US 20050187524A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0187524 A1

Willis et al. (43) Pub. Date: Aug. 25, 2005

(54) SEALING VALVE ASSEMBLY FOR MEDICAL PRODUCTS

(76) Inventors: **Allan F. Willis**, Evesham, NJ (US); **Alan Conlin**, Pocatello, ID (US); **Donald J. McMichael**, South Jordan, UT (US); **Teresa K. Conlin, legal representative**, Pocatello, ID (US)

Correspondence Address:
DORITY & MANNING, P.A.
POST OFFICE BOX 1449
GREENVILLE, SC 29602-1449 (US)

(21) Appl. No.: **11/035,757**

(22) Filed: **Jan. 14, 2005**

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/741,730, filed on Dec. 19, 2000, now Pat. No. 6,908,449.

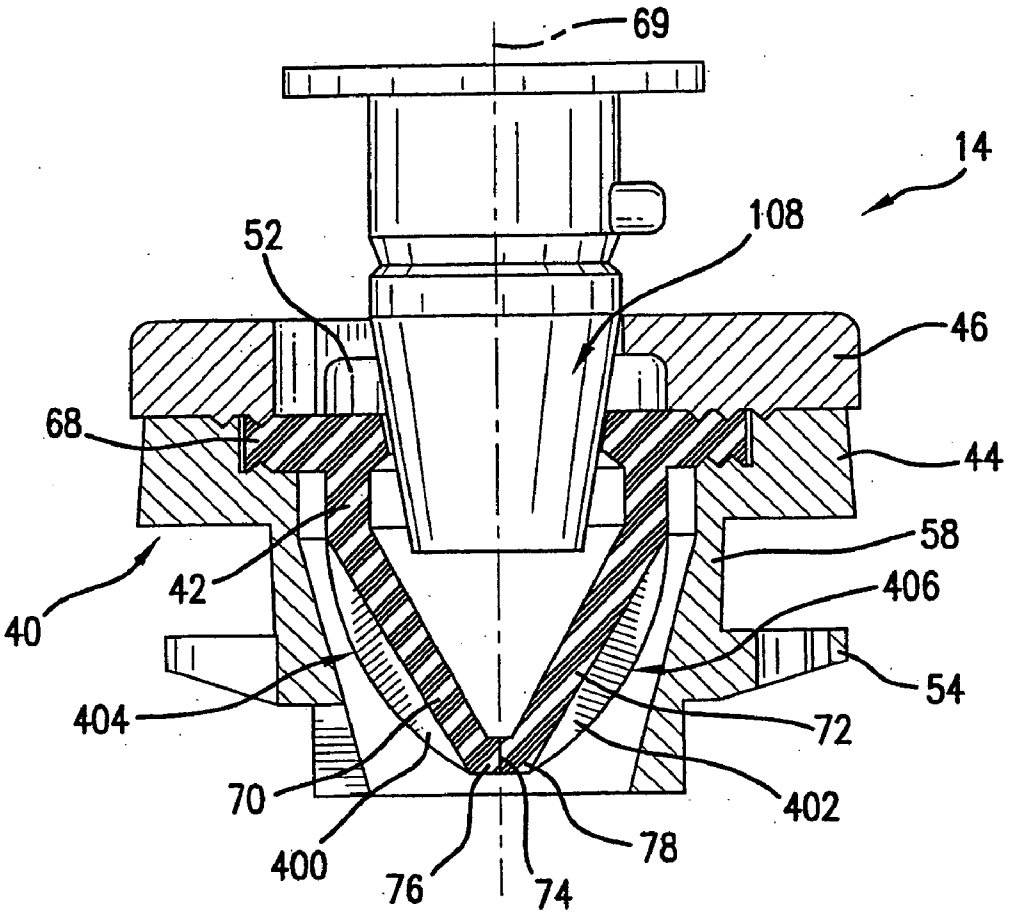
Publication Classification

(51) **Int. Cl.**[7] **A61M 5/14**

(52) **U.S. Cl.** **604/256**

(57) **ABSTRACT**

A sealing valve assembly is provided for medical products. The valve assembly includes a valve member mountable within a passageway of a medical product body element, the valve member defining a peripheral portion spaced from a central axis and including two walls extending from the peripheral portion toward the central axis. The walls include ends that contact each other to preclude flow through the passageway. The valve member may be formed of a material having a durometer of less than about 20 Shore A. The valve member may also have a higher durometer material with other wall configurations, or may have a wall member having a varying durometer.



