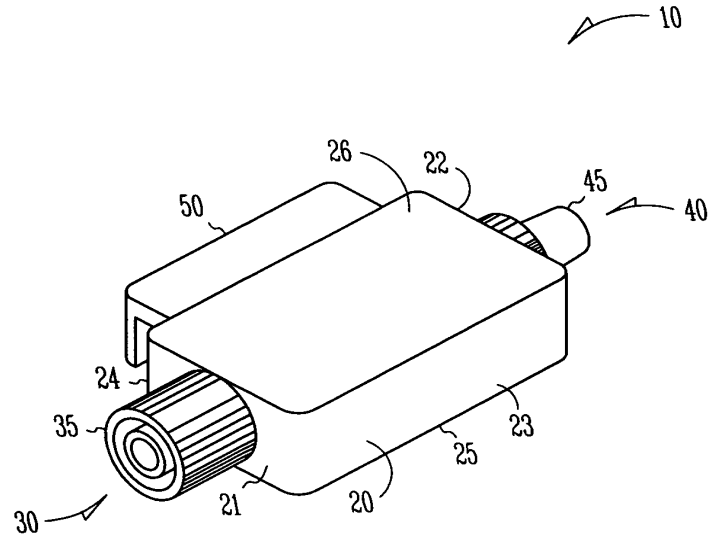


Fig. 1

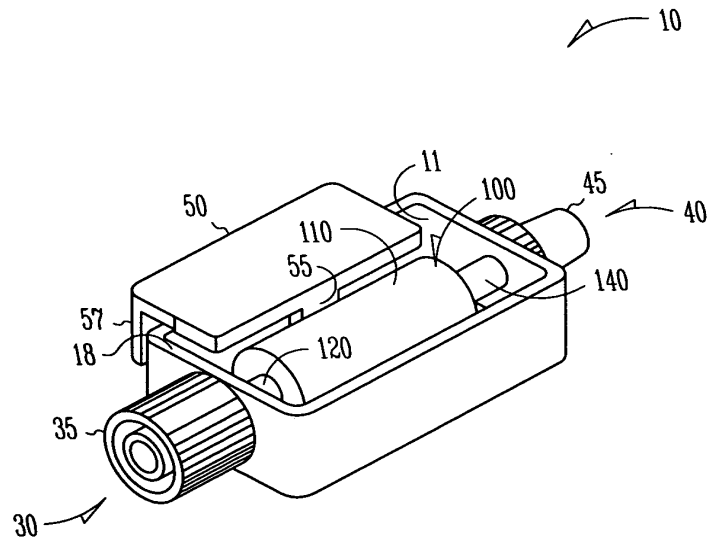


Fig. 2



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

2/19

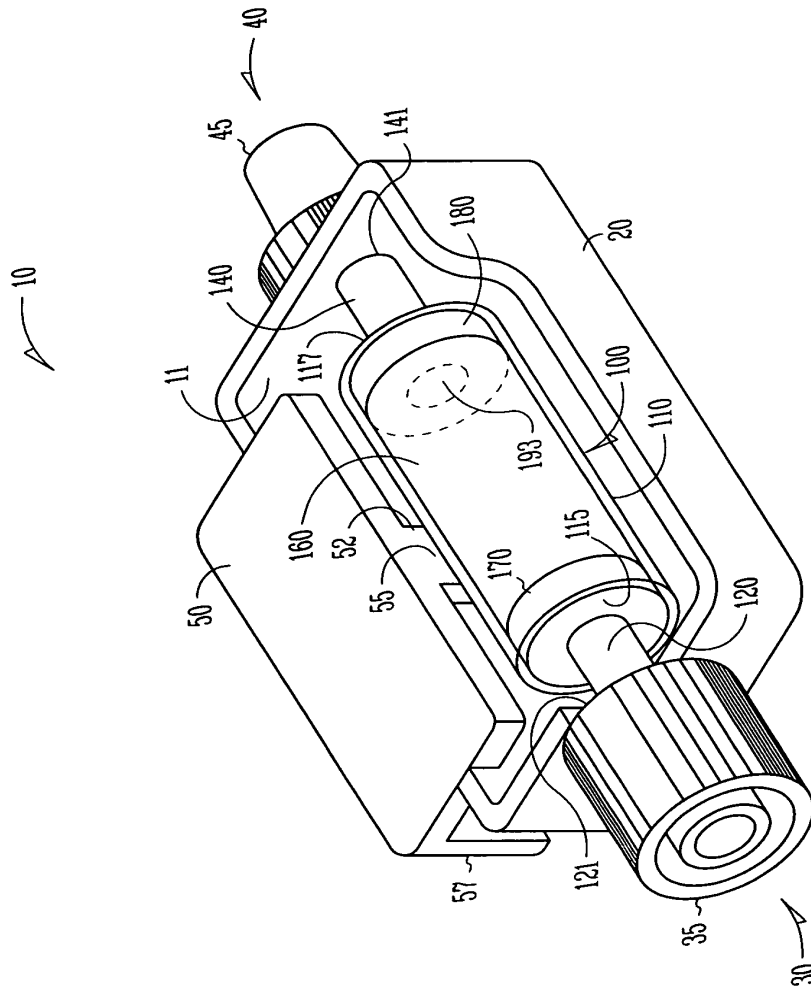


Fig. 3



TITLE: . COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

3/19

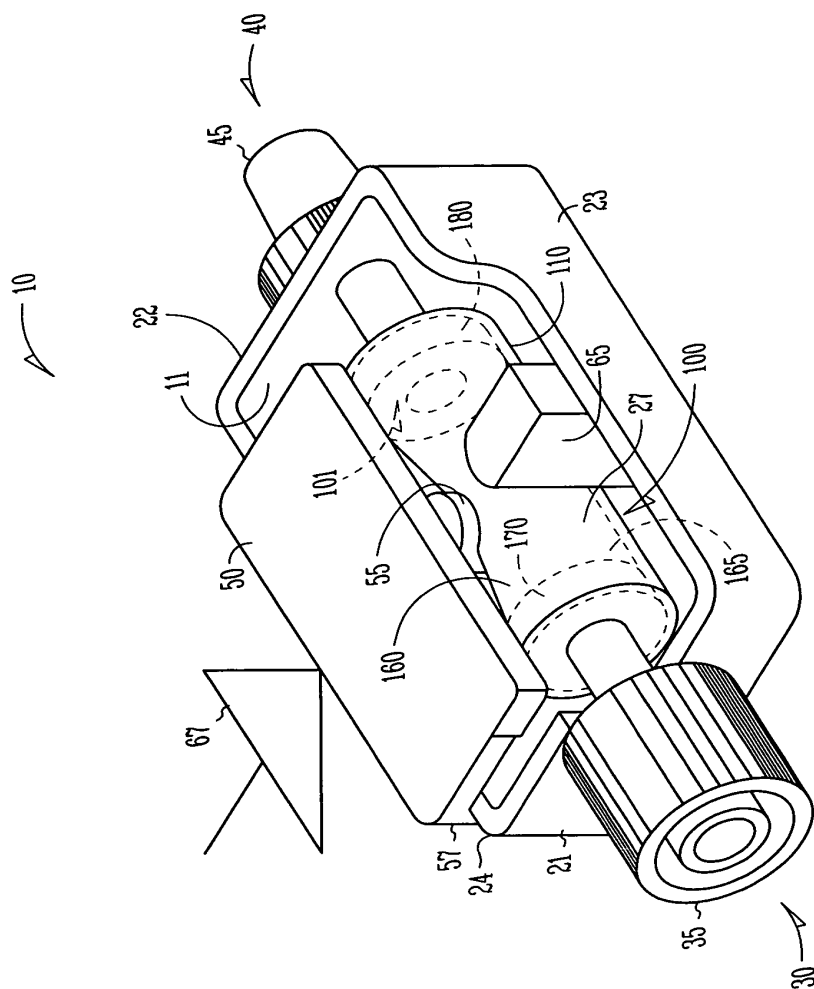


Fig. 4



TITLE: . COMPOSITE STASIS VALVE
 INVENTORS NAME: David Schaffer et al.
 SERIAL NO.: 10/371,190

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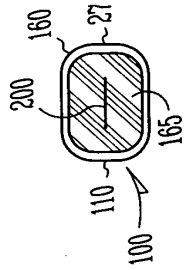


Fig. 8

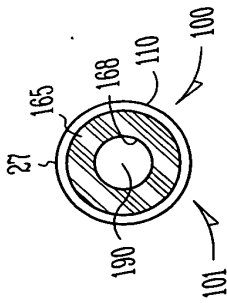


Fig. 6

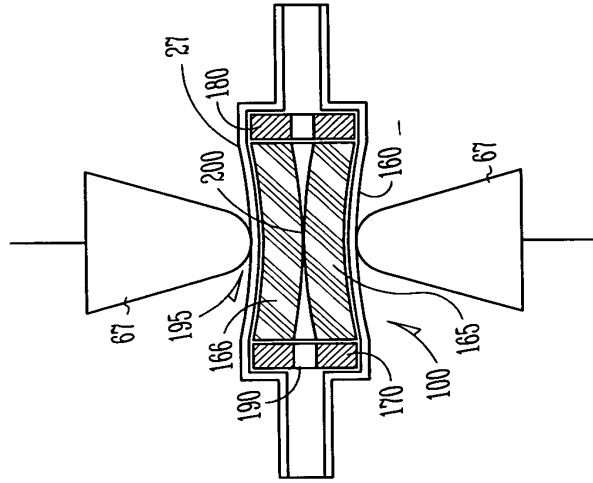


Fig. 7

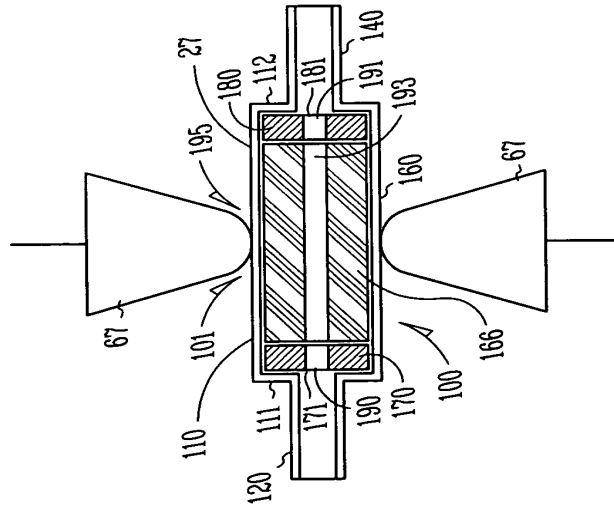


Fig. 5



TITLE: . COMPOSITE STASIS VALVE
 INVENTORS NAME: David Schaffer et al.
 SERIAL NO.: 10/371,190

5/19

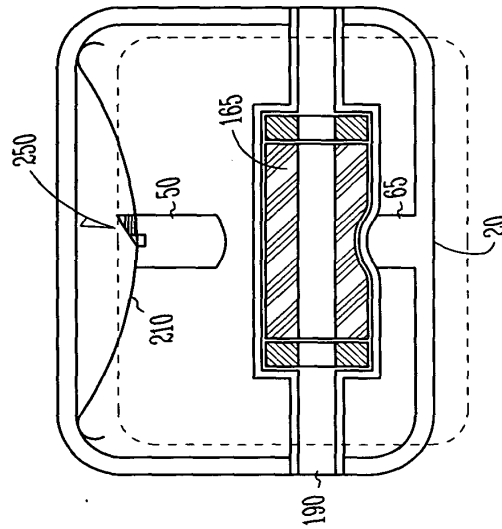


Fig. 9A

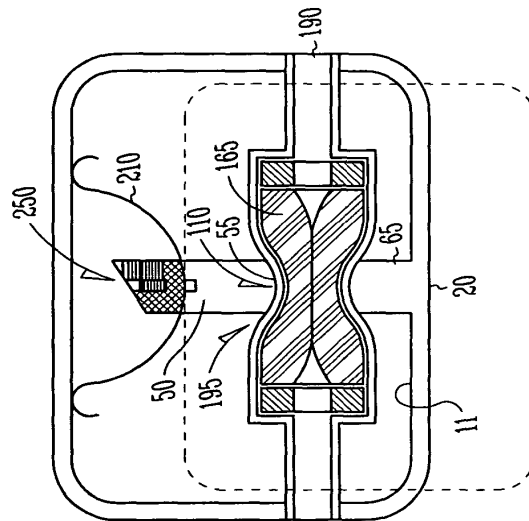


Fig. 10A



TITLE: . COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

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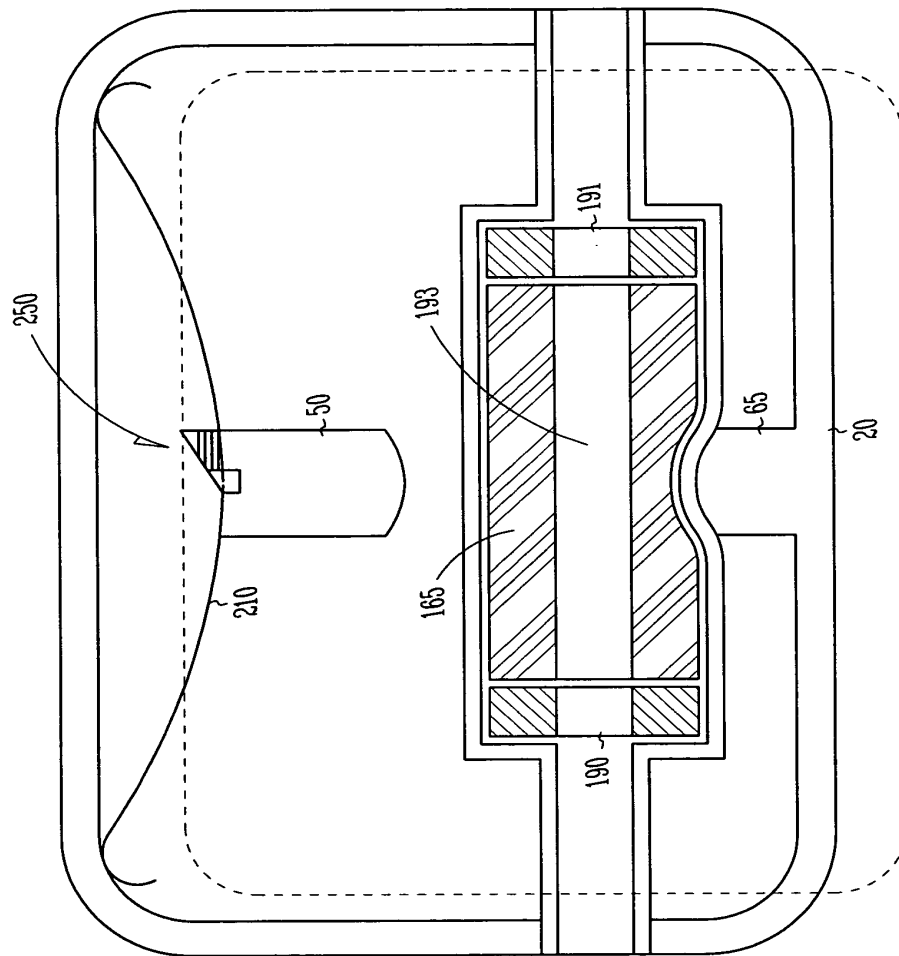


