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(54) Title: CATHETER SYSTEM FOR CONTINUOUS IRRIGATION

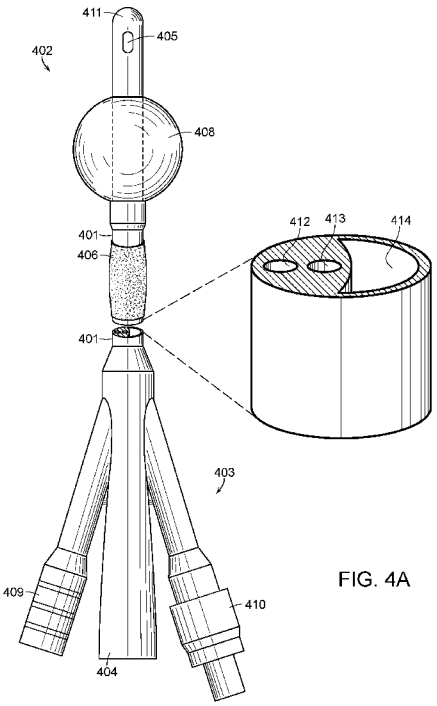

FIG. 4A

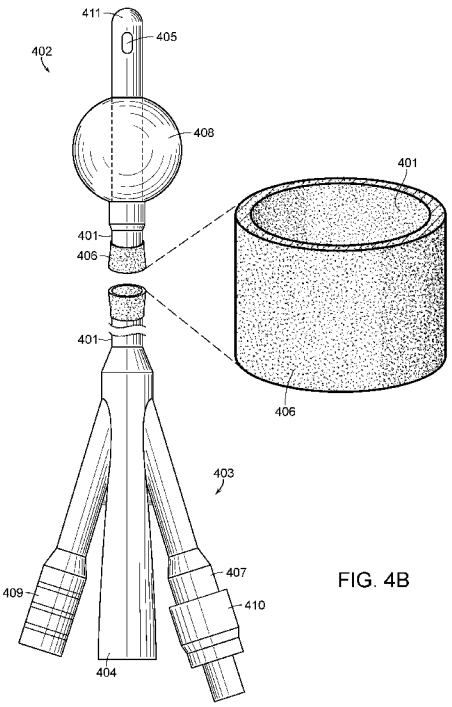

FIG. 4B

(57) Abstract: An indwelling urinary catheter system having an elongated tubular catheter body 401 having a distal end and a proximal end; at least one sleeve portion 406 constructed out of a semi-permeable membranes surrounding at least one portion of the catheter body; at least one lumen to instill fluid into the catheter body; and a means to continuously efflux the instilled fluid through the semi-permeable membrane for circumferential egress of fluid out of the membrane around the catheter body. The catheter may further include a drainage lumen 414 extending through the catheter body from just short of the distal end to the proximal end and an opening or eyelet 405 in the catheter body just short of the distal end of the catheter body to permit urine to drain from a patient's bladder into the drainage lumen. A retaining mechanism may also be comprised.

[Continued on next page]

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TITLE: CATHETER SYSTEM FOR CONTINUOUS IRRIGATION

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[0001] RELATED APPLICATIONS

[0002] This application claims priority to U.S. Provisional Application No. 62/454,829 filed February 5, 2017. The entire contents of the above application are hereby incorporated by reference as though fully set forth herein.

[0003] FIELD

[0004] The present invention pertains to a catheter, and more particularly, to intra-urethral or indwelling catheters capable of effluxing fluids.

[0005] BACKGROUND

[0006] The traditional Foley-type catheter is well known in the art and comprises an inflatable balloon disposed within the patient's bladder and a discharge tube extending through the urethra to the exterior. The Foley-type catheter provides passive urinary drainage, and the ability to clamp the catheter closed at a location exterior of the patient.

[0007] Urethral catheters, such as Foley-catheters, are used to drain urine from the bladder. A urinary tract infection (also called "UTI") is an infection in the urinary system, which includes the bladder and kidneys. When a urinary catheter is inserted into the bladder, germs can migrate along the catheter and cause an infection in the bladder or kidney; resulting in a catheter-associated urinary tract infection (or "CAUTI"). CAUTIs are the most common of hospital-acquired infections. In fact, 40% of all nosocomial

infections and over 100,000 admissions to hospital within the USA annually are attributable to CAUTIs. [1] Outcomes associated with CAUTIs include bacteremia and sepsis. While morbidity that is attributable to a single episode of catheterization is limited, the high frequency of catheter use (around 25% of hospitalized patients) means that the cumulative burden of CAUTIs on patients and hospitals is substantial.[2]

[0008] When sterile urinary catheters are inserted into the bladder, components in urine, blood, or surrounding tissue, such as polysaccharides, ions, and glycoproteins, are deposited on the surface of the device allowing the formation of biofilms. Biofilms are highly structured and actively growing bacterial communities that consist of multiple bacterial layers protected by a thick exopolysaccharide layer[3]. Biofilms are resistant to antibiotics/antimicrobials due to the fact that these agents cannot penetrate sufficiently through the exopolysaccharide layer.

[0009] According to Centers for Disease Control and Prevention (CDC), there was no change in overall catheter-associated urinary tract infections (CAUTI) rates between 2009 and 2014. (see https://www.cdc.gov/hai/surveillance/). This is not surprising, as while a variety of approaches for prevention of biofilm formation include the use of biocoatings, impregnating materials with antibiotics, antimicrobials or other

[1] D. Cardo et al. National Nosocomial Infections Surveillance (NNIS) System Report, data summary from January 1992 through June 2004, issued October 2004. Am. J. Infect. Control, 32 (2004), pp. 470–485.

[2] Lo, E. et al. (2008). Strategies to Prevent Catheter- Associated Urinary Tract Infections in Acute Care Hospitals. *Infection Control and Hospital Epidemiology, 29*(S1), S41-S50. doi:10.1086/591066

[3] Tenke, P.; Koves, B.; Nagy, K.; Hultgren, S.J.; Mendling, W.; Wullt, B.; Grabe, M.; Wagenlehner, F.M.; Cek, M.; Pickard, R.; et al. Update on biofilm infections in the urinary tract. World J. Urol. 2012, 30, 51–57.

materials as well as catheters capable of eluting antibiotics and/or antimicrobials have been used, none have been fully effective. Further, one of the major complications associated with antibiotic based coatings is the development of resistance. For example, one approach has been to attach active biocides such as antibiotics to biomaterial surfaces, or to impregnate them into the biomaterial itself by coating device surfaces or impregnating device surfaces with antibiotics such as ciprofloxacin, gentamicin, norfloxacin, and nitrofurazone. When used in clinical studies, the uncontrolled release profiles of the drugs resulted in the elution of initial high local concentrations that may initially damage the cells followed by concentrations that are not inhibitory.[4] By not killing all of the bacteria effectively, any subsequent infection will be more difficult to eradicate due to the development of resistance.

[00010] Looking at the physiology of the urethra, UTIs are generally avoided because the act of urination (voiding) flushes everything, including bacteria. Further, there are glands in urethra that secretes protecting mucus. Several drug eluting urinary catheters are known in the prior art. Drug-eluting urinary catheters generally consist of three parts - the catheter tube, a polymer coating that binds the drug to the tube and releases the drug. The drug is slowly and continuously released into the bladder or along urethra; however, there is no continual washing of the periurethral space, where bacteria adhere, form biofilms and result in bacterial infections.

[4] Walder, B.; Pittet, D.; Tramer, M.R. Prevention of bloodstream infections with central venous catheters treated with anti-infective agents depends on catheter type and insertion time: Evidence from a meta-analysis. Infect. Control Hosp. Epidemiol. 2002, 23, 748–756.

[00011] It would therefore be useful to magnify the effect of the glands in the urethra that protect from infection in the context of catheters.

[00012] **BRIEF SUMMARY OF THE INVENTION**

[00013] It is therefore one object of the present invention to provide an indwelling urinary catheter system having (1) an elongated tubular catheter body having a distal end and a proximal end; (2) at least one sleeve portion constructed substantially out of a semipermeable membranes surrounding at least one portion of the catheter body; (3) at least one lumen to instill fluid into the catheter body; and (4) a means to continuously efflux the instilled fluid through the semipermeable membrane of at least one sleeve resulting in the circumferential egress of fluid out of the semipermeable membrane around the catheter body. The catheter may further include a drainage lumen extending through the catheter body from just short of the distal end to the proximal end and an opening or eyelet in the catheter body just short of the distal end of the catheter body to permit urine to drain from a patient's bladder into the drainage lumen. The catheter body is disposed within the urethra of the patient and a retaining mechanism, such as an inflatable balloon, is disposed within the patient's bladder to retain the catheter in position. The fluid instilled into the catheter body and effluxed from the sleeve portion(s) may include, but is not limited to, antiseptics, antibiotics or antimicrobials, and/or combinations thereof to prevent biofilm formation on the exterior surface of the catheter body. The fluid may also include certain therapeutic agents used in intravesical therapy, such as immunotherapy agents or chemotherapeutic agents. The fluid may also include agents for patient comfort, such as antispasmodics and pain medicines. All such agents

can be effluxed directly into the bladder through the semipermeable sleeve portion around the catheter tip placed within the bladder.

[00014] It is another object of the present invention to provide different embodiments of the urinary catheter system that match the particular anatomical characteristics of a patient with respect to male or female anatomy. For example, a retention collar may be positioned on the catheter body for female patients or a space may be provided for the prostate for male patients.

[00015] **BRIEF DESCRIPTION OF THE DRAWINGS**

[00016] **Figure 1.** Figure 1 is cross section view of a traditional catheter for insertion into the bladder.

[00017] **Figure 2.** Figure 2 is a front perspective view of a traditional 2-way urinary catheter.

[00018] **Figure 3.** Figure 3 is a front perspective view of a traditional 3-way urinary catheter with a cutaway cross section of the catheter body.

