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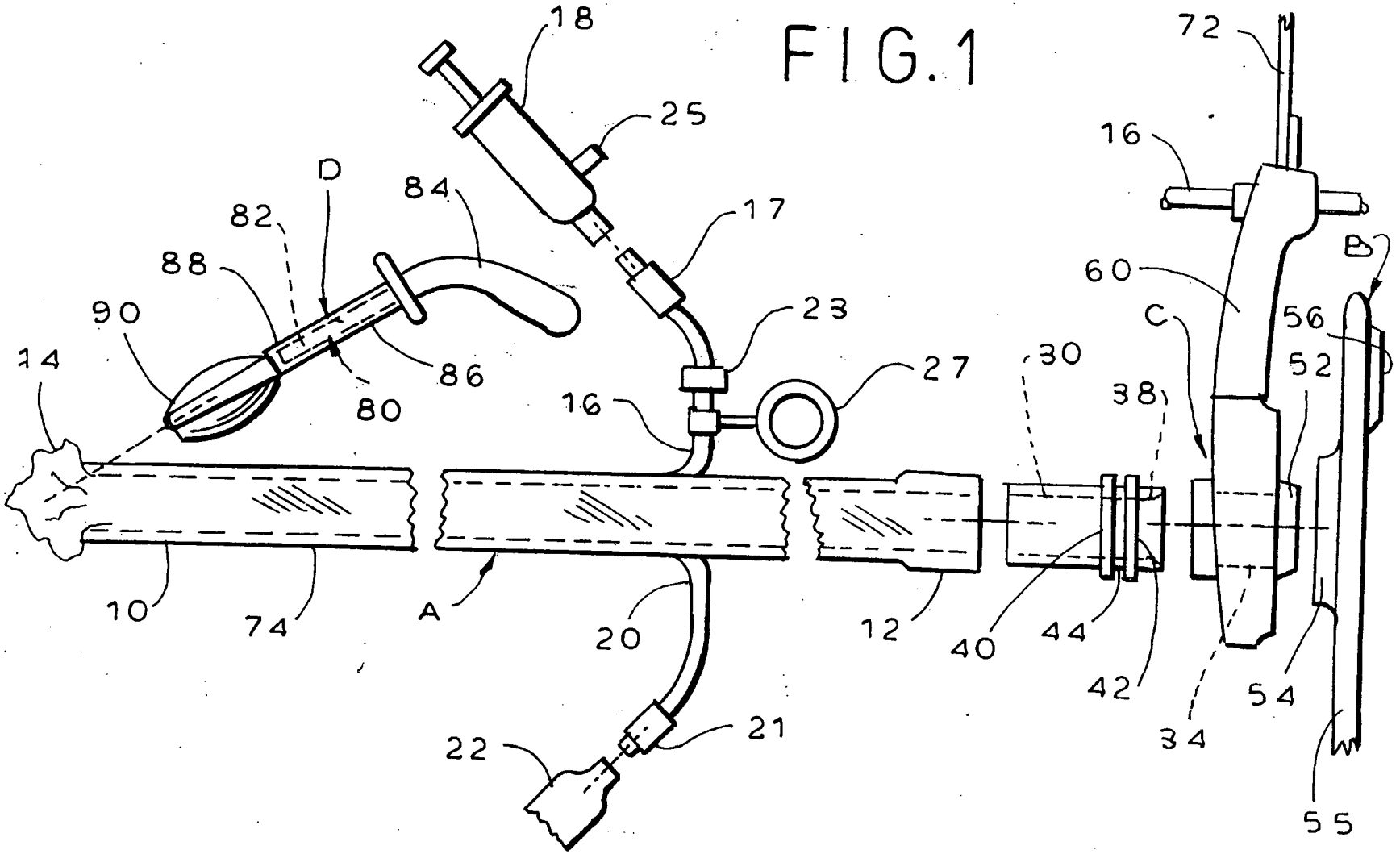
FECAL MANAGEMENT APPLIANCE AND METHOD AND APPARATUS FOR INTRODUCING SAME

ABSTRACT OF THE DISCLOSURE

The end of the elongated tubular element of the appliance that is designed to be inserted into a body cavity or vessel is formed entirely of soft, compliant material. That end carries an inflatable balloon formed in its fully inflated shape. The balloon is inflated to a predetermined low pressure level to prevent pressure necrosis in the adjacent tissue. A method and apparatus for introducing the soft end of the appliance into the body cavity are also provided. The introducer apparatus includes rigid core surrounded by a soft, compliant sleeve. The sleeve extends beyond the rigid core to form an invertable section. The soft end of the appliance is situated adjacent the apparatus, the balloon is wrapped around the apparatus, and the sleeve section is inverted over the appliance, compressing the balloon and forming a soft, rounded insertion tip. The unit is then introduced into the body cavity. After the appliance is separated from the apparatus, the apparatus is withdrawn.

FIG. 1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FECAL MANAGEMENT APPLIANCE AND METHOD FOR INTRODUCING SAME

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The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

TITLE OF THE INVENTION

FECAL MANAGEMENT APPLIANCE AND METHOD AND APPARATUS FOR INTRODUCING SAME

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates to a fecal or waste management appliance, and to a method and apparatus for introducing the appliance into a body cavity, and more particularly to a fecal management appliance including a tubular element with a balloon carrying distal end formed entirely of soft, compliant material, that includes integral inflation and irrigation lumens, and has a detachable collection receptacle rotatably connected to its proximal end, and to a method and a separate apparatus for introducing the distal end of appliance into a body cavity.

Contamination by fecal matter of skin, open wounds, burns, sutured surgical incisions and the like located proximate the rectum or stoma may be extremely detrimental to patient recovery. Further, healthcare professionals that accidentally come in contact with such waste while caring for patients with those conditions, many of which have severe medical problems requiring intense care, may unintentionally spread infectious diseases.

Accordingly, it is highly desirable to have a system for the management and collection of bowel contents that effectively prevents contamination of the patient and of the healthcare workers providing care to the patient.

2. DESCRIPTION OF PRIOR ART

One such system designed to provide bowel management is marketed by Zassi Medical Evolutions, Inc. of Fernandina Beach, Florida 32034. The Zassi system consists of an elongated flexible catheter, the proximal end of which is detachably connected to a waste collection bag. The distal end of the catheter is designed to be inserted through the rectum or stoma into the bowel of the patient.

The distal end of the Zassi catheter includes a rigid portion to permit insertion and positioning of the catheter into the bowel. The catheter carries two inflatable balloons, one balloon being situated within the catheter lumen. The other surrounds the catheter at the site of the inside balloon. The balloons are separately inflatable to block the distal end of the catheter and to seal the catheter to the rectum or stoma, respectively. A separate inflation lumen is provided for each balloon. A third lumen delivers irrigation fluid to the bowel.

Dual balloon systems of this type are known and are disclosed in U.S. Patent No. 5,569,216 issued October 29, 1996 to Kim, entitled "Multipurpose Colostomy Device Having Balloons On An End Thereof" and in International Publication Number WO 02/26293, published April 4, 2002, and entitled "Improved Colostomy Device."

Aside from the complexity and cost of the dual balloon system disclosed by Kim and utilized in the Zassi bowel management system, the Zassi apparatus has a

drawback. That drawback relates to the pressure exerted by the balloons upon the adjacent tissue, during and after inflation.

Balloons located on the exterior of the distal end of catheters have been used for many years to hold the catheters in place in a patient's rectum. Such catheter systems are frequently used for enema application but are also used for the collection and directing of fecal material from the rectum to a collection system. Those catheters, sometimes known as Foley catheters, are large versions of devices commonly used for urinary catheterization.

There are many professionals in the medical community who do not approve of the use of inflatable devices in the rectum, as they believe that tissue damage will result from excess pressure exerted on adjacent tissue by the inflated balloon for an extended time. Such tissue necrosis is believed to occur when the pressure from the balloon prevents the tissue from being sufficiently profused by blood.

In practice, after these Foley-type catheters are inserted into the rectum, the balloon is inflated to its full size, regardless of the pressure that it exerts on tissue. Thus, the size of the balloon selected becomes critical. However, since the caregiver has no knowledge of the internal anatomy of the patient, the choice of balloon size is no more than a guess.