Fig. 9B



TITLE: COMPOSITE STASIS VALVE
 INVENTORS NAME: David Schaffer et al.
 SERIAL NO.: 10/371,190

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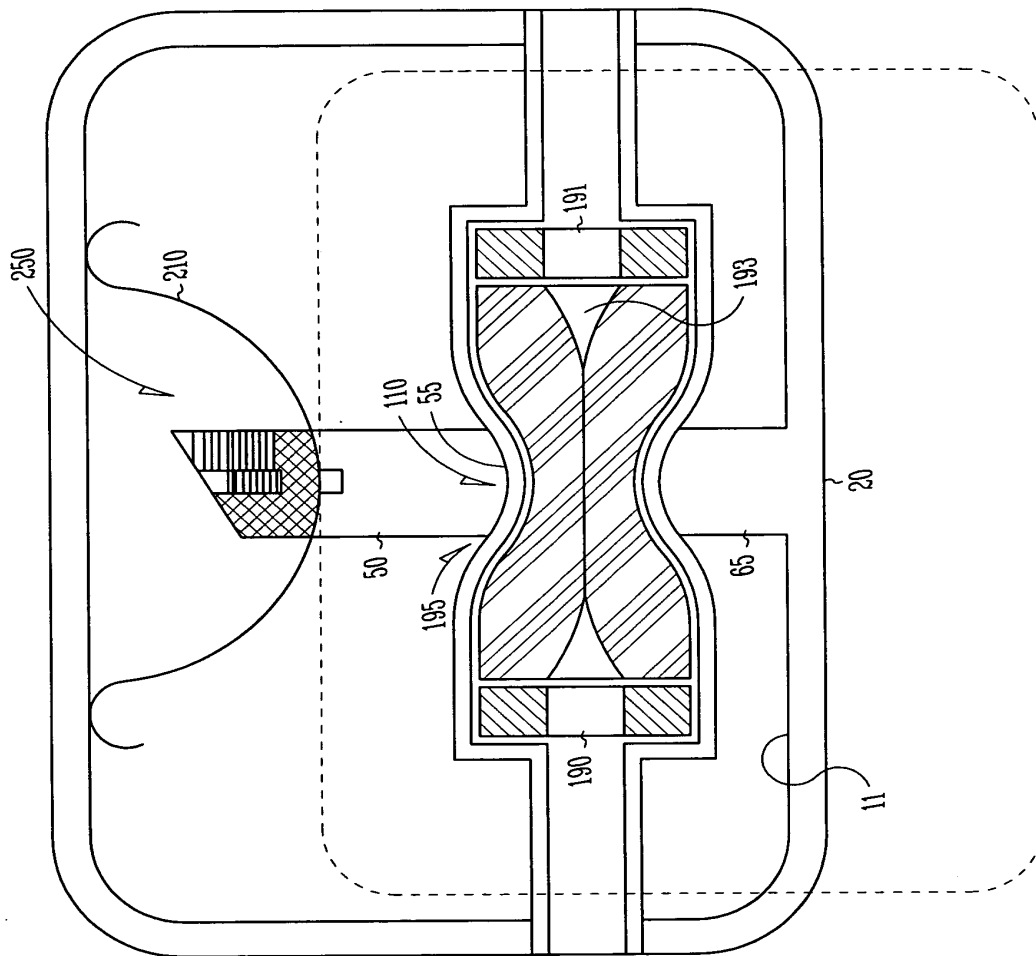


Fig. 10B



TITLE: - COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

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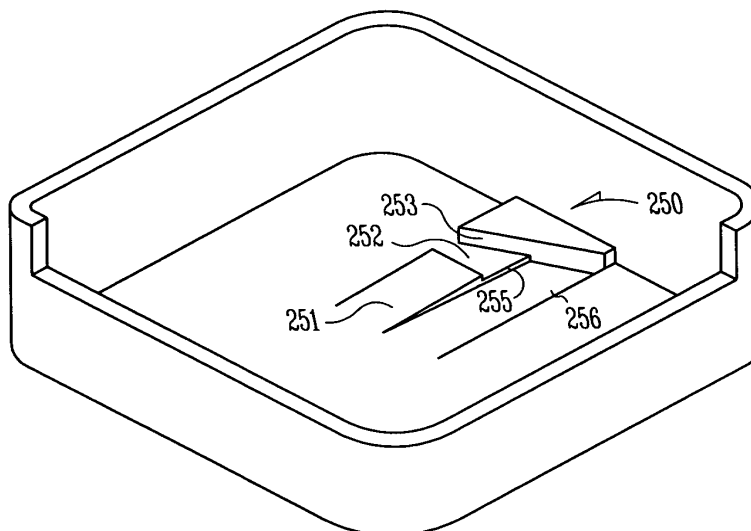


Fig. 11



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

9/19

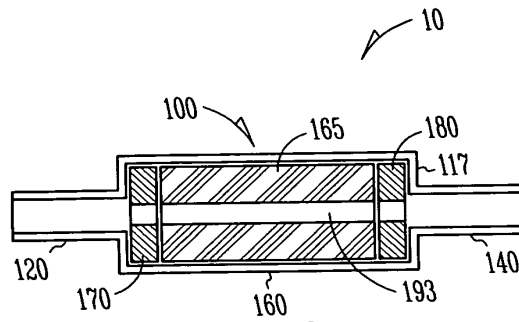


Fig. 12

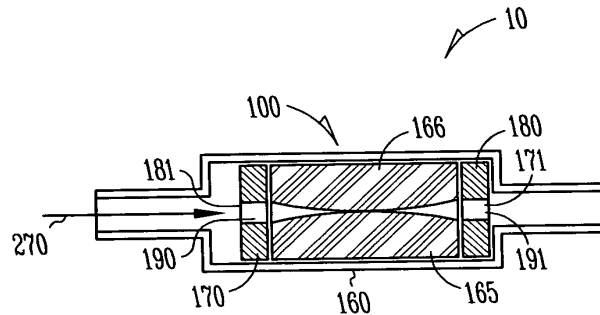


Fig. 13

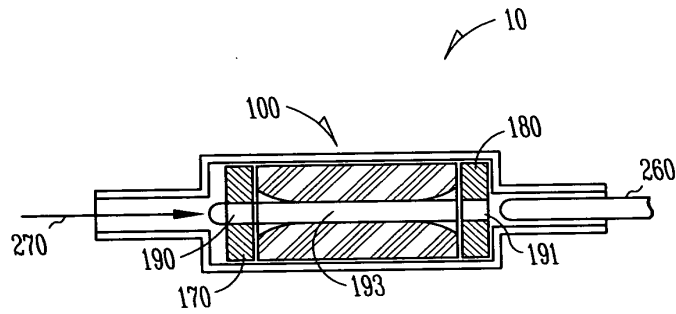


Fig. 14

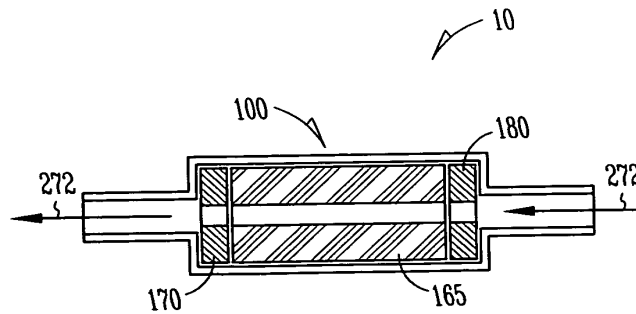


Fig. 15



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

10/19

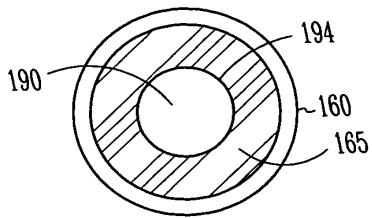


Fig. 16

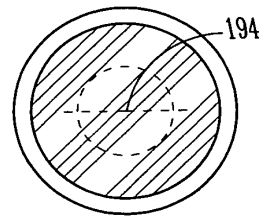


Fig. 17

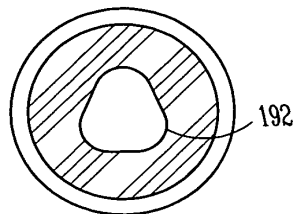


Fig. 18

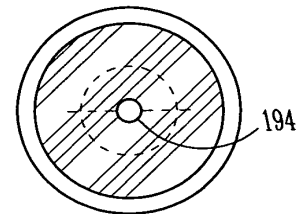


Fig. 19



TITLE: ~ COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

11/19

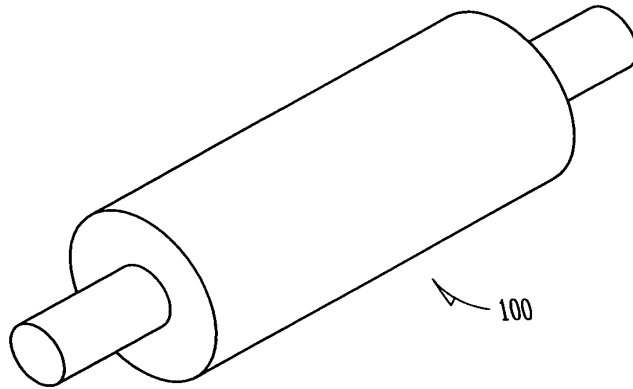


Fig. 20

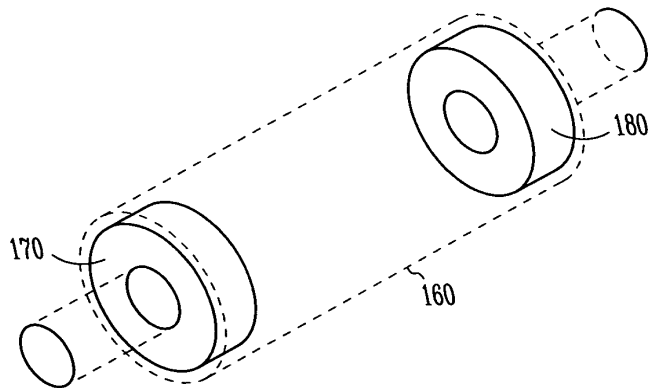


Fig. 21

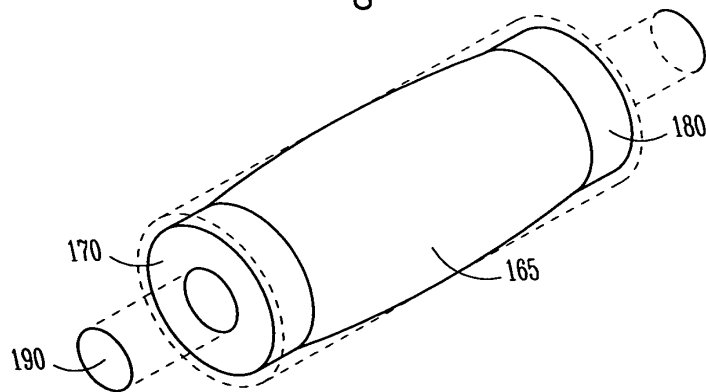


Fig. 22



TITLE: COMPOSITE STASIS VALVE
 INVENTORS NAME: David Schaffer et al.
 SERIAL NO.: 10/371,190

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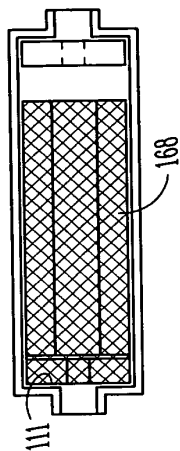


Fig. 25

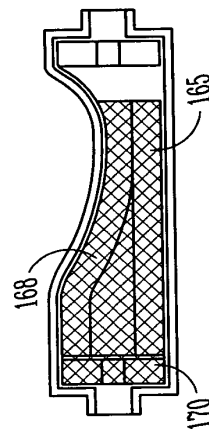


Fig. 26

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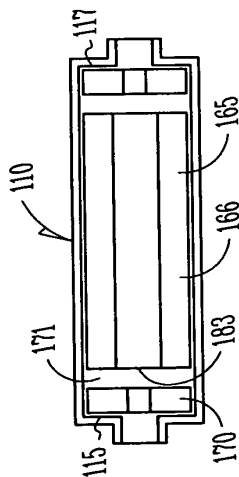


