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GB 0823752 US 4569344

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F16K

(54) Control valve

(57) A patient suction catheter system has a patient coupling 29, a catheter 24 surrounded by a sterility preserving collapsible envelope 25 and a vacuum control valve mechanism 10 extend between the coupling 29 and the control valve mechanism 10. The catheter 24 and surrounding envelope 10 is normally closed and is biased toward the closed position by a resilient cap 19 formed integrally with the valve closure 10a. Air trapped in the valve bore 13 beneath the valve stem 14 also biases the valve to the closed position.

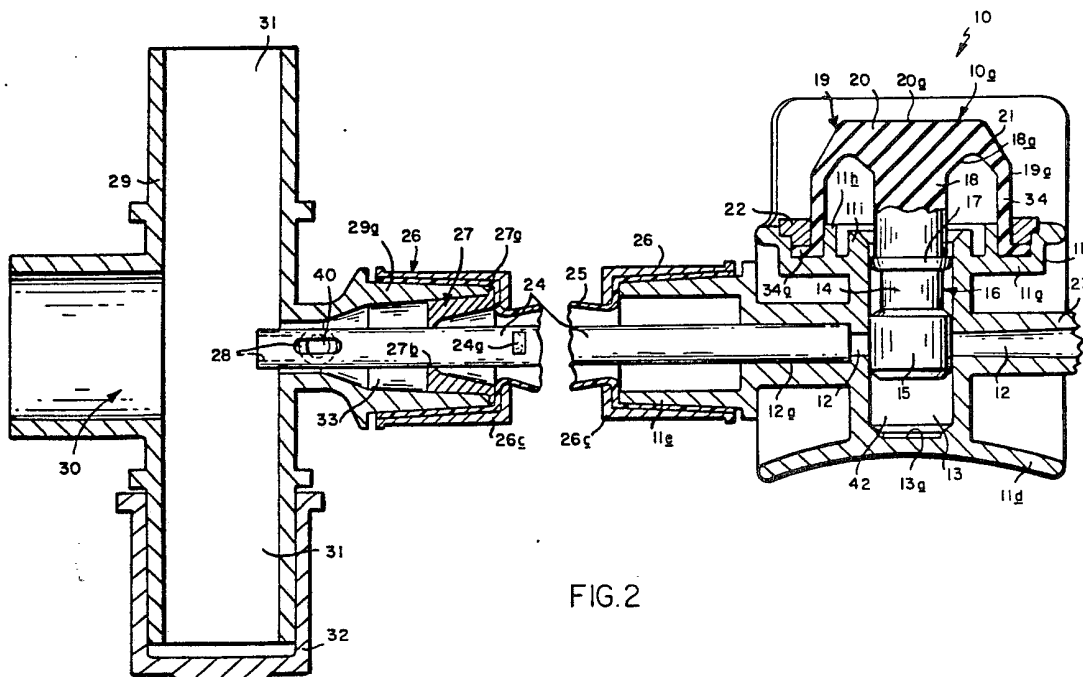


FIG. 2

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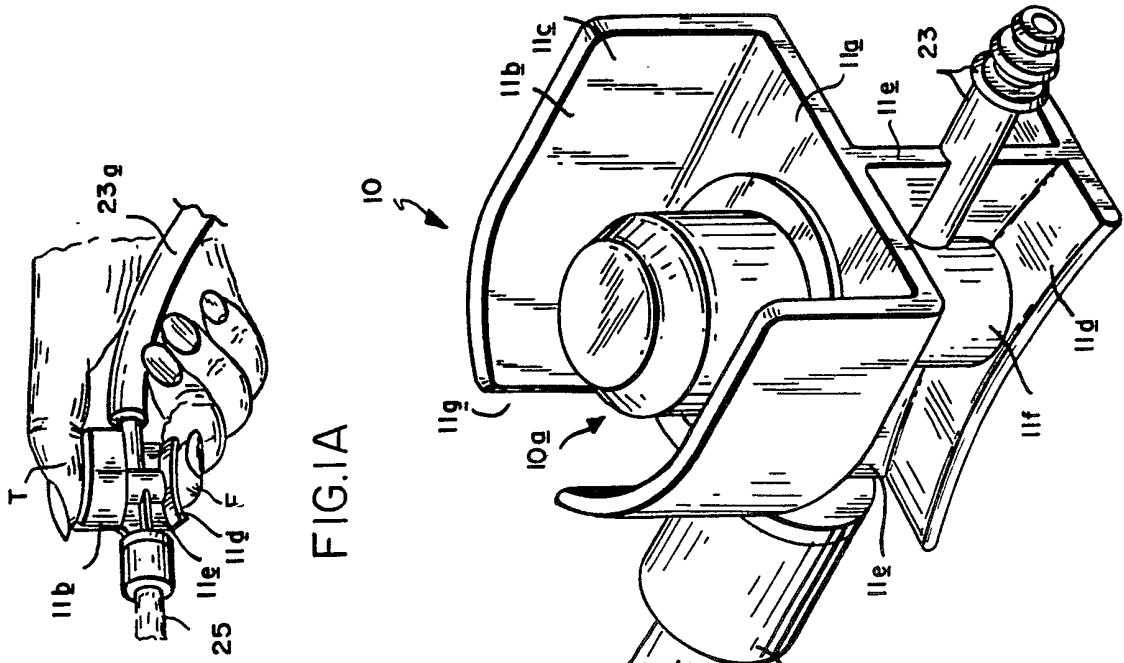