The balloon system in the Zassi bowel management system, as disclosed by Kim, suffers from this problem. The balloon system can be inflated to a pressure that could result in prevention of the tissue from being sufficiently profused by blood since there appears to be no mechanism to limit the pressure applied to the tissue by the balloon.

Further, in order to conveniently insert the end of a catheter into the rectum or stoma, the end must have sufficient rigidity. If the end of the catheter does not have

sufficient rigidity, it can be quite difficult to insert and properly position the end of the catheter.

It is possible to build devices designed to be inserted in the bowel with sufficient rigidity to permit insertion but it is usually detrimental to have such rigidity once the device is properly positioned. Many products use rigid tube systems for insertion. One such system is disclosed in U.S. Patent No. 4,516,578 issued May 14, 1985 to Shuffield entitled "Rectal Device and Method of Inserting Same". In those devices, the portion of the device to be inserted is compressed within one tube. That tube is inserted in the desired location within the bowel. The device is then pushed out of the end of the first tube by a second member (usually a smaller nesting tube).

That system requires a hard outer tube to hold the device in its compressed form as it is inserted. The outer tube also has to be rigid to allow the device to be pushed out of it without stretching. Finally, the hard outer tube has to be strong enough to hold the device in its compressed form but still thin enough to minimize the diameter of the insertion system.

There are several shortcomings resulting from that type of insertion system. First, the hard outer tube can have traumatic impact to soft tissue. This is especially true as the wall thickness of the outer tube is reduced to minimize the diameter of the assembly. The thin tube wall causes difficulty in avoiding sharp edges at the tube end or along any openings in the tube. This is especially detrimental if the outer tube needs to be split along one side of its length to allow removal of the device from the side of the assembly. The sharp edge would be evident along the length of the tube, resulting in the potential for tissue damage.

Further, the requirement for the rigidity in the hard outer tube results in a greater than desired wall thickness to ensure sufficient strength. Finally, the hard outer tube can result in excess tissue bruising, simply because it is hard.

The discussion of documents, acts, materials, devices, articles and the like is included in this specification solely for the purpose of providing a context for the present invention. It is not suggested or represented that any or all of these matters formed part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Throughout the description and claims of the specification, the word "comprise" and variations of the word, such as "comprising" and "comprises", is not intended to exclude other additives, components, integers or steps.

BRIEF SUMMARY OF THE INVENTION

The present invention is a medical appliance for fecal management in which the distal end of the appliance is formed entirely of soft, compliant material, incapable of causing any injury to the tissue. The appliance utilizes a single low-pressure balloon that can be controlled to prevent excess pressure on the adjacent tissue and hence prevent the adjacent tissue from being denuded of blood.

The invention transfers the rigid portion of a distal end of the appliance needed for insertion to a separate apparatus, designed to be withdrawn after introduction of the appliance in the bowel, thus allowing the entire inserted distal end of the appliance to be soft and compliant so that it cannot damage the tissue. The introducer apparatus includes a rigid core element surrounded by a soft, compliant sleeve. The soft sleeve is attached to the rigid core element, allowing the two to function as a unit. A section of sleeve extends beyond the end of the rigid core element. That section has a generally bulbous shape. The reminder of the sleeve is attached to the surface of the core element.

The soft end of the appliance to be inserted in the body cavity is wrapped around the introducer apparatus, flush with the end of the core element. The bulbous sleeve section that extends beyond the core element is inverted back over portion of the end of the appliance that is wrapped around the apparatus. The inverted sleeve section acts to compress the end of the appliance and contains the compressed.

appliance end. This results in a smooth, rounded, compressed mass at the tip of the introducer apparatus that facilitates insertion.

The compressed appliance end is introduced into the body cavity by pushing the distal end of the rigid introducer apparatus through the anal sphincter or stoma. The proximal end of the rigid core element is manipulated until the appliance is positioned as desired. Both the constriction of the inverted sleeve section and the force of the anatomy squeezing the distal end of the introducer apparatus compress the soft end of the appliance, wrapped around the apparatus, significantly

Once in position, the appliance and the introducer apparatus are separated. The exposed portion of the appliance is held firmly while the introducer apparatus is pushed in the distal direction. This pushes the inverted sleeve section off the end of the appliance, separating the appliance from the apparatus. Alternatively, if the appliance has a balloon structure in it, the inflating of the balloon can separate the appliance and the introducer apparatus. Once the appliance and the introducer apparatus are separated, the introducer apparatus is withdrawn from the body cavity, leaving the distal end of the appliance in place.

With regard to the damage potentially caused by a balloon inflated to a high pressure, the invention allows the use of a balloon catheter in the rectum with drastically reduced potential for tissue damage due to pressure necrosis. After insertion, the balloon in my device can be inflated only to a pressure that is known to be low enough to allow full profusion of the tissue. Due to force balance, the balloon can therefore apply no more than this pressure to the tissue, always permitting full profusion of the tissue. Further, the balloon is fabricated in its fully inflated shape. As a consequence, the balloon can be expanded to its full size with an internal pressure less than pressures potentially harmful to tissue.

It is desirable to reduce friction and provide a gas and odor barrier along certain of the surfaces of the appliance. This can be accomplished by applying a thin coating of appropriate material to the walls of the appliance in the required surface areas.

The present invention provides a waste management appliance for the rectum or stoma comprising an elongated tubular element having a distal end and a proximal end; an inflatable balloon surrounding said distal element end; and externally accessible inflation lumen operably connected to said balloon; a waste collection receptacle; and means for detachably mounting said receptacle to said proximal element end, wherein said distal element end is formed entirely of soft, compliant material.

In accordance with one aspect of the present invention, a fecal management appliance is provided. The appliance includes an elongated tubular element having a distal end and a proximal end. An inflatable balloon surrounds the distal element end of the tubular element. An externally accessible inflation lumen is operably connected to the balloon. A fecal collection receptacle is provided. Means are provided for detachably mounting the receptacle to the proximal end of the element. The distal end of the element is formed entirely of soft, compliant material.

Preferably, the distal end of the element is formed of silicone. The balloon is also formed entirely of soft, compliant material. That material could be silicone, as well.

Preferably, the balloon is substantially toroidal in shape when fully inflated. Means are provided for inflating the balloon to a pre-determined maximum pressure. Those means include means for supplying inflation fluid to the inflation lumen. The inflation fluid supply means may include a syringe with a plunger and a spring. A pressure gauge and a valve may be included to prevent over pressure.

The balloon is formed in its fully inflated size and shape. It is formed of a material that allows the balloon to be inflated to its final shape with less pressure than is potentially harmful to tissue.

The tubular element includes a wall. At least a portion of the inflation lumen is attached to the wall. The wall has an interior surface. At least a portion of the

inflation lumen is integral with the interior wall surface. The wall has an opening through which the inflation lumen extends.

An externally accessible irrigation lumen may also be provided. The irrigation lumen has an end proximate the edge of the distal end of the element. At least a portion of the irrigation lumen is integral with the wall of the element. Preferably, at least a portion of the irrigation lumen is attached to the interior wall surface. The wall has an opening through which the irrigation lumen extends.

Preferably, the inflation lumen extends a significant portion of the length of the element. The irrigation lumen also preferably extends a significant portion of the length of the element.

Preferably, the inflation lumen is attached to the wall, along a significant portion of the length thereof. The irrigation lumen is also preferably attached to the interior wall surface, along a significant portion of the entire length of the element.

The inflation lumen has a section situated within the element and a section external to the element. The irrigation lumen also has a section situated within the element and a second external to the element.

The appliance further comprises means for supplying irrigation fluid to the irrigation lumen. The irrigation fluid supply means may include a syringe.

The receptacle mounting means includes a plate with an opening. Means are provided for attaching the proximal end of the tubular element to the plate, in alignment with a plate opening. Those attaching means include means for permitting rotation of the proximal end of the tubular element relative to the plate. The rotation permitting means include a first part adapted to receive the proximal end of the tubular element and a second part mounted to the plate. The first part is rotatably mounted to the second part.

The plate can include means for retaining the external inflation lumen section. The plate further can include means for retaining the external irrigation lumen section.

The appliance is designed for use with a stationary member, such as a bed rail or the like. It includes means for attaching the plate to the stationary member.