Fig. 23

100

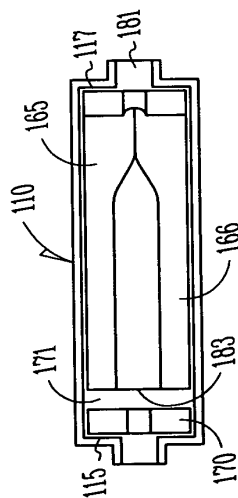


Fig. 24



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

13/19

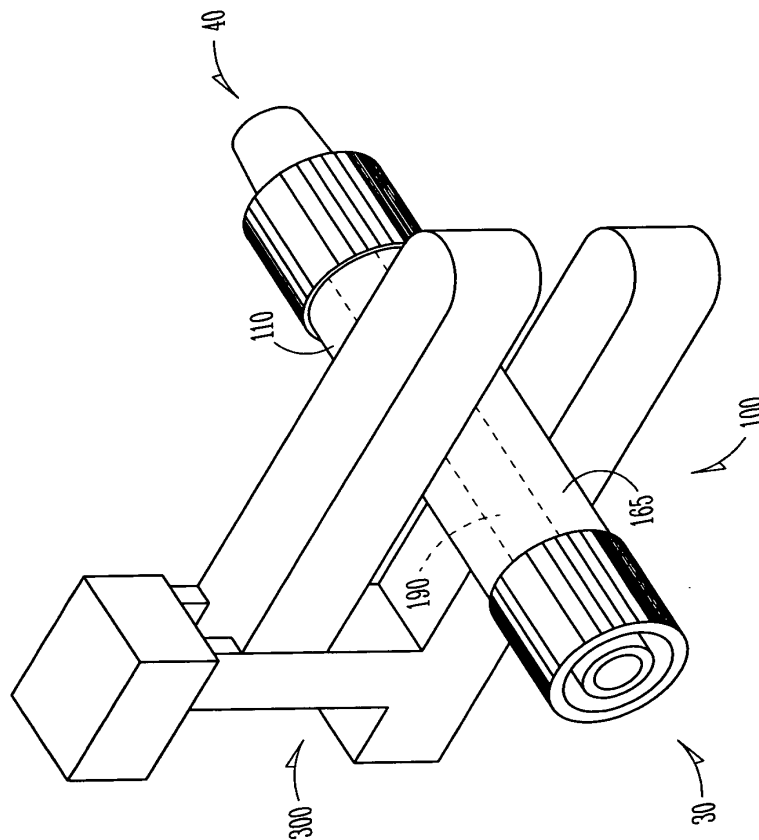


Fig. 27



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

14/19

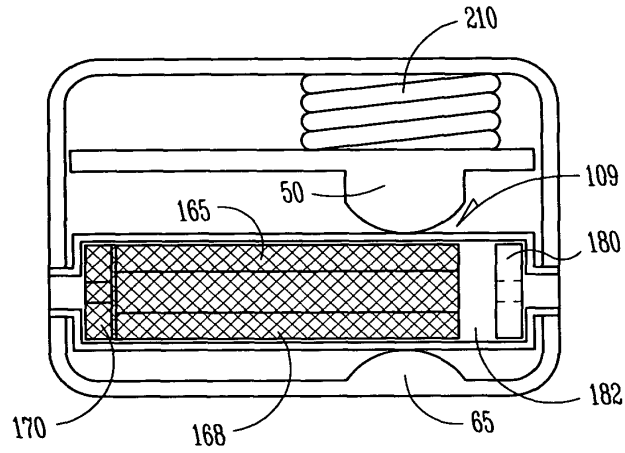


Fig. 28

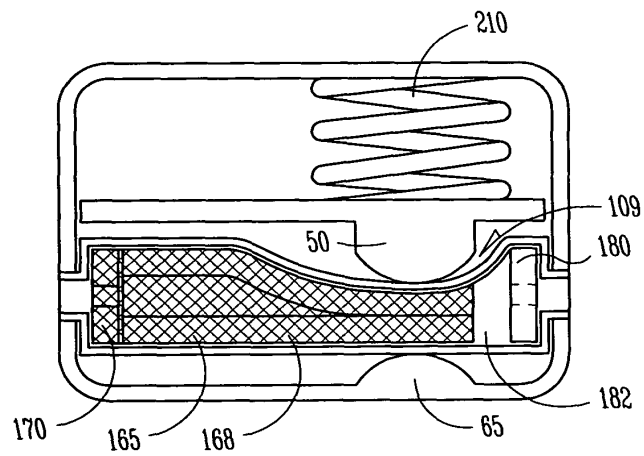


Fig. 29



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

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10

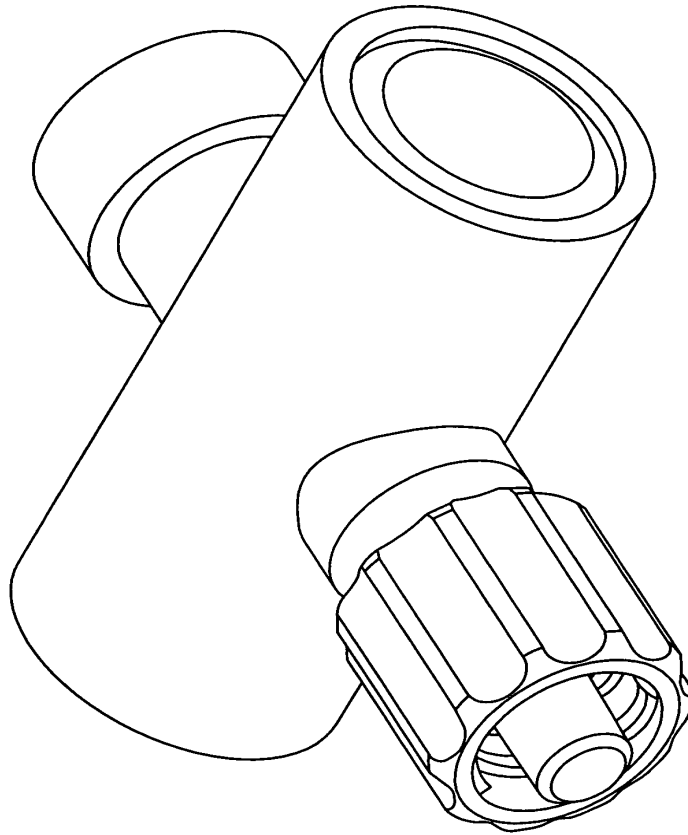


Fig. 30



TITLE: COMPOSITE STASIS VALVE
INVENTORS NAME: David Schaffer et al.
SERIAL NO.: 10/371,190

16/19

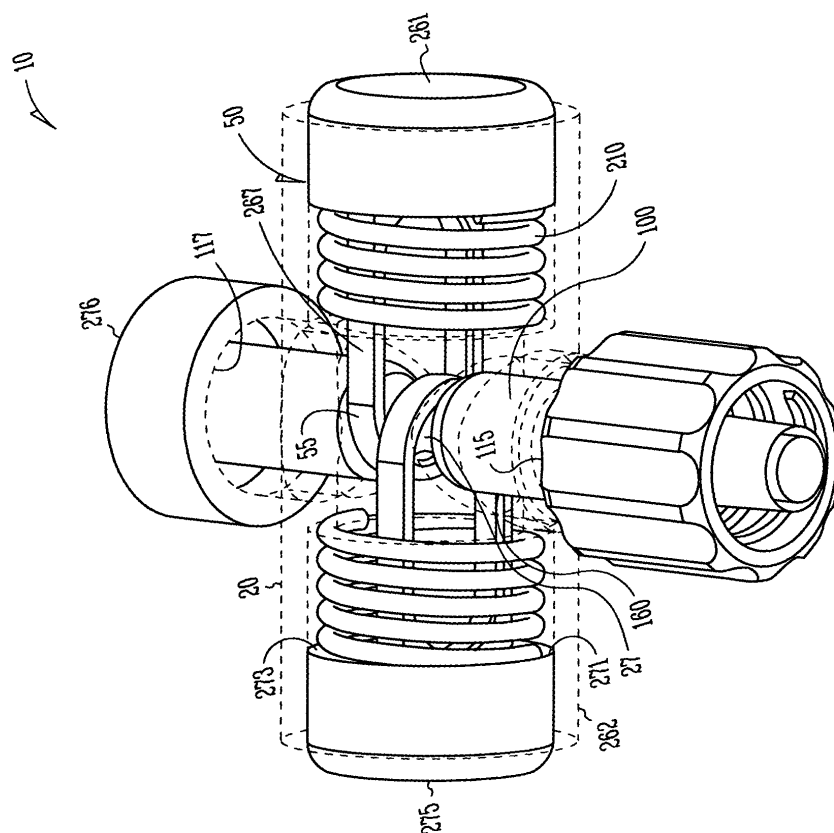


Fig. 31



TITLE: COMPOSITE STASIS VALVE
 INVENTORS NAME: David Schaffer et al.
 SERIAL NO.: 10/371,190

17/19

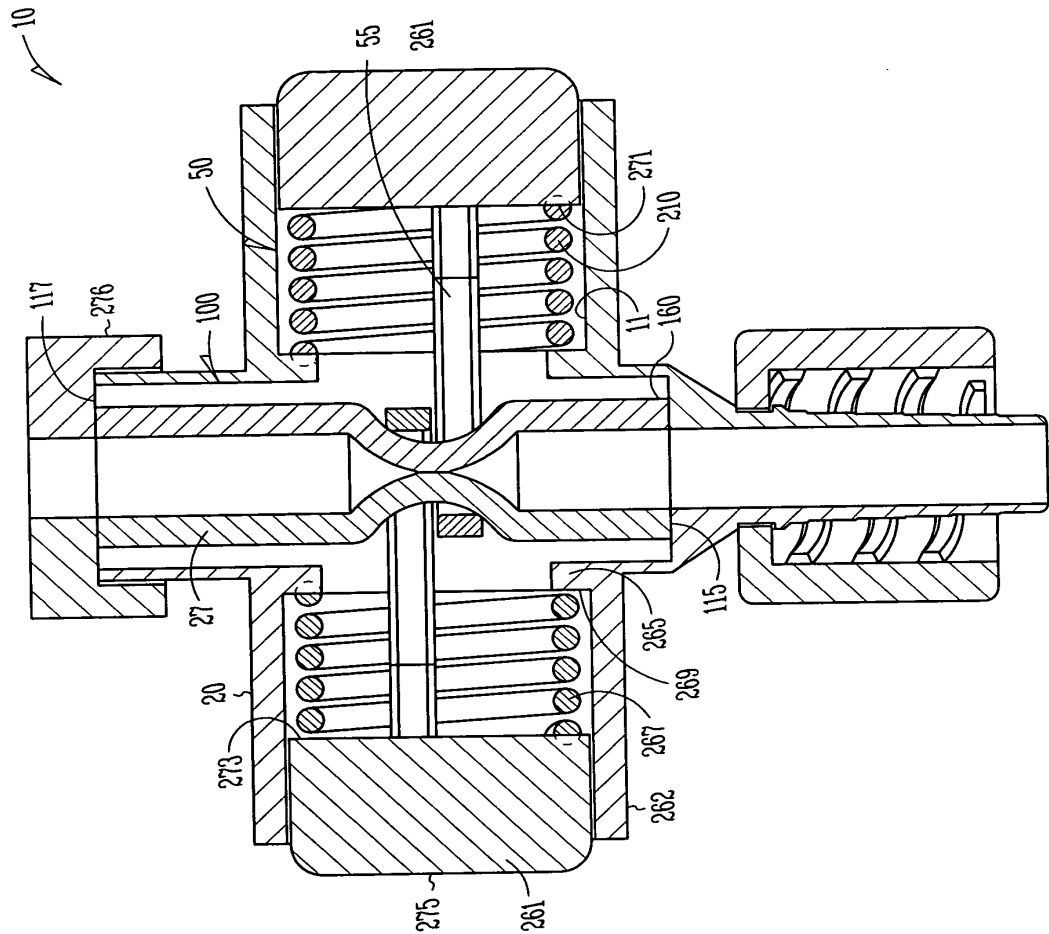


Fig. 32



TITLE: COMPOSITE STASIS VALVE
 INVENTORS NAME: David Schaffer et al.
 SERIAL NO.: 10/371,190