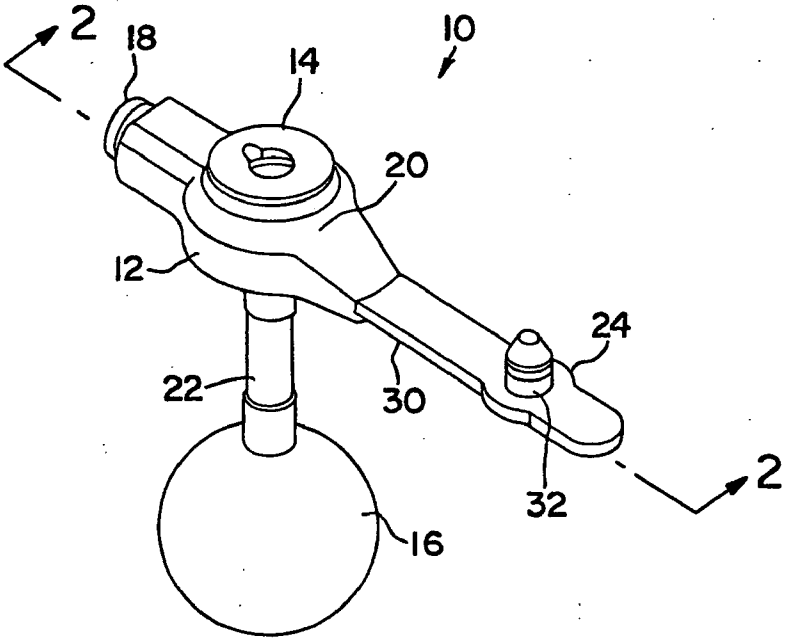

2
18
14
10
20
12
24
22
30
32
2
16

FIG. 1

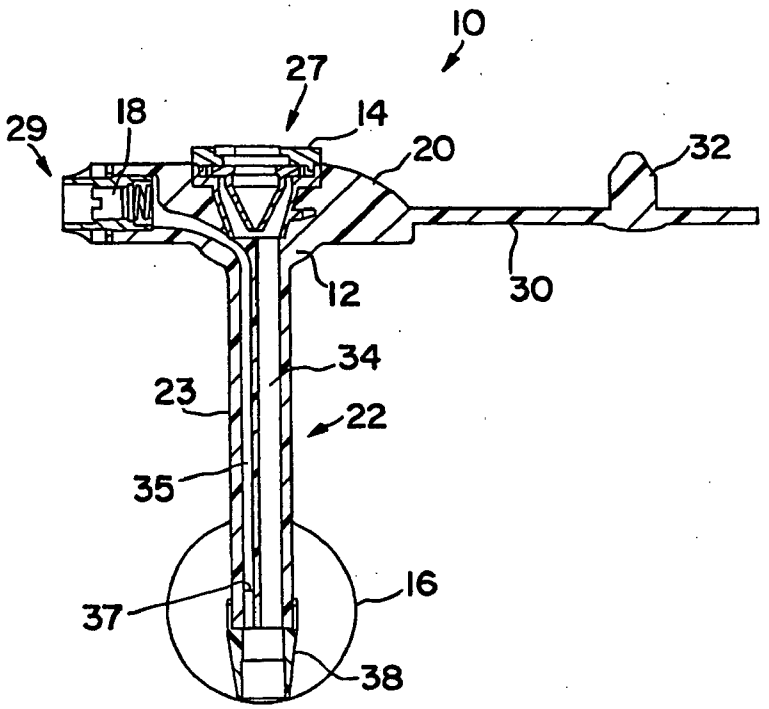

10
27
29
18
14
20
32
IN
12
30
34
23
22
35
16
37
38

FIG. 2

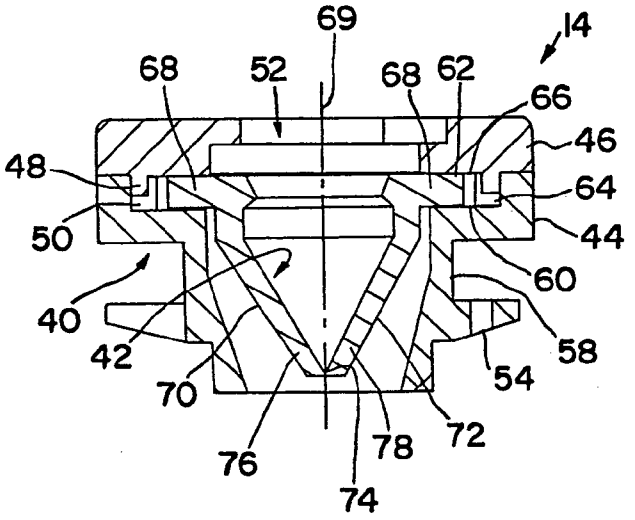


FIG. 3

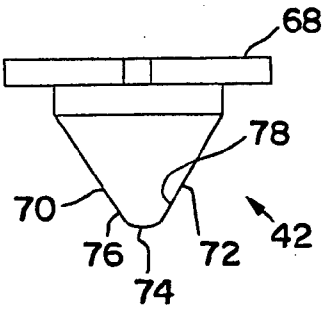


FIG. 4

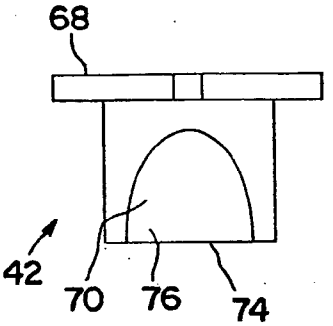


FIG. 5

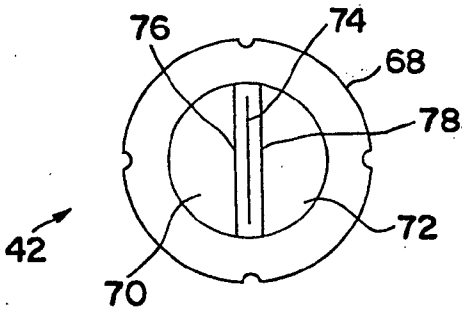


FIG. 6

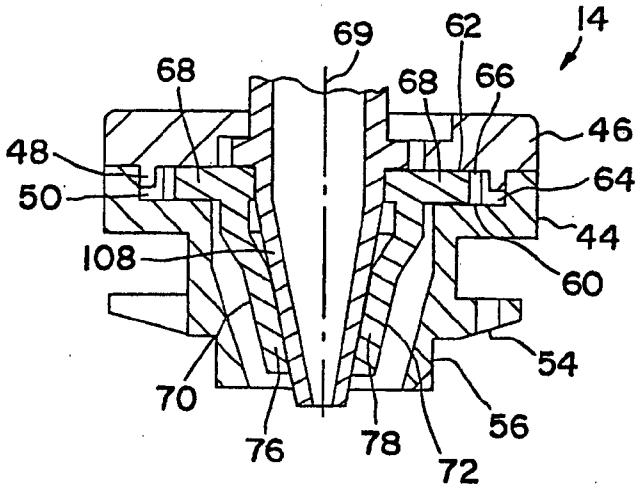


FIG. 7