The means for detachably mounting the collection receptacle to the plate includes first and second inter-engagable coupling parts. The first part is fixed to the plate, surrounding the plate opening. The receptacle has a wall with an opening. The second part is fixed to the receptacle wall, surrounding the wall opening.

Since the end of the appliance adapted to be introduced into a body cavity is made entirely of soft, compliant material, apparatus for introducing the apparatus, separate from the appliance, is provided. The introducer apparatus includes a substantially rigid elongated core having a distal end and a proximal end, and a sleeve having a distal end and a proximal end. The core is received within the sleeve, with a section of the sleeve extending beyond the distal end of the core.

The extended sleeve section is invertible to engage the distal end of the tubular element of the appliance. The section of the distal end of the sleeve that extends beyond the distal end of the core has a generally bulbous shape. Preferably, the invertable sleeve section is formed of soft, compliant material.

Preferably, the proximal end of the sleeve is attached to the core. This permits the appliance and the apparatus to function as a unit.

Preferably, means are provided for forming a friction reducing, gas and odor barrier coating on the surface of the element. Preferably, the coating is a few microns thick and is composed of parylene that is vacuum deposited on the internal and external surfaces of the element.

In accordance with another aspect of the present invention, apparatus for introducing a medical appliance into a body cavity is provided. The apparatus includes a substantially rigid elongated core having a distal end and a proximal end, and a sleeve having a distal end and a proximal end. The core is received within the sleeve. A section of the distal end of the sleeve extends beyond the distal end of the core. That section is invertible to engage the medical appliance.

The section of the distal end of the sleeve that extends beyond the core has a generally bulbous shape. That section of the distal end of the sleeve is formed of soft, compliant material.

Preferably, the proximal end of the sleeve is attached to the shaft.

In another aspect, the present invention provides a method for introducing the distal end of f medical appliance into a body cavity utilizing introducer apparatus with a substantially rigid core and a sleeve section extending beyond the core, the method comprising the steps of placing the distal end of the medical appliance adjacent the apparatus, proximate the sleeve section, inverting the sleeve section over the distal end of the medical appliance to engage same, introducing the end of the apparatus with the inverted sleeve section and engaged end of the medical appliance into the body cavity, separating the appliance from the apparatus and withdrawing the apparatus.

In accordance with another aspect of the present invention, a method is provided for introducing the soft end of a medical appliance into a body cavity utilizing an introducer apparatus. The apparatus has a substantially rigid elongated core received within a sleeve, with a section of the sleeve extending beyond the core. The method includes the steps of placing the distal end of the medical appliance adjacent the apparatus, proximate the sleeve section. The sleeve section is then inverted over the distal end of the medical appliance, to engage the medical appliance. The distal end of the core, with the inverted sleeve section engaging the appliance, is introduced into the body cavity. The apparatus is then separated from the appliance and withdrawn from the body cavity. The apparatus is then separated from the appliance and withdrawn from the body cavity, leaving the appliance in place.

The method further includes the step of wrapping the distal end of the medical appliance around the apparatus, before inverting the sleeve section.

The medical appliance may include an inflatable balloon at the distal end. In that case, the method further includes the step of inflating the balloon after the end of the apparatus with the inverted sleeve section engaging the medical appliance is

introduced into the body cavity. This causes the inverted sleeve section to return to its non-inverted position, disengaging the medical appliance.

The method further comprises the step of coating the surface of the appliance with a friction-reducing gas and odor barrier layer. The layer is a few microns thick and is formed of parylene. It is vacuum deposited on the appliance surface.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

To these and to such other aspects which may hereinafter appear, the present invention relates to a fecal management appliance, and to a method and apparatus for introducing the end of the appliance into a body cavity, as set forth in detail in the following specification, and recited in the annexed claims, taken together with the accompanying drawings, wherein like numerals refer to like parts, and in which:

Figure 1 is an exploded plan view of the parts of the medical appliance and introducer apparatus of the present invention;

Figure 2 is a cross-sectional view of the distal end of the medical appliance;

Figure 3 is a cross-sectional view taken along line 3-3 of Figure 2;

Figure 4 is a cross-sectional view of the proximal end of the medical appliance;

Figure 5 is a view taken along line 5-5 of Figure 4;

Figure 6 is a cross-sectional view of the distal end of the medical appliance engaged by the introducer apparatus; and

Figures 7(a) through 7(e) are sequential schematic views of the distal end of the medical appliance and introducer apparatus, illustrating the various stages of the introduction method.

DETAILED DESCRIPTION OF THE INVENTION

As seen in Figure 1, the medical appliance of the present invention includes an elongated flexible tubular element, generally designated A, having a distal end 10 that is designed to be introduced into a body cavity, and a proximal end 12. Element A is preferably approximately 1 meter long and 23 mm in diameter. It collapses to 8 mm in diameter to facilitate passage through the anal sphincter.

A fecal waste receptacle, generally designated B, is rotatably connected to proximal end 12 of element A, through an adapter plate, generally designated C. Affixed to the exterior surface of the distal end 10 of element A is a low-pressure inflatable balloon 14, shown in its deflated state in Figure 1.

Balloon 14 is inflated with fluid, such as air, water or saline, through an inflation lumen 16 to a diameter of about 58 mm, with a pressure of less than 52 mm Hg. (1.0 pound per square inch). Lumen 16 is connected by a Luer type valve connector 17 to an inflation fluid source, such as a syringe 18. The syringe is also used to withdraw the inflation fluid, to deflate the balloon.

Preferably, a second, irrigation lumen 20 is also provided. Luman 20 extends to the edge of the distal end 10 of element A and is connected by a Luer type valve connector 21 to a source of irrigation fluid, such as a syringe 22. Lumens 16 and 20 are preferably 1 mm to 1.5 mm in diameter.

The distal end 10 of element A and balloon 14 are both made entirely of soft, compliant material so as not to injure any body tissue. That material may be, for example, silicone.

A separate introducer apparatus, generally designated D, is provided to facilitate introduction and placement of the distal end 10 of element A in the rectum.

As explained below, apparatus D is rigid. It is designed to engage distal end 10 of element A and facilitate its introduction into and positioning within the bowel. Apparatus D is then separated from the medical appliance and removed from the body cavity, leaving only the soft, compliant distal end 10 of element A in the body.

As best seen in Figure 2, balloon 14 surrounds the distal end 10 of appliance A. Preferably, the balloon has a toroidal shape when fully inflated. The wall of the balloon is preferably fabricated in its fully inflated shape. It is formed of material that allows the balloon to be inflated to its final shape with less pressure than is potentially harmful to tissue. As detailed below, the pressure of the fluid within balloon 14 is carefully regulated such that the balloon cannot apply a pressure beyond a pre-determined level on the surrounding tissue.

As seen in Figure 3, inflation lumen 16 and irrigation lumen 20 are preferably formed as an integral part of the interior surface of the wall of element A. Each of the lumens 16, 20 has a portion that extends within element A and a portion that extends through an opening 24, 26, respectively, in the wall of element A, for attachment to fluid sources 18, 22, respectively. Preferably, the internal portions of lumens 16 and 20 extend along the entire length of element A. It is then possible to fabricate element A with the external portions of the lumens located at any point along the length of the element.

Inflation lumen 16 has a closed end adjacent the edge of distal end 10 of element A. However, a passage 28 connects lumen 16 with the interior of balloon 14 to permit the inflation fluid, usually water or saline, to be introduced into balloon 14 to inflate the balloon and to be removed from the balloon to deflate the balloon.

Irrigation lumen 20 extends to a point proximate the edge of distal end 10 of element A and has an open end such that the irrigation fluid can be introduced into the bowel. The irrigation fluid is supplied as needed from a source, such as syringe 22.

The balloon inflation system can function in two ways. It can allow the balloon to shrink in volume if the internal pressure increases, maintaining only the desired pressure on tissue, such as by spring loading the syringe plunger to a pre-determined level. Alternatively, the balloon can be fixed in volume once the pressure is reached on insertion. If this is done at a time when the bowel is relaxed, the pressure on tissue will only increase when the bowel is in constriction. As this is only a periodic event, the tissue will be fully profused between constrictions.

The balloon is inflated and the pressure is regulated remotely from the tubular element. The inflation lumen 16 extends from the balloon to the inflation fluid source located outside of the body. The fluid source can be manually operated or can be regulated by an electronic or mechanical system.