18/19

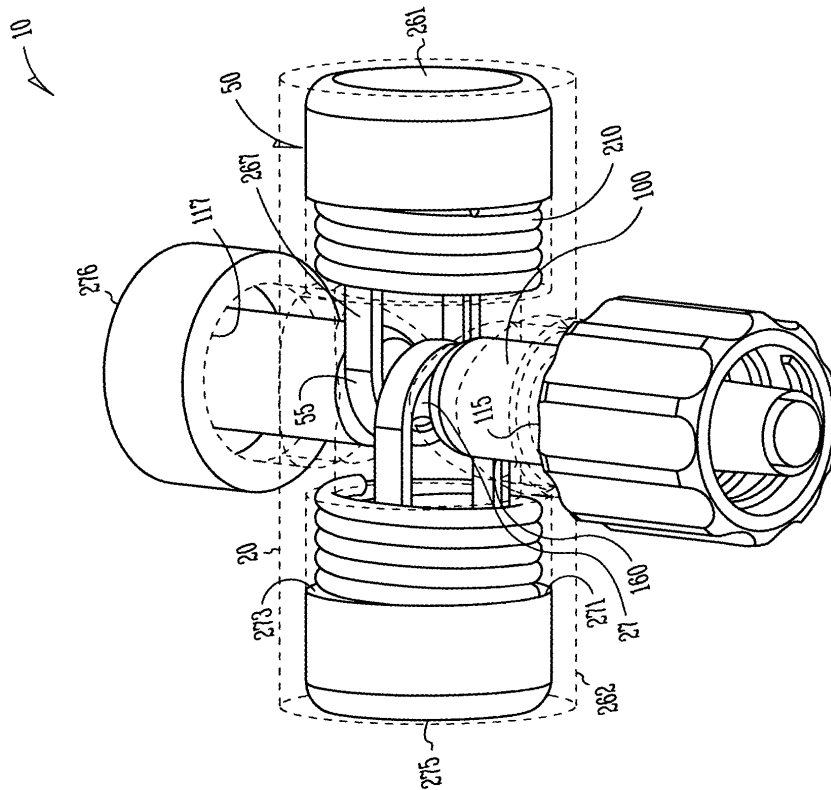


Fig. 33

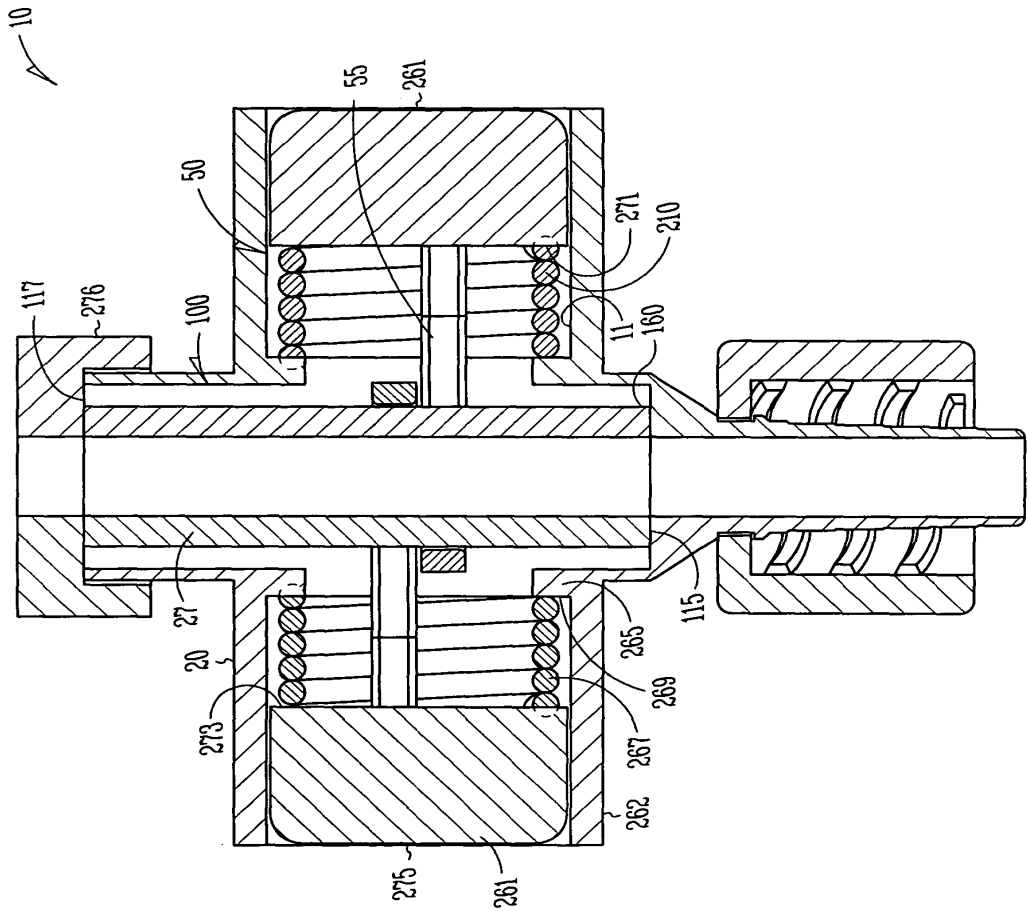


Fig. 34



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

3763

Applicant: David Schaffer et al.
Title: COMPOSITE STASIS VALVE

Docket No.: 905.038US1
Filed: February 19, 2003
Examiner: Unknown
Customer No.: 21186

Serial No.: 10/371190
Due Date: N/A
Group Art Unit: 3763
Confirmation No.: 9260

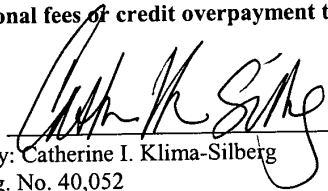
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

- ☒ A return postcard.
- ☒ An Information Disclosure Statement (2 pgs.), Form 1449 (2 pgs.), and copies of 45 cited documents.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees of credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
Customer Number 21186

By: 
Atty: Catherine I. Klima-Silberg
Reg. No. 40,052

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LISA ROSORSKE
Name

Lisa Rosorske
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(GENERAL)

Customer Number 21186

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S/N 10/371190

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	David Schaffer et al.	Examiner:	Unknown
Serial No.:	10/371190	Group Art Unit:	3763
Filed:	February 19, 2003	Docket:	905.038US1
Title:	COMPOSITE STASIS VALVE		

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 19-0743 in order to have this Information Disclosure Statement considered.

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INFORMATION DISCLOSURE STATEMENT

Serial No :10/371190

Filing Date: February 19, 2003

Title: COMPOSITE STASIS VALVE

Page 2
Dkt: 905.038US1

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

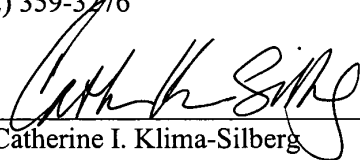
DAVID SCHAFFER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 359-3276

Date Sept 23, 2003

By

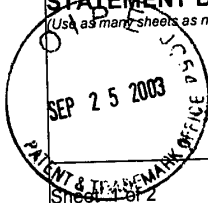

Catherine I. Klima-Silberg
Reg. No. 40,052

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Lisa Rosorske
Name

Lisa Rosorske
Signature

Substitute for form 1449A/PTO
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)



Complete if Known

Application Number	10/371190
Filing Date	February 19, 2003
First Named Inventor	Schaffer, David
Group Art Unit	3763
Examiner Name	Unknown

Attorney Docket No: 905.038US1

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TECHNOLOGY CENTER R3700

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
	US-4,000,739	01/04/1977	Stevens, R.	128	214.4	07/09/1975
	US-4,424,833	01/10/1984	Spector, K., et al.	137	849	10/02/1981
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	US-5,520,655	05/28/1996	Davila, L., et al.	604	167	07/15/1994
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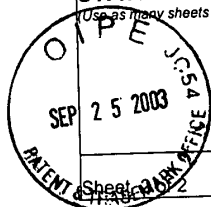
EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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<i>Complete if Known</i>	
Application Number	10/371190
Filing Date	February 19, 2003
First Named Inventor	Schaffer, David
Group Art Unit	3763
Examiner Name	Unknown
Attorney Docket No: 905.038US1	

	US-5,858,007	01/12/1999	Fagan, J., et al.	604	256	07/03/1996
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DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

EP 1046843

2/9/1

DIALOG(R)File 351:Derwent WPI

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WPI Acc No: 2000-657778/200064 XRPX Acc No: N00-487690

Pinch valve has support for flexible tube) in the region where clamp contacts it and sealing sleeve fitted over the support whose ends form seal with adapters at either end of tube

Patent Assignee: FERTON HOLDING SA (FERT-N)

Inventor: SCHULZ M

Number of Countries: 026 Number of Patents: 004

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
EP 1046843	A2	20001025	EP 2000107096	A	20000406	200064 B
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Priority Applications (No Type Date): DE 1017622 A 19990419

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
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EP 1046843	A2	G	6	F16K-007/06	
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Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT
LI LT LU LV MC MK NL PT RO SE SI

DE 19917622	A1	F16K-007/06
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DE 19917622	C2	F16K-007/06
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US 6361016	B1	F16K-007/06
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Abstract (Basic): EP 1046843 A2

NOVELTY - The pinch valve has a support (10) for a flexible tube (9) in the region where the clamp (14) contacts it. A sealing sleeve is fitted over the support whose ends (2, 3) form a seal with adapters (6, 7) at either end of the tube.

USE - Pinch valve.

ADVANTAGE - Replacement of the flexible tube is easier and continuous regulation of the fluid flow between a maximum and minimum value is possible.

DESCRIPTION OF DRAWING(S) - The drawing shows a cross-section of the valve.

Ends of sealing sleeve (2, 3)

Adapters for flexible tube (6, 7)

Flexible tube (9)

Support for tube (10)

Clamp (14)

pp; 6 DwgNo 1/1

Title Terms: PINCH; VALVE; SUPPORT; FLEXIBLE; TUBE; REGION; CLAMP; CONTACT;
SEAL; SLEEVE; FIT; SUPPORT; END; FORM; SEAL; END; TUBE

Derwent Class: P32; Q66

International Patent Class (Main): F16K-007/06

International Patent Class (Additional): A61C-017/00

File Segment: EngPI



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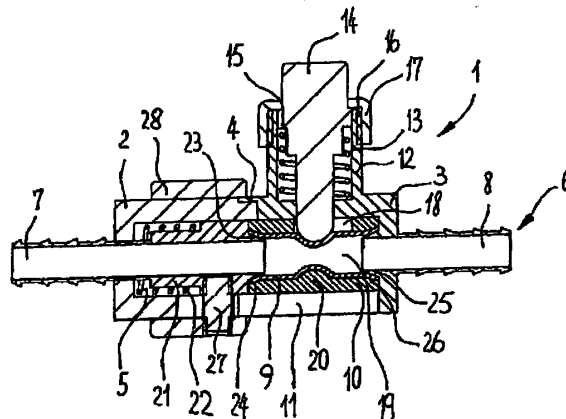
(30) Priorität: 19.04.1999 DE 19917622

(71) Anmelder: **Ferton Holding SA**
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(54) **Quetschventil**

(57) Bei einem Quetschventil mit einem Durchfluß-Regelorgan in der Ausbildung eines flexiblen Schlauchabschnittes (9) als eine Teillänge (6) einer Fluidleitung ist der Schlauchabschnitt für eine direkte Berührung mit einem seinen Durchflußquerschnitt (19) verändernden Drücker (14) an einem in das Ventilgehäuse (2, 3) ein-

gesetzten separaten Einsatzkörper (10) angeordnet, der zur Abstützung des Schlauchabschnittes (9) starr ausgebildet ist und gemeinsam mit dem Schlauchabschnitt einen abgedichteten Anschluß an zwei Adapterstücke (2, 3) der Fluidleitung aufweist.



EP 1 046 843 A2

Beschreibung

[0001] Die Erfindung bezieht sich auf ein Quetschventil mit einem Durchfluß-Regelorgan in der Ausbildung eines flexiblen Schlauchabschnittes gemäß der durch den Oberbegriff des Patentanspruches 1 angegebenen Art.

[0002] Bei einem aus der EP 0 097 288 B1 bekannten Quetschventil dieser Art bildet der flexible Schlauchabschnitt eine Teillänge einer Fluidleitung. Über die Fluidleitung wird ein Luft-Pulver-Gemisch an eine Düse eines Handstückes angeliefert, mit welchem bei einem der Zahnreinigung dienenden Prophylaxe-Gerät dieses Gemisch gemeinsam mit einem aus der Düse noch austretenden Wasserstrahl gegen eine zu reinigende Zahnfläche versprüht wird. Das Quetschventil ist mit einer zylindrischen Gehäusekammer ausgebildet, welche von dem Schlauchabschnitt durchquert wird. In der Gehäusekammer ist ein entgegen einer Rückstellfeder pneumatisch beweglicher Kolben angeordnet, mit welchem auf den Schlauchabschnitt eingewirkt wird, sobald ein vorbestimmter Betätigungsdruck über eine ventilsteuerte Anschlußleitung in die Gehäusekammer zugeleitet wird. Unter diesem vorbestimmten Betätigungsdruck wird der Schlauchabschnitt durch den Kolben vollständig abgeklemmt, sodaß damit eine Durchflußsperre für das Luft-Pulver-Gemisch hin zu der Düse des Handstückes erhalten wird. Diese Durchflußsperre wird wieder beseitigt, sobald der Betätigungsdruck ventilsteuert aufgehoben und dann der Kolben durch die Rückstellfeder in eine Ausgangslage zurückbewegt ist. Zur Vermeidung einer übermäßigen Materialbeanspruchung des Schlauchabschnittes kann bei diesem bekannten Quetschventil der Kolben auch für die Aufnahme eines separaten Druckgliedes ausgebildet sein, welches in einer mit dem vorbestimmten Betätigungsdruck erhaltenen Anschlagstellung des Kolbens an dem Ventilgehäuse durch Federkraft gegen den Schlauchabschnitt angedrückt wird, damit er zum Erreichen der Durchflußsperre dann durch dieses separate Druckglied vollständig abgeklemmt wird.

[0003] Aus der GB 2 147 394 A ist ein Quetschventil bekannt, bei welchem auf eine Teillänge einer Fluidleitung innerhalb einer zylindrischen Gehäusekammer des Ventils mit einem als ein pneumatisch beweglicher Kolben ausgebildeten Drücker unter Vermittlung einer zur Auskleidung der Gehäusekammer vorgesehenen Hülse eingewirkt wird. Die Hülse besteht aus einem hochelastischen Material größerer Dicke, wie bsp. porösem Gummi oder porösem Kunststoff, und erfüllt den Zweck, eine übermäßige Materialbeanspruchung der Fluidleitung während des Abklemmens durch den Drücker zu vermeiden.

[0004] Aus der DE-AS 1 097 778 ist ein Quetschventil bekannt, bei welchem ein Schlauchabschnitt der eine Teillänge einer Fluidleitung bildet, aus wenigstens zwei Materiallagen besteht, die entweder frei aneinander anliegen oder fest miteinander verbunden sind und

aus unterschiedlich nachgiebigen Werkstoffen bestehen. Auf diesen in eine Gehäusekammer des Ventils austauschbar eingesetzten Schlauchabschnitt wird mit einem durch einen Spindeltrieb beweglichen Drücker eingewirkt, um eine veränderliche Durchflußregelung zu erhalten. Die äußere Materiallage des Schlauchabschnittes ist dabei zur Erzielung einer Abstützwirkung wesentlich dicker ausgebildet als die innere Lage und besteht bsp. aus einem als Formkörper ausgeführten gummiartigen Werkstoff, der die mit einer Folie ausgeführte innere Lage aufnimmt. Der Werkstoff für die Folie ist nach den Eigenschaften des Fluids ausgewählt, dessen Durchfluß mit dem Quetschventil geregelt werden soll, wobei dafür insbesondere Kunststoffe wegen der gegenüber Gummi höheren Verschleißfestigkeit und günstigeren Reibungsbeiwerte angegeben sind.

[0005] Der Erfindung liegt die Aufgabe zugrunde, ein Quetschventil der angegebenen Art derart auszubilden, daß mit einer vergleichbar einfachen Ausbildung des Ventils eine einfache Austauschmöglichkeit des Schlauchabschnittes besteht, mit welchem der Durchfluß eines flüssigen oder auch eines gasförmigen Mediums durch eine Fluidleitung stufenlos veränderbar zwischen einem maximalen und einem minimalen Wert geregelt werden kann.