[00019] **Figure 4A.** Figure 4A is a front perspective view of one embodiment of the urinary catheter of the present invention with a cutaway cross section of the catheter body.

[00020] **Figure 4B.** Figure 4B is a front perspective view of one embodiment of the urinary catheter of the present invention with a cutaway cross section of the sleeve section.

[00021] **Figure 5A.** Figure 5A is a front perspective view of an alternative embodiment of the urinary catheter of the present invention with a cutaway cross section of the catheter body.

[00022] **Figure 5B.** Figure 5B is a front perspective view of an alternative embodiment of the urinary catheter of the present invention with a cutaway cross section of the sleeve.

[00023] **Figure 6A.** Figure 6A is a front perspective view of an alternative embodiment of the urinary catheter of the present invention with a cutaway cross section of the catheter body.

[00024] **Figure 6B.** Figure 6B is a front perspective view of an alternative embodiment of the urinary catheter of the present invention with a cutaway cross section of the sleeve.

[00025] **Figure 7A.** Figure 7A is a cross section view of the placement of a catheter in a male.

[00026] **Figure 7B.** Figure 7B is a cross section view of the placement of a catheter in a female.

[00027] **Figure 8A.** Figure 8A is a front perspective view of one embodiment of the present invention for use in female patients.

[00028] **Figure 8B.** Figure 8B is a front perspective view of one embodiment of the present invention for use in female patients with a cutaway cross section of the sleeve.

[00029] **Figure 9A.** Figure 9A is a front perspective view of one embodiment of the present invention for use in male patients.

[00030] **Figure 9B.** Figure 9B is a front perspective view of one embodiment of the present invention for use in male patients with a cutaway cross section of the sleeve.

[00031] **Figure 10A.** Figure 10A is a front perspective view of one embodiment of the present invention with a couvelaire tip.

[00032] **Figure 10B.** Figure 10B is a front perspective view of one embodiment of the present invention with a dufour tip.

[00033] **Figure 10C.** Figure 10C is a front perspective view of one embodiment of the present invention with a coude tip.

[00034] **Figure 11A.** Figure 11A is a front perspective view of an alternative embodiment of the present invention with a couvelaire tip.

[00035] **Figure 11B.** Figure 11B is a front perspective view of an alternative embodiment of the present invention with a dufour tip.

[00036] **Figure 11C.** Figure 11C is a front perspective view of an alternative embodiment of the present invention with a coude tip.

[00037] **Figure 12A.** Figure 12A is a front perspective view of an alternative embodiment of the present invention with a couvelaire tip.

[00038] **Figure 12B.** Figure 12B is a front perspective view of an alternative embodiment of the present invention with a dufour tip.

[00039] **Figure 12C.** Figure 12C is a front perspective view of an alternative embodiment of the present invention with a coude tip.

[00040] **DETAILED DESCRIPTION**

[00041] For the purposes of the present invention, the term "semipermeable" is intended to encompass not only those materials that are semipermeable by their nature (i.e. those that allow certain substances to pass through it while not allowing other materials to pass through it) but materials that may be made semipermeable by creating

pores of a predetermined size that would allow certain substances to pass through it while not allowing other materials to pass through it.

[00042] Turning to the drawings, there shown in Fig. 1 is a traditional catheter for insertion into a cavity, duct, or a vessel to permit injection or withdrawal of fluids into or from the cavity, duct, or vessel, or to establish patency of a passageway. For example, the catheter body **16** may be inserted through a patient's urethra and into the patient's bladder **10** for draining urine from the bladder and/or instilling fluid into the bladder through slots in the tip **12** of the catheter. A retaining device, such as the balloon **14**, is used to maintain placement of the catheter in the bladder.

[00043] Turning to Fig. 2, a traditional 2-way urinary catheter is represented with a catheter body **201** having a distal end **202** and a proximal end **203** with the catheter body **201** connecting an opening or eyelet **204** at the distal end **202** to a drainage lumen **205** at the proximal end **203** of the catheter body **201** through which fluid may flow into the drainage lumen **205** when the catheter is used to drain fluid from the bladder. An inflatable tube section **206** with an inflation lumen **207** extends along the length of the catheter body **201** and communicates with the inflatable tube section **206**. Inflation fluid, such as distilled water, is passed through inflation lumen **207** into the tube section **206** to inflate the tube section **206**, and the inflation fluid is withdrawn from the tube section **206** into and through the inflation lumen **207** when it is desired to deflate the tube section **206**.

[00044] Turning to Fig. 3, a traditional 3-way urinary catheter is represented that is essentially the same as the catheter shown in Fig. 2, except it includes an instillation lumen **309** that extends from the catheter body **301** at the proximal end **303.** The fluid

instilled into the catheter body **301** is passed through tube **311** in the catheter body **301** and into the bladder through the opening or eyelet **304** and then the fluid is subsequently drained through the opening or eyelet **308** through tube **312** in the catheter body **301** and out the drainage lumen **305**. As shown in the cross section, the fluid instilled into the catheter body **301** passes through tube **311** in the catheter body. Inflation fluid is passed through inflation lumen **307** and through tube **310** to inflate the tube section **306**. Fluid that is drained through eyelet **308** at the distal end **302** passes through tube **312** and out the drainage lumen **305.**

[00045] Referring to Fig. 4A, the catheter of the present invention includes an elongated tubular catheter body **401** having a distal end **402** and a proximal end **403**. A drainage lumen **404** extends through tube **414** in the catheter body **401** from the distal end **402** to the proximal end **403**. The drainage lumen **404** communicates with an opening or eyelet **405** in the catheter body **401** at the distal end **402** of the catheter body **401** through which the fluid may flow into the drainage lumen **404** when the catheter is used to drain a fluid from a cavity, duct, or vessel (e.g., draining urine from a person's bladder). A sleeve portion **406** constructed from a semipermeable membrane is formed over the catheter body **401.** An instillation lumen **410** extends from the catheter body **401** at the proximal end **403.** The instillation lumen **410** connects with the sleeve portion **406** using tube **413** that runs through the length of the catheter body **401**. The fluid instilled into the catheter body **401** through the tube **413** is continuously effluxed from the sleeve portion **406** through the semipermeable membrane in a circumferential controlled delivery to continuously irrigate the periurethral space and the catheter body **401** to prevent formation of biofilm and further ensuing bacterial infection. The fluid may include, but is

not limited to, antiseptics, antibiotics or antimicrobials and/or combinations thereof to prevent biofilm formation on the exterior surface of the catheter body. Inflation fluid is passed through inflation lumen **409** and through tube **412** in the catheter body **401** to inflate the tube section **408**.

[00046] Turning to Fig. 4B, a cross section cutaway of the sleeve portion **406** illustrates that the sleeve circumferentially surrounds the catheter body **401**. In the preferred embodiment, the sleeve **406** is manufactured as a continuous part over the catheter body **401**. It may be secured to the catheter body **401** using methods known in the art such as adhesive attachment or heat press melting. Additionally, the sleeve **406** is preferably constructed from a non-elastic material to allow the effluxed fluid to irrigate the periurethral space without putting pressure on the urethra. In the preferred embodiment, the fluid effluxed from the sleeve **406** exits through the urethral opening and may be collected by a sponge or padded surface. Ideally around 300-500mL of fluid a day would be effluxed resulting in a collection rate in the sponge or padded surface of about 20ccs per hour. This is manageable in a hospital care setting with intermittent replacement of the sponge or padded surface.

[00047] Referring to Fig.4A, the preferred embodiment a retaining mechanism near the distal end **402** of the catheter body **401** is generally an inflatable tube section **408** with an inflation lumen **409** that extends the length of the catheter body **401** through tube **412** and communicates with the inflatable tube section **408**. Inflation fluid, such as distilled water, is passed through inflation lumen **409** into the tube section **408** to inflate the tube section **408**, and the inflation fluid is withdrawn from the tube section **408** into and through the inflation lumen **409** when it is desired to deflate the tube section **408**.

When the inflatable tube section **408** is not inflated, it lies substantially parallel along the central axis of the catheter body **401**, forming a cylinder having a diameter that substantially matches the outer diameter of the catheter body **401**.

[00048] The fluid instilled into the catheter body **401** and effluxed out of the semipermeable membrane sleeve **406** of the catheter body may be pushed through the device using various mechanisms, including but not limited to, a pressure and flow regulating valve to control rate of flow for a specific fluid at a specific pressure that is installed at the effluxing instillation lumen **410** or using a pump tension device, such as a plastic ball that is blown up and then pushes fluid out at a constant rate. It is also contemplated that an intravenous (IV) pump operating at a continuous rate may also be used to move fluid through the instillation lumen **410** and out of the semipermeable membrane of the sleeve portion **406**. Again, the rate would be predetermined based on the semipermeable membrane material as well as the molecular weight cut off (MWCO) of the agent instilled into the catheter and effluxed through the semipermeable membrane to ensure that the agent is being pushed with sufficient pressure and at a sufficient rate to effectively continuously wash the periurethral space around the catheter body **401**.

[00049] It is further contemplated that a drug eluting portion could be located within the tip **411** of catheter body **401** that goes into the bladder that could be used to deliver drugs to the bladder itself, such as an antispasmodic, pain medicines, antibiotics, antiseptics, antimicrobials and combinations thereof.