In one preferred embodiment, the balloon is operably connected to a fluid reservoir, such as syringe 18. The syringe can be a 60 cubic centimeter commercial polycarbonate Luer lock syringe with a silicone plunger seal and a barrel between 1 to 1.25 inches in diameter. The volume of the syringe can be changed to place the fluid within under pressure that is purely dependent on the force applied on the plunger. Spring loading the plunger of syringe 18 with a spring 19 with the appropriate force will set the internal balloon to the desired pressure. The fluid path to the balloon could then be left open to maintain that pressure or it could be closed by a valve or clamp 23 to maintain the balloon's volume. The pressure within the syringe thus determines the size of the balloon and thus the pressure applied to the tissue.

For accurate pressure measurements, the elastic force of the balloon would have to be taken into consideration. However, the effect of the elasticity of the material of which the balloon is made is minimized if the balloon is fabricated in the desired fully inflated shape. Then, the pressure within the balloon would determine the pressure exerted on tissue, up to its pre-determined size.

There may be situations where the caregiver uses a balloon that is too small for the patient's anatomy. In this situation, the balloon would be inflated with the prescribed volume without the pressure increasing. Therefore, the balloon is not pressing on the anatomy sufficiently to make a seal. Conversely, if the balloon pressure exceeds the limit with the introduction of the prescribed volume of fluid, the caregiver can tell that the balloon is too large for the patient's anatomy.

Alternatively, f the pressure is monitored as the balloon is inflated, the caregiver can tell if the balloon is too large or small. As above, if the balloon is too small, the balloon pressure does not reach the prescribed pressure with the entire prescribed volume being injected. Conversely, if the balloon is too large the maximum pressure will be reached prior to the injection of the prescribed volume of fluid. The accuracy of the volume measurement within the balloon can be maintained by using an incompressible fluid or by compensation for the pressure increase by the ideal gas law, if a gas is used.

The appliance could be supplied with a pre-filled fluid reservoir that is maintained under a near constant pressure by a resilient mechanical system, for example, a syringe 18 with a plunger between the fluid and a near constant force spring. The spring pressing on the plunger would maintain the fluid at the desired pressure. Once the appliance is inserted into the patient, the valve on clamp 23 would be opened allowing fluid from the syringe to fill and inflate the balloon to the desired

pressure. The valve or clamp 23 could be left open to maintain that pressure over time or it could be closed to maintain the fixed volume.

The same components could be supplied without fluid, but with a fluid supply port 25. The caregiver would supply the fluid and supply the pressure to put in a known range of volume of fluid. The syringe plunger backed by the spring 19 would act as a pressure gauge. The caregiver would be instructed to stop injecting fluid once the proper pressure is reached. If the fluid injected is not within the prescribed range, the balloon is the wrong size and must be removed.

Alternatively, the inflation system could include a simple pressure gauge 27 attached to lumen 16 to allow the caregiver to only inflate the device to the target pressure. This configuration requires the system to function in the fixed volume state once the pressure is determined on insertion. It is also possible to fabricate the syringe plunger with the pressure gauge incorporated into it. The plunger stem could contain an integrated or assembled spring that indicates the pressure in the fluid in the syringe barrel. The spring could create a gap between two portions of the plunger stem. As the pressure increases, the spring compresses and the two portions of the plunger move closer together. Scales on the two portions can indicate pressure by their relative position to each other.

Referring now to Figures 1, 4 and 5, the proximal end 12 of element A is rotatably connected to adapter plate C by first and second part 30. Part 30 is generally tubular in shape and has an outer diameter that is substantially equal to or slightly larger than the inner diameter of element A. Proximate end 12 of element A is received over and fixed on one end of part 30.

The other end of part 30 is rotatably received within part 60, which has a generally tubular center section. However, part 30 is sized such that when snapped

into part 60, there is not too much friction between the part 30 and part 60 to prohibit rotation.

There is a circular opening through plate C, through which the end 38 of part 30 extends. Part 30 creates a waste path from element A to the pouch, when it is mounted on plate C.

The exterior surface of part 30 has a pair of outwardly extending spaced circumferential surface protrusions 40, 42 defining a circumferential recess or groove 44. The interior surface of plate C has an inwardly extending annular protrusion 46 which is adapted to be received in groove 44 to permit part 30, and hence proximal end 12 of element A, to be manually rotated relative to plate C.

Plate C is preferably made of plastic and has a body with a lower, generally circular portion 50 through which opening 34 extends. Part 32 is fixed to one side of portion 50 and acts to cover the end of part 12. The other side of portion 50 of plate C carries a first inter-engaging part 52 in the form of an annular protrusion or ring welded to its surface. Part 52 surrounds opening 34 in plate C. Receptacle B preferably takes the form of a standard ostomy pouch 55.

Pouch 55 includes an entrance opening defined by a second inter-engaging part 54, in the form of an annular channel, welded to the pouch wall. Part 52 is detachably received into part 54 in a "snap-fit" fashion.

The contours of inter-engaging parts 52, 54 are shaped so that when the parts are engaged and the pouch is attached to the plate, a fluid tight seal is formed. This seal is strong enough to prevent the weight of the filled pouch from causing accidental attachment of the pouch.

Inter-engaging parts of this type are well known in the art and commonly used in two-piece ostomy appliances. The particular coupling structure preferred for the

present invention is disclosed in U.S Patent No. 5,693,036 issued on December 2, 1997 to Kilgour entitled: Method Of Injection Moulding An Undercut Formation On A Circular Body And A Closure Assembly Including A Coupling Element, owned by Bristol-Myers Squibb Company of Lawrenceville, New Jersey.

Pouch 55 preferably has a capacity of 1 to 1.5 liters. It is formed of multiple layers of plastic film welded together. It may include an activated carbon filter 56 for odor control, as is common in ostomy pouches. Filter 56 permits flatus gas to escape from the pouch interior such that pressure does not build up within the pouch. Preferably, the exterior wall of pouch B is transparent and is provided with measurement markings. The pouch may also include a layer of film to act as a non-return valve.

The top portion 60 of the body of plate C is substantially rectangular and includes first and second parts 62, 64 with openings 63, 65 respectively adapted to receive inflation lumen 16 and irrigation lumen 20 for stowage. In this manner, the external portions of lumens 16 and 20 can be retained by plate C and will not interfere with the caregiver or patient.

Plate C is designed to hang from a stationary object, such as a bed rail 70. A clip 72 is provided for that purpose. Clip 72 extends upwardly from portion 60 of plate C and can be received over bed rail 70, in a conventional manner.

In order to reduce friction and provide a gas and odor barrier, a thin coating of parylene 74 is vacuum deposited over the internal and external surfaces of element A, except for the portion of the internal surface of end 12 of element A that is received over part 30. The parylene coating is preferably a few microns thick. The surface of balloon 14 is not coated with the parylene because such a coating might cause the balloon to accidentally slip out of the body.

Apparatus D is depicted in Figure 1 as it appears separately from element A, and in Figure 6 as it appears engaged with element A. The sequence of how introducer apparatus D is used to engage the distal end 10 of element A and introduce it through the anus or stoma is depicted in Figures 7(a) through 7(e).

Apparatus D consists of two portions. The first portion is a rigid plastic elongated core element 80 in the form of a stiff rod orshaft with a distal end 82. A handle portion 84 is located at the proximal end of the core element. The second portion of the apparatus is a soft, complaint silicone sleeve 86 that may be molded to shape. Core element 80 is received within sleeve 86. Sleeve 86 is fixed on core element 80 by adhesive or other suitable means. In this manner, core 80 and sleeve 86 are attached together to form a unit.

A section 90 of sleeve 86 extends beyond the distal end 82 of core 80. Section 90 is generally bulbous in shape and preferably has a length of about 15 mm. However, section 90 can have a length in the range of between half the diameter of the sleeve to several times the sleeve diameter. Section 90 of sleeve 86 is shown in its initial, non-inverted state, in Figures 1 and 7(a) through 7(c). Section 90 is formed so that it can be inverted over the distal end of element A, including balloon 14 in its uninflated condition, to engage element A and compress balloon 14, as seen in Figures 6 and 7(d).