[0006] Zur Lösung dieser Aufgabe wird erfindungsgemäß ein Quetschventil bereitgestellt, welches mit den kennzeichnenden Merkmalen des Patentanspruches 1 ausgebildet ist.

[0007] Bei dem erfindungsgemäßen Quetschventil wird durch die Anordnung des Schlauchabschnittes an einem separaten Einsatzkörper, der zur Abstützung des Schlauchabschnittes starr ausgebildet ist und gemeinsam mit dem Schlauchabschnitt einen abgedichteten Anschluß an zwei Adapterstücken der Fluidleitung aufweist, eine maßgebliche Voraussetzung dafür geschaffen, daß der Schlauchabschnitt einem verringerten Materialverschleiß unterliegt. Umgekehrt kann der Schlauchabschnitt wegen des Vorhandenseins eines solchen, seiner unmittelbaren Abstützung dienenden separaten Einsatzkörpers jetzt eine vielfach vermehrte Quetschhäufigkeit erfahren, bis ein Austausch des Schlauchabschnittes wegen Materialermüdung für die Beibehaltung einer konstanten Regelcharakteristik des Quetschventils vorgenommen werden muß. Wegen der Gemeinsamkeit mit dem Einsatzkörper läßt sich dabei der Austausch des Schlauchabschnittes entsprechend einfach realisieren, insbesondere wenn dafür eine Ausbildung als ein Einmalprodukt zur Verfügung gestellt ist, welches bsp. über eine an dem Ventilgehäuse vorhandene Auswurföffnung manipulierbar ist.

[0008] Weitere vorteilhafte und zweckmäßige Ausbildungen des erfindungsgemäßen Quetschventils sind in den weiteren Patentansprüchen angegeben.

[0009] Ein Ausführungsbeispiel des erfindungsgemäßen Quetschventils ist in der Zeichnung mit einer Schnittdarstellung einer bevorzugten Ausführungsform dargestellt und wird nachfolgend näher beschrieben.

[0010] Das in der Zeichnung dargestellt Quetschventil 1 ist mit einem aus zwei Teilen 2 und 3 bestehenden Ventilgehäuse ausgeführt. Die beiden Gehäuseteile 2, 3 sind über ein Schraubgewinde 4 miteinander verbunden und umgeben eine zylindrische Ventilkammer 5, die von einer Teillänge 6 einer Fluidleitung durchsetzt wird.

[0011] Die Teillänge 6 einer Fluidleitung ist ausgebildet mit zwei Adapterstücken 7 und 8, die mit ihren über das Ventilgehäuse vorstehenden Enden ein Aufschieben von Schlauchenden der an das Quetschventil 1 angeschlossenen Fluidleitung erlauben. Der eigentliche Anschluß an die Fluidleitung wird durch einen flexiblen Schlauchabschnitt 9 erhalten, der in einer mit den beiden Adapterstücken 7 und 8 axial fluchtenden Durchgangsbohrung eines separaten Einsatzkörpers 10 aufgenommen ist.

[0012] Der Einsatzkörper 10 ist für eine Abstützung des Schlauchabschnittes 9 starr ausgebildet und kann über ein Auswurföffnung 11 des Gehäuseteils 3 in die Ventilkammer 5 eingesetzt werden. Gegenüberliegend zu der Auswurföffnung 11, die bsp. mit einem Schraubdeckel verschlossen werden kann, ist der Gehäuseteil 3 mit einem hohlzylindrischen Gehäuseansatz 12 versehen, der einen durch eine Rückstellfeder 13 nach außen vorgespannten Drücker 14 aufnimmt. Der Drücker 14 wird über einen Ringbund 15 an der Innenwand des Gehäuseansatzes 12 axial geführt, wenn er im Zusammenwirken mit einer mit einem Gewinde 16 des Gehäuseansatzes 12 verschraubten Schraubkappe 17 entgegen der Rückstellkraft der Feder 13 nach innen bewegt wird.

[0013] Das innere Ende des Drückers 14 durchsetzt eine Durchtrittsöffnung des Gehäuseteils 3 und eine schlitzförmig ausgebildete weitere Durchtrittsöffnung 18 des Einsatzkörpers 10. Der Drücker 14 erhält damit eine direkte Berührung mit dem Schlauchabschnitt 9, sodaß der Schlauchabschnitt mittels des Drückers 14 gequetscht und letztlich auch vollständig abgeklemt werden kann, wenn eine völlige Durchflusssperre für das durch die Fluidleitung geleitete Fluid erhalten werden soll. Der maßgebliche Durchtrittsquerschnitt 19 des Schlauchabschnittes 9 kann also an dem Ort der Krafteinwirkung des Drückers 14 stufenlos verändert werden, wobei der Drücker an diesem Ort der Krafteinwirkung noch mit einem Widerlager 20 des Einsatzkörpers 10 zusammenwirkt.

[0014] In der Zeichnung ist für den Drücker 14 eine Einstelllage gezeigt, in welcher der Durchflußquerschnitt 19 des Schlauchabschnittes 9 auf eine vorbestimmte Zwischengröße eingestellt ist. Diese Zwischengröße des Durchflußquerschnittes 19 kann weiter verringert werden, wenn dafür der Drücker 14 weiter nach innen verschoben wird, wobei eine Grenze dann erhalten ist, wenn die Durchflusssperre erreicht ist.

[0015] Um einen einfachen Austausch des Einsatzkörpers 10 gemeinsam mit dem Schlauchabschnitt zu ermöglichen, ist für das eine Adapterstück 7 eine relativ

zu dem Ventilgehäuse 2, 3 beweglichen Anordnung vorgesehen. Das Adapterstück 7 ist dafür mit einem Führungskörper 21 verbunden, der in der Ventilkammer 5 aufgenommen ist. Der Führungskörper 21 ist durch eine Feder 22 gegen den Einsatzkörper 10 vorgespannt, um mit einer konisch ausgebildeten Dichtlippe 23 einen abgedichteten Anschluß an das an einer konisch ausgebildeten Sitzfläche 24 des Einsatzkörpers 10 anliegende Ende des Schlauchabschnittes 9 zu erhalten. Die Vorspannkraft der Feder 22 ist so bemessen, daß auch für das zweite Adapterstück 8, welches mit dem Gehäuseteil 3 fest verbunden ist, ein abgedichteter Anschluß an das andere Ende des Schlauchabschnittes 9 erhalten wird. Für diesen abgedichteten Anschluß ist das fest angeordnete Adapterstück 8 ebenfalls mit einer konischen Dichtlippe 25 versehen, die mit dem an einer konischen Sitzfläche 26 des Einsatzkörpers 10 anliegenden Ende des Schlauchabschnittes 9 abgedichtet wird. Der Führungskörper 21 ist daneben über einen Mitnehmer 27 mit einem Schieberglied 28 verbunden, welches außen an dem Gehäuseteil 2 angeordnet ist. Durch eine Verschiebung des Schiebergliedes 28 entgegen der Kraft der Vorspannfeder 22 kann der Führungskörper 21 und damit das Anschlußende des Adapterstückes 7 an den Schlauchabschnitt 9 in eine Relativlage verschoben werden, in welcher der Einsatzkörper 10 über die Auswurföffnung 11 aus der Ventilkammer 9 entnommen werden kann.

[0016] Das vorbeschriebene Quetschventil kann bsp. für eine Durchflußregelung eines Fluids bei dem Arbeiten mit einem Endoskop vorgesehen werden. Das Ventil wird dann zweckmäßig an einem Grundkörper des Endoskops als Ersatz eines sonst üblichen Trompetenventils angeordnet.

[0017] Der Schlauchabschnitt 9 und der Einsatzkörper 10 sind vorteilhaft als ein Einmalprodukt ausgebildet. Diese Einmalprodukt kann entweder in seiner Gesamtheit oder auch nur mit dem Schlauchabschnitt für einen Austausch vorgesehen sein, sobald eine mit dem Schlauchabschnitt verwirklichte Regelcharakteristik des Quetschventils nicht mehr stimmen sollte und also von einer Materialermüdung des Schlauchabschnittes auszugehen ist.

[0018] Anstelle einer Anordnung des Schlauchabschnittes in einer Durchgangsbohrung des Einsatzkörpers kann auch eine Anordnung des Schlauchabschnittes auf einer zylindrischen Außenfläche des Einsatzkörpers vorgesehen sein. Der Einsatzkörper wäre dann massiv ausgebildet und würde mit seiner zylindrischen Außenfläche mit den Anschlußenden der beiden Adapterstücke axial fluchten, um im Zusammenwirken mit dem Schlauchabschnitt einen mittels des Drückers stufenlos veränderbaren Durchfluß-Regelkanal des Ventils auszubilden.

[0019] Anstelle der beweglichen Anordnung nur eines Adapterstückes, die grundsätzlich auch für das zweite Adapterstück vorgesehen werden kann, kann

der Einsatzkörper mit zwei Teilstücken ausgebildet werden, die durch Federkraft gegeneinander und gegen die beiden Anschlüsse des Schlauchabschnittes an den beiden Adapterstücke vorgespannt sind. Auch mit dieser alternativen Ausbildung wäre eine einfache Austauschbarkeit des Schlauchabschnittes und/ oder des Einsatzkörpers sichergestellt.

Patentansprüche

1. Quetschventil mit einem Durchfluß-Regelorgan in der Ausbildung eines flexiblen Schlauchabschnittes (9), welcher als eine Teillänge (6) einer Fluidleitung über zwei Adapterstücke (7, 8) an die Fluidleitung anschließbar ist für eine Durchflußregelung eines Fluids mittels eines Drückers (14), der entgegen einer Rückstellkraft (13) gegen den Schlauchabschnitt (9) andrückbar ist für eine Veränderung des Durchflußquerschnittes (19) durch eine mit dem Drucker (14) übersetzte Quetschung des Schlauchabschnittes (9), dadurch gekennzeichnet, daß der Schlauchabschnitt (9) für eine direkte Berührung mit dem Drucker (14) an einem in das Ventilgehäuse (2, 3) eingesetzten separaten Einsatzkörper (10) angeordnet ist, der starr zur Abstützung des Schlauchabschnittes (9) ausgebildet ist und gemeinsam mit dem Schlauchabschnitt (9) einen abgedichteten Anschluß an die beiden Adapterstücke (2, 3) der Fluidleitung aufweist.
 2. Quetschventil nach Anspruch 1, dadurch gekennzeichnet, daß der Schlauchabschnitt (9) in einer Durchgangsbohrung des Einsatzkörpers (10) aufgenommen ist, die mit den beiden Adapterstücken (7, 8) axial fluchtet und im Zusammenwirken mit dem Schlauchabschnitt (9) einen mittels des Druckers (14) stufenlos veränderbaren Durchfluß-Regelkanal des Quetschventils (1) ausbildet.
 3. Quetschventil nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß wenigstens eines (7) der beiden Adapterstücke (7, 8) eine relativ zu dem Einsatzkörper (10) bewegliche Anordnung an dem Ventilgehäuse (2, 3) aufweist.
 4. Quetschventil nach Anspruch 3, dadurch gekennzeichnet, daß das bewegliche Adapterstück (7) durch Federkraft (22) in einen abgedichteten Anschluß an den Einsatzkörper (10) und an das zugeordnete Ende des Schlauchabschnittes (9) vorgespannt ist.
 5. Quetschventil nach Anspruch 3 oder 4, dadurch gekennzeichnet, daß bei einer an dem Ventilgehäuse (2, 3) beweglichen Anordnung nur eines Adapterstückes (7) das zweite Adapterstück
- (8) mit dem Ventilgehäuse (2, 3) fest verbunden ist.
 6. Quetschventil nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß an dem Einsatzkörper (10) konische Sitzflächen (24, 26) für die beiden Enden des Schlauchabschnittes (9) ausgebildet sind, an welche korrespondierende Dichtlippen (23, 25) der beiden Adapterstücke (7, 8) anschließen.
 7. Quetschventil nach Anspruch 6, dadurch gekennzeichnet, daß die Dichtlippe (23, 25) jedes Adapterstückes (7, 8) durch das zugeordnete Ende des Schlauchabschnittes (9) gegen dessen Sitzfläche (24, 26) an dem Einsatzkörper (10) abgedichtet ist.
 8. Quetschventil nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß der Drucker (14) als ein entgegen einer Rückstellfeder (13) relativ zu dem Ventilgehäuse (2, 3) bewegliches Stellglied ausgebildet ist, mit welchem eine veränderbare Quetschung des Schlauchabschnittes (9) für eine stufenlos veränderbare Durchflußregelung stufenlos einstellbar ist.
 9. Quetschventil nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß der Einsatzkörper (10) über eine Auswurföffnung (11) des Ventilgehäuses (2, 3) in eine Ventilkammer (5) einsetzbar ist, welche eine Durchtrittsöffnung für den außen an dem Ventilgehäuse (2, 3) angeordneten Drucker (14) aufweist.
 10. Quetschventil nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, daß in der Ventilkammer (5) ein Führungskörper (21) für das bewegliche Adapterstück (7) aufgenommen ist, der durch eine Vorspannfeder (22) in den abgedichteten Anschluß des von ihm mitgeführten Adapterstückes (7) an den Einsatzkörper (10) und an das zugeordnete Ende des Schlauchabschnittes (9) vorgespannt ist.
 11. Quetschventil nach Anspruch 9 oder 10, dadurch gekennzeichnet, daß der Führungskörper (21) durch einen Mitnehmer (27) eines außen an dem Ventilgehäuse (2, 3) angeordneten Schiebergliedes (28) in eine Relativlage verschiebbar ist, in welcher der Einsatzkörper (10) gemeinsam mit dem Schlauchabschnitt (9) über die Auswurföffnung (11) aus dem Ventilgehäuse (2, 3) entnommen werden kann.
 12. Quetschventil nach einem der Ansprüche 8 bis 11, dadurch gekennzeichnet, daß der Drucker (14) von einem hohlzylindrischen Gehäuseansatz (12) aufgenommen ist und durch die Rückstellfeder (13) gegen eine mit einem Gewinde (16) des Gehäuseansatzes (12) verschraubte Schraubkappe (17)

vorgespannt ist, durch deren Drehung der Drücker (14) für eine stufenlose Veränderung des Durchflußquerschnittes (19) des Schlauchabschnittes (9) bewegbar ist.