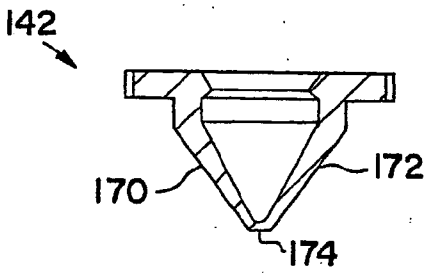


FIG. 8

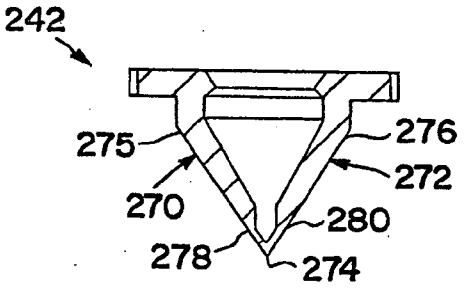


FIG. 9

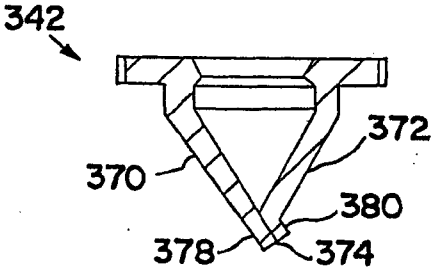


FIG. 10

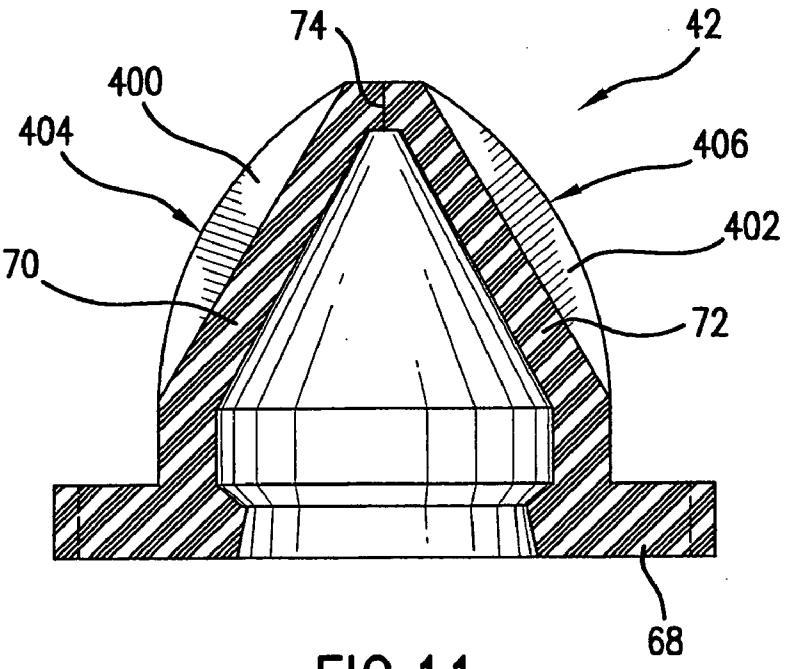


FIG.11

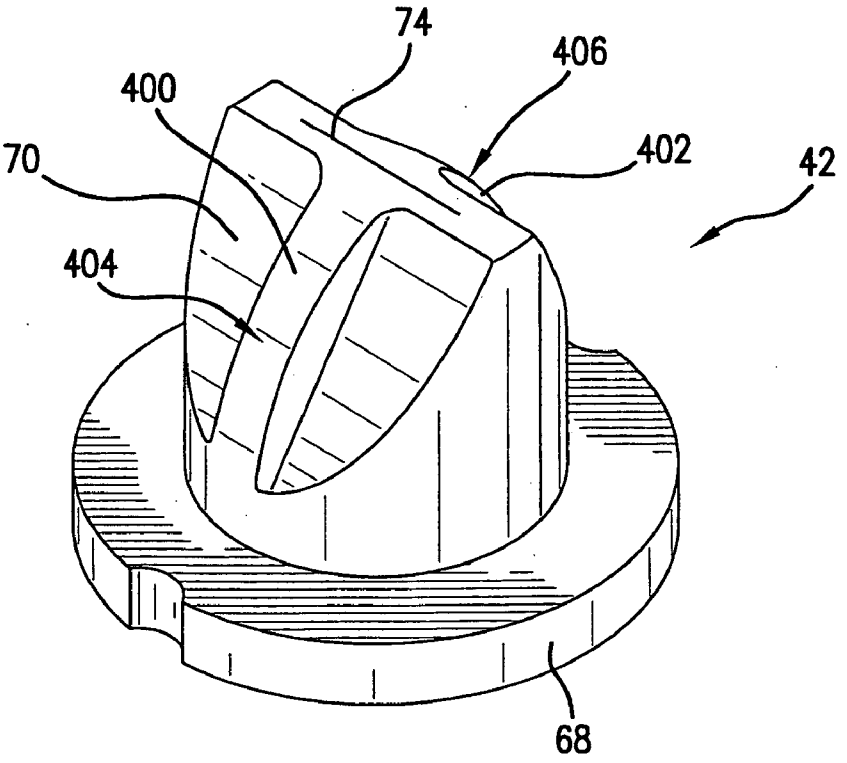


FIG.12

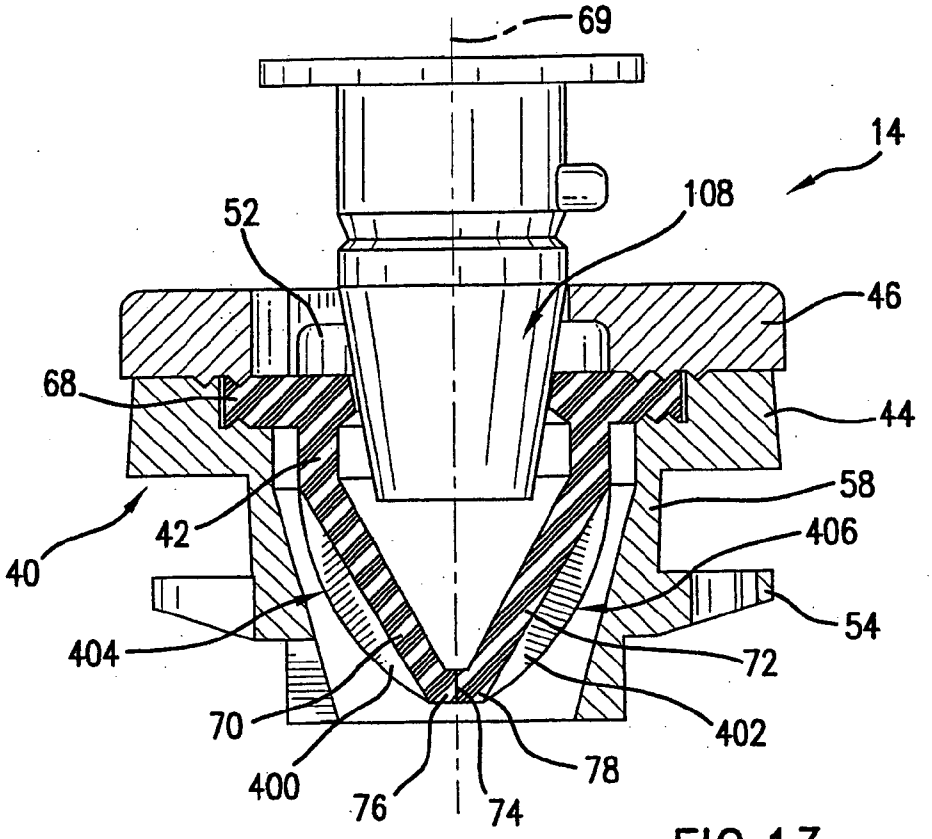

69
14
108
52
46
68
44
58
42
406
40
54
404
72
70
402
400
78
76
74

FIG.13

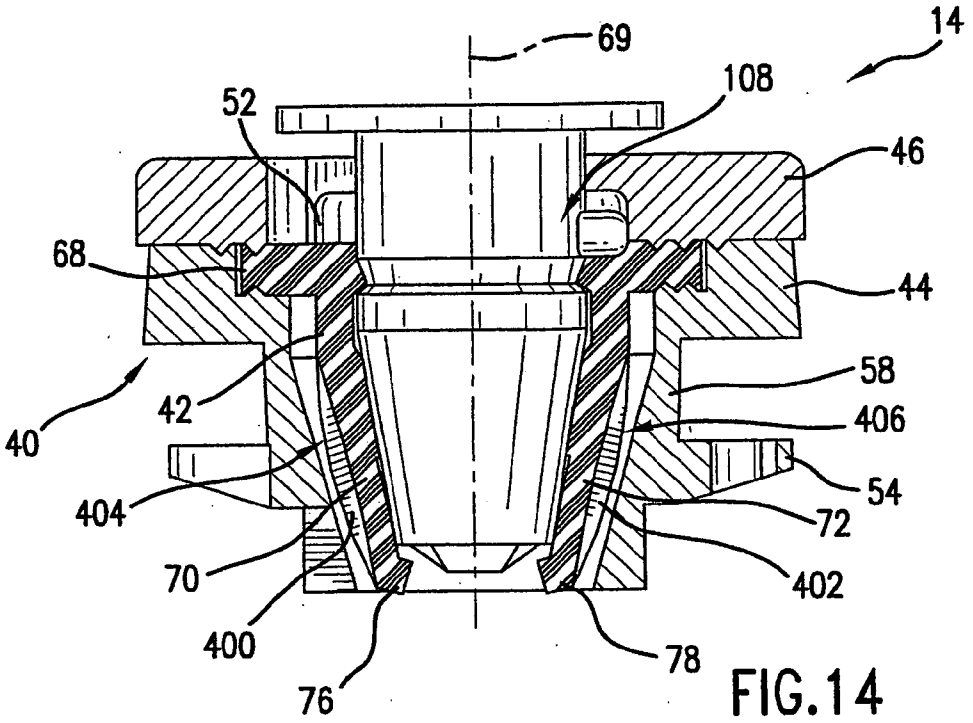

69
14
108
52
46
68
44
58
42
406
40
54
404
72
70
402
400
78
76

FIG.14

SEALING VALVE ASSEMBLY FOR MEDICAL PRODUCTS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part (CIP) of U.S. patent application Ser. No. 09/741,730, filed on Dec. 19, 2000, entitled "Sealing Valve Assembly For Medical Products" whose inventors are Allan F. Willis and Alan Conlin. Application Ser. No. 09/741,730 is incorporated by reference herein in its entirety for all purposes.