[00050] Turning to Fig. 5A, an alternative embodiment of the present invention is represented with an elongated tubular catheter body **501** having a distal end **502** and a proximal end **503**. A drainage lumen **504** extends through tube **513** in the catheter body

501 from the distal end **502** to the proximal end **503**, and the drainage lumen **503** communicates with an opening or eyelet **505** in the catheter body **501** at the distal end **502** of the catheter body **501** through which the fluid may flow into the drainage lumen **504** when the catheter is used to drain a fluid from a cavity, duct, or vessel (e.g., draining urine from a person's bladder). The retaining mechanism in this example is an inflatable tube section **507** with an inflation lumen **508** that extends though the length of the catheter body **501** though tube **511** and communicates with the inflatable tube section **507**. Inflation fluid, such as distilled water, is passed through inflation lumen **508** into the tube section **507** to inflate the tube section **507**, and the inflation fluid is withdrawn from the tube section **507** into and through the inflation lumen **508** when it is desired to deflate the tube section **507**. When the inflatable tube section **507** is not inflated, it lies substantially parallel along the central axis of the catheter body **501**, forming a cylinder having a diameter that substantially matches the outer diameter of the catheter body **501**.

[00051] A sleeve portion **506** constructed from a semipermeable membrane is formed over the catheter body **501** above the tube section **507**. An instillation lumen **509** extends from the catheter body **501** at the proximal end **504.** The instillation lumen **509** connects with the sleeve portion **506** using tube **512** that runs through the length of the catheter body **501.** The fluid instilled into the catheter body **501** through the tube is continuously effluxed from the sleeve portion **506** through the semipermeable membrane and into the bladder.

[00052] Turning to Fig. 5B, a cross section cutaway of the sleeve portion **506** illustrates that the sleeve circumferentially surrounds the catheter body **501**. In the preferred embodiment, the sleeve **506** is manufactured as a continuous part over the

catheter body **501**. It may be secured to the catheter body **501** using methods known in the art such as adhesive attachment or heat press melting. The fluid effluxed through the sleeve **506** includes, but is not limited to, certain therapeutic agents used in intravesical therapy, such as immunotherapy agents or chemotherapeutic agents, as well as antispasmodic agents and numbing agents such as lidocaine. The semipermeable membrane of the sleeve **506** allows certain substances to pass through it but not others, such as allowing fluids to efflux out of the sleeve **506** but not allowing bacteria or other contaminants into the sleeve **506**. The semipermeable membrane also allows the use of a small amount of fluid everywhere circumfrentially along the length of the catheter body portion in the bladder as well as into the bladder space. The pore size of the semipermeable membrane is predetermined based on the agent instilled into the catheter and effluxed from the semipermeable membrane to ensure that the agent may pass through the semipermeable membrane of the sleeve **506** and may be effluxed with sufficient pressure and at a sufficient rate to effectively continuously wash the bladder with the fluid. This method is a superior mechanism to deliver therapies such as antispasmodic agents and numbing agents than an instillation performed using a traditional catheter. With a traditional catheter, instillations are performed on an intermittent basis wherein the medicine is delivered through a single lumen catheter and then removed. The patient then voids the bladder to remove the medicine. The present invention allows the medicine to be slowly effluxed into the bladder at a continuous rate. This is especially useful after transurethral surgery on a patient. The catheter of the present invention can be placed shortly after surgery so that a drug, such as an

antispasmodic or pain medication, may be effluxed from the sleeve **506** for the next four to six hours, resulting in steady patient pain and discomfort management.

[00053] The fluid instilled into the catheter body and effluxed out of the semipermeable membrane of the sleeve portion **506** over the catheter body **501** and into the bladder may be pushed through the device using various mechanisms, including but not limited to, a pressure and flow regulating valve to control rate of flow for a specific fluid at a specific pressure that is installed at the effluxing instillation lumen port **510** or using a pump tension device, such as a plastic ball that is blown up and it then pushes fluid out at a constant rate. It is also contemplated that an intravenous (IV) pump operating at a continuous rate may also be used to move fluid through the instillation lumen and out of the semipermeable membrane of the sleeve portion **506**. Again, the rate would be predetermined based on the agent instilled into the catheter and effluxed from the semipermeable membrane to ensure that the agent is being pushed with sufficient pressure and at a sufficient rate to effectively continuously wash the bladder space.

[00054] Turning to Figs. 6A-B, another embodiment of the present invention uses both sleeve portions of Figs. 4-5. This results in a 4 way catheter capable of both effluxing fluid to continuously irrigate the periurethral space as well as effluxing fluid to continuously wash the bladder space.

[00055] As shown in Fig. 6A an elongated tubular catheter body **601** having a distal end **602** and a proximal end **603**. A drainage lumen **604** extends through tube **617** in the catheter body **601** from the distal end **602** to the proximal end **603**, and the drainage lumen **604** communicates with an opening or eyelet **605** in the catheter body **601** at the distal end **602** of the catheter body **601** through which the fluid may flow into

the drainage lumen **604** when the catheter is used to drain a fluid from a cavity, duct, or vessel (e.g., draining urine from a person's bladder). A first sleeve portion **606** constructed from a semipermeable membrane is formed over the catheter body **601.** An instillation lumen **607** extends from the catheter body **601** at the distal end **602.** The instillation lumen **607** connects with the first sleeve portion **606** using tube **616** that runs through the length of the catheter body **601.** The fluid instilled into the catheter body **601** through the tube is continuously effluxed from the sleeve portion **606** through the semipermeable membrane in a circumferential controlled delivery to continuously irrigate the periurethral space and the catheter body **601** to prevent formation of biofilm and further ensuring bacterial infection. The fluid may include, but is not limited to, antiseptics, antibiotics or antimicrobials and/or combinations thereof to prevent biofilm formation on the exterior surface of the catheter body.

[00056] A second sleeve portion **609** constructed from a semipermeable membrane is formed over the catheter body **601** above the tube section **610**. An instillation lumen **611** extends from the catheter body **601** at the distal end **602.** The instillation lumen **611** connects with the sleeve portion **609** using tube **618** that runs through the length of the catheter body **601** The fluid instilled into the catheter body **601** through the tube **618** is continuously effluxed from the sleeve portion **609** through the semipermeable membrane and into the bladder itself.

[00057] The fluid effluxed through the sleeve **609** includes, but is not limited to, certain therapeutic agents used in intravesical therapy such as immunotherapy agents or chemotherapeutic agents, antispasmodic agents and numbing agents, such as lidocaine.

[00058] The fluid instilled into the catheter body and effluxed out of the semipermeable membrane of the sleeve portions **606** and **609** may be pushed through the device using various mechanisms, including but not limited to, pressure and flow regulating valves to control rate of flow for a specific fluid at a specific pressure that is installed at the effluxing instillation lumen ports **607** and **611,** or using a pump tension device, such as a plastic ball that you blow up and it then pushes fluid out at a constant rate. It is also contemplated that an intravenous (IV) pump operating at a continuous rate may also be used to move fluid through the instillation lumens **607** and **611** and out of the semipermeable membrane of the sleeve portions **606** and **609**, respectively. Again, the rate would be predetermined based on the agent instilled into the catheter and effluxed from the semipermeable membrane to ensure that the agent is being pushed with sufficient pressure and at a sufficient rate to effectively continuously wash the periuretheral and bladder spaces.

[00059] Turning to Fig. 6B, a cross section cutaway of the sleeve portions **606** and **609** illustrates that the sleeve circumferentially surrounds the catheter body **601**. In the preferred embodiment, the sleeve portions **606** and **609** are manufactured as continuous parts over the catheter body **601**. They may be secured to the catheter body **601** using methods known in the art such as adhesive attachment or heat press melting.

[00060] Turning to Fig. 7A-B, the differences in anatomy for the placement of a urinary catheter are shown. The male anatomy of Fig. 7A results in a larger portion of the catheter body in the periurethral space than the female counterpart. Fig. 7A shows the bladder **701**, rectum **702**, pubic bone **703**, prostate **704**, urethra **705** and the catheter **706.**

The catheter **706** must also be fed past the prostate **704** in males before it can be retained in the bladder **701**. The female anatomy of Fig. 7B results in a shorter portion of the catheter body needed to fill the periurethral space. Fig. 7B shows the bladder **707**, rectum **708**, pubic bone **709**, vagina **710**, urethra **711** and catheter **712**.

[00061] Taking these anatomical differences into consideration, Fig. 8A-B shows the distal end of the catheter of Fig. 4 as used for female anatomy whereas Fig. 9A-B shows the distal end of the catheter of Fig. 5 as used for male anatomy. The sleeve portion **801** of Fig. 8A-B is shorter than the sleeve portion **901** of Fig. 9A-B. Additionally, there is a larger space **903** between the sleeve portion **901** and the inflatable portion **902** than the space **803** between the sleeve portion **801** and the inflatable portion **802**, which accommodates placement of the catheter in the presence of the prostate.

[00062] As shown in Figs. 10A-C, one embodiment of the invention shown in Figs. 4A-B with sleeve portion **1001**, catheter body **1002**, retaining device **1003**, drainage eyelet **1004** and alternative instillation eyelet **1005** may have various shapes to the end that is inserted into the bladder. For example, Fig. 10 A shows a couvelaire tip, Fig. 10B shows a dufour tip and Fig. 10C shows a coude tip.

[00063] As shown in Figs. 11A-C, one embodiment of the invention shown in Figs. 5A-B with sleeve portion **1006**, catheter body **1002**, retaining device **1003**, drainage eyelet **1004** and alternative instillation eyelet **1005** may have various shapes to the end that is inserted into the bladder. For example, Fig. 11 A shows a couvelaire tip, Fig. 11B shows a dufour tip and Fig. 11C shows a coude tip.

[00064] As shown in Figs. 12A-C, one embodiment of the invention shown in Figs. 6A-B with sleeve portions **1001** and **1006**, catheter body **1002**, retaining device

1003, drainage eyelet **1004** and alternative instillation eyelet **1005** may have various shapes to the end that is inserted into the bladder. For example, Fig. 12 A shows a couvelaire tip, Fig. 12B shows a dufour tip and Fig. 12C shows a coude tip.