FIG. 1A

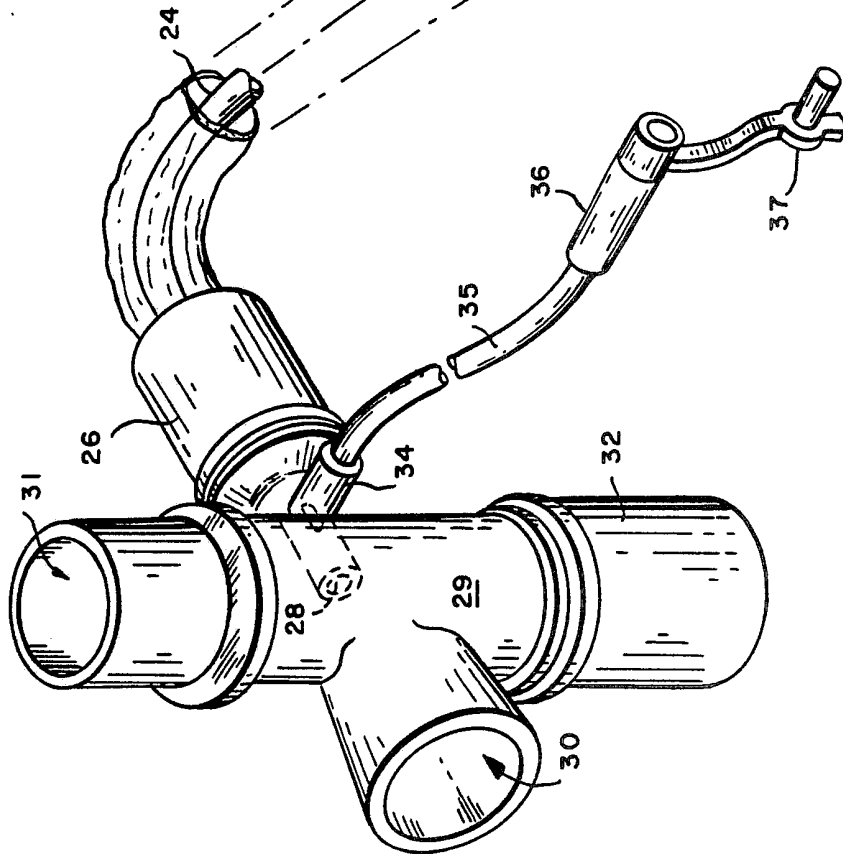


FIG. 1

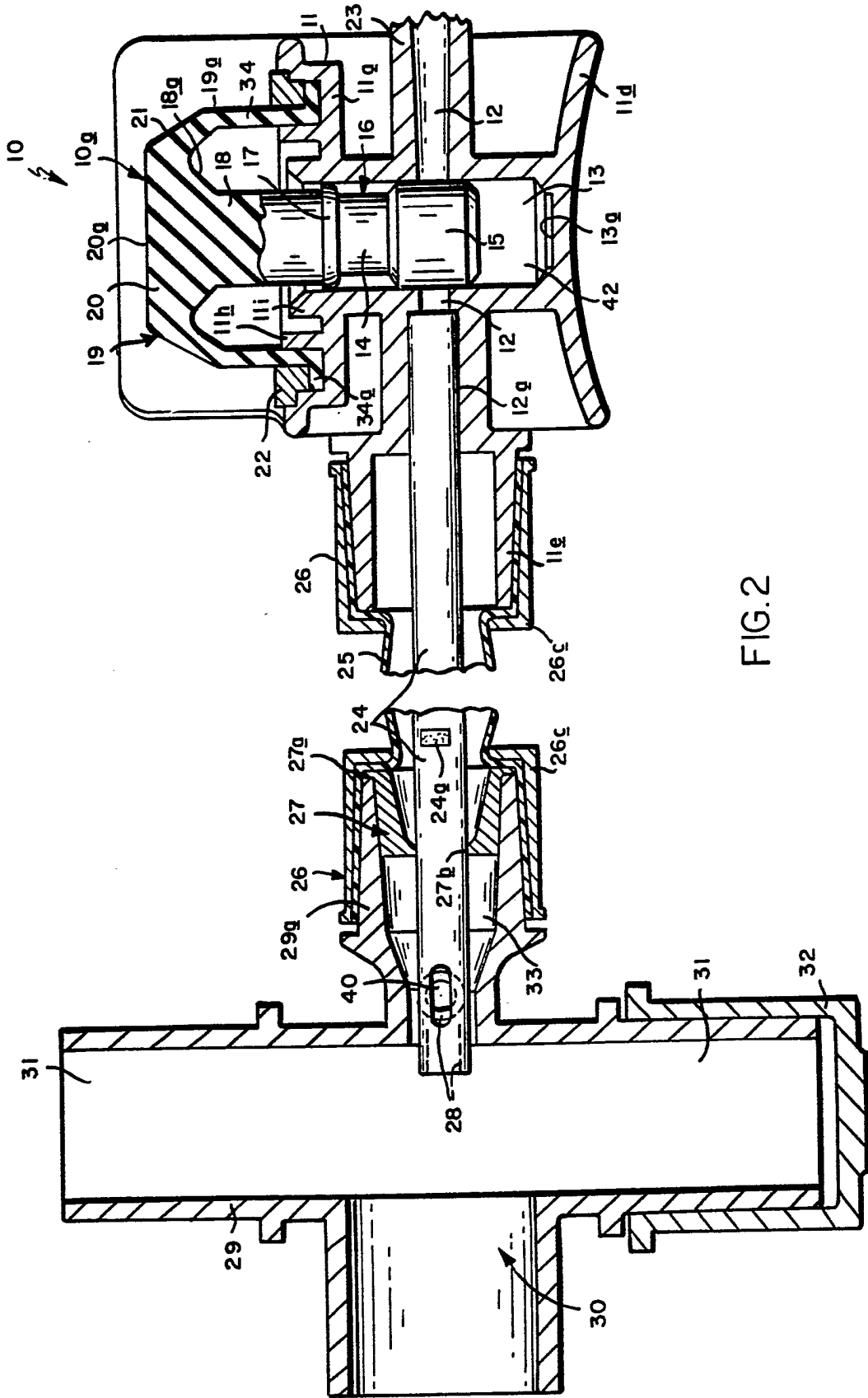


FIG. 2

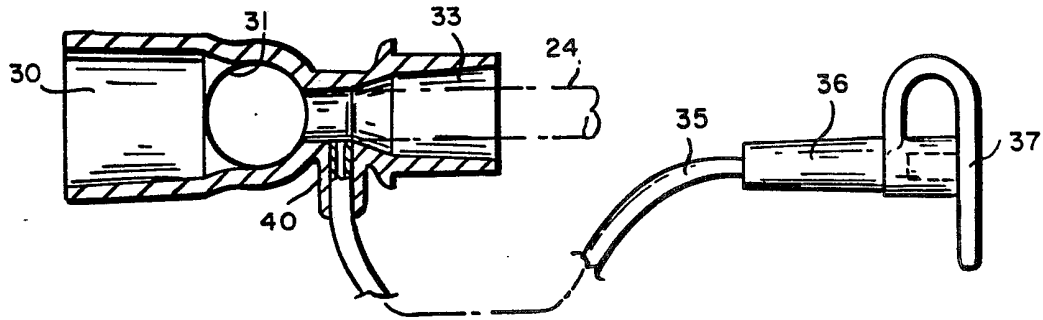


FIG. 6

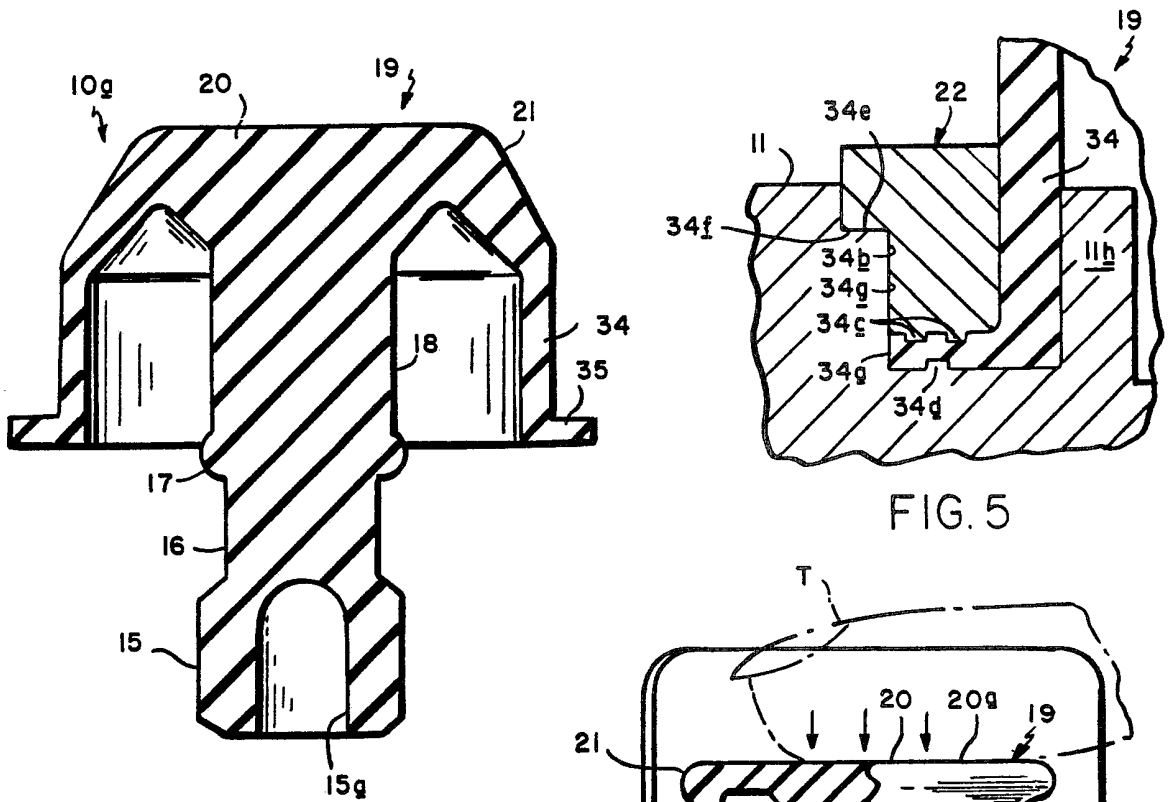
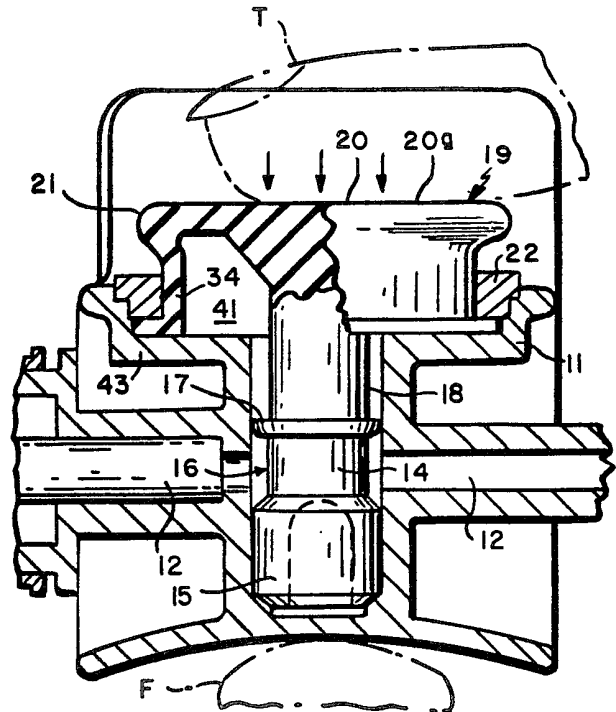


FIG. 5

FIG. 4

FIG. 3



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CONTROL VALVE FOR SUCTION CATHETER DEVICE AND
VENTILATION/ASPIRATION SYSTEM

BACKGROUND OF THE INVENTION

5 This invention relates to patient suction
catheter devices used to aspirate body fluids from
various internal cavities, and particularly to an
aspirating device for use with a patient
ventilation apparatus, i.e., a
ventilation/aspiration system, to remove fluid
accumulations from the trachea, bronchi and lungs
of a patient. The invention also relates to a
unique control valve mechanism for use in a
10 suction catheter device.

15 During ventilation of a patient through a
tracheal or endotracheal procedure, debris such as
blood, blood clots, mucous, flem and other body
fluids can accumulate in the trachea, lungs and
bronchi and inhibit ventilation, e.g., by plugging
the tracheal or endotracheal ventilating tube
through which the patient is ventilated. In order
for ventilation to proceed efficiently and to
prevent injury to the patient and other
20 undesirable effects, these fluids must be
aspirated out of the patient. Typically this is
done by inserting a catheter connected to a
vacuum source, which sucks out the accumulated
body fluids.

25 To minimize the risk of the patient having an
undesirable reaction due to any interruption in
the ventilation process, such as hypoxia,

hypoventilation or hyperapnia, ventilation/
aspiration systems have been developed to allow
for periodic aspiration without interruption of
ventilation by maintaining the tracheal or
5 endotracheal ventilation tube in place over a
prolonged period and repeatedly applying vacuum as
needed by operation of a vacuum control or suction
valve. Such systems are disclosed in U.S. Patents
3,991,762 and 4,569,344, the disclosures of which
10 are incorporated herein by reference. Various
types of vacuum control (suction) valves have been
used in such systems, or with suction catheters in
general, including those having a rotatable valve
as shown in U. S. Patent 3,991,762 or a plunger