As seen in Figures 7(b) and 7(c), prior to engaging element A, apparatus D is placed proximate the distal end 10 of element A, with the edge of distal end 10 located adjacent the end 82 of core element 80. Balloon 14 in its deflated state is wrapped around core element 80 of apparatus D. Sleeve section 90 is then inverted over end 10 of element A, as seen in Figure 7(d), such that balloon 14 is fully compressed. The distal end 10 of element A, including the compressed balloon, is

thus engaged by apparatus D. It should be noted that in this condition, inverted sleeve section 90 forms a soft, rounded tip on apparatus D to facilitate introduction of element A and apparatus D into the bowel.

Once properly positioned within the bowel, the distal end 10 of element A is separated from apparatus D. This can be accomplished by retaining element A in position as apparatus D is moved distally to disengage it from element A. Apparatus D may then be withdrawn from the bowel. However, disengagement can also be accomplished by inflation of the balloon. Inflation of balloon 14 will automatically cause sleeve section 90 to return to its non-inverted condition, separating apparatus D from element A, as seen in Figure 7(e). After removal, introducer apparatus D is discarded.

It will now be appreciated that the present invention relates to a medical appliance with an end designed to be introduced into a body cavity that is made entirely of soft, compliant material. The balloon is inflated to a predetermined low pressure level to prevent pressure necrosis on the adjacent tissue.

The present invention also relates to a method and apparatus for introducing the medical appliance into the body cavity. The introducer apparatus includes a rigid core element surrounded by a soft, compliant sleeve, to form an invertable section. The distal end of the appliance is situated adjacent the apparatus, the balloon is wrapped around the apparatus and the sleeve section is inverted over the appliance, engaging the appliance, compressing the balloon and forming a soft, rounded insertion tip. The unit is then introduced into the body cavity. After the appliance is separated from the apparatus, the apparatus is withdrawn.

While only a single preferred embodiment of the present invention has been disclosed for purposes of illustration, it is obvious that many variations and

modifications could be made thereto. It is intended to cover all of these variations and modifications that fall within the scope of the invention, as defined by the following claims:

CLAIMS:

1. A waste management appliance for the rectum or stoma comprising an elongated tubular element having a distal end and a proximal end; an inflatable balloon surrounding said distal element end; an externally accessible inflation lumen operably connected to said balloon; a waste collection receptacle; and means for detachably mounting said receptacle to said proximal element end, wherein said distal element end is formed entirely of soft, compliant material.
2. The appliance of Claim 1 wherein said material is silicone.
3. The appliance of Claim 1 further comprising means for inflating said balloon to a predetermined maximum pressure.
4. The appliance of Claim 1 wherein said balloon is formed entirely of soft, compliant material.
5. The appliance of Claim 1 wherein said balloon is formed in its fully inflated shape.
6. The appliance is Claim 1 wherein said balloon is formed of silicone.
7. The appliance of Claim 1 wherein said tubular element comprises a wall and wherein at least a portion of said inflation lumen is attached to said wall.
8. The appliance of Claim 1 wherein said tubular element comprises a wall with an interior surface and wherein at least a portion of said inflation lumen is integral with said interior wall surface.
9. The appliance of Claim 1 wherein said tubular element comprises a wall with an opening through which said inflation lumen extends.

10. The appliance of Claim 1 further comprising an externally accessible irrigation lumen having an end proximate said distal element end.

11. The appliance of Claim 10 wherein said element comprises a wall and wherein at least a portion of said irrigation lumen is attached to said wall.

12. The appliance of Claim 10 wherein said element comprises a wall with an interior surface and wherein at least a portion of said irrigation lumen is integral with interior wall surface.

13. The appliance of Claim 10 wherein said tubular element comprises a wall with an opening through which said irrigation lumen extends.

14. The appliance of Claim 1 wherein said inflation lumen extends substantially the entire length of said element.

15. The appliance of Claim 10 wherein said irrigation lumen extends substantially the entire length of said element.

16. The appliance of Claim 1 wherein said element has a wall and wherein said inflation lumen is attached to said wall along substantially the entire length thereof.

17. The appliance of Claim 1 wherein said element has a wall with an interior surface and wherein said inflation lumen is attached to said interior wall surface along substantially the entire length of said element.

18. The appliance of Claim 1 further comprising means for supplying inflation fluid to said inflation lumen.

19. The appliance of Claim 18 wherein said inflation supply means comprises a syringe.

20. The appliance of Claim 19 wherein said syringe comprises a plunger and a spring or spring mechanism.

21. The appliance of Claim 1 wherein said inflation lumen has a section situated within said element and a section external to said element.

22. The appliance of Claim 10 wherein said irrigation lumen has a section situated within said element and a section external to said element.

23. The appliance of Claim 3 wherein such inflating means comprises a pressure gauge.

24. The appliance of Claim 10 further comprising means for supplying irrigation fluid to said irrigation lumen.

25. The appliance of Claim 1 wherein said receptacle mounting means comprises a plate with an opening and means for attaching said proximal end of said element to said plate, in alignment with said plate opening.

26. The appliance of Claim 25 wherein said attaching means comprises means for permitting rotation of said proximal element end relative to said plate.

27. The appliance of Claim 26 wherein said rotation permitting means comprises a first part adapted to receive said proximal element end and a second part mounted on said plate, said first part being rotatably mounted to said second part.

28. The appliance of Claim 25 wherein said plate further comprises means for retaining said inflation lumen.

29. The appliance of Claim 10 wherein said receptacle mounting means comprises a plate with an opening and means for attaching said proximal end of said element to said plate in alignment with said plate opening.

30. The appliance of Claim 29 wherein said plate further comprises means for retaining said irrigation lumen.

31. The appliance of Claim 25 for use with a stationary member, further comprising means for attaching said plate to said stationary member.

32. The appliance of Claim 25 wherein said receptacle mounting means comprises first and second inter-engagable coupling parts.

33. The appliance of Claim 32 wherein said first coupling part is fixed to said plate surrounding said plate opening.

34. The appliance of Claim 32 wherein said receptacle comprises a wall with an opening and wherein said second coupling part is fixed to said receptacle wall surrounding said wall opening.

35. The appliance of Claim 33 wherein said receptacle comprises a wall with an opening and wherein said second coupling part is fixed to said receptacle wall surrounding said wall opening.

36. The appliance of Claim 1 wherein such distal end of said element adapted to be introduced into a body cavity, further comprising introducer apparatus separate from said appliance.

37. The appliance of Claim 36 wherein said introducer apparatus comprises a substantially rigid elongated core having a distal end and a proximal end, and a sleeve having a distal end and a proximal end, said core being received some distance within said sleeve, with a section of said distal end of said sleeve extending beyond said distal end of said core, said sleeve section being invertable to engage said appliance.

38. The appliance of Claim 37 wherein said sleeve is attached to said core.

39. The appliance of 37 wherein said section of said sleeve has a substantially bulbous shape.

40. The appliance of Claim 37 wherein said section of said sleeve is formed of soft, compliant material.

41. The appliance of claim 1 further comprising a coating of friction-reducing material.

42. The appliance of claim 1 further comprising a coating of gas and odor barrier material.

43. The appliance of claim 41 wherein said coating is a few microns thick.

44. The appliance of claim 42 wherein said coating is a few microns thick.

45. Apparatus for introducing the soft end of a medical appliance into a body cavity, the apparatus comprising a substantially rigid elongated core having a distal end and a proximal end, and a sleeve having a distal end and a proximal end, said core being received within said sleeve, with a section of said distal end of said sleeve extending beyond said distal end of said core, said sleeve section being invertable to engage the soft end of the appliance.

46. The appliance of Claim 45 wherein said sleeve is attached to said core.

47. The appliance of 45 wherein said section of said sleeve has a substantially bulbous shape

48. The appliance of Claim 45 wherein said section of said sleeve is formed of soft, complaint material.

49. A method for introducing the distal end of a medical appliance into a body cavity utilizing introducer apparatus with a substantially rigid core and a sleeve section extending beyond the core, the method comprising the steps of placing the distal end of the medical appliance adjacent the apparatus, proximate the sleeve section, inverting the sleeve section over the distal end of the medical appliance to engage same, introducing the end of the

apparatus with the inverted sleeve section and engaged end of the medical appliance into the body cavity, separating the appliance from the apparatus and withdrawing the apparatus.