[00065] It is necessary for the fluid to be effluxed continuously at a basal rate to effect the continual washing of the periurethral space, where bacteria adhere, to prevent formation of biofilms and resulting bacterial infections. However, it is also contemplated that the fluid may be continuously effluxed from the semipermeable membrane(s) in a peristaltic wave action along the length of the catheter body in addition to the basal rate.

[00066] For the purposes of promoting an understanding of the principles of the invention, reference has been made to the preferred embodiments illustrated in the drawings, and specific language has been used to describe these embodiments. However, this specific language intends no limitation of the scope of the invention, and the invention should be construed to encompass all embodiments that would normally occur to one of ordinary skill in the art. The particular implementations shown and described herein are illustrative examples of the invention and are not intended to otherwise limit the scope of the invention in any way. For the sake of brevity, conventional aspects of the method (and components of the individual operating components of the method) may not be described in detail. Furthermore, the connecting lines, or connectors shown in the various figures presented are intended to represent exemplary functional relationships and/or physical or logical couplings between the various elements. It should be noted that many alternative or additional functional relationships, physical connections or logical connections might be present in a practical device. Moreover, no item or component is essential to the practice of the invention unless the element is specifically described as

"essential" or "critical". Numerous modifications and adaptations will be readily apparent to those skilled in this art without departing from the spirit and scope of the present invention.

What is claimed is:

1. A urinary catheter assembly comprising:
    a. an elongate catheter body having a proximal end and a distal end,
    b. a first sleeve portion constructed substantially out of a semipermeable membrane and disposed on an outer surface of at least one portion of the catheter body;
    c. a first instillation lumen at the distal end of the catheter body in fluid communication with the first sleeve portion; and
    d. a means to continuously and circumferentially efflux a first fluid flowing through the first instillation lumen and out of the semipermeable membrane of the first sleeve.

2. The urinary catheter assembly according to claim 1 further comprising a retaining mechanism towards the distal end of the catheter body.

3. The urinary catheter assembly according to claim 2 wherein the first sleeve portion is between the proximal end of the catheter body and the retaining mechanism.

4. The urinary catheter assembly according to claim 3 wherein the first fluid is selected from the group comprising antiseptics, antibiotics, antimicrobials or combinations thereof.

5. The urinary catheter assembly according to claim 2 wherein the first sleeve portion is between the distal end of the catheter body and the retaining mechanism

6. The urinary catheter assembly according to claim 5 wherein the first fluid is selected from the group comprising immunotherapeutic agents, chemotherapeutic agents, antiseptics, antibiotics, antimicrobials or combinations thereof.

7. The urinary catheter assembly according to claim 2 wherein the first sleeve portion is at the tip of the distal end of the catheter body

8. The urinary catheter assembly according to claim 7 wherein the first fluid is selected from the group comprising antispasmodics, non-narcotic analgesics, nonsteroidal anti–inflammatory drugs (NSAIDs), narcotic pain medications, antibiotics, antiseptics, antimicrobial, immunotherapeutic agents, chemotherapeutic agents or combinations thereof.

9. The urinary catheter assembly according to any one of the preceding claims wherein the catheter body and first sleeve portion are integrally constructed.

10. The urinary catheter assembly according to any one of the preceding claims further comprising a means to regulate a flow rate and a pressure of the first fluid effluxing through the first sleeve.

11. The urinary catheter assembly according to claim 10 wherein the means to regulate the flow rate and the pressure of the first fluid effluxing through the first sleeve is a pressure and flow regulating valve.

12. The urinary catheter assembly according to claim 10 wherein the means to regulate the flow rate and the pressure of the first fluid effluxing through the first sleeve is a pump tension device.

13. The urinary catheter assembly according to claim 10 wherein the means to regulate the flow rate and the pressure of the first fluid effluxing through the first sleeve is an intravenous (IV) pump operating at a continuous rate.

14. The urinary catheter assembly according to any one of claims 10 to 13 wherein the flow rate and the pressure is predetermined based on the material used for the semipermeable membrane and calculated based on a molecular weight cut off (MWCO) of the fluid instilled through the first instillation lumen.

15. The urinary catheter assembly according to any one of the preceding claims wherein the pore size of the semipermeable membrane of the first sleeve is predetermined and calculated based on a molecular weight cut off (MWCO) of the fluid instilled through the first instillation lumen.

16. The urinary catheter assembly according to any one of the preceding claims further comprising:
    a. a second sleeve portion constructed substantially out of a semipermeable membrane and disposed on an outer surface of at least one portion of the catheter body;
    b. a second instillation lumen at the distal end of the catheter body in fluid communication with the second sleeve portion; and
    c. a means to continuously and circumferentially efflux a second fluid flowing through the second instillation lumen and out of the semipermeable membrane of the second sleeve.

17. The urinary catheter assembly according to claim 16 wherein the first sleeve portion is between the proximal end of the catheter body and the retaining mechanism.

18. The urinary catheter assembly according to claim 17 wherein the first fluid is selected from the group comprising antiseptics, antibiotics, antimicrobials or combinations thereof.

19. The urinary catheter assembly according to claim 16 wherein the second sleeve portion is between the distal end of the catheter body and the retaining mechanism.

20. The urinary catheter assembly according to claim 19 wherein the second fluid is selected from the group comprising immunotherapeutic agents, chemotherapeutic agents, antiseptics, antibiotics, antimicrobials or combinations thereof.

21. The urinary catheter assembly according to any one of claims 16, 19 or 20 wherein the catheter body and second sleeve portion are integrally constructed.

22. The urinary catheter assembly according to any one of claims 16 , 19, 20 or 21 further comprising a means to regulate a flow rate and a pressure of the second fluid effluxing through the second sleeve.

23. The urinary catheter assembly according to claim 22 wherein the means to regulate the flow rate and the pressure of the second fluid effluxing through the second sleeve is a pressure and flow regulating valve.

24. The urinary catheter assembly according to claim 22 wherein the means to regulate the flow rate and the pressure of the second fluid effluxing through the second sleeve is a pump tension device.

25. The urinary catheter assembly according to claim 22 wherein the means to regulate the flow rate and the pressure of the second fluid effluxing through the second sleeve is an intravenous (IV) pump operating at a continuous rate.

26. The urinary catheter assembly according to and one of claims 23 to 25 wherein the flow rate and the pressure is predetermined based on the material used for the semipermeable membrane and calculated based on a molecular weight cut off (MWCO) of the fluid instilled through the second instillation lumen.

27. The urinary catheter assembly according to claim any one of claims 16 to 26 wherein the pore size of the semipermeable membrane of the second sleeve is predetermined and calculated based on the molecular weight cut off (MWCO) of the fluid instilled through the second instillation lumen.

28. The urinary catheter assembly according to any one of the preceding claims further comprising a drainage lumen and at least one drainage opening at the distal end of the catheter body, wherein the lumen extends through the catheter body and is in fluid communication with the at least one drainage opening.

29. A sleeve constructed from a semipermeablee, non-elastic membrane for use with a catheter having a proximal and distal end wherein the sleeve is disposed on the outer surface of at least one portion of the catheter body such that a fluid is continuously and circumferentially effluxed out of the sleeve and around the catheter body.

30. The sleeve according to claim 29 wherein a flow rate and a pressure of the fluid effluxed out of the sleeve is predetermined based on the material used for the semipermeable membrane and calculated based on the molecular weight cut off (MWCO) of the fluid.

31. The sleeve according to claims 29 or 30 wherein a pore size of the semipermeable membrane of the sleeve is predetermined and calculated based on the molecular weight cut off (MWCO) of the fluid.

32. The sleeve according to any one of claim 29, 30 and 31 wherein the continuously and circumferentially effluxed fluid moves along the catheter body in a peristaltic wave.

33. The sleeve according to claims 29, 30 or 31 wherein the fluid is selected from the group comprising antiseptics, antibiotics, antimicrobials, immunotherapeutic agents, chemotherapeutic agents, antispasmodics, non-narcotic analgesics, nonsteroidal anti–inflammatory drugs (NSAIDs), narcotic pain medications, or combinations thereof.