15 valve, as shown in U.S. Patent Nos. 3,517,669,
4,451,257 and 4,212,300 or a simple vent to the
atmosphere which is closed by the finger to
achieve suction.

20 The prior art systems disclosed in U. S.
patents 3,991,762 and 4,569,344 comprise a suction
catheter extending between a suction valve and a
patient coupling element which couples the patient
to a ventilation device via an tracheal or
25 endotracheal ventilation tube. The catheter is
moved through the patient coupling element and
endotracheal ventilation tube into and out of the
trachea. A collapsible envelope is located around
the catheter and attached at its ends to the
30 suction valve and the patient coupling element so
that the catheter can be manipulated through the
envelope to periodically insert and remove it from
the trachea to aspirate the patient as needed
without contact with the hands of the operator.

The catheter and suction valve remain attached to the patient coupling element over a period of time and may be used to repeatedly aspirate the patient as required.

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The prior art aspiration and ventilation/ aspiration systems and the suction valves embodied therein have serious disadvantages. In most cases the flow path of the aspirated body fluids through the valve is not isolated, i.e., sealed from the atmosphere, with the risk of transmitting disease to the operator and of contaminating the system with resulting risk of transmitting disease to the patient. The ventilation/aspiration system described in U. S. Patent No. 4,569,344 attempts to avoid these disadvantages by a vacuum control valve structure which is alleged to isolate from the atmosphere the flow path of the aspirated body fluids through the valve and catheter. However, this vacuum control valve has the disadvantages of being complex in structure and of having pockets and interior valve surfaces in or on which the aspirated body fluids can collect to provide a breeding ground for bacteria with risk of contaminating the patient. This system also has the disadvantage that the interior of the protective envelope is open to the atmosphere i.e., it is not a closed system, with resulting risk of contamination of the catheter and hence of the patient.