BACKGROUND OF THE INVENTION

[0002] Various types of valves incorporating sealing devices are known and widely used in the medical field. For example, mechanical sealing valves are required for various types of catheters, lavage devices, and endoscopy systems developed for a wide range of medical purposes. The valve sealing mechanisms typically preclude the flow of substances (gaseous or fluid) through the medical device in one direction, for example from the patient to the outside environment, while permitting the introduction or flow of desired substances (food, medication, etc.) in the other direction, for example into the patient through the medical device. Enteral feeding devices utilizing a gastrostomy catheter ("feeding tube") are examples of conventional medical devices utilizing a sealing valve to prevent gastric fluids, gases, or particles from unintentionally exiting the patient's body via the catheter. U.S. Pat. Nos. 5,997,503 and 5,997,546, both owned by Applicants' Assignee and incorporated by reference herein, disclose balloon catheters suitable for use as skin-level gastrostomy catheters for enteral feeding. Various other devices and catheters have also been proposed for gastrostomy feeding and are known to those skilled in the art.

[0003] Conventional sealing valves include duckbill valves, flap valves, slit seal valves, etc. Silicone rubber duckbill seals having durometer ratings of about 50 Shore and a wall thickness of about 0.040 inches have been employed in sealing gastrostomy catheters. Such sealing valves are typically kept closed via back pressure present on one side of the valve unless and until the seal is opened from the other side of the valve by insertion of a feeding tube or by a pressure differential across the seal.

[0004] Over time, conventional sealing valves may degrade or lose some of their flexibility (i.e., their ability to return to an initial sealing position after deflection) due to repeated or extended periods of opening of the valve. Also, in certain bodily environments, such as the acidic environment of the gastro-intestinal tract, exposure to bodily fluids or stomach contents may have a corrosive or other negative effect on the sealing valve over time.

[0005] Thus, there is a need for an improved medical sealing valve for use in various medical devices, particularly gastrostomy catheter devices.

SUMMARY OF THE INVENTION

[0006] Objects and advantages of the invention will be set forth in part in the following description or may be apparent from the description or may be learned through practice of the invention.

[0007] It should be noted that any given range presented herein is intended to include any and all lesser included ranges. For example, a range of from 45-90 would also include 50-90, 45-80, 46-89, and the like.

[0008] According to the invention, an improved sealing valve assembly is provided for use in a wide array of medical products, including catheters, lavage devices, endoscopy systems, etc. The valve assembly according to the invention is not limited in its particular use and may be used in any medical product wherein it is necessary to permit fluid flow through the product in one direction while preventing backflow of fluids through the product in the opposite direction. For example, the valve assembly is particularly useful in a gastrostomy catheter. Accordingly, it should be appreciated that the present invention also includes medical products or devices incorporating the inventive valve assembly.

[0009] The valve assembly includes a valve housing defining a passageway therethrough. A valve member is seated in the valve housing within the passageway. The valve member includes a peripheral portion spaced from the central axis of the valve assembly and two walls extending from the peripheral portion towards the central axis. The walls include ends that contact and seal against each other to preclude flow through the passageway. The valve member may be formed of a material having a durometer of less than about 20 Shore.

[0010] In another embodiment, the valve member walls may define a cross-section that tapers in thickness from about 0.005 to about 0.010 inches at their respective sealing end to about 0.040 inches at a location spaced from the sealing end. The walls may taper continuously or discontinuously.

[0011] In accordance with another aspect of the invention, at least one of the valve member walls may define an overlapping portion extending at an angle with respect to a plane of the remaining portion of the wall. This overlapping portion overlaps and seals against a portion of the other wall. The overlapping portion may be parallel to the other wall.

[0012] In accordance with yet another aspect of the invention, the valve member walls may include a first portion including a material having a durometer of about 50 Shore A and a second portion having a durometer of less than about 20 Shore A. The second portion is disposed at the sealing end of the wall. The first portion is disposed spaced from the sealing end.

[0013] In accordance with another exemplary embodiment a medical product is provided that includes a valve housing that defines an opening with a central axis. The opening extends through the valve housing so that the opening forms part of a fluid path through the medical product. A valve member is disposed within the opening and has a single seal interface defined by at least two opposing flexible walls. The valve member includes a peripheral portion that has opposing flexible walls that extend from the peripheral portion towards the central axis. The opposing flexible walls include ends that contact each other along the single seal interface. A stiffening member is also included and is located on one of the opposing flexible walls. The stiffening member remains free from contact with the valve housing when the valve member is in the closed position and also remains free from contact with the valve housing when the valve member is in the open position.

[0014] The invention will be described in greater detail below with reference to the figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1** is a perspective view of a medical product, in particular a gastrostomy catheter, according to the present invention;

[0016] **FIG. 2** is a cross-sectional view of the gastrostomy catheter of **FIG. 1** taken along line A-A of **FIG. 1** particularly illustrating a valve assembly disposed within a catheter body element;

[0017] **FIG. 3** is an enlarged cross-sectional view of the valve assembly of **FIG. 2** taken along line A-A of **FIG. 1**;

[0018] **FIG. 4** is a side view of a first embodiment of the valve member of the valve assembly from the perspective taken in **FIG. 3**;

[0019] **FIG. 5** is a side view of the valve member of **FIG. 4** rotated 90 degrees;

[0020] **FIG. 6** is a top view of the valve member of **FIG. 4**;

[0021] **FIG. 7** is a cross-sectional view of the assembly of **FIG. 3** with the end of a feeding tube inserted therein;

[0022] **FIG. 8** is a cross-sectional view of an alternate embodiment of a valve member;

[0023] **FIG. 9** is a cross-sectional view of a second alternate embodiment of a valve member;

[0024] **FIG. 10** is a cross-sectional view of a third alternate embodiment of a valve member;

[0025] **FIG. 11** is a cross-sectional view of an exemplary embodiment of a valve member that includes a pair of stiffening members;

[0026] **FIG. 12** is a perspective view of the valve member of **FIG. 11**;

[0027] **FIG. 13** is a cross-sectional view of a valve housing assembly configured with a valve member in the closed position that includes a stiffening member in accordance with one exemplary embodiment; and

[0028] **FIG. 14** is a cross-sectional view of the valve housing assembly and valve member of **FIG. 13** in which the valve member is in the open position.