50. The method of Claim 49 further comprising the step of wrapping the distal end of the medical appliance around the apparatus before inverting the sleeve section.

51. The method of Claim 49 wherein the distal end of the medical appliance includes a balloon, further comprising the step of wrapping the balloon around the apparatus before inverting the sleeve section.

52. The method of Claim 49 wherein the introducer apparatus comprises a sleeve of which the sleeve section forms a part, further comprising the steps of inserting the rigid core into the sleeve and affixing said core to said sleeve

53. The method of Claim 49 wherein the medical appliance includes an inflatable balloon at the distal end, further comprising the step of inflating the balloon, after the end of the apparatus with the inverted sleeve section and engaged end of the medical appliance is introduced into the body cavity, to cause the sleeve section to return to its non-inverted position, separating the appliance from the apparatus.

54. The method of Claim 49 further comprising the step of coating the surface of the appliance with a friction-reducing material.

55. The method of claim 49 further comprising the step of coating the surface of the appliance with gas and odor barrier material.

56. The method of claim 54 wherein the step of coating comprises vacuum depositing.

57. The method of claim 55 wherein the step of coating comprises vacuum depositing.

58. A waste management appliance according to claim 1 substantially as hereinbefore described with reference to the figures.

59. An apparatus according to claim 45 substantially as hereinbefore described with reference to the figures.

60. A method according to claim 49 substantially as hereinbefore described with reference to the figures.

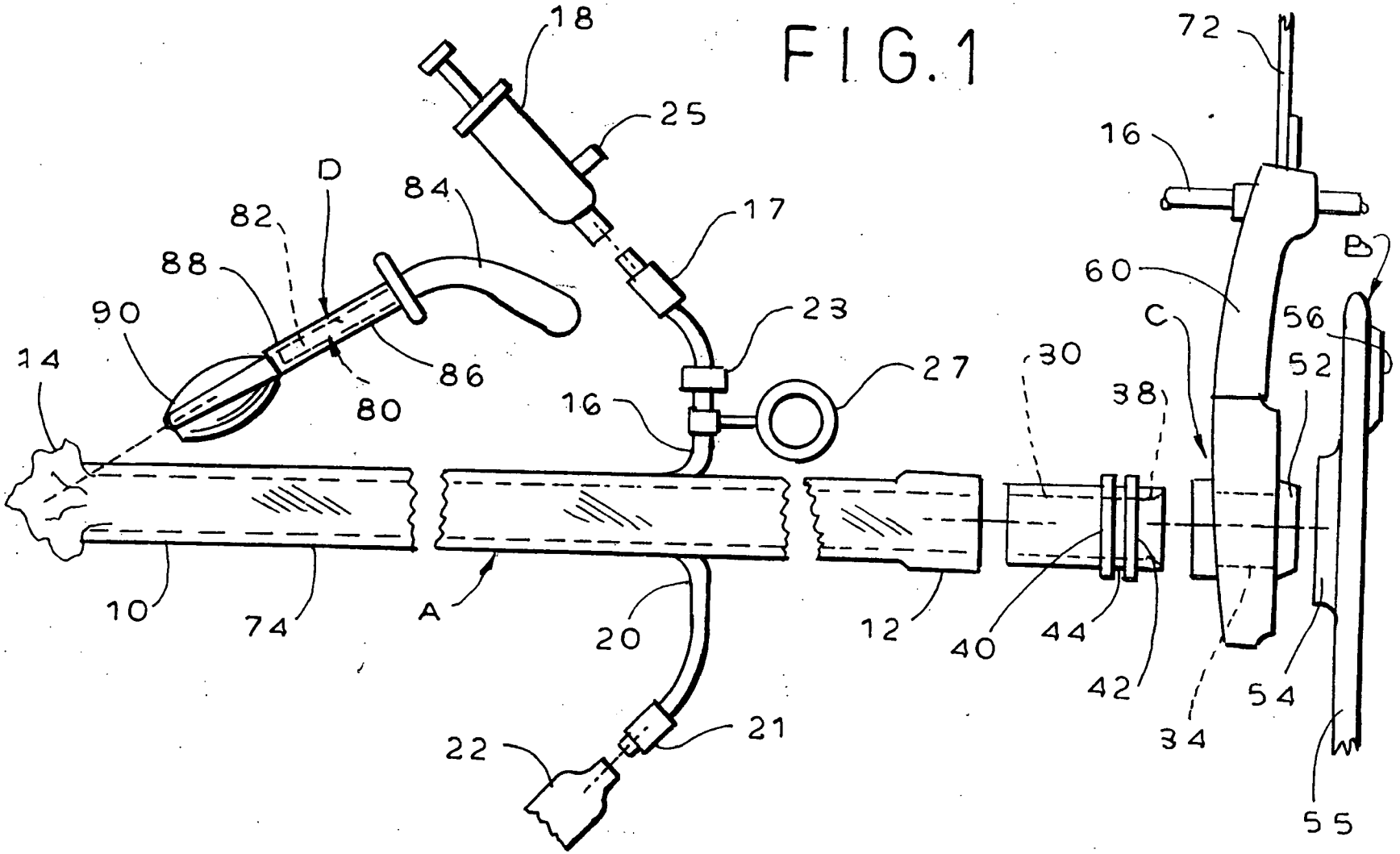
Dated: 8 September 2004

PHILLIPS ORMONDE & FITZPATRICK

Attorneys for:

BRISTOL-MYERS SQUIBB COMPANY

FIG. 1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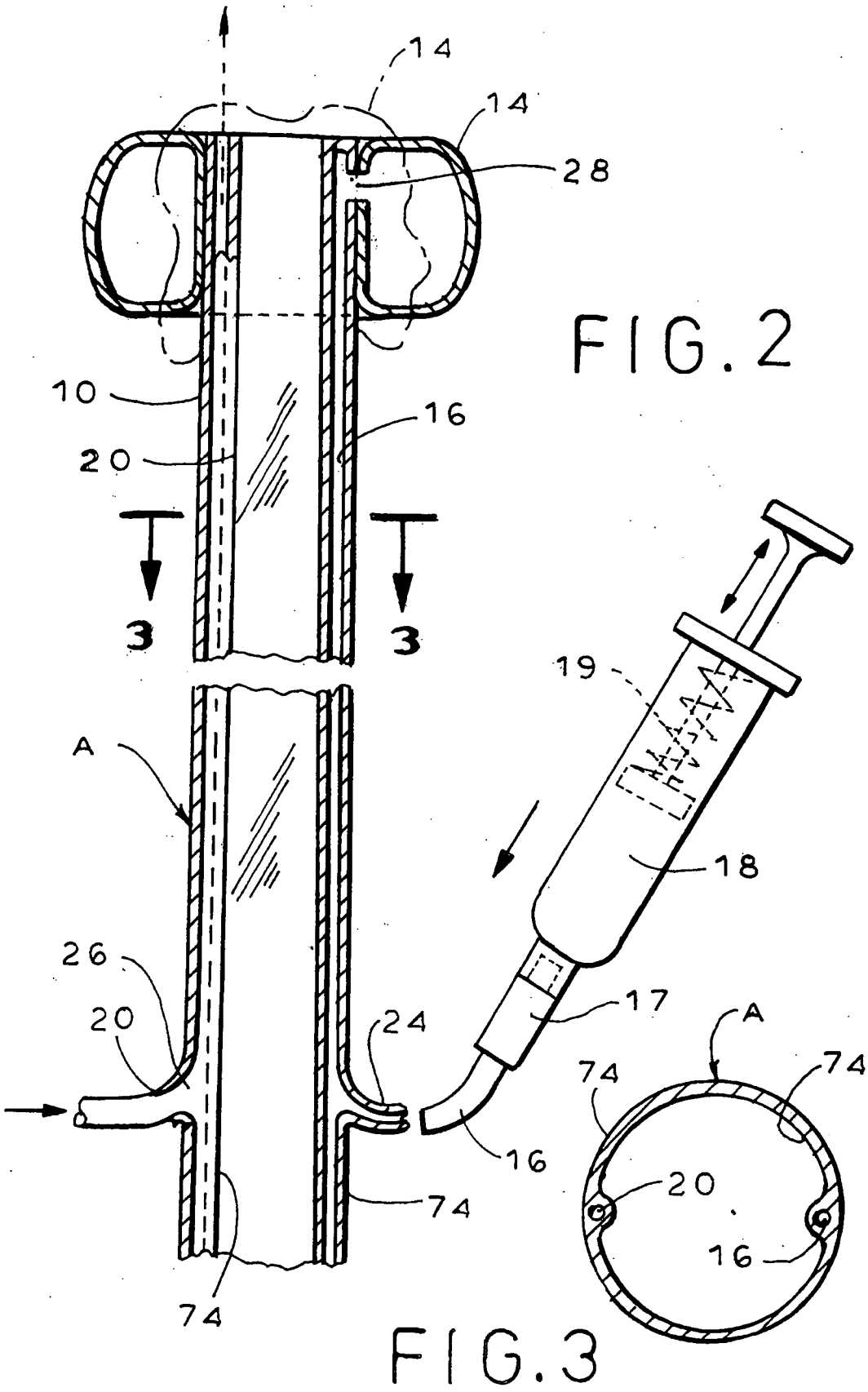