THE INVENTION

The present invention provides a suction catheter device and vacuum control valve mechanism which do not have the aforesaid disadvantages.

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The suction catheter device and vacuum control valve mechanism of the present invention are simple in structure and to manufacture and are easy to operate. Yet they provide a complete seal between the atmosphere and the fluid being aspirated and between the catheter and the atmosphere so as to prevent the possibility of contamination. The vacuum control valve is self cleaning and is so designed that there are substantially no pockets or surfaces in or on which the aspirated body fluids can collect. The present invention also provides a completely sealed (closed) ventilation/aspiration system, which embodies such suction catheter device and vacuum control valve and their advantages, which allows for the rapid insertion and removal of the suction catheter into and out of the patient without interruption of ventilation, in which the inside of the protective envelope is sealed from the environment and which allows for repeated use over a prolonged period through preservation of a sterile and uncontaminated environment throughout the system.

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SUMMARY OF THE INVENTION

The suction catheter device and ventilation/aspiration system of the present invention comprise a catheter which is enclosed within a sterile, flexible envelope, one end of

said catheter (the patient end) passing through a ventilating cross-piece (patient coupling element) via a one-way wiper/sealer, and the other end of said catheter being connected to a vacuum source via the vacuum control valve of the present invention. The vacuum control valve comprises a resilient and elastomeric valve (preferably one piece) having a valve stem slideable in the bore of a valve body between normally closed and open positions, wherein the valve stem is in normally closed position and when moved to open position by application of external pressure to the valve stem, is biased toward the closed position through the elasticity of the valve and/or the force of trapped compressed air within the valve. This bias automatically causes the valve stem to return to the closed position upon release of the external pressure. The valve stem is provided with means for sealing the fluid path through the valve from the ends of the bore and the ends of the bore are closed to the outside atmosphere. All components of the suction catheter device and ventilation/aspiration system and vacuum control valve of the present invention are completely sealed and sterile so as to prevent contamination of the patient from outside sources or contamination of the outside environment from the aspirated body fluids and so as to minimize pockets and surfaces in or on which the aspirated fluids can collect. The vacuum control valve is so designed that it can be held and operated in one hand leaving the other hand free for other manipulations.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Fig. 1 is a perspective view of a suction catheter device and ventilation/aspiration system and vacuum control valve of the present invention.

10 FIG. 1A is a perspective view of the vacuum control valve mechanism of FIG. 1 held and being operated in one hand.

15 FIG. 2 is a partial cross-section of the device shown in FIG. 1 with the vacuum control valve mechanism being shown in its normal open position.

FIG. 3 is a partial cross-section of the control valve mechanism shown in FIGS. 1 and 2 in the depressed, open position.

20 FIG. 4 is a side elevational view in cross section of the control valve shown in FIGS. 2 and 4.

25 FIG. 5 is an enlarged cross-section of the seal formed between the valve and valve body of the control valve mechanism of FIG. 1.

30 FIG. 6 is a top view partially in section of the patient coupling member shown in FIG.1 showing the means for irrigating the suction catheter.

DETAILED DESCRIPTION OF
THE PREFERRED EMBODIMENTS

5 The suction catheter system of the present invention, and particularly the control valve mechanism used therewith, may be described in greater detail with reference to the accompanying drawings.

10 With reference to the drawings 24 represents a conventional suction catheter. One end of the catheter 24 slidably passes through patient coupling element 29 for insertion into the patient's body cavity, typically the trachea via a tracheal or endotracheal ventilation tube (not
15 shown), for aspiration of fluids through catheter openings 28. The other end of the catheter is secured to control valve mechanism 10 for applying vacuum or suction to the catheter through the control valve mechanism via its connector 23 and
20 suction tube 23a (FIG. 1A) to a vacuum source.

The control valve mechanism 10 is illustrated in greater detail in FIGS. 2 to 5. It comprises a valve 10a and a valve body 11. There are two
25 positions of valve 10a, namely a relaxed normal position in which the valve is closed (i.e., suction is cut off from the catheter), as shown in FIG. 2, and a depressed position in which the valve is open (i.e., suction is communicated
30 through the valve to the catheter), as shown in FIG. 3.

Valve body 11 is preferably made of a rigid plastic such as, but not limited to, styrene acrylonitrile (SAN) and has a passageway 12 therethrough for the passage of the patient's body

fluids when the valve is in the open position. Intersecting this passageway is valve bore 13, which is generally perpendicular to and extends above and below said passageway. Bore 13 has a cross-section equal to or greater than the passageway. Bore 13 is closed at the lower end and open at the upper end. Any relatively rigid material can be used for the valve body so long as it is resistant to the patient's aspirated body fluids.

The valve body may be transparent, translucent or opaque.

Valve 10a is a one piece valve fabricated of resilient, elastomeric, deformable material, such as, but not limited to, natural or synthetic rubber, e.g., butyl natural rubber. Any resilient elastomeric, deformable material can be used which is resistant to the patient's aspirated body fluids. Valve 10a comprises a valve stem 14, which is located in the valve bore 13 and which is slideable therewithin between normal, relaxed, closed position and depressed open position. The valve stem has means for sealing (closing) the passageway 12 when aligned therewith as shown in FIG. 2. This means comprises a first sealing portion or land 15 at or near the lower end of the valve stem which is in sealing and slidable contact with the wall of the bore. First sealing portion 15 additionally serves to maintain a seal between the passageway 12 and the closed lower end 13a of the valve bore, thereby trapping air in the chamber 42 between such sealing portion 15 and the

end 13a of the bore. The valve stem also has means for allowing flow through the passageway when aligned therewith in the open position. This means comprises an open portion 16 in the form of a reduced diameter portion of the valve stem to provide an annular recess 16, as shown. However, it may be an aperture through the valve stem.

The valve stem additionally has means for maintaining a seal between the passageway and the open upper end of the valve bore. This means comprises a second sealing portion or land 17 in the form of an annular rib at or near the upper end of the valve stem and in slideable but sealing engagement with the bore wall. It should be noted that the first and second sealing portions 15 and 17 serve to prevent aspirated body fluids, i.e., debris, from the patient from passing downwardly or upwardly, respectively, beyond such sealing portions. They also function to wipe away aspirated body fluids which may collect in the valve bore or on the bore surface, e.g., aspirated body fluids which are trapped in the recess 16 and on the bore wall opposite such recess when the valve stem is moved from open to close position after an aspiration. Such body fluids are wiped back into the passageway and removed by suction by movement of the valve stem from closed to open position during the subsequent aspiration. Body fluids which might collect on the bore wall below the passageway during an aspiration are wiped away by subsequent movement of the valve stem from open to close position. These self cleaning wiping actions prevent any contamination from collecting

within the valve and serve as a breeding ground for bacterial growth with risk of contamination to the patient.