DETAILED DESCRIPTION

[0029] Embodiments of the invention will now be described in detail with reference to the examples shown in the figures. Each example is provided by way of explaining the invention, and not as a limitation of the invention. Various modifications and variations can be made in the invention without departing from the scope and spirit of the invention. For example, features illustrated or described with respect to one embodiment may be used in another embodiment to yield still a further embodiment.

[0030] In the following description, the improved sealing device is described with reference to a gastrostomy catheter for purposes of explaining and illustrating the sealing valve assembly. This is not meant as a limitation of the invention. It should be appreciated that the improved sealing device according to the present invention has wide application in the medical field and can be used in any medical device that incorporates a seal to prevent the flow of substances in one direction while permitting the flow of substances in the opposite direction.

[0031] A gastrostomy catheter **10** is shown in **FIGS. 1 and 2** as an example of a medical product incorporating the improved valve sealing assembly according to the present invention. The use and operation of such gastrostomy catheters is known to those skilled in the art and need not be described in detail herein. Reference is made to U.S. Pat. Nos. 5,997,546 and 5,997,503 incorporated herein by reference for a detailed explanation of gastrostomy catheters.

[0032] As used herein, the term "distal" refers to the direction of the patient and the term "proximal" refers to the direction of the clinician.

[0033] Referring briefly to **FIGS. 1 and 2**, the gastrostomy device **10** includes a catheter body element **12** having a head **20**, an elastomeric sleeve forming a balloon **16**, and a catheter segment **22**. The catheter segment **22** includes a shaft **23** having a dispensing tip **38** attached to its distal end. A first central opening or port **27** in the head **20** incorporates a valve housing assembly **14** that enables the injection of nutrients, enteral feeding solution, medications, etc., into the patient through the head **20** and into a first lumen **34** of the catheter segment **22**. The valve housing assembly **14** includes the improved sealing valve according to the invention, as described in greater detail below. A plug **32** may be provided at the end of a lanyard **30** attached to the catheter head **20**. The plug **32** can be inserted into the first port **27** when the port is not being used to administer fluids into the patient.

[0034] A second port **29** in the head **20** serves as an opening through which fluid such as air or saline solution may be injected into or removed from the balloon **16** through a second lumen **35** having a distal opening **37**. An inflation valve assembly **18** is disposed in the second port **29** for permitting the clinician to control inflation and deflation of the balloon **16**, as is understood by those skilled in the art.

[0035] The valve housing assembly **14** is shown in greater detail in **FIG. 3**. The valve housing assembly **14** includes a valve housing **40** and the improved sealing valve member **42**. The valve housing **40** has an annular member **44** and a relatively flat cap member **46** connected to the annular member **44**, for example by a press-fit or an adhesive. The cap member **46** may have a ridge **48** that fits within a groove **50** in the annular member **44** for securing the two parts together. The valve housing **40** includes a flange **54** that extends into a corresponding groove in the catheter body element **12** to seat and secure the valve housing therein. The flange **54** extends radially from a lower tubular portion **58** of the valve housing **40**. The tubular portion **58** may have inner walls that angle towards a centerline axis **69** of the valve housing assembly **14**. The walls of the tubular portion **58** parallel to the plane of **FIG. 3** may be parallel to the axis **69**.

[0036] A passage **52** is defined through both portions of the valve housing assembly **14**. The passage **52** is in fluid communication with the feeding lumen **34** through the valve member **42** for introducing nutrients, feeding solutions, medication, etc., into the patient's stomach, intestine, or other body cavity. The valve member **42** is disposed within the passage **52** for selectively blocking the fluid path through feeding lumen **34**.

[0037] The valve member **42** incorporates novel features of the present invention and various embodiments of the valve member **42** are partially shown in **FIGS. 3-10**. Referring to **FIG. 3**, the valve member **42** includes a proximal flange portion **68** disposed between facing surfaces **64**, **66** of the annular member **44** and the cap member **46**. Small circular ridges **60**,**62** on the facing surfaces **64**,**66** engage the flange portion **68** and help to seat and hold the valve member **42** in place. The valve member **42** includes two walls **70**, **72** on opposite sides of the central axis **69** that extend from the peripheral portion **68** and are angled towards the central axis **69**. The walls **70**,**72** meet at a single seal interface **74** defined by ends **76**,**78** of the walls. Parts **68**, **70**, and **72** form what is known in the art as a duckbill valve. As explained in greater detail below, to achieve satisfactory sealing, the thickness and profile of the walls **70**,**72** may be designed in various ways according to the present invention depending on the durometer of the material used for the valve member **42**.

[0038] The seal interface **74** is biased to a closed position and maintained in the closed position by body cavity pressure unless forced open by an object inserted into the valve member **42** through the cap member **46** or by a significant pressure differential between the patient cavity and the external environment. An object useful to open the valve member **42** could be a feeding tube, a feeding tube adapter, or a pressure relief tube. As an example, **FIG. 7** shows the valve housing assembly **14** of **FIG. 3** with the end of a feeding tube **108** inserted therein. Note that the tube end **108** pushes open the walls **70**,**72** of valve member to allow communication with the patient's body cavity through the valve housing **14** and feeding lumen **34**.

[0039] The various components of medical device **10** are preferably formed from bio-compatible materials such as medical grade silicone. More particularly, the valve member **42** may be made of a liquid injection molding silicone elastomer such as MED-4810 (10 Shore Durometer) or MED-4820 (20 Shore Durometer), available from NuSil Technology of Carpintera, Calif. The valve member is molded, and the sealing interface **74** is created by slitting or cutting apart the respective walls after molding.