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13. Quetschventil nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, daß der Schlauchabschnitt (9) und/ oder der Einsatzkörper (10) als ein austauschbares Einmalprodukt ausgebildet ist bzw. sind.

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14. Quetschventil nach einem der Ansprüche 1 bis 13, dadurch gekennzeichnet, daß der Einsatzkörper (10) aus zwei Teilstücken besteht, die durch Federkraft gegeneinander und gegen die beiden Anschlüsse des Schlauchabschnittes (9) an die beiden Adapterstücke (6, 7) vorgespannt sind.

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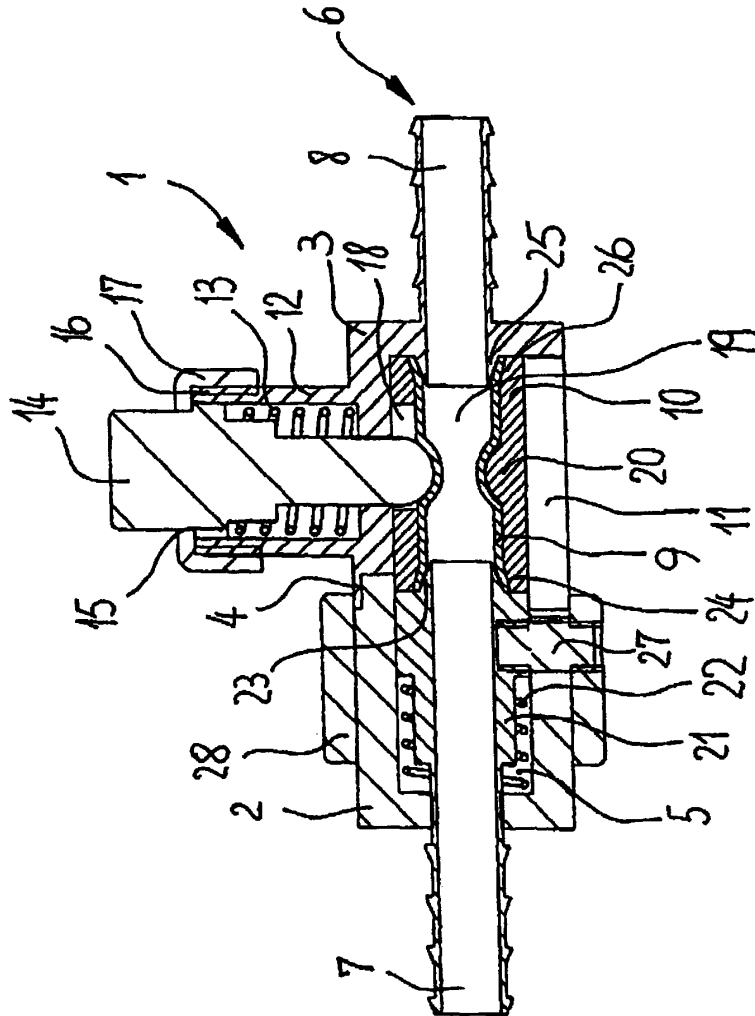
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BREVET D'INVENTION

P. V. n° 41.255

Classification internationale :



1.529.535

F 16 k

Dispositif d'obturation et d'ouverture de la section de passage d'une tubulure souple.
M. JEAN GUYOT résidant en France (Seine).

Demandé le 7 décembre 1965, à 16^h 5^m, à Paris.

Délivré par arrêté du 13 mai 1968.

(Bulletin officiel de la Propriété industrielle, n° 25 du 21 juin 1968.)

(Brevet d'invention dont la délivrance a été ajournée en exécution de l'article 11, § 7, de la loi du 5 juillet 1844 modifiée par la loi du 7 avril 1902.)

L'invention a pour objet, notamment à titre de produit industriel nouveau, un dispositif d'obturation et d'ouverture de la section de passage d'une tubulure en matière souple susceptible de véhiculer un fluide.

Un dispositif conforme à l'invention est composé de deux tronçons de profilés en U engagés l'un dans l'autre par l'une de leurs ailes, leurs ouvertures, dirigées en sens inverses, contenant chacune un ressort de compression prenant appui d'une part contre la face interne d'une aile d'un profilé et contre la face externe de l'aile de l'autre profilé ; la tubulure souple passe entre les faces internes des deux ailes engagées chacune dans l'ouverture de l'autre profilé.

L'invention sera mieux comprise et des caractéristiques secondaires ainsi que ses avantages apparaîtront au cours de la description d'un mode de réalisation donné ci-dessous à titre d'exemple. On se référera au dessin annexé dans lequel :

La figure 1 est une vue générale extérieure du dispositif obturateur de l'invention monté sur une tubulure souple ;

La figure 2 est une vue en coupe selon II-II de la figure 1 ;

La figure 3 est une vue analogue à la figure 2 montrant le dispositif dans une position de compression libérant la section de passage de la tubulure souple.

Les figures 1 et 2 représentent le dispositif de l'invention dans son état normal de repos dans lequel il écrase une tubulure souple 1 et en obture complètement la section de passage.

Ce dispositif comprend un corps 2 percé de part en part par un premier trou transversal 3 et par un second trou longitudinal 4, perpendiculaire dans l'ensemble au précédent. Le corps 2 peut être galbé extérieurement comme on le voit sur la figure 1, pour présen-

ter une forme de poire dépourvue d'angles gênants. Cette apparence extérieure n'est pas imposée par l'invention ; elle pourrait, bien entendu, revêtir toute autre forme voulue.

Le premier trou 3 est de section droite carrée. Il abrite deux tronçons de profilés en U, 5 et 6, identiques, engagés l'un dans l'autre par l'une de leurs ailes. Autrement dit, une aile 5a pénètre dans l'ouverture du profilé 6 tandis qu'une aile 6a pénètre dans l'ouverture du profilé 5. Les deux ouvertures des profilés en U sont dirigées en sens opposés et un ressort de compression est placé dans chacune d'elles.

Le ressort 7 prend appui d'une part contre la face externe de l'aile 6a du profilé 6 et, d'autre part, contre la face interne de l'aile 5b de l'autre profilé 5.

De même, le ressort 8 prend appui d'une part contre la face externe de l'aile 5a du profilé 5 et, d'autre part, contre la face interne de l'aile 6b du profilé 6.

Les ailes extérieures les plus éloignées l'une de l'autre, 5b et 6b, sont pourvues, sur leurs tranches, de prolongements 5c, 5d et 6c, 6d dirigés vers l'intérieur du profilé.

Ces prolongements constituent, avec la base du U, un logement abritant une extrémité d'un ressort. Ils servent aussi à fermer complètement chaque tronçon de profilé dans sa partie extérieure visible hors du corps 2.

Les ressorts 7 et 8 poussent l'une contre l'autre les ailes 5a et 6a. Entre ces dernières est placée la tubulure souple 1 qui traverse entièrement le corps 2 par le second trou 4. Celui-ci a une section droite circulaire de diamètre faiblement supérieur à celui de la tubulure 1.

On voit bien sur la figure 2 qu'à l'état normal de repos du dispositif de l'invention, la tubulure souple 1 est écrasée entre les ailes 5a et 6a sous l'action des ressorts 7 et 8.

[1.529.535]

— 2 —

Pour donner passage à un fluide dans la tubulure 1, on exerce des forces de compression suivant les flèches F (fig. 3) sur les ailes extérieures 5b et 6b. Les ressorts 7 et 8 sont comprimés, les ailes 5a et 6a sont écartées et la tubulure 1 reprend, par élasticité naturelle ou sous l'effet de la pression du fluide, sa forme circulaire initiale.

Pour que l'usage du dispositif soit plus commode, il est préférable que sa longueur totale, de l'aile 5b à l'aile 6b, en position de compression par les forces extérieures F, soit au moins égale à la largeur du corps 2 à cet endroit. On remarquera que, dans cette même position, la tubulure 1 est parfaitement libre et que l'on peut alors faire coulisser facilement le dispositif pour l'amener à un emplacement quelconque désiré le long de cette tubulure.

Il est entendu que l'invention n'est pas limitée à la réalisation décrite et représentée, mais qu'elle couvre au contraire toutes les variantes qui lui seraient apportées sans sortir de son cadre ni de son esprit.

RÉSUMÉ

L'invention a pour objet, notamment à titre de produit industriel nouveau, un dispositif d'obturation et d'ouverture de la section de passage d'une tubulure en matière souple, ledit dispositif étant caractérisé notamment par les points suivants pris isolément ou en combinaison :

1° Il est composé de deux tronçons de profilés en U engagés l'un dans l'autre par l'une

de leurs ailes, leurs ouvertures, dirigées en sens inverses, contenant chacune un ressort de compression prenant appui d'une part contre la face interne d'une aile d'un profilé et contre la face externe de l'aile de l'autre profilé, la tubulure souple passant entre les faces internes des deux ailes engagées chacune dans l'ouverture de l'autre profilé.

2° Il existe, en plus, un corps traversé de part en part par un premier trou dans lequel sont introduits les deux tronçons assemblés de profilés en U et par un second trou dont l'axe est sensiblement perpendiculaire à l'axe du premier trou, la tubulure souple prise entre les tronçons assemblés traversant entièrement ledit corps par le second trou.

3° Les ailes extérieures les plus éloignées l'une de l'autre des deux tronçons de profilés assemblés présentent, sur chacune de leurs trois tranches libres, un prolongement dirigé vers l'intérieur, l'ensemble de ces trois prolongements constituant avec la base du profilé en U un logement abritant une extrémité d'un des ressorts de compression.

4° La longueur totale des deux tronçons assemblés maintenus en position de compression par des forces extérieures est au moins égale à la largeur du corps à l'endroit du premier trou.

JEAN GUYOT

Par procuration :

BEAU DE LOMÉNIE, André ARMENGAUD
& G. HOUSSARD

Fig. 1

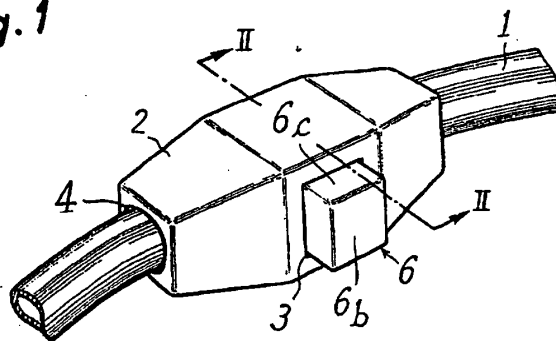


Fig. 2

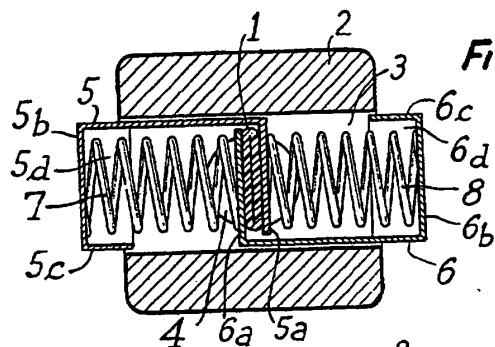
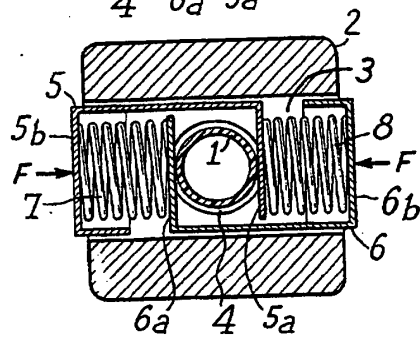


Fig. 3





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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/371,190	02/19/2003	David Schaffer	905.038US1	9260
21186	7590	09/20/2004	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.			SIRMONS, KEVIN C	
P.O. BOX 2938			ART UNIT	
MINNEAPOLIS, MN 55402			PAPER NUMBER	

3763

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/371,190	Applicant(s) SCHAFFER ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1	figs. 1-4	Species 1	Figs. 9A, 9B, 10A, 10B
Species 3	fig. 27	Species 4	Figs. 28-29

Applicant is further required to elect for the following sub species:

Sub species A	Figs. 12-15	Sub species B	fig. 23
Sub species C	Figs. 24	Sub species D	fig. 24
Sub species E	fig. 26.		

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, some claims appear to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Catherine I. Klima-Silberg on 9/17/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 703-306-5410. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Application/Control Number: 10/371,190
Art Unit: 3763

Page 4

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kevin C. Sirmons
Patent Examiner
9/20/04

Index of Claims 	Application No.		Applicant(s)	
	10/371,190		SCHAFER ET AL.	
	Examiner		Art Unit	
	Kevin C. Simons		3763	

✓	Rejected
=	Allowed

—	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date									
Final	Original										
	1	1-9/19/64									
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Bib Data Sheet

CONFIRMATION NO. 9260

SERIAL NUMBER 10/371,190	FILING DATE 02/19/2003 RULE	CLASS 604	GROUP ART UNIT 3763	ATTORNEY DOCKET NO. 905.038US1
-----------------------------	---------------------------------------	--------------	------------------------	--------------------------------------

APPLICANTS

David Schaffer, Coral Springs, FL;
 Michael Schaffer, Coral Springs, FL;
 Brian Fischer, Minneapolis, MN;

** CONTINUING DATA ***** *Ves KCS*
 This appln claims benefit of 60/357,937 02/19/2002

** FOREIGN APPLICATIONS ***** *None KCS*

IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY **
 ** 04/16/2003

Foreign Priority claimed ☐ yes ☒ no 35 USC 119 (a-d) conditions met ☐ yes ☒ no ☐ Met after Allowance <i>KCS</i> Verified and Acknowledged Examiner's Signature _____ Initials _____	STATE OR COUNTRY FL	SHEETS DRAWING 19	TOTAL CLAIMS 31	INDEPENDENT CLAIMS 5
--	---------------------------	-------------------------	-----------------------	----------------------------

ADDRESS
 21186
 SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
 P.O. BOX 2938
 MINNEAPOLIS , MN
 55402

TITLE
 Composite stasis valve

FILING FEE RECEIVED 623	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue)
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3763
JFW

S/N 10/371,190

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Schaffer et al.