5 The normal relaxed diameters of the aforesaid resilient elastomeric sealing portions 15 and 17 of the valve stem are slightly greater than the diameter of the bore so that such sealing portions are urged into resilient sealing engagement with
10 the bore wall.

To operate the control valve mechanism it is necessary to have means for depressing the valve stem within the valve bore between the normal
15 relaxed closed position and the depressed open position, and to have means for biasing the valve stem toward the normal relaxed closed position so that the valve automatically returns to a closed position upon release of the depressing force.
20 Both of these functions are readily accomplished in the following manner. Valve stem 14 is provided with an integral extension 18 at its upper end, as shown in FIGS. 2, 3 and 4, which is part of the one piece valve 10a and which extends
25 upwardly above the open upper end of the valve bore so that it can be easily manually depressed, e.g., by the operator's thumb T (FIGS. 1a and 3) to thereby depress the valve stem. Integral with this upper extension and also part of the one
30 piece elastomeric valve is an inverted cap shaped portion 19 having an end wall 20 providing a thumb or finger engaging surface 20a for depressing the valve stem, and a depending side wall 19A, comprising a downwardly and outwardly

extending biasing portion 21 and a downwardly
extending lower side wall portion 34. The lower
end of the side wall 19a is sealingly secured to
the valve body by means of a radial integral
5 flange 34a, as described in greater detail
hereinafter. This depending side wall and its
juncture with the end wall function as a spring to
yieldably resist depression of the valve stem, and
thereby bias the valve stem toward its normal
10 relaxed closed position, through the elastomeric,
resilient and deformable biasing portion 21 and
lower side wall portion 34. Biasing portion 21
and lower side wall portion 34 allow the cap
shaped portion to flex upon application of a
15 depressing force to thereby deform portion 21 and
lower side wall portion 34, as shown in FIG. 3,
and then cause the cap shaped portion to
automatically return to its normal relaxed closed
position, as shown in FIG. 2, upon removal of the
20 depressing force as a result of the resilient
elasticity of the biasing portion and lower side
wall portion. The particular shape of the cap
shaped portion, e.g., the widening of the valve
stem extension at 18a where it extends into the
25 end wall 20 and the decreasing width of biasing
portion 21 as it extends downwardly and outwardly
from the end wall and the angular relationship
between the end wall and the biasing portion and
between the lower side wall portion and the
30 biasing portion, all contribute to achieve
optimum biasing effect (spring action) while at
the same time achieving sufficient rigidity to
efficiently and effectively transmit a depressing
force axially to the valve stem. It should be

understood that the flexing and deformation of the cap portion may occur at the biasing portion 21, at both such biasing portion and lower side wall portion 34, or may spread to other areas in view of the resiliency and elasticity of the material from which the valve is fabricated. Since it is the engagement of the end portion of the depending wall with the valve body which causes deformation of the cap shaped member when the valve stem is depressed, and the resulting spring effect, one can refer to such cap shaped member as springingly contacting, or as being in springing contact with, the valve body.

The cap shaped portion is located over and around the upper end of the bore 13 and the extension 18 of the valve stem and is mounted to the valve body, as shown, to secure the valve stem within the valve bore and retain it in the normal relaxed closed position.

The cap shaped portion is secured and sealed to the valve body by annular elastomeric flange 34a, which is located in an annular groove 34b in the valve body, and by sealing ring 22 (FIG. 5). Sealing ring 22 may be made of the same relatively rigid plastic material as the valve body and is ultrasonically welded or otherwise secured, e.g., by a solvent bond or an adhesive, to the valve body to compress the elastomeric flange 34a into sealing contact with the floor and side wall 34g of the annular groove 34b to thereby seal off the interior 41 of the cap portion 19, the upper end of the valve bore and the passageway 12 from the outside environment. Sealing the cap member in

5 this fashion serves as a second seal (the first is
sealing rib 17) between the passageway and the
outside environment, providing an extra margin of
safety. It also cooperates with sealing rib 17 to
trap air in the chamber 41 formed by the cap
portion and the valve body to further yieldably
resist depression of the valve stem and assist in
automatically returning the valve stem to closed
position. Sealing rib 17 also prevents any
10 aspirated body fluids from entering and collecting
in chamber 41 whereas sealing portion 15 prevents
any such fluids from entering and collecting in
chamber 42. In effect, the lower end of bore 13
is closed and hermetically sealed from the
15 atmosphere by the end wall 13a and the upper end
is closed and hermetically sealed from the
atmosphere by the seal formed by flange 34a.
Although the sealing portions 15 and 17 seal the
passageway from the atmosphere, it is highly
20 advantageous to provide secondary hermetic seals
34a and 13a.

Annular ribs 34c extending from the lower
surface of the sealing ring and an annular rib 34d
25 upstanding from the floor of annular groove 34b
tend to further deform the flange 34a to increase
the sealing effect against the floor and walls of
the groove. The ledge 34e in groove 34b and
cooperating ledge 34f in the sealing ring are
30 designed so as to avoid the application of
excessive force to the flange 34a.

The aforesaid side wall 34g constitutes the inner wall of a cup shaped portion 43 (FIG. 3) in horizontal platform 11a of the valve body. The floor of the cup has an upstanding annular wall 11h (FIGS. 2 and 5) to laterally support the lower end portion of lower side wall portion 34 of the cap shaped portion of the valve and to supply an additional sealing surface against which the flange 34a is sealingly pressed by ring 22. The floor of the cup also has an upstanding, annular, internally tapered (adjacent its open end) wall 11i to facilitate insertion of the elastomeric valve stem into the bore during assembly. The lower end of the valve stem has a blind passage 15a to increase radial flexibility and thereby facilitate insertion of the elastomeric, resilient valve stem into the undersized bore.

The term "relaxed", as used herein with reference to the valve, refers to a non stressed condition, i.e., not under tension or compression.

Platform 11a has an upstanding protective wall 11b which extends partially around the upstanding cap portion of the valve and slightly above it to prevent accidental depression of the valve stem to open position, which is highly undesirable because sustained application of vacuum to the trachea and lungs may be harmful. Wall 11b is open at one side at 11c to receive the thumb T or finger to depress the valve stem, as shown in FIGS. 1A and 3. The particular shape and size of the valve body permits it to be held in one hand as shown in FIG. 1A with the forefinger or middle finger F

(FIG. 3) or both located under the lower arcuate horizontal flange 11d leaving the thumb free to press down on the cap portion to depress the valve stem and open the valve and in doing so to move
5 down into the opening 11c, as shown. Narrow opening 11g in wall 11b opposite opening 11c may receive the thumb nail or tip of the thumb, as shown in FIG. 1A, to facilitate downward movement of the thumb to open the valve.