[0040] As mentioned, the thickness and profile of the walls **70**, **72** will depend on the durometer of the material used to form the valve member **42**. For example, for a wall thickness of about 0.040 inches, the durometer of the valve member may be about 20 Shore A or less, and may be in the range of from about 8 Shore A to about 15 Shore A, and more particularly about 10 Shore A. Applicants have discovered that use of a lower durometer material than had been used previously in the art for the valve member unexpectedly provides an improved seal and greater seal flexibility without sacrificing the structural integrity of the valve member.

[0041] However, if the durometer of the valve member **42** is higher, such as up to about 50 Shore A as has been used previously, the wall cross sections of the valve member can be altered to provide improved seal flexibility. For example, alternate embodiments of the valve member **42** are shown in **FIGS. 8-10**.

[0042] The valve members in **FIGS. 8 and 9** have walls with varying cross-section dimensions. The valve member **142** in **FIG. 8** includes two walls **170**,**172** that are continuously tapered, narrowing toward the sealing interface **174**. The walls may taper up to about 15% of their upper wall thickness. For example, the walls **170**, **172** may taper from about 0.040 inches to about 0.005 to about 0.010 inches at the seal interface. The valve member **242** in **FIG. 9** includes two walls **270**, **272** having a constant cross-sectional thickness along their upper portions **274**, **276** of about 0.040 inches and reduced thickness edge portions **278**, **280** having a thickness of about 0.005 to about 0.010 inches. The valve member **342** in **FIG. 10** has walls **370**, **372** which may have a thickness throughout of about 0.040 inches. The Wall **372** has an edge portion angled with respect to the remaining portion of the wall **372**. The angled portion **380** is parallel to and overlaps a portion **378** of the wall **370**. The overlapping edge portions **378**, **380** may have a thickness and length of about 0.040 inches.

[0043] Each of the valve members of **FIGS. 8-10** may be molded of relatively high durometer materials, with the modified wall structure providing improved sealing and wall flexibility.

[0044] As another option, a valve member **42** having a shape as shown in **FIGS. 3-7** could be molded having a varying durometer that decreases in the direction of the seal interface. In such a valve member, the peripheral portion **68** and the upper portion of a wall or the walls **70**,**72** may be made from a material of relatively higher durometer (for example in the range of about 50 Shore A), and the remaining portion may be made of a lower or a gradiently decreasing durometer material (for example, decreasing to the range of about 20 Shore A or less, more particularly about 8 Shore A to about 15 Shore A, and even more particularly to about 10 Shore A). The softer tip of the walls **70**,**72** would thus provide improved sealing while the harder upper portion would maintain the shape of the valve member.

[0045] **FIGS. 11 and 12** show another exemplary embodiment of the valve member **42**. Here, the valve member **42** is provided with a stiffening member **400** on the wall **70**. Another stiffening member **402** is located on wall **72**. Although shown as incorporating a pair of stiffening members **400** and **402**, it is to be understood that any number of stiffening members may be employed in accordance with other exemplary embodiments. For instance, only a single stiffening member **400** may be employed in certain exemplary embodiments. Alternatively, the valve member **42** may be provided with three stiffening members on wall **70** and two stiffening members on wall two in accordance with other exemplary embodiments. The stiffening members **400** and **402** may be integrally formed with the valve member **42** or may be separate components that are attached thereon in accordance with various exemplary embodiments.

[0046] The stiffening members **400** and **402** act to strengthen the walls **70** and **72**. Additional strength may be desired, for instance, in preventing unwanted opening of the valve member **42** due to an increased pressure inside of the body cavity into which the gastrostomy device **10** is employed. Additionally or alternatively, added strength to the walls **70** and **72** of the valve member **42** may be desired in order to ensure that the valve member **42** opens upon application of a desired force when inserting a feeding tube, feeding tube adapter, pressure relief tube, or the like. By acting as a strengthening component, the stiffening members **400** and **402** may act to urge the walls **70** and **72** towards one

another so as to create a tighter seal interface **74**. Alternatively, the stiffening members **400** and **402** may be configured so that their presence does not act to urge the legs **70** and **72** towards one another so as to increase the strength of the seal at the seal interface **74**.

[**0047**] The stiffening members **400** and **402** may also be employed in order to help the walls **70** and **72** retain their original shape when the feeding tube, feeding tube adapter, pressure relief tube, or the like is removed. It is sometimes the case that valve members will become deformed if they are placed into a certain position for an extended amount of time. For example, if a feeding tube adapter were inserted into the valve member **42** so as to keep the valve member **42** in an open position for an extended period of time, the walls **70** and **72** may become plasticly deformed such that removal of the feeding tube adapter may cause the walls **70** and **72** to only partially retake their closed position shape. In this instance, the walls **70** and **72** may not completely return to their original shape so that seal interface **74** is not created and hence the valve member **42** will not be fully closed. The stiffening members **400** and **402** may therefore act as "memory" components such that they urge the walls **70** and **72** into their original, closed shape after the valve member **42** is opened.