Examiner: Kevin Sirmons

Serial No.: 10/371,190

Group Art Unit: 3763

Filed: February 19, 2003

Docket: 905:038US1

Title: COMPOSITE STASIS VALVE

RESPONSE TO RESTRICTION REQUIREMENT

MS AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Applicant has received the Restriction Requirement dated September 20, 2004.

Applicant elects Species 1, and subspecies A, B, C, identified therein. According to page 2 of the Office Action, Species 1 is identified as Figures 1 - 4, 9A, 9B, 10A, and 10B, and subspecies A - Figures 12 - 15, subspecies B - Figure 23, and subspecies C - Figure 24. Claims 1 - 14 and claims 17 - 31 read thereon.

The Examiner is invited to telephone Applicant's attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

DAVID SCHAFFER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

(612) 359-3276

Date

Oct 20, 2004

By

Catherine I Klima-Silberg

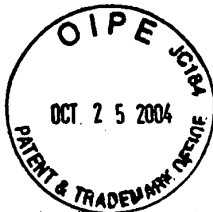
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 20 day of October, 2004.

CANDIS BUENDING

Name

Signature



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Schaffer et al.
Title: COMPOSITE STASIS VALVE

Docket No.: 905.038US1
Filed: February 19, 2003
Examiner: Kevin C Simons

Serial No.: 10/371,190
Due Date: October 20, 2004
Group Art Unit: 3763

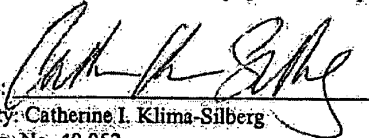
Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

- ☒ A return postcard.
- ☒ Response to Restriction Requirement (1 pg.).

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
Customer Number 21186

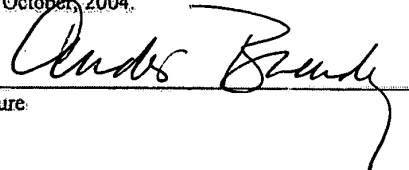
By: 
Atty: Catherine I. Klima-Silberg
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20th day of October, 2004.

CANDIS BUENDING

Name

Signature



SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
(GENERAL)



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/371,190	02/19/2003	David Schaffer	905.038US1	9260
21186	7590	01/11/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

2P

Office Action Summary	Application No. 10/371,190	Applicant(s) SCHAFFER ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
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Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1	figs. 1-4	Species 2	Figs. 9A, 9B, 10A, 10B
Species 3	fig. 27	Species 4	Figs. 28-29

Applicant is further required to elect from ONE of the following sub species:

Sub species A	Figs. 12-15	Sub species B	fig. 23
Sub species C	Figs. 24	Sub species D	fig. 24
Sub species E	fig. 26.		

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, some claims appear to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Several telephone calls were made to Catherine I. Klima-Silberg on 1/7/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note: The examiner was unclear as to which Species (1 or 2) applicant intended to choose. Furthermore, applicant elected all the sub-species in which applicant was required to only elect one sub-species.

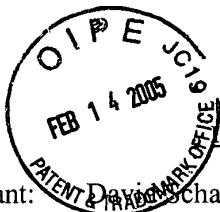
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 703-306-5410. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons
Patent Examiner
1/7/05





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Schaffer et al.

Title: COMPOSITE STASIS VALVE

Docket No.: 905.038US1

Filed: February 19, 2003

Examiner: Kevin C Sirmons

Serial No.: 10/371,190

Due Date: February 11, 2005

Group Art Unit: 3763

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

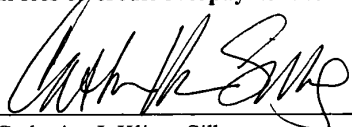
☒ A return postcard.

☒ Response to Restriction Requirement (1 page).

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

Customer Number 21186

By: 

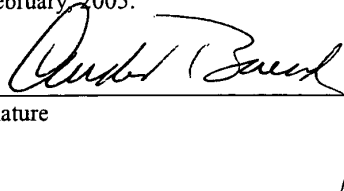
Atty: Catherine I. Klima-Silberg

Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9 day of February, 2005.

CANDIS BUENDING

Name



Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

(GENERAL)

S/N 10/371,190

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Schaffer et al.
Serial No.: 10/371,190
Filed: February 19, 2003
Title: COMPOSITE STASIS VALVE

Examiner: Kevin Sirmons
Group Art Unit: 3763
Docket: 905.038US1

RESPONSE TO RESTRICTION REQUIREMENT

MS AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicant has received the Restriction Requirement dated January 11, 2005.

Applicant elects Species 1, and subspecies E, identified therein. Claims 1 - 4, 7 - 10, 12 - 21, 26 - 29 read thereon.

The Examiner is invited to telephone Applicant's attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

DAVID SCHAFFER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 359-3276

Date

Feb. 9, 2005

By



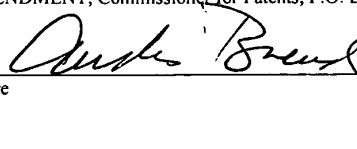
Catherine I Klima-Silberg
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 9 day of February, 2005.

CANDICE BLUMENFELD

Name

Signature



PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number

1057190

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	31	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	31 minus 20 =	* 11
INDEPENDENT CLAIMS	5 minus 3 =	* 2
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

2/14/05

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	* 31	Minus ** 31	= -
Independent	* 5	Minus *** 5	= -
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

1 10 17 22 26

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	\$375
X\$ 9=	99
X42=	87
+140=	
TOTAL	559

RATE	FEE
BASIC FEE	\$750
X\$18=	
X84=	
+280=	
TOTAL	

SMALL ENTITY

OR OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/371,190	02/19/2003	David Schaffer	905.038US1	9260
21186	7590	05/05/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938			SIRMONS, KEVIN C	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/371,190	SCHAFFER ET AL.	
	Examiner	Art Unit	
	Kevin C. Sirmons	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 27 February 2005.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) 5, 6, 10-16 and 22-25 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-3, 7-9, 17, 18, 20, 21 and 26-29 is/are rejected.

7) ☒ Claim(s) 4 and 19 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9/25/03</u> .	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) ☐ Notice of Informal Patent Application (PTO-152) 6) ☐ Other: _____.
---	---

DETAILED ACTION

Election/Restrictions

Applicant's election of Species I, figs. 1-4 and subspecies E fig. 26 in the reply filed on 2/27/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5, 6, 11, 22-25, 30 and 31 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/27/05.

The examiner has withdrawn claims 10 and 12-16 from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaffer U.S. Pat. No. 5,429,616.

Schaffer discloses a valve comprising: a seal module (50) having a lumen sized to allow the passage of fluids or gasses, the seal module having a proximal end and a distal end (50); a resilient member disposed against an actuator (60); and the actuator disposed against a portion of the seal module (24), the actuator movable from a first position to a second position, in the first position the actuator is disposed against the portion of the seal module collapsing the lumen between the proximal end and the distal end of the seal module creating a seal, in the second position the actuator is disposed away from the portion of the seal module by a force allowing the lumen to return to an unsealed configuration (figs. 3-6); as to claim 2, (fig. 3); as to claim 3, (50 is partially enclosed).

Claims 1 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Rantanen-Lee U.S. Pat. No. 5,035,399.

Rantanen-Lee discloses a valve (fig. 3); as to claim 7 (108B); as to claim 8, (102); as to claim 9, (108A and B);

Claims 1-3, 7-9, 17, 18, 20, 21, 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Livingston U.S. Pat. No. 3,759,331.

Livingston discloses a valve (fig. 2).

Allowable Subject Matter

Claims 4 are 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons
Primary Examiner
Art Unit 3763

Kevin C. Sirmons
5/2/05

Substitute for form 1449A/PTO
**INFORMATION DISCLOSURE
 STATEMENT BY APPLICANT**
 (Use as many sheets as necessary)

SEP 25 2003

Sheet 1 of 2

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known
 Application Number 10/371190
 Filing Date February 19, 2003
 First Named Inventor Schaffer, David
 Group Art Unit 3763
 Examiner Name Unknown

Attorney Docket No: 905.038US1

RECEIVED
 OCT 01 2003
 TECHNOLOGY CENTER R3700

US PATENT DOCUMENTS

Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate
KLS	US-4,000,739	01/04/1977	Stevens, R.	128	214.4	07/09/1975
	US-4,424,833	01/10/1984	Spector, K., et al.	137	849	10/02/1981
	US-4,430,081	02/07/1984	Timmermans, H.	604	256	01/06/1981
	US-4,436,519	03/13/1984	O'Neill, W.	604	175	05/28/1981
	US-4,610,674	09/09/1986	Suzuki, T., et al.	604	282	08/29/1985
	US-4,626,245	12/02/1986	Weinstein, L.	604	167	08/30/1985
	US-4,723,550	02/09/1988	Bales, T., et al.	128	344	11/10/1986
	US-4,726,374	02/23/1988	Bales, T., et al.	128	344	07/15/1987
	US-4,798,594	01/17/1989	Hillstead, R.	604	167	09/21/1987
	US-4,895,565	01/23/1990	Hillstead, R.	604	167	05/16/1988
	US-4,909,798	03/20/1990	Fleischhacker, J., et al.	604	256	11/12/1987
	US-4,929,235	05/29/1990	Merry, J., et al.	604	167	07/31/1985
	US-4,932,633	06/12/1990	Johnson, W., et al.	251	149.1	11/21/1988
	US-4,946,133	08/07/1990	Johnson, W., et al.	251	149.1	11/21/1988
	US-4,960,259	10/02/1990	Sunnanvader, L., et al.	251	7	03/28/1989
	US-5,006,113	04/09/1991	Fischer	604	167	04/17/1990
	US-5,041,095	08/20/1991	Littrell, P.	604	167	12/22/1989
	US-5,092,857	03/03/1992	Fleischhacker, J.	604	256	05/17/1991
	US-5,102,395	04/07/1992	Cheer, J., et al.	604	167	06/26/1991
	US-5,114,408	05/19/1992	Fleischhacker, J., et al.	604	167	10/18/1990
	US-5,125,903	06/30/1992	McLaughlin, B., et al.	604	167	08/01/1991
	US-5,127,626	07/07/1992	Hilal, et al.	251	149.1	10/12/1990
	US-5,154,701	10/13/1992	Cheer, J., et al.	604	167	10/31/1991
	US-5,167,637	12/01/1992	Okada, Y., et al.	604	167	10/30/1991
	US-5,176,652	01/05/1993	Littrell, P.	604	167	04/26/1991
	US-5,195,980	03/23/1993	Catlin, D.	604	167	01/03/1992
	US-5,267,966	12/07/1993	Paul, R.	604	167	09/28/1992
	US-5,273,546	12/28/1993	McLaughlin, B., et al.	604	167	04/08/1992
	US-5,304,156	04/19/1994	Sylvanowicz, et al.			01/02/1992
	US-5,350,363	09/27/1994	Goode, R., et al.	604	167	06/14/1993
	US-5,423,762	06/13/1995	Hillstead, R.	604	167	04/15/1993
	US-5,520,655	05/28/1996	Davila, L., et al.	604	167	07/15/1994
	US-5,538,505	07/23/1996	Weinstein, L., et al.	604	167	04/19/1994
	US-5,643,227	07/01/1997	Stevens, R.	604	264	01/19/1995
	US-5,702,370	12/30/1997	Sylvanowicz, et al.	604	256	04/18/1994
✓	US-5,722,958	03/03/1998	Gravener, R. D., et al.	604	169	05/23/1996

EXAMINER

Sirmas

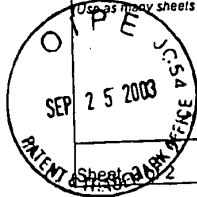
DATE CONSIDERED

5/2/05

Substitute Disclosure Statement Form (PTO-1449)
 * EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Use as many sheets as necessary)



Complete if Known	
Application Number	10/371190
Filing Date	February 19, 2003
First Named Inventor	Schaffer, David
Group Art Unit	3763
Examiner Name	Unknown

Attorney Docket No: 905.038US1

KCS	US-5,858,007	01/12/1999	Fagan, J., et al.	604	256	07/03/1996
	US-5,897,497	04/27/1999	Fernandez, J.	600	435	07/27/1995
	US-6,024,729	02/15/2000	Dehdashtian, M., et al.	604	256	03/10/1998
	US-6,086,570	07/11/2000	Aboul-Hosn, W., et al.	604	256	09/29/1998
	US-6,142,981	11/07/2000	Heck, A., et al.	604	256	01/07/1997
	US-6,221,057	04/24/2001	Schwartz, R. S., et al.	604	246	01/29/1999
	US-6,322,541	11/27/2001	West, R., et al.	604	256	09/10/1999

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
	EP-1046843	10/25/2000	Ferton, Holding	F16K	7/06	
	FR-1529535	10/15/1968	Guyot, Jean M.			

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
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EXAMINER

Sirmers

DATE CONSIDERED

5/2/05

Substitute Disclosure Statement Form (PTO-1449)

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional)? Applicant is to place a check mark here if English language translation is attached

Notice of References Cited	Application/Control No. 10/371,190	Applicant(s)/Patent Under Reexamination SCHAFFER ET AL.	
	Examiner Kevin C. Sirmons	Art Unit 3763	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,035,399	07-1991	Rantanen-Lee, Ann M.	251/10
	B	US-3,759,331	09-1973	Livingston, William L.	169/17
	C	US-5,429,616	07-1995	Schaffer, David I.	604/250
	D	US-			
	E	US-			
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	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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10/371,190

Kevin C. Sirmons

SCHAFFER ET AL.

3763

[illegible]

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

Index of Claims



Application No.

10/371,190

Examiner

Kevin C. Simons

Applicant(s)

SCHAFFER ET AL.