10 Platform 11a and flange 11d are joined by an integral vertical strut 11e and tubular portion 11f in which the bore is located.

15 Although the control valve mechanism can be normally open in the relaxed position and closed in the depressed position if used for purposes other than aspirating the trachea, it is important
20 when used to aspirate the trachea that the passageway be normally closed since sustained application of vacuum to the trachea is highly undesirable.

25 An advantageous feature of the present invention is the use of trapped air within sealed chamber 42 in the valve bore and within sealed chamber 41 of the cap portion to assist in returning the valve to the relaxed closed position. Upon application of a depressing force
30 to the cap member the trapped air within sealed chamber 42 is compressed by downward movement of the valve stem and the air in sealed chamber 41 is compressed by deformation of the cap shaped portion. Upon release of the depressing force,

the compressed trapped air in 41 and 42 assists in forcing the valve stem upward to its original, relaxed positions. An axial passage may be provided through the valve 10a to provide
5 communication between the two sealed chambers 41 and 42 to decrease the force required to depress the valve stem. Also, to decrease such force, chamber 41 may be vented to the atmosphere through a conventional hydrophobic bacterial filter, e.g.,
10 a polytetra fluoro ethylene membrane filter, which permits air to be vented therethrough, but prevents liquid and bacteria from passing therethrough.

15 The suction catheter device of the present invention is preferably assembled and sold as a complete and sealed unit, ready for immediate use as a tracheal or endotracheal
ventilation/aspiration unit. Such unit comprises,
20 in addition to the control valve mechanism and catheter tube previously described, the T-shaped patient coupling element 29, through which the catheter tube is inserted into the patient's trachea, and a sterility preserving collapsible
25 envelope 25 surrounding the catheter tube. Envelope 25 is sealingly secured to the patient coupling element 29 at one end and to the control valve mechanism at the other end by use of
internally tapered slip collars 26 (FIG. 2) with
30 the ends of the envelope adhesively or cohesively (e.g., solvent bonding) sealed and secured between the internally tapered surfaces of the slip collars and the externally tapered surfaces of extensions 11e and 29a of the valve body and

5 patient coupling element 29, respectively, and
between the inturned end walls 26c of slip collars
26 and the ends of extensions 11e and 29a, such
that the inside of the envelope and the outside
10 surface of the catheter tube are completely sealed
from the outside environment. The collapsible
envelope is preferably a flexible, lightweight
transparent or translucent film material, such as
polyethylene, and is ordinarily of such length
15 that when it is fully outstretched, that is, when
the patient coupling element and the control valve
mechanism are at their greatest distance apart,
the patient end of the catheter tube is withdrawn
from the patient and is located within the
20 patient coupling element, as shown in FIGS. 1 and
2.

The end portion of catheter 24 which is
25 secured to the suction valve (commonly referred to
as the proximal end of the catheter), is sealingly
secured, e.g., adhesively or cohesively, in the
enlarged end portion 12a of passageway 12, as
shown in FIG. 2A.

25 The ends of the envelope may be sealed and
secured to each of the tapered extensions 11e and
29a by swage fitting between such extensions and
the slip collars.

30 The suction catheter is inserted into the
trachea through the patient coupling element by
manipulation of the catheter tube from outside the
envelope to move the valve mechanism toward the
patient coupling element which causes the envelope

to collapse axially. It is removed from the trachea to the position shown in FIGS. 1 and 2 by manipulation from outside the envelope to move the valve mechanism away from the patient coupling element to cause the envelope to be axially stretched.

Patient coupling element 29 has a first opening 30, through which ventilating air is introduced to the patient and through which the catheter tube is inserted into the trachea; second and third openings 31, one of which is for connection to a ventilation device and the other of which may be optionally closed by cap 32 or used in connection with ventilating the patient; and a fourth opening 33 opposite said first opening and through which said catheter is sealingly guided when inserted into and removed from the patient. The catheter extends through an internally tapered elastomeric, resilient wiper/sealer ring 27 (FIG. 2) of, but not limited to, silicone rubber (preferably 50 durometer) which is sealed and secured in place within the internally tapered extension 29a by means of a radial flange 27a and the inturned end wall of slip collar 26 as shown in FIG. 2. The annular sealing and wiping surface 27b of the wiper/sealer ring 27 is resiliently pressed against the periphery of the catheter to form a seal to prevent any air or contamination from entering the collapsible envelope while permitting the catheter to be freely slidable therein and permitting air to be exhausted from the envelope when it is collapsed during insertion of the catheter, i.e.,

it functions as a one way valve. This is achieved
by making the opening formed by annular wiping
surface 27a slightly smaller than the outside
diameter of the catheter and by virtue of the
5 internally tapered surface of extension 29a
resiliently urging surface 27a into sealing
contact with the catheter. Sealer/wiper ring 27
functions to wipe debris off the catheter when it
is withdrawn to thereby prevent it from entering
10 the collapsible envelope. It also prevents
ventilating air from entering the envelope,
thereby expanding the envelope.

The patient coupling element also optionally
15 has means for flowing irrigation fluid onto the
catheter through port 40 (FIGS. 2 and 6) when the
catheter is withdrawn and suction is applied to
wash off any debris that may have collected on the
catheter. The irrigation fluid and debris are
20 sucked through the catheter. Port 40 is
positioned such that irrigation fluid can be
directed at or near at least one of the catheter
openings 28 to clear away debris that may collect
in or near the openings and prevent blockage of
25 the catheter tube. A colored band 24a is provided
on the outside surface of catheter 24. Band 24a
is substantially aligned with the edge of the
collar 26 of the patient coupling element and is
visible through the transparent envelope when the
30 catheter is fully retracted and the openings 28 of
the catheter are located opposite the irrigation
port 40 as shown in FIG. 2. This insures
alignment of the irrigation port with the openings
when the catheter is irrigated. It is desirable

to position the irrigation port a sufficient distance from opening 30 of the coupling element to prevent any substantial amount of irrigation fluid from entering the patient through port 30. Irrigation tube 35, having an adapter 36 and cap 37, is sealingly attached adhesively or cohesively to the irrigation port as shown. Adapter 36 at the end of tube 35 is adapted to be attached to a source of irrigation fluid to irrigate the catheter and is capped by cap 37 when not being used for irrigation and as sold to maintain the system closed.

It should be appreciated at this point that the suction catheter device and ventilation/aspiration system of the present invention are completely sealed from the outside environment leaving no possibility for contaminants to be transmitted to the inside or outside of the catheter (and possibly to the patient) from the outside, and no possibility for contaminants to be transmitted from the patient to the outside (and possibly to the person handling the device). Since the catheter tube can be inserted and withdrawn without being exposed to an unsterile environment and without any place in which the patient's aspirated body fluids can collect with consequent growth of bacteria, it can be repeatedly used on a particular patient for a prolonged period of time without danger either to the patient or to the person handling the device, generally up to twenty-four hours being the recommended norm.