[**0048**] **FIG. 13** shows the valve housing **14** configured with the valve member **42** along with a feeding tube **108** that is positioned therein but does not contact the valve member **42** so as to open the valve member **42**. As such, the valve member **42** is in the closed position so that the seal interface **74** is formed. The valve member **42** includes a pair of stiffening members **400** and **402** on the walls **70** and **72**. The stiffening members **400** and **402** do not contact the valve housing **40**. **FIG. 14** shows the valve housing assembly **14** and valve member **42** of **FIG. 13** with the feeding tube **108** inserted therein so as to open the valve member **42**. In this instance, the feeding tube **108** pushes the walls **70** and **72** towards the valve housing assembly **14**. The stiffening members **400** and **402** remain free from contact with the valve housing assembly **14** in the open position. As can be seen, a space remains between the stiffening members **400** and **402** and the inner walls of the tubular portion **58**. As such, the stiffening members **400** and **402** remain free from contact with the valve housing assembly **14** during times in which the valve member **42** is both in the open and closed positions.

[**0049**] The stiffening members **400** and **402** may be of any shape or any thickness in accordance with various exemplary embodiments. For example, in accordance with one exemplary embodiment the stiffening members **400** and **402** have a thickness of about 0.05 inches. The stiffening member **400** may have an arcuate shaped outer surface **404**. The arcuate shaped outer surface **404** may extend along the entire angled length of leg **70**. The other stiffening member **402** may also be provided with an arcuate shaped outer surface **406** that likewise extends along the entire outer length of the angled portion of leg **72**. It is to be understood, however, that in accordance with other exemplary embodiments one or more of the surfaces of the stiffening members **400** and **402** need not be completely or partially arcuate shaped.

[**0050**] In accordance with one exemplary embodiment the valve member **42** may be formed at least in part by a material that has a durometer of less than 10 Shore A. Additionally or alternatively, at least one of the walls **70** or **72** may define a first portion that includes a material with a durometer of about 50 Shore A and a second portion with a durometer of less than about 20 Shore A. Here, the second portion is disposed at the respective end of at least one of the walls **70** or **72**, and the first portion is disposed spaced from the respective end. It is to be understood that various exemplary embodiments exist in which one or more of the stiffening members **400** and **402** may be provided on any of the valve members as previously discussed in accordance with prior exemplary embodiments. The stiffening members **400** and **402** so provided may be configured so that they remain free from contact with the valve housing assembly **14** at times in which the valve member **42** is in both the open and closed positions.

[**0051**] Thus, applicants have disclosed above numerous designs and/or material selections that provide for improved sealing across the seal interface of a valve member as well as improved flexibility of the valve member. Such improved sealing flexibility may provide a longer lifespan to medical devices such as gastrostomy catheters and to the valve members and related valve assemblies used therein. Such improved sealing may also provide a more reliable product in terms of reducing or eliminating undesired leakage.

[**0052**] It should be appreciated by those skilled in the art that various modifications and variations can be made in the present invention without departing from the scope and spirit of the invention. It is intended that the invention include such modifications and variations as come within the full scope of the appended claims and any equivalents thereof.

What is claimed is:

1. A medical product defining a fluid path, the medical product comprising a valve assembly disposed in the path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

at least one of the flexible walls defining a cross-section that tapers to a thickness at its respective end of about 10% to about 30% of its thickness extending from the peripheral portion.

2. The medical product as in claim 1, wherein the valve member is formed of a material having a durometer of about 50 Shore A or less.

3. The medical product as in claim 1, wherein the valve member is formed of a material having a durometer of less than about 20 Shore A.

4. The medical product as in claim 1, wherein the at least one wall tapers continuously in a direction towards its respective end.

5. The medical product as in claim 1, wherein the at least one wall changes thickness discontinuously in a direction towards its respective end.

6. The medical product as in claim 1, wherein the at least one flexible wall tapers in thickness from about 0.005 to about 0.010 inches at its respective end to about 0.040 inches at a location spaced from the respective end.

7. The medical product as in claim 1, wherein the medical product is a gastrostomy catheter, the fluid path defined between a patient's body cavity and an exterior of the body.

8. A medical product defining a fluid path, the medical product comprising a valve assembly disposed in the path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

at least one of the flexible opposing walls defining an overlapping portion extending at an angle to the at least one wall for overlapping a portion of another wall adjacent its respective end.

9. The medical product as in claim 8, wherein the valve member is formed of a material having a durometer of about 50 Shore A or less.

10. The medical product as in claim 8, wherein the valve member is formed of a material having a durometer of less than about 20 Shore A.

11. The medical product as in claim 8, wherein the overlapping portion of the at least one wall extends substantially parallel to the other wall.

12. The medical product as in claim 8, wherein the walls have a thickness of about 0.040 inches.

13. The medical product as in claim 8, wherein the medical product is a gastrostomy catheter, the fluid path defined between a patient's body cavity and an exterior of the body.

14. A medical product defining a fluid path, the medical product comprising a valve assembly disposed in the path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

a stiffening member located on one of the opposing flexible walls, wherein the stiffening member remains free from contact with the valve housing when the valve member is in the closed position, and wherein the stiffening member remains free from contact with the valve housing when the valve member is in the open position.

15. The medical product as in claim 14, wherein a pair of stiffening members are present on the valve member such that one stiffening member is located on one of the opposing flexible walls and the other stiffening member is located on the other one of the opposing flexible walls, wherein the stiffening members remain free from contact with the valve housing when the valve member is in the closed position, and wherein the stiffening members remain free from contact with the valve housing when the valve member is in the open position.

16. The medical product as in claim 14, wherein the valve member and the stiffening member are integrally formed with one another.

17. The medical product as in claim 14, wherein the stiffening member has an arcuate surface.

18. The medical product as in claim 14, wherein the valve member is at least partially made from a material that has a durometer value of less than 10 Shore A.

19. The medical product as in claim 18, wherein the valve member is at least partially made from a material that has a durometer value between about 8 Shore A to less than 10 Shore A.

20. The medical product as in claim 14, wherein the medical product is a gastrostomy catheter, the fluid path defined between a patient's body cavity and an exterior of the body.

* * * * *