Art Unit

3763

✓	Rejected
=	Allowed

—	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date			
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Claim		Date			
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Claim		Date			
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S/N 10/371,190



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	David Schaffer et al.	Examiner:	Kevin C Sirmons
Serial No.:	10/371,190	Group Art Unit:	3763
Filed:	February 19, 2003	Docket No.:	905.038US1
Title:	COMPOSITE STASIS VALVE		

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This responds to the Office Action mailed on May 5, 2005. Please amend the above-identified patent application as follows.

This response is accompanied by a Petition, as well as the appropriate fee, to obtain a one-month extension of the period for responding to the Office Action, thereby moving the deadline for response from August 5, 2005 to September 5, 2005.

IN THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) A valve comprising:
a seal module having a lumen sized to allow the passage of fluids or gases, the seal module having a proximal end and a distal end;
a resilient member disposed against an actuator, wherein the resilient member is a spring;
the actuator disposed against a portion of the seal module, the actuator movable from a first position to a second position, in the first position the actuator is disposed against the portion of the seal module collapsing the lumen between the proximal end and the distal end of the seal module creating a seal, in the second position the actuator is disposed away from the portion of the seal module by a force allowing the lumen to return to an unsealed configuration; and
at least one detent, the detent retaining a lumen of the seal module in at least one of a closed position or an open position.
2. (Original) The valve as recited in claim 1, wherein the actuator is disposed away from the portion of the seal module by a compressive force.
3. (Original) The valve as recited in claim 1, wherein the seal module is enclosed in a housing.
4. (Canceled)
5. (Canceled)
6. (Withdrawn) The valve as recited in claim 1, wherein the actuator includes an extension configured to slidably engage into a first incline ramp extending from an interior wall of a housing and an angular wall with a depression having a ledge extending therebetween, where the

extension of the actuator is further configured to engage over the ledge of the depression and into a second incline ramp.

7. (Original) The valve as recited in claim 1, wherein the seal module is collapsible by the actuator and by an opposing protrusion.

8. (Original) The valve as recited in claim 1, wherein the actuator includes an actuating member having a U-shaped configuration.

9. (Original) The valve as recited in claim 1, having two actuators disposed on opposing sides of a housing.

10. (Canceled)

11. (Canceled)

12. (Canceled)

13. (Canceled)

14. (Canceled)

15. (Canceled)

16. (Canceled)

17. (Currently Amended) A valve comprising:

a seal module having a proximal end and a distal end, wherein the seal module includes a plurality of seal members including a first seal member, a second seal member, and a third seal member extending between the first and the second seal members, the plurality of seal members

each having a lumen sized to allow the passage of fluids or gases between the proximal end and the distal end;

one or more resilient members disposed against one or more actuators, wherein one or more of the resilient members is a spring; and

the one or more actuators disposed against a portion of the seal module, the one or more actuators movable from a first position to a second position, in the first position the one or more actuators are at least partially ~~circumferentially~~ circumferentially disposed about the portion of the seal module collapsing the lumen between the proximal end and the distal end of the seal module creating a seal, in the second position the one or more actuators are ~~circumferentially~~ circumferentially disposed away from the portion of the seal module allowing the lumen to return to an unsealed configuration.

18. (Original) The valve as recited in claim 17, wherein the one or more actuators each include an actuating member having a U-shaped configuration.

19. (Canceled)

20. (Original) The valve as recited in claim 17, wherein the one or more actuators are disposed on opposing sides of a housing.

21. (Original) The valve as recited in claim 17, wherein each of the one or more actuators is disposed away from the portion of the seal module by a compressive force.

22. (Canceled)

23. (Canceled)

24. (Canceled)

25. (Canceled)

26. (Currently Amended) A method comprising:
forming a seal module having a lumen sized to allow the passage of fluids or gases;
disposing an actuator against a portion of the seal module with a resilient material,
wherein the resilient material is a spring, the actuator movable from a first position to a second
position;
collapsing the lumen between a proximal end and a distal end of the seal module creating
a seal;
moving the actuator away from the portion of the seal module in the second position
allowing the lumen to return to an unsealed configuration; and
moving at least one detent, and retaining the lumen of the seal module in at least one of a
closed position or an open position.
27. (Original) The method as recited in claim 26, wherein moving the actuator away from
the portion of the seal module includes moving the actuator by a compressive force.
28. (Original) The method as recited in claim 26, wherein collapsing the seal module
includes depressing the seal module with the actuator and an opposing protrusion.
29. (Original) The method as recited in claim 26, wherein collapsing the seal module
includes depressing the seal module with two opposing actuators.
30. (Canceled)
31. (Withdrawn) The method as recited in claim 26, including moving an extension of the
actuator along an incline ramp of an interior wall of a housing and into a depression, disposing
the extension under the force of a compression spring, urging the extension against an angular
wall, pushing the extension to one side over a ledge, and disposing the extension into a return
incline ramp.

REMARKS

This responds to the Office Action mailed on May 5, 2005, and the references cited therewith.

Claims 1, 17, and 26 are amended, claims 4, 10-16, 19, and 22-25 are canceled without prejudice or disclaimer; as a result, claims 1-9, 17-21, 26-29, and 31 are now pending in this application.

§102 Rejection of the Claims

Claims 1-3 were rejected under 35 U.S.C. § 102(b) for anticipation by Schaffer (US 5,429,616). Claims 1 and 7-9 were rejected under 35 U.S.C. § 102(b) for anticipation by Rantanen-Lee (US 5,035,399). Claims 1-3, 7-9, 17, 18, 20, 21, 26-29 rejected under 35 U.S.C. § 102(b) for anticipation by Livingston (US 3,759,331). Applicant respectfully submits the rejections are now moot. Reconsideration and allowance of the pending claims are respectfully requested.

Allowable Subject Matter

Claims 4 and 19 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant has amended claims 1, 17, and 26 to include the allowable subject matter therein. Applicant respectfully requests allowance of claims 1-9, 17-21, 26-29, and 31.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

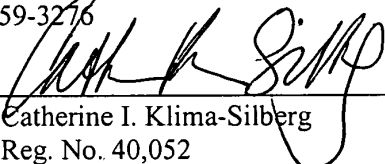
Respectfully submitted,

DAVID SCHAFFER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 359-3276

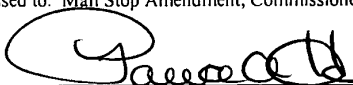
Date Aug. 12, 2005

By 
Catherine I. Klima-Silberg
Reg. No. 40,052

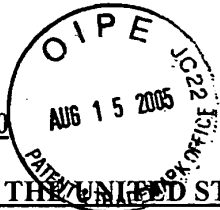
CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12TH day of August, 2005.

PATRICIA A. HULTMAN

Name


Signature

S/N 10/371,190



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Schaffer et al.
Serial No.: 10/371,190
Filed: February 19, 2003
Title: COMPOSITE STASIS VALVE

Examiner: Kevin Sirmons
Group Art Unit: 3763
Docket No: 905.038US1

PETITION FOR A ONE-MONTH EXTENSION OF TIME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In accordance with the provision of 37 CFR § 1.136(a), it is respectfully requested that a one-month extension of time be granted in which to respond to the Office Action mailed May 5, 2005, said period of response being extended from August 5, 2005 to September 5, 2005.

Our check in the amount of \$60.00 is enclosed to cover the required extension fee.
Please charge any additional fees or credit overpayment to deposit Account No. 19-0743.

Respectfully Submitted,

DAVID SCHAFFER ET AL.

08/16/2005 GWORDDF1 00000009 10371190

01 FC:2251

60.00 DP

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 359-3276

Date: Aug. 12, 2005

By: Catherine I. Klima-Silberg

Catherine I. Klima-Silberg
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelop addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12TH day of August 2005.

PATRICIA A. HULTMAN

Name

Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

3763
JFW

Applicant: David Schaffer et al.

Title: COMPOSITE STASIS

Docket No.: 905.038US1

Filed: February 19, 2003

Examiner: Kevin C Sirmons



Serial No.: 10/371,190

Due Date: September 5, 2005

Group Art Unit: 3763

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

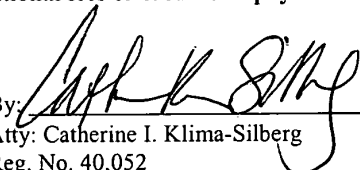
We are transmitting herewith the following attached items (as indicated with an "X"):

- ☒ Return postcard.
- ☒ Amendment and Response (7 pgs.).
- ☒ Petition for Extension of Time (1 pg.)
- ☒ Check in the amount of \$60.00 to cover the Extension of Time Fee.

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

Customer Number 21186

By: 

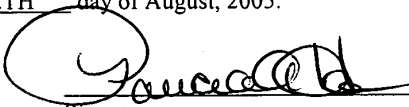
Atty: Catherine I. Klima-Silberg

Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12TH day of August, 2005.

PATRICIA A. HULTMAN

Name



Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

(GENERAL)

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application No. **103 4190**

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	31	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	31 minus 20 =	11
INDEPENDENT CLAIMS	5 minus 3 =	2
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

2/14/05

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	31	31	= -
Independent	5	5	= -
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

8-15-05

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	16	31	= -
Independent	3	5	= -
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total			=
Independent			=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	\$375
X\$ 9=	99
X42=	89
+140=	
TOTAL	558

RATE	FEE
BASIC FEE	\$750
X\$18=	
X84=	
+280=	
TOTAL	

SMALL ENTITY OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL	

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL	

RATE	ADDITIONAL FEE
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X42=	

RATE	ADDITIONAL FEE
X\$18=	
X34=	

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/371,190	02/19/2003	David Schaffer	905.038US1	9260
21186	7590	11/01/2005		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402				
EXAMINER SIRMONS, KEVIN C				
ART UNIT		PAPER NUMBER		
3767				

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/371,190	Applicant(s) SCHAFER ET AL.	
	Examiner Kevin C. Simons	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-9, 17-21, 26-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-9, 17-21 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-9, 17-21 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaffer U.S. Pat. No. 5,429,616.

Schaffer discloses a valve comprising: a seal module (50) having a lumen sized to allow the passage of fluids or gasses, the seal module having a proximal end and a distal end (50); a resilient member (28) disposed against an actuator (44, 46 and 48), wherein the resilient member is a spring (28); and the actuator disposed against a portion of the seal module (24), the actuator movable from a first position to a second position, in the first position the actuator is disposed against the portion of the seal module collapsing the lumen between the proximal end and the distal end of the seal module creating a seal, in the second position the actuator is disposed away from the portion of the seal module by a force allowing the lumen to return to an unsealed configuration (figs. 3-6); at least one detent, the detent retaining a lumen of the seal module in at least one of a closed or an open position (60); as to claim 2, (fig. 3); as to claim 3, (50 is partially enclosed); as to claims 7-9, (fig. 5); as to claim 17, (figs. 1, 2, and 5); as to claims 18-21, and 26-29, (see above rejections).

Claims 1-3, 7-9 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Rantanen-Lee U.S. Pat. No. 5,035,399.

Rantanen-Lee discloses a seal module (fig. 2) having a lumen sized to allow the passage of fluids or gasses, the seal module having a proximal end and a distal end (fig. 2); a resilient member (102) disposed against an actuator (108), wherein the resilient member is a spring (102); and the actuator disposed against a portion of the seal module (fig. 2), the actuator movable from a first position to a second position, in the first position the actuator is disposed against the portion of the seal module collapsing the lumen between the proximal end and the distal end of the seal module creating a seal, in the second position the actuator is disposed away from the portion of the seal module by a force allowing the lumen to return to an unsealed configuration (figs. 1-2); at least one detent, the detent retaining a lumen of the seal module in at least one of a closed or an open position (figs 1 and 2); as to claims 2-3, (figs. 1 and 2); as to claim 7 (figs. 1-2); as to claim 8, (figs. 1-2); as to claim 9, (figs. 1 and 2); as to claims 26-29, (figs. 1 and 2).

Claims 1-3, 7-9, 17, 18, 20, 21, 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Livingston U.S. Pat. No. 3,759,331.

Livingston discloses a seal module (figs. 2 and 4) having a lumen sized to allow the passage of fluids or gasses, the seal module having a proximal end and a distal end (figs. 2 and 4); a resilient member (72) disposed against an actuator (57 and 66), wherein the resilient member is a spring (fig. 4); and the actuator disposed against a portion of the seal module (fig. 2 and 4),

the actuator movable from a first position to a second position, in the first position the actuator is disposed against the portion of the seal module collapsing the lumen between the proximal end and the distal end of the seal module creating a seal, in the second position the actuator is disposed away from the portion of the seal module by a force allowing the lumen to return to an unsealed configuration (figs. 2 and 4); at least one detent, the detent retaining a lumen of the seal module in at least one of a closed or an open position (figs 2 and 4); as to claims 2-3, (figs. 2 and 4); as to claims 7-9 (figs. 2 and 4); as to claims 17, 18, 20, 21 and 26-29, (figs. 2 and 4).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin C. Sirmons
Primary Examiner
Art Unit 3763
10/31/05



Index of Claims 	Application/Control No.		Applicant(s)/Patent under Reexamination	
	10/371,190		SCHAFFER ET AL.	
	Examiner		Art Unit	
	Kevin C. Simons		3767	

✓	Rejected
=	Allowed

—	(Through numeral) Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date									
Final	Original										
	1	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	4	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
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[illegible]

Kevin C. Simons

3767

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Class	Subclass	Date	Examiner

[illegible]



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/371,190	02/19/2003	David Schaffer	905.038US1	9260
21186	7590	10/05/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Abandonment	Application No.	Applicant(s)	
	10/371,190	SCHAFFER ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

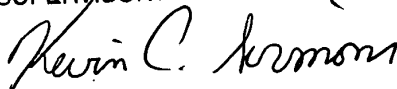
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

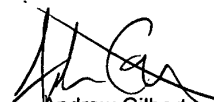
This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 11/1/2005.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

The applicant failed to respond to the office action mailed 11/1/2005 therefore the application has gone abandoned.

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER




Andrew Gilbert
9/29/2006

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.