The control valve mechanism is designed to prevent accumulation of aspirated debris within it, i.e., it is self-cleaning. It is internally sealed from the atmosphere so that there is no
5 chance of contamination by or to the atmosphere. It consists of only three simple, easily moldable parts, namely, the one piece valve, the one piece valve body and the one piece sealing ring, and is easily and inexpensively manufactured and
10 assembled, as is the entire suction catheter device and ventilation/aspiration device. It gives the operator positive, one-hand control of the application of vacuum to the catheter tube, freeing the other hand for other manipulations,
15 such as the introduction of irrigation fluid or withdrawal of the catheter.

The entire assembly shown in FIG. 1 is packaged in a sterile package, e.g., envelope or
20 tray, which is opened by the customer. Accordingly, it is completely sterile.

A resilient valve is described in U. S. Patent
25 No. 3,595,445.

The above description is intended to illustrate the preferred embodiments of the present invention, but should not be construed to
30 limit the scope of the invention which is defined by the following claims.

CLAIMS

1. A control valve mechanism comprising

5 a valve body having a passageway therethrough
and a bore intersecting said passageway,

a resilient, elastomeric valve comprising

10 a valve stem portion slidably located
within said valve bore between a closed
position and an open position, said
valve stem portion having

15 means for sealing said passageway
when aligned therewith in said
closed position,

20 means for allowing flow through
said passageway when aligned
therewith in said open position,

25 means for maintaining seals between
said passageway and the ends of
said valve bore to isolate said
passageway from the atmosphere;

30 said valve having deformable resilient
elastomeric means to permit said valve
stem to be moved in said bore from one
of said closed and open positions to the
other by deformation of said deformable
means from a normal condition to a
deformed condition by the application of
force to said valve, the elasticity of

said deformable means acting as a spring to return the valve to its said one position when said force is removed.

5 2. The control valve mechanism in accordance with claim 1, including

10 means for sealingly mounting and securing said valve to said valve body with said valve stem located within said bore.

15 3. The control valve mechanism in accordance with claim 2, wherein said means for sealing said passageway is aligned with and seals said passageway when said deformable means is in said normal condition.

20 4. The control valve mechanism of claim 3, wherein said valve stem includes means for wiping debris from said valve bore.

5. The control valve mechanism of claim 4, said means for maintaining seals comprising said wiping means.

25 6. The control valve mechanism of claim 4, said seal-maintaining means and said wiping means comprising portions of said valve stem in sealing and slidable engagement with said bore.

30 7. The control valve mechanism of claim 2, wherein one end of said valve bore is closed to the atmosphere to form a space between said closed end and said valve stem, said means for maintaining seals isolating said space from said passageway to entrap air in said space and prevent debris from collecting in said space

whereby movement of said valve stem to said deformed position compresses said trapped air thereby biasing said valve toward the normal position.

5 8. The control valve mechanism of claim 2, wherein
said valve stem has an extension extending out of and
beyond an end of said bore and wherein said deformable
elastomeric means comprises a hollow cap shaped portion
of said valve extending from said valve stem extension
10 and located over and around said end of said bore.

9. The control valve mechanism of claim 8, wherein
said cap shaped portion has an end wall and a depending
side wall, and wherein said mounting and securing means
15 comprises means for sealingly mounting the end portion
of said side wall to said valve body, whereby the
interior of said hollow cap, said end of said bore and
said passageway are sealed from the atmosphere.

20 10. The control valve mechanism of claim 9, wherein
said seal maintaining means seals the interior of said
cap from said passageway, thereby preventing debris
from collecting in said cap interior and entrapping air
in said cap interior.

25 11. A control valve mechanism according to claim 10,
wherein the other end of said bore is closed to form a
space between said closed end and said valve stem with
air entrapped therein, whereupon movement of said valve
30 stem to depressed position by depression and
deformation of said cap portion compresses said
entrapped air, thereby assisting in biasing said valve
toward the normal position.

12. A control valve mechanism according to claim 3,
said elastomeric, deformable means being in a relaxed
condition when in said normal condition.

5 13. A control valve mechanism comprising

a valve body having a passageway therethrough
and a valve bore intersecting said passageway;

10 a resilient, elastomeric valve comprising a
valve stem located in said valve bore and
slideable therewithin between a normal
position and a depressed position, said valve
stem having

15 means for sealing said passageway when
aligned therewith,

20 means for allowing flow through said
passageway when aligned therewith, and

means for maintaining seals between said
passageway and the ends of said valve
bore,

25 means for depressing said valve stem, and

30 means for yieldably resisting depression of
said valve stem to bias said valve stem toward
the normal position from the depressed
position, said means being integral with said
valve stem; and

means for sealingly mounting and securing said valve stem to said valve body within said valve bore.

5 14. A control valve mechanism having a normal position and a depressed position, one of which is a closed position and the other an open position, comprising

10 a valve body having a passageway therethrough for the passage of gases or fluids when said control valve mechanism is in the open position and a valve bore intersecting said passageway and extending above and below said passageway, said valve bore being closed to the atmosphere at the lower end and open at the other
15 end;

a valve having a valve stem located in said valve bore, said valve stem having

20 a first sealing portion at or near one end sealingly slideable within said valve bore and adapted to maintain a seal between said passageway and the closed end of said valve bore, trapping
25 air therebetween;

a second sealing portion at or near the other end, sealingly slideable within said valve bore and adapted to maintain
30 a seal between said passageway and the open end of said valve bore;

an open portion between said first and second sealing portions adapted to permit passage of gases or fluids through said passageway when aligned therewith;

one of said first or second sealing
portions being adapted to seal said
passageway when aligned therewith;

5

said valve having means for depressing said valve stem
within said valve bore,

10 wherein application of a depressive force to said
depressing means causes said valve stem to move toward
the closed end of said valve bore thereby compressing
air trapped therein, and whereupon removal of such
depressive force automatically causes said valve to
return to the normal position as a result of the force.
15 applied against said valve stem by said trapped
compressed air.

15. A control valve mechanism having a normal position
and a depressed position, one of which is a closed
20 position and the other an open position, comprising

25 a valve body having a passageway therethrough
for the passage of gases or fluids when said
control valve mechanism is in the open
position, and a valve bore intersecting said
passageway and extending above and below said
passageway,

30 a valve having a valve stem located in said
valve bore, said valve stem having

a first sealing portion sealingly
slideable within said valve bore and
adapted to maintain a seal between said

passageway and one end of said valve bore;

5 a second sealing portion sealingly slideable within said valve bore and adapted to maintain a seal between said passageway and the other end of said valve bore; and

10 an open portion between said first and second sealing portions adapted to permit passage of gases or fluids through said passageway when aligned therewith in said open position;

15 one of said first or second sealing portions being adapted to close said passageway when aligned therewith in said closed position;

20 said valve also comprising means for transmitting a depressing force on said valve to thereby depress said valve stem within said valve bore and move said valve stem from its normal position to its depressed position, and

25 elastomeric and deformable means biasing said valve stem against depression thereof, whereby when said depressive force is released the valve stem is automatically returned to its normal position.