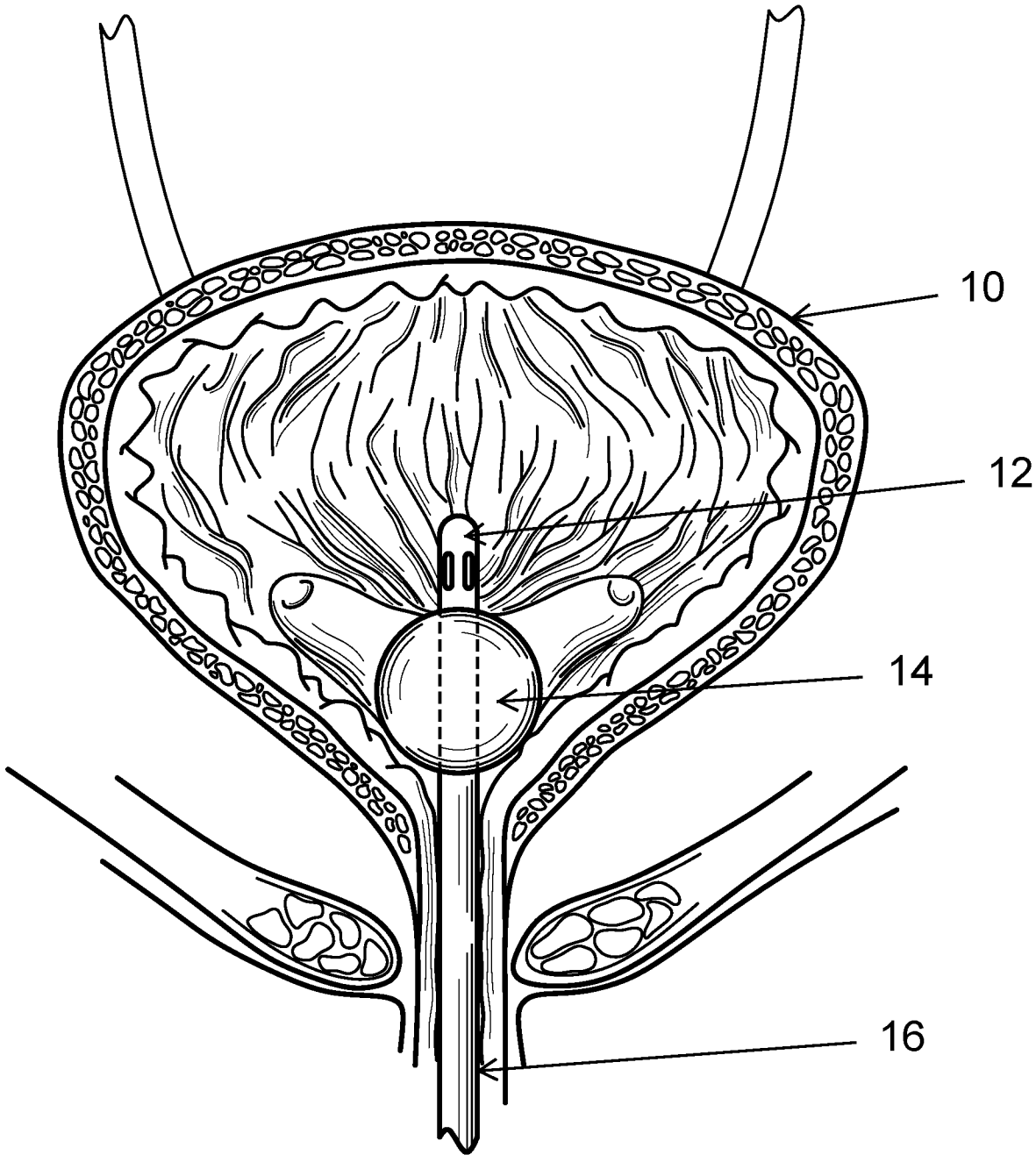

FIG. 1

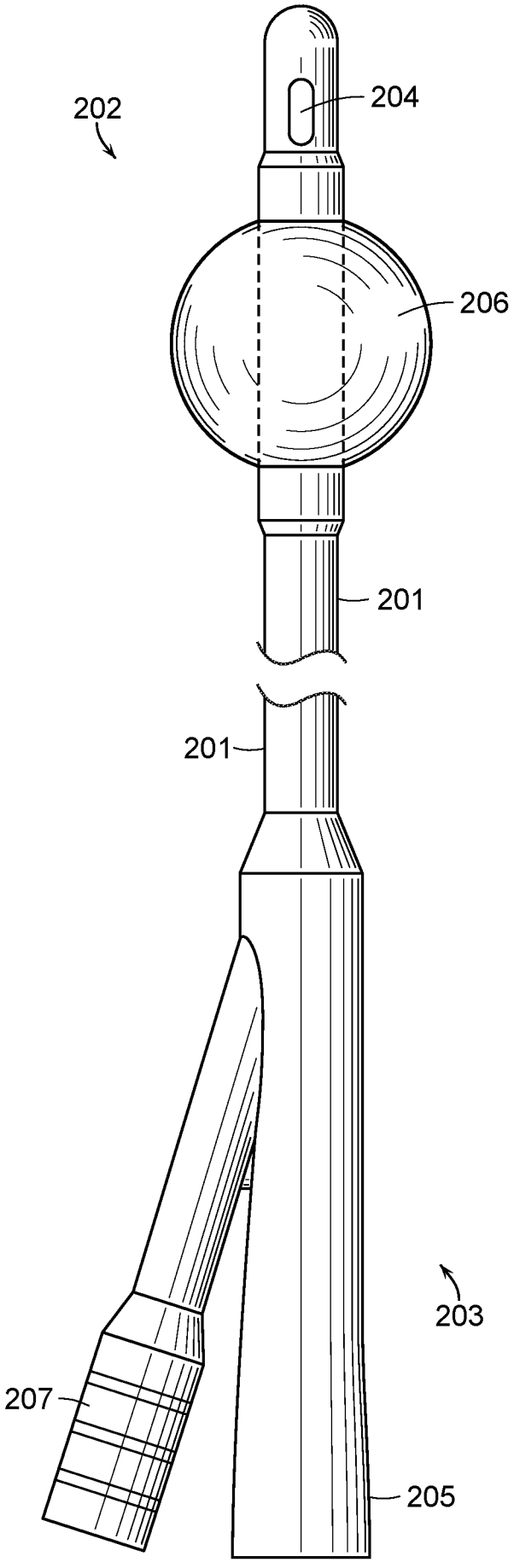

FIG. 2

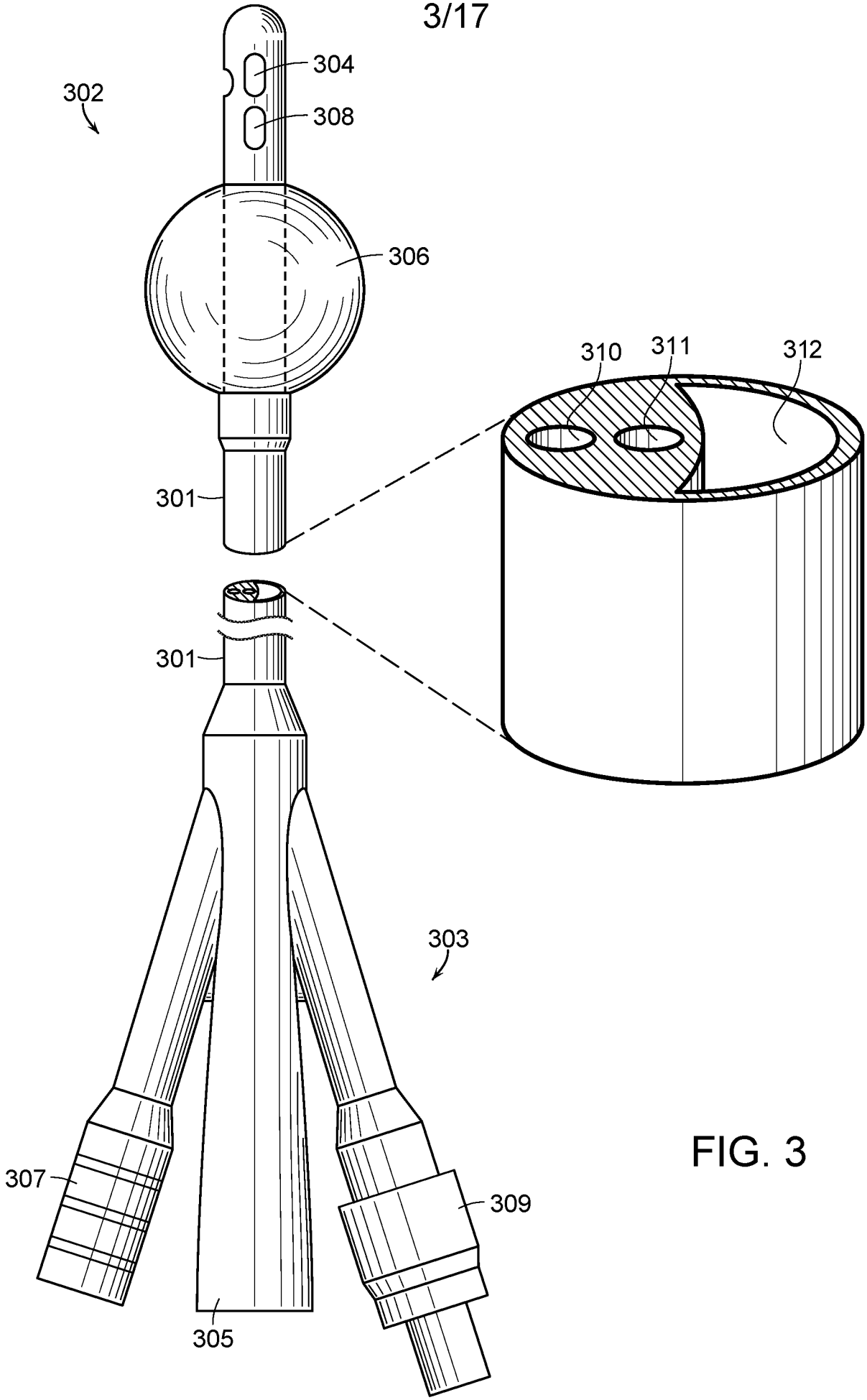

FIG. 3