FIG. 2

FIG. 3

FIG. 4

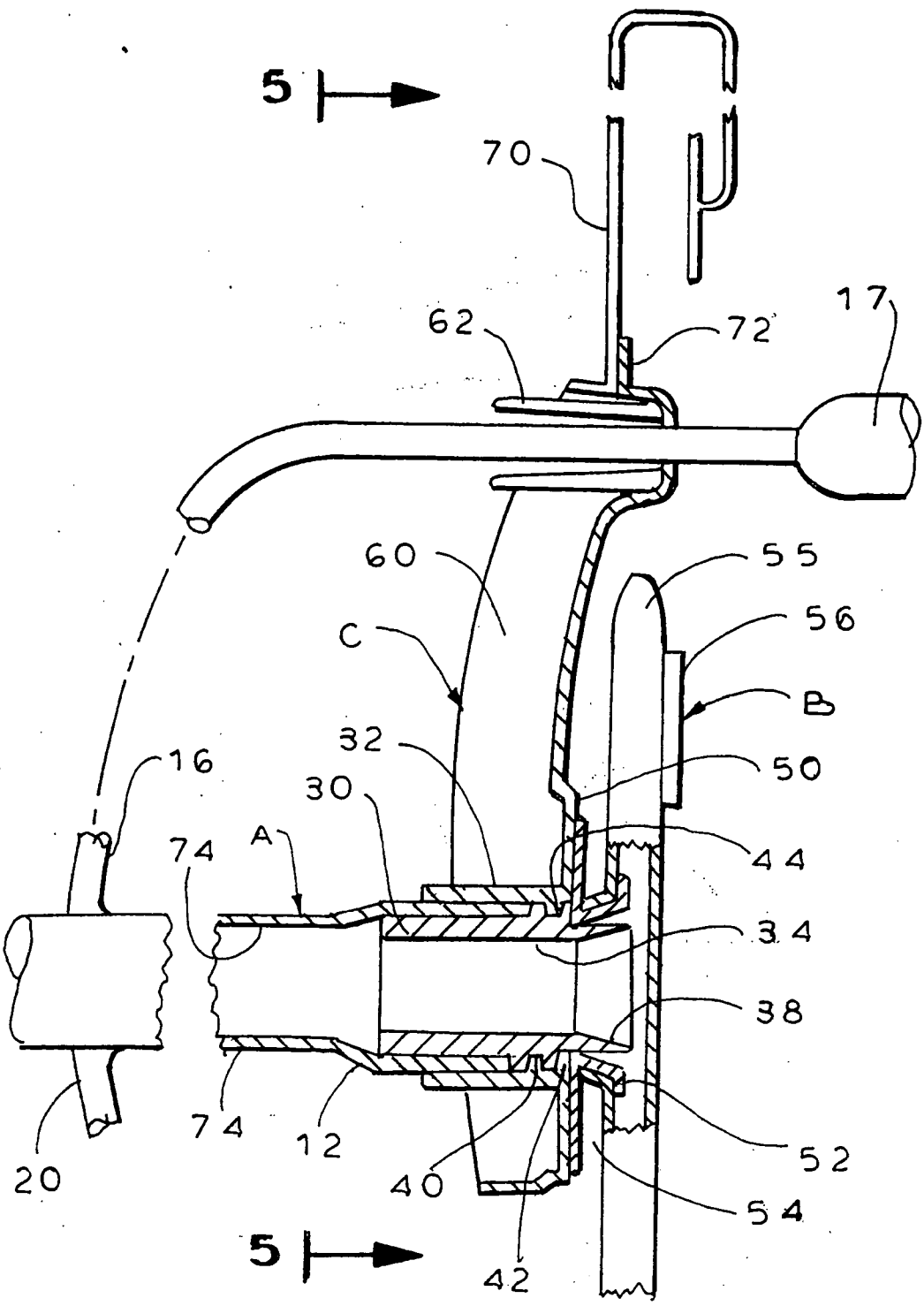

FIG. 5

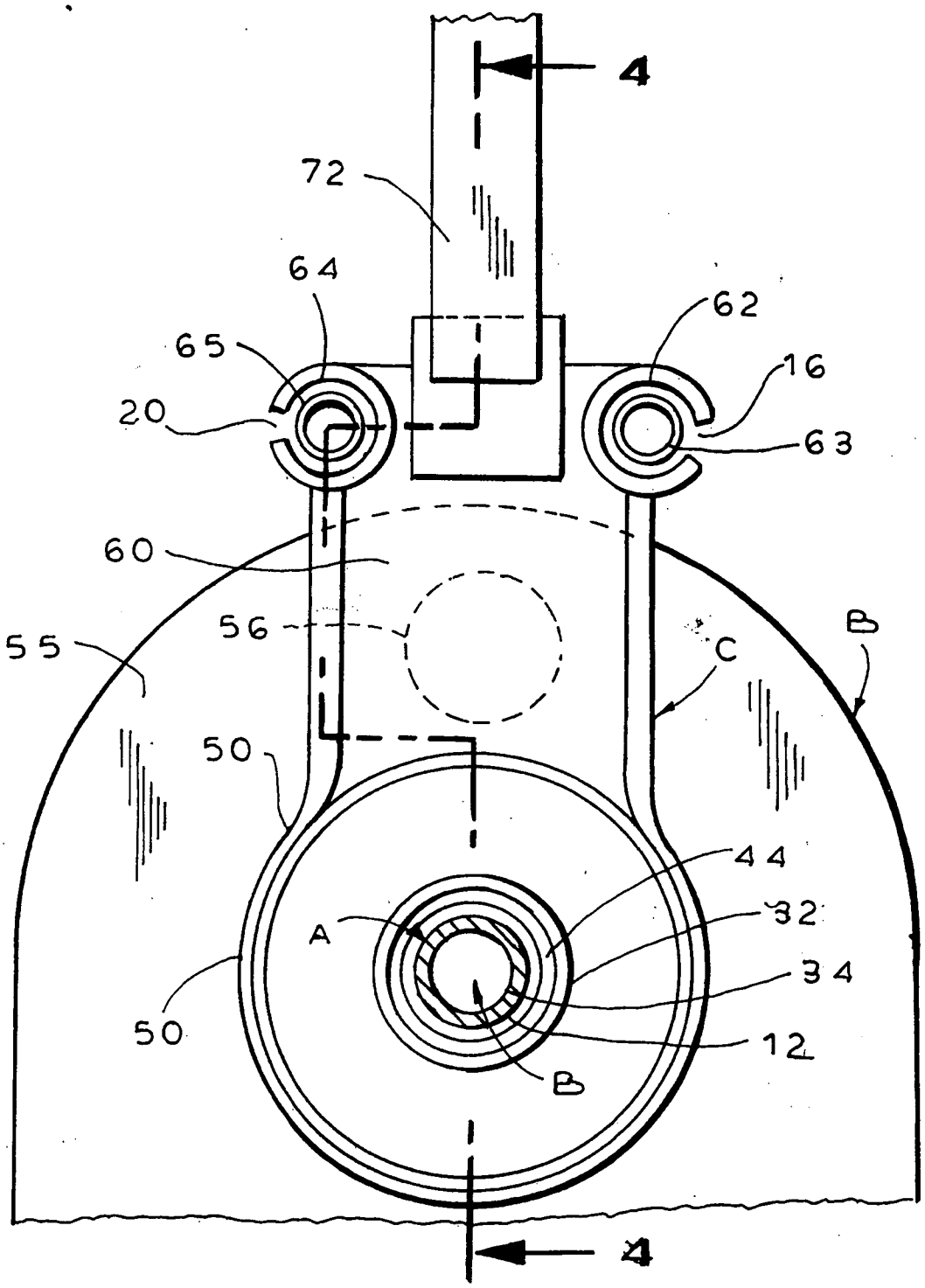

FIG. 6

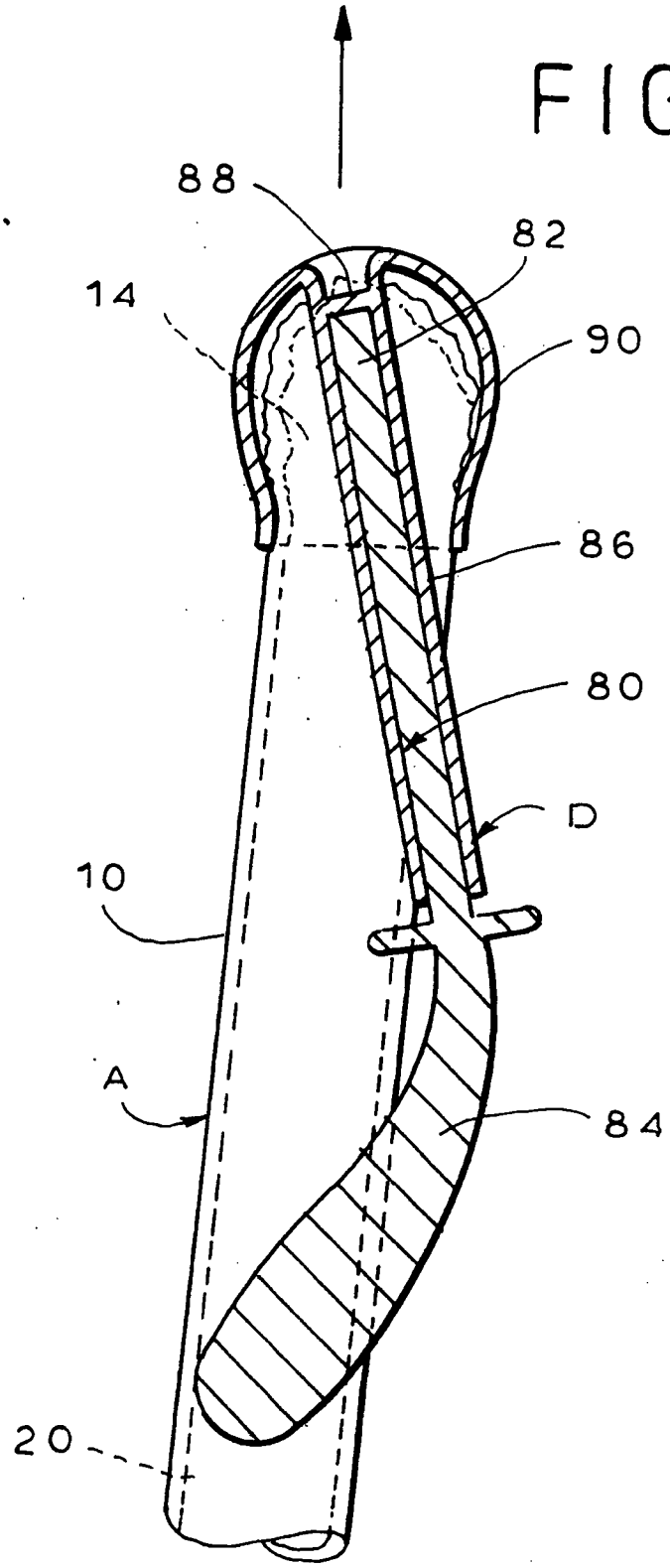

FIG. 7(a)