16. The control valve mechanism in accordance with claim 15, wherein said valve is fabricated of a resilient elastomeric material.

5 17. The control valve mechanism in accordance with claim 16, wherein said bore has a closed end and an open end and wherein said means for transmitting a depressive force comprises an extension of said valve stem extending above the open end of said valve bore
10 which is adapted to be manually depressed.

18. The control valve mechanism in accordance with claim 15, wherein when said valve stem is in its normal position the valve is in a relaxed condition and the
15 first sealing portion is aligned with and seals said passageway.

19. The control valve mechanism in accordance with claim 15, wherein said first sealing portion is adapted
20 to be aligned with and close said passageway when said control valve is in its normal position.

20. The control valve mechanism in accordance with claim 19, wherein said means for transmitting a
25 depressing force comprises an extension of said valve stem extending beyond an open end of said bore and said biasing means comprises a hollow cap portion joined to said extension of said valve stem and springingly
engaging said valve body so as to bias said valve stem
30 against depression thereof and toward the relaxed position.

21. The control valve mechanism in accordance with claim 20, wherein said cap portion is sealingly mounted to said valve body over the open end of said valve bore so as to position said valve stem within said valve bore and to form an additional seal between said passageway and the atmosphere and to seal the interior of said cap portion from the atmosphere.

22. The control valve mechanism in accordance with claim 21, the interior of said cap portion forming with said valve body a sealed chamber in which air is entrapped, said air being compressed by depression of said valve stem to thereby additionally bias the valve stem toward normal position.

23. The control valve mechanism in accordance with claim 22, said cap shaped portion being in the shape of an inverted cap having an end wall and a side wall, said valve stem extension being joined to said end wall, said side wall being sealably secured to said valve body.

24. The control valve mechanism in accordance with claim 23, said depending wall having a radial flange located in a recess in said valve body, a sealing ring secured to said valve body to sealably compress said flange against a wall of said recess.

25. The control valve mechanism in accordance with claim 20, said valve body having a protective wall extending at least partially around said cap portion to protect against accidental depression of said valve stem, said protective wall having a finger receiving slot therein to permit a force to be applied by the thumb or finger to depress said valve stem.

26. The control valve mechanism in accordance with Claim 15, wherein said first and second sealing portions are adapted to wipe debris from said valve bore into said passageway during movement of said valve stem.

5 27. The control valve mechanism in accordance with Claim 15, wherein said bore has a closed end and an open end, said second sealing portion maintaining a seal between said open end and said passageway and said first sealing portion maintaining a seal between said passageway and
10 said closed end.

28. A control valve mechanism substantially as hereinbefore described with reference to the accompanying drawings.

29. A suction catheter device for the aspiration of
15 fluids from a body cavity comprising a catheter having one end adapted for insertion into said body cavity, another end for communication with a vacuum source, and a control valve mechanism according to any one of the preceding claims between said one and other end of the catheter for
20 controlling aspiration of fluids along said catheter.

30. A suction catheter device for the aspiration of fluids from a body cavity comprising

a catheter having one end adapted for insertion
into said body cavity and another end for
communication with a vacuum source;

5 a control valve mechanism having a normally
closed position and a depressed, open position,
said mechanism being attached to said other end
of said catheter and adapted, upon connection
to a vacuum source, to communicate said vacuum
source to said catheter when in the depressed,
10 open position, said control valve mechanism
comprising

a valve body having a passageway therethrough
for communication of said vacuum source to said
catheter tube, and a valve bore intersecting
15 said

passageway and extending above and below
said passageway, said valve bore being
closed at the lower end and open at the
upper end;

5 a valve of resilient elastomeric
material, said valve comprising a valve
stem having

10 a first sealing portion sealingly
slideable within said valve bore
and adapted to maintain a seal
between said passageway and one end
of said valve bore and to close
15 said passageway when said control
valve mechanism is in the closed
position;

20 a second sealing portion, sealingly
slideable within said valve bore
and adapted to maintain a seal
between said passageway and the
other end of said valve bore, and

25 an open portion between said first
and second sealing portions adapted
to permit communication of said
vacuum source through said
passageway when aligned therewith;

30 said valve having means for depressing
said valve stem within said valve bore
and for elastomerically resisting said
depression to thereby bias the stem

against depression and toward a closed position;

5 wherein application of a depressive force to said
depressing means causes said valve stem to move to said
depressed open position, thereby aligning said open
portion of said valve stem with said passageway and
wherein upon removal of such depressive force, said
biasing means automatically causes said valve stem to
10 return to the closed position.

31. The device in accordance with claim³⁰, wherein
said depressing means comprises an extension of said
valve stem extending above the open upper end of said
15 valve bore and being adapted to be depressed to thereby
depress said valve stem.

32. The device in accordance with claim³¹, wherein
said biasing means comprises an inverted cap shaped
20 portion of said valve integral with said valve stem,
said cap shaped portion being adapted to springingly
engage said valve body so as to bias said valve stem
toward the normal closed position.

25 33. The device in accordance with claim³², wherein
said cap shaped portion is sealingly mounted to said
valve body over and around the open upper end of said
valve bore so as to secure said valve stem within said
valve bore and to form an additional seal between said
30 passageway and the atmosphere.

34. The device in accordance with claim³³, wherein
said first and second sealing portions are adapted to
wipe debris from said valve bore into said passageway
during movement of said valve stem.

35 . The device in accordance with claim 30 ,
5 additionally comprising a patient coupling element
through which said catheter is sealingly guided into
said body cavity and a sterility preserving collapsible
envelope surrounding said catheter and attached to said
patient coupling element and to said control valve
mechanism such that said catheter is sealed from the
outside environment, thereby providing a closed
10 ventillation/aspiration system.

36 . The device in accordance with claim 35 , including
15 sealing and wiping means removably mounted in said
patient coupling element around and in sealing but
slidable engagement with said catheter tube to seal the
space between said catheter and said envelope from the
environment and to wipe debris from said catheter.

37 . The device in accordance with claim 36 , adapted to
20 aspirate fluid from the trachea, lungs or bronchi of a
patient during ventilation, wherein said patient
coupling element is a tracheal or endotracheal
coupling element having means for introducing and
exhausting ventilating air and means for flowing
25 irrigation fluid onto said catheter tube to clean said
tube and prevent it from becoming clogged.

38 . The device in accordance with claims, 1, 15 and
30 , said control valve mechanism being designed to
permit the opening and closing thereof with the thumb
or finger of one hand while holding such mechanism in
said one hand, thereby leaving the other hand free for
other manipulations while the valve mechanism is being
operated.

39. A suction catheter device substantially as hereinbefore described with reference to the accompanying drawings.