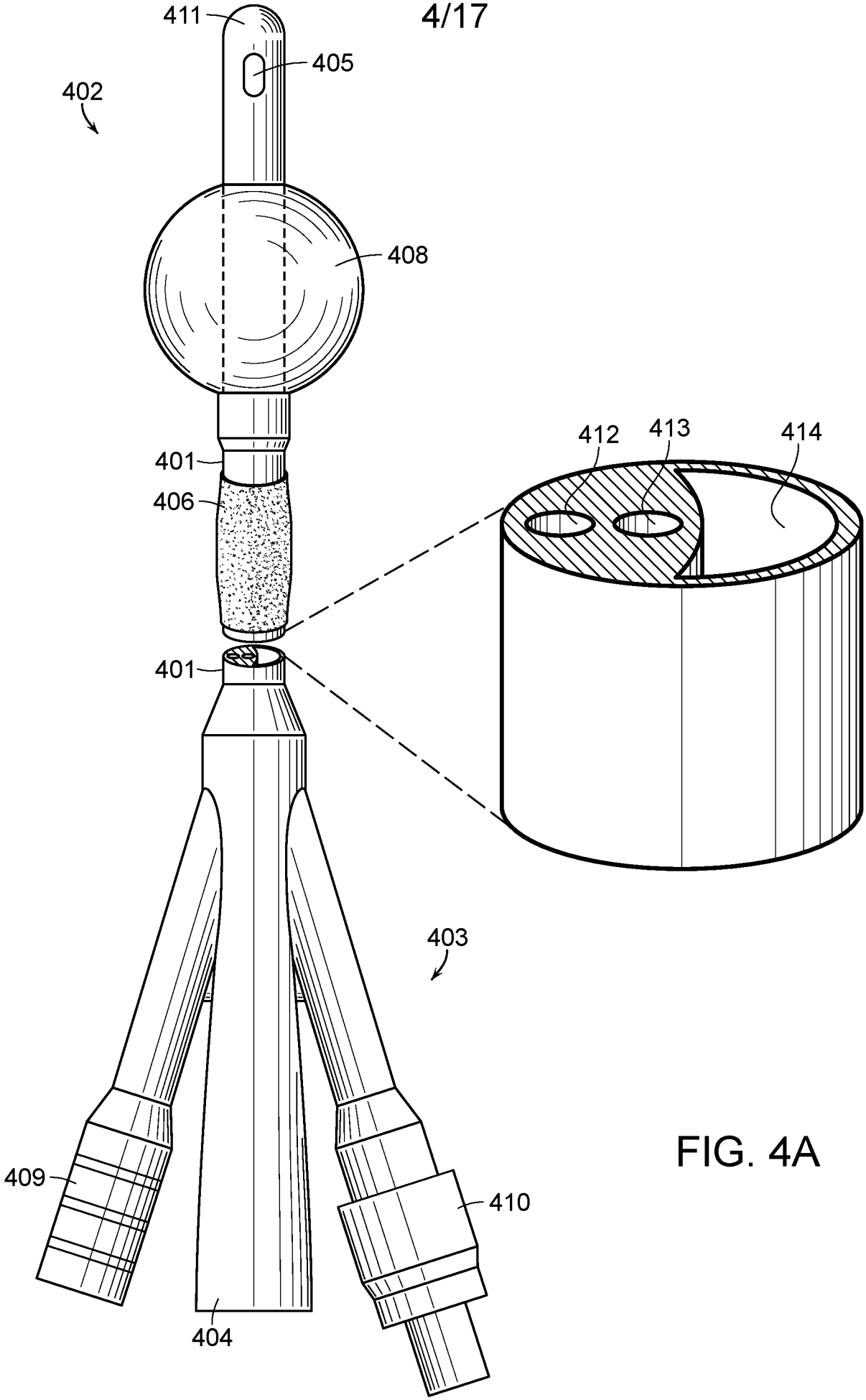

FIG. 4A

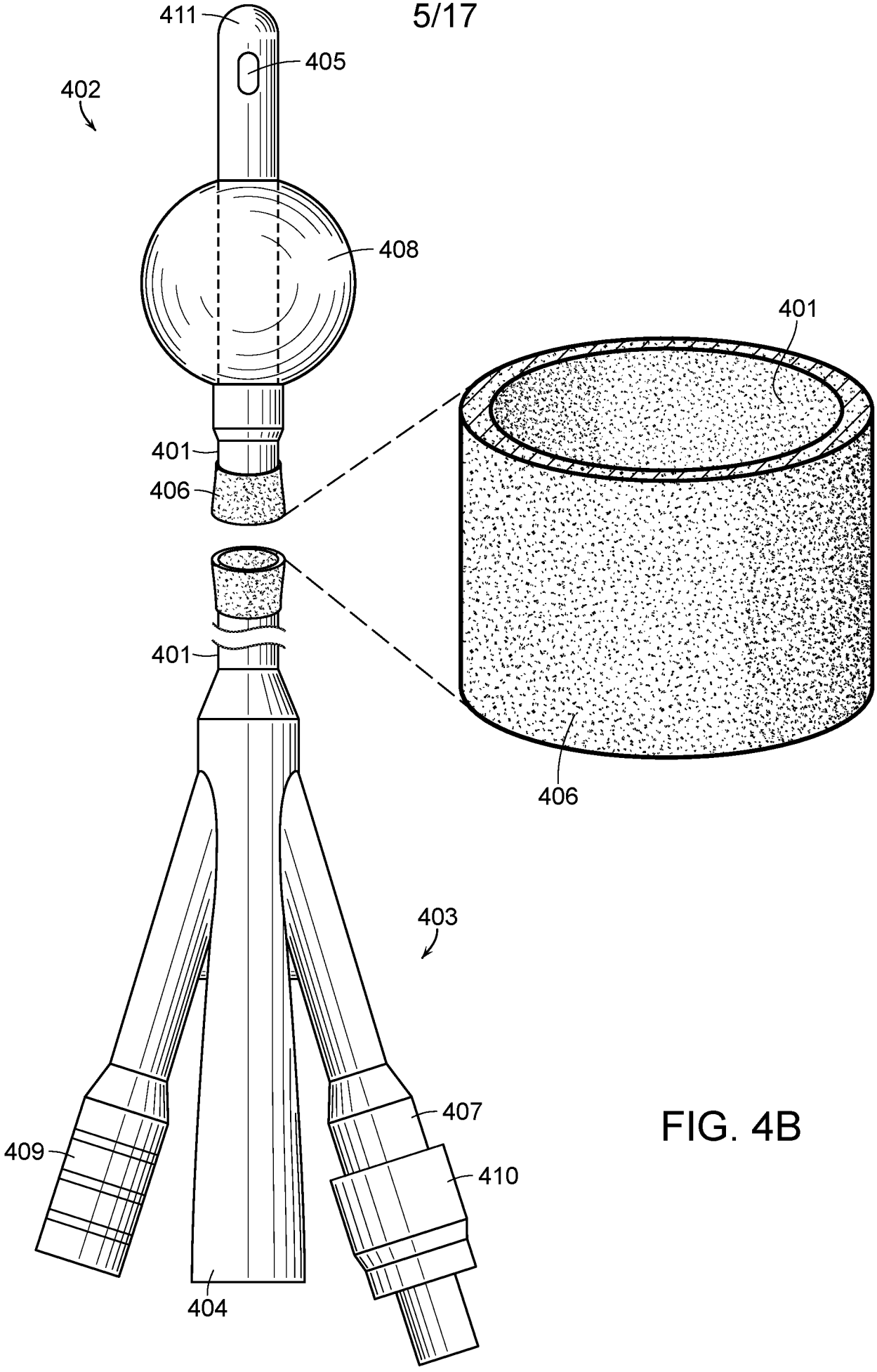

FIG. 4B

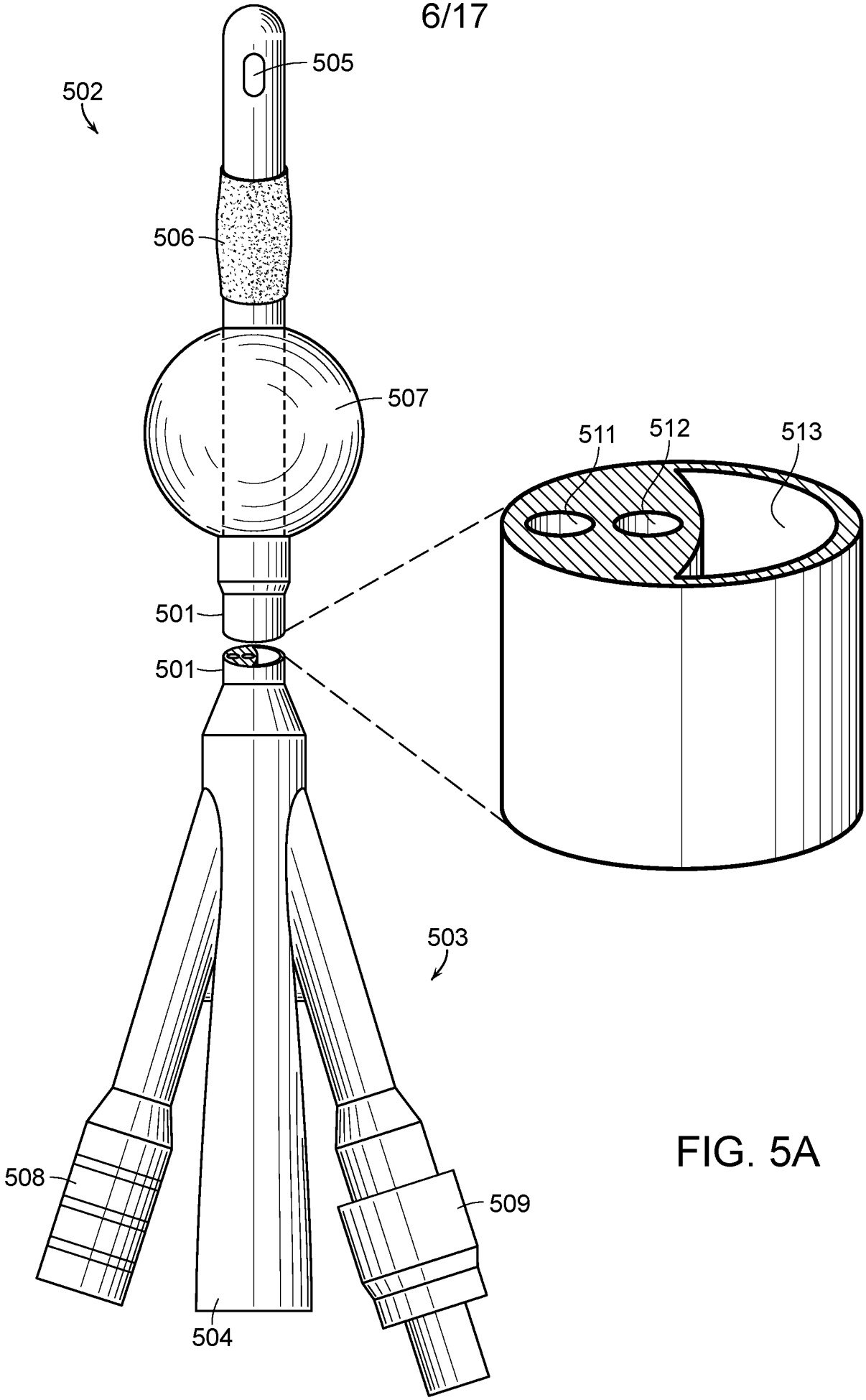

FIG. 5A

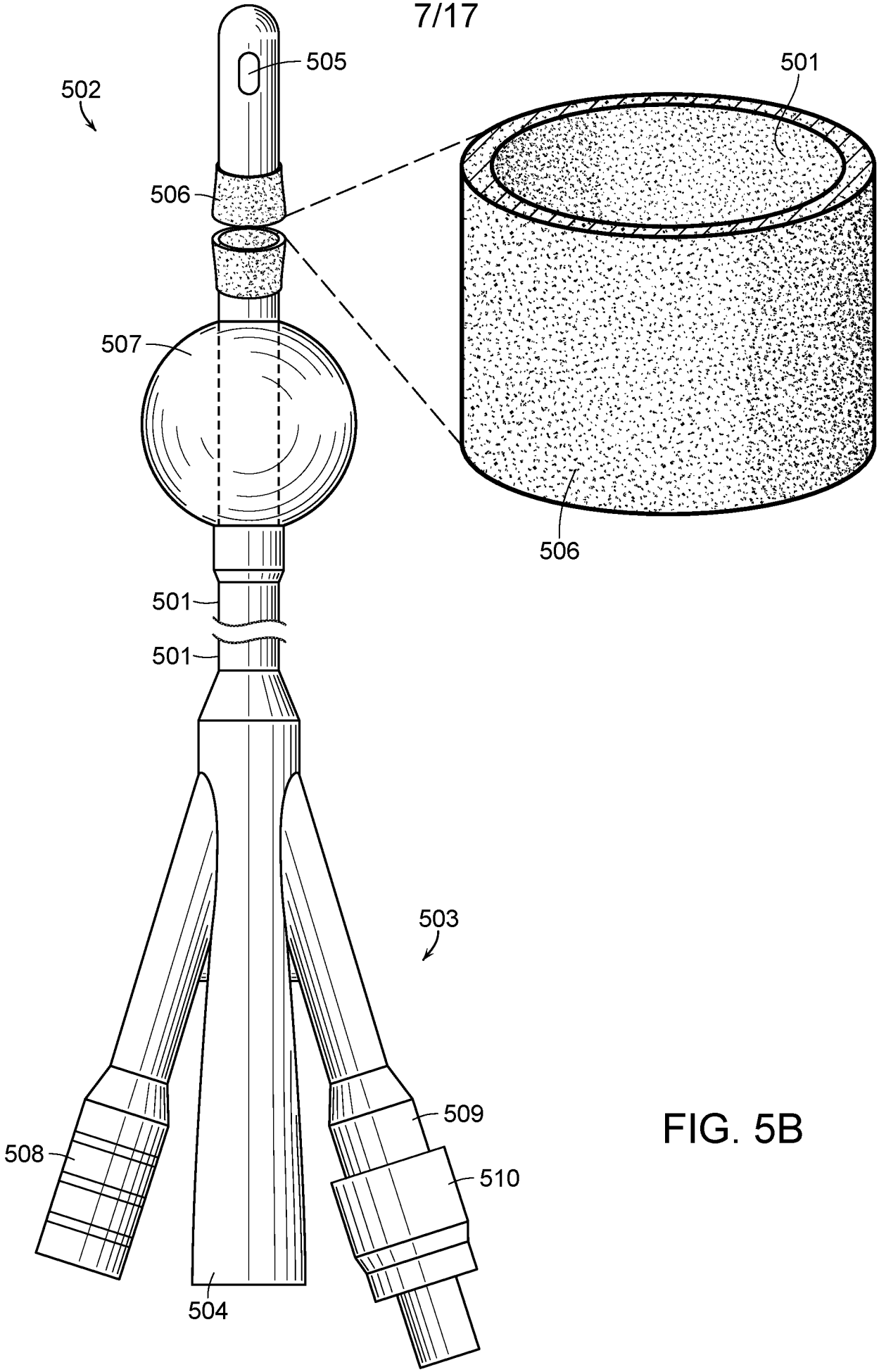

FIG. 5B

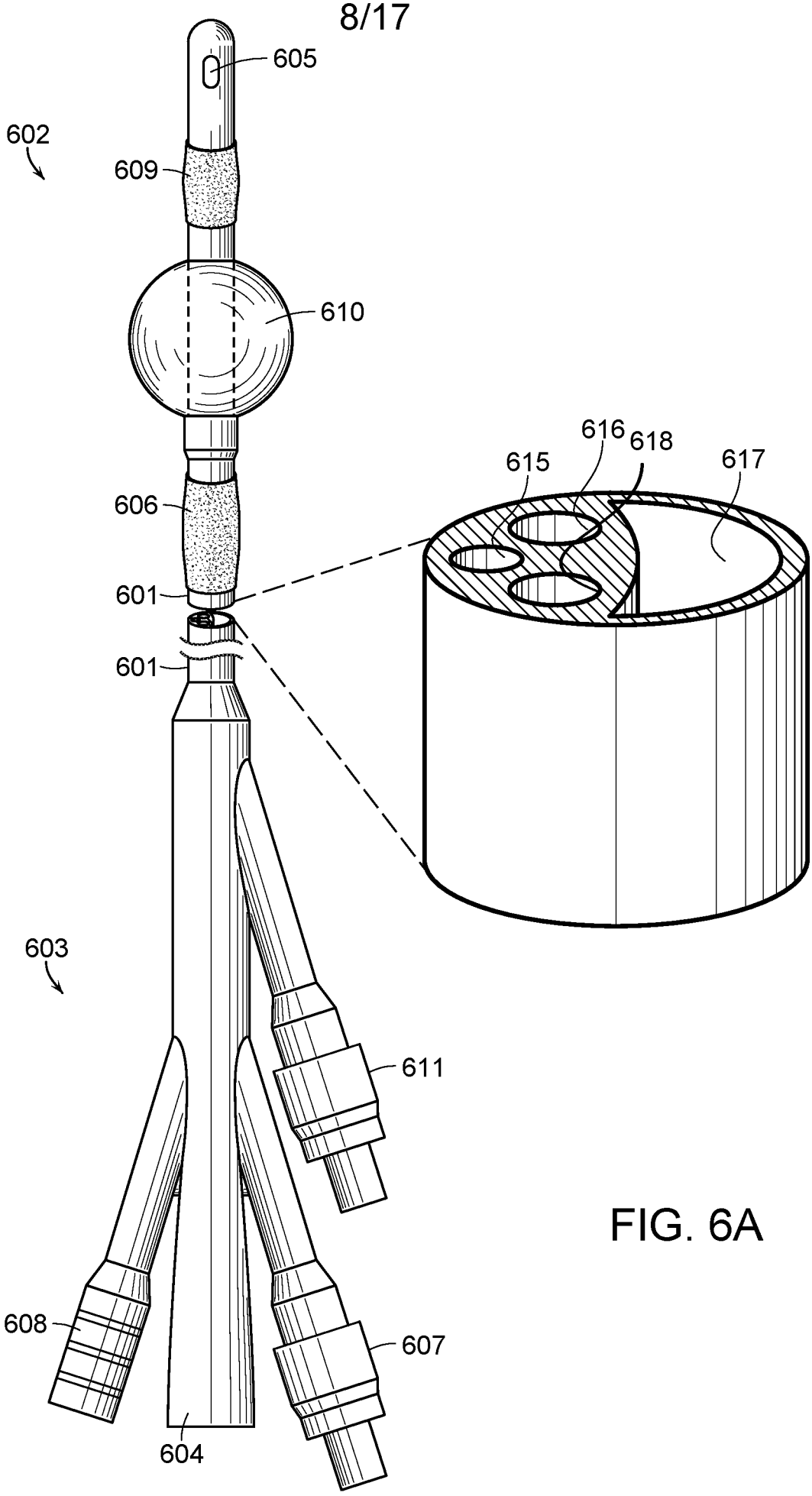

FIG. 6A

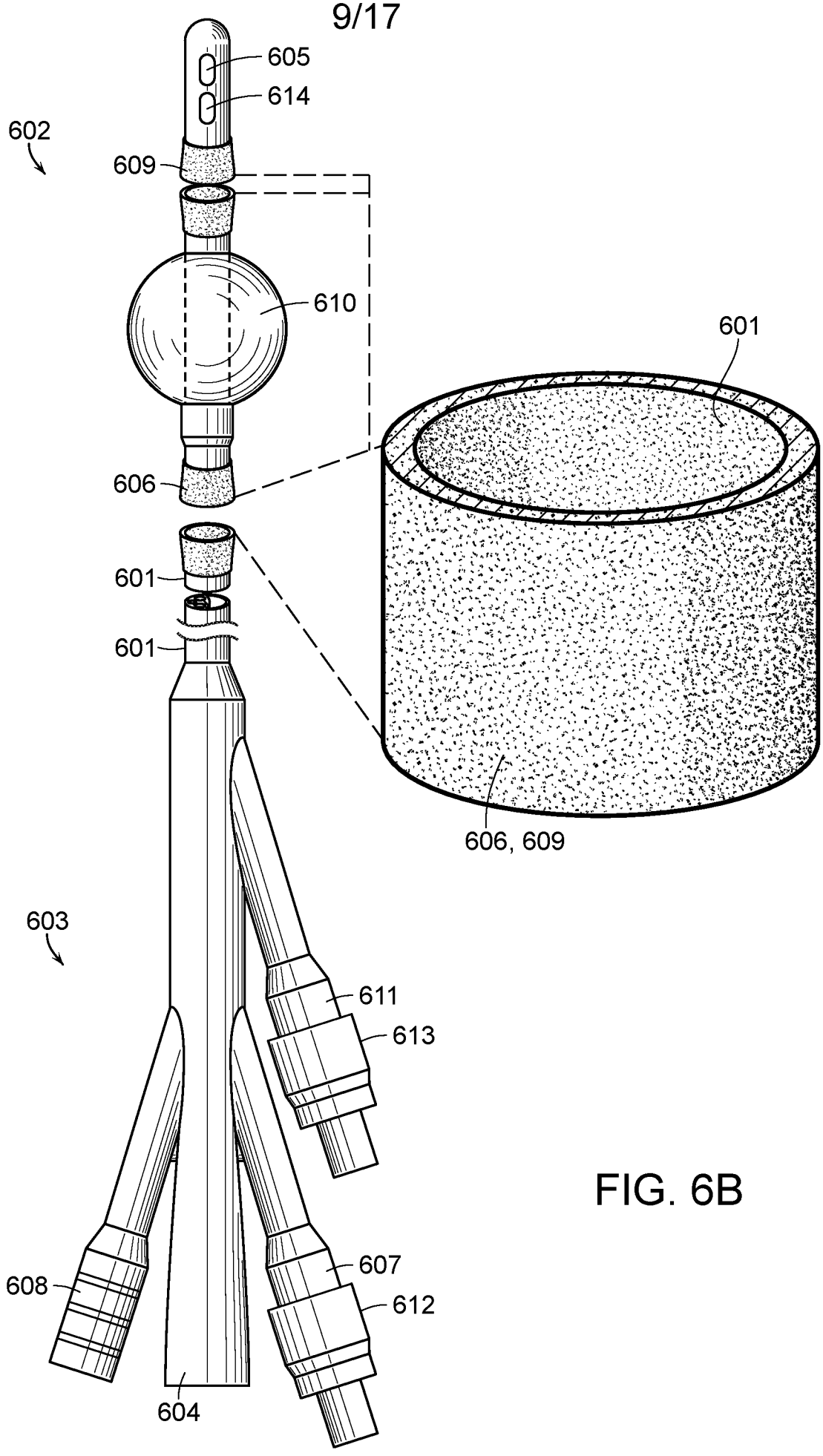
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FIG. 6B

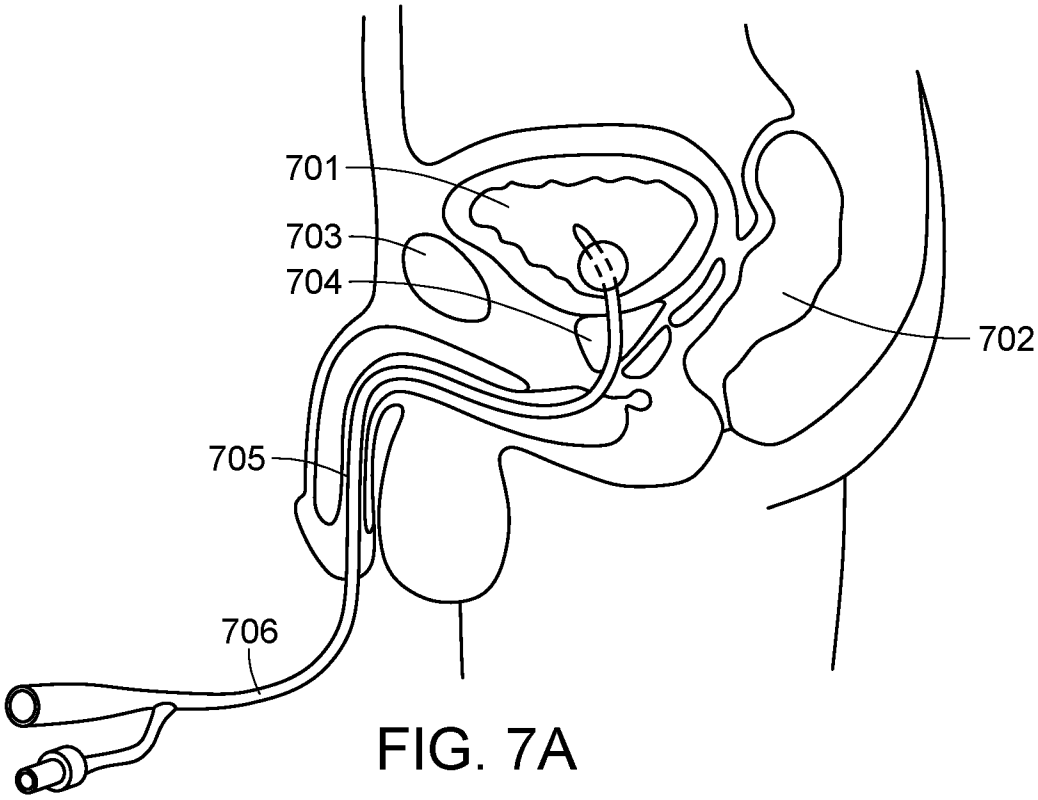

FIG. 7A

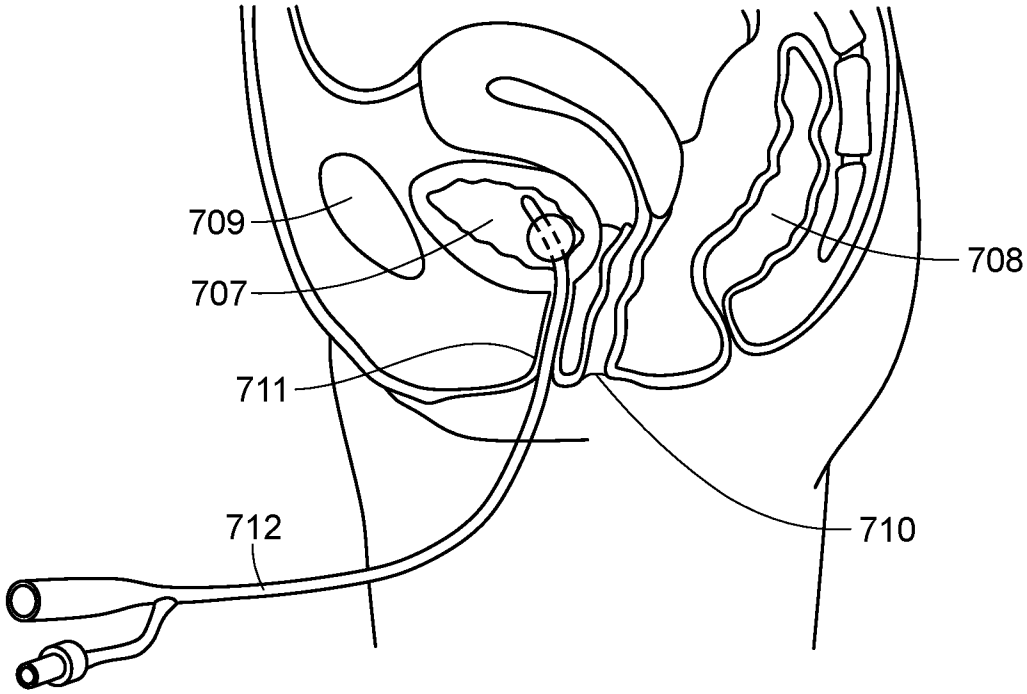

FIG. 7B

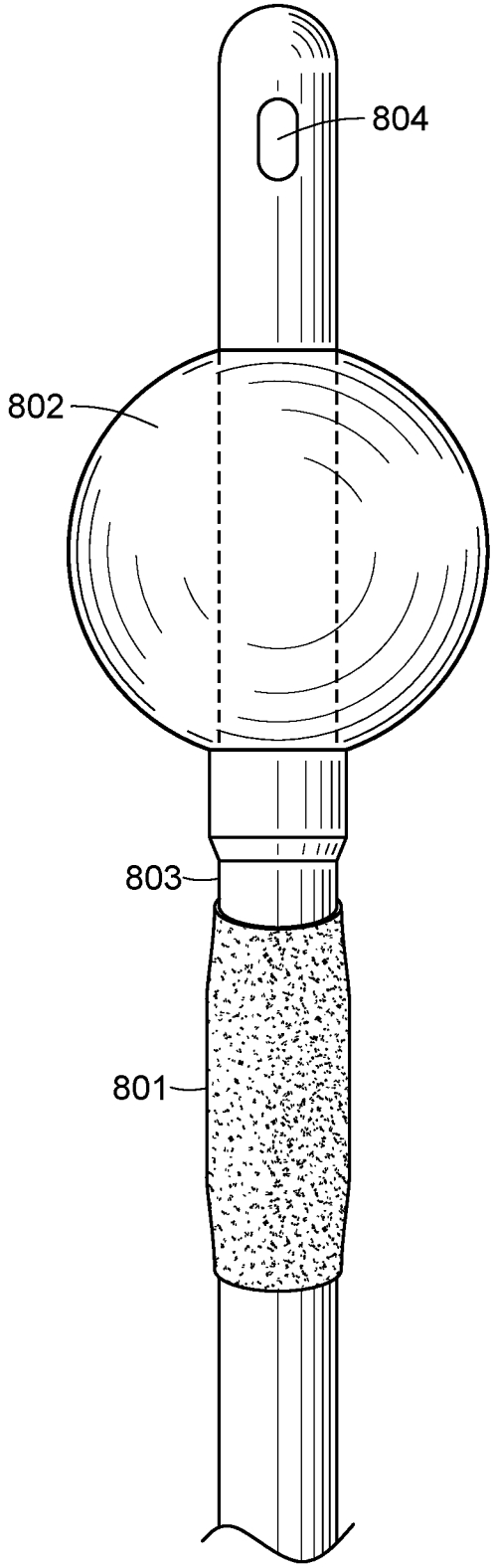

FIG. 8A