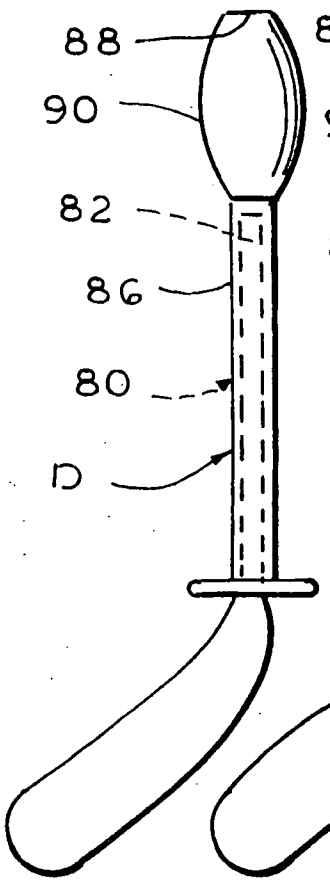

FIG. 7(b)

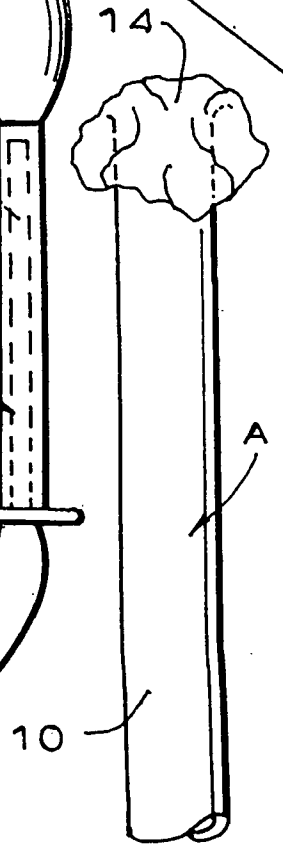

FIG. 7(c)

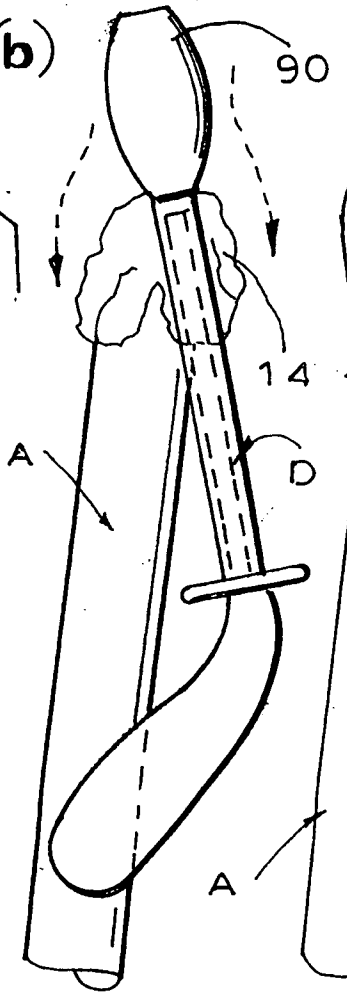

FIG. 7(d)

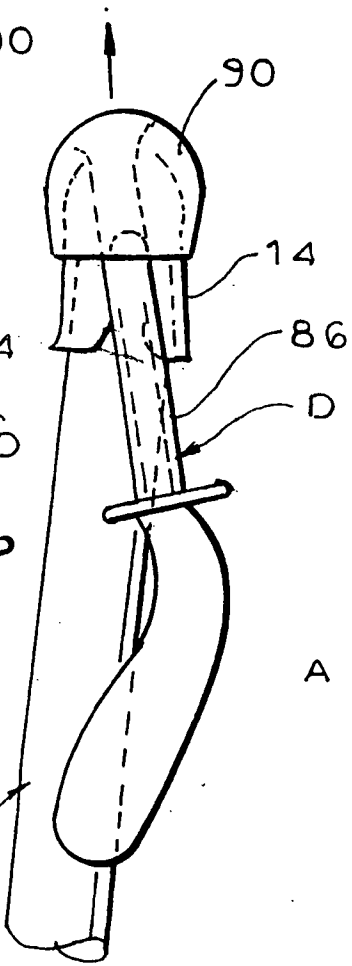

FIG. 7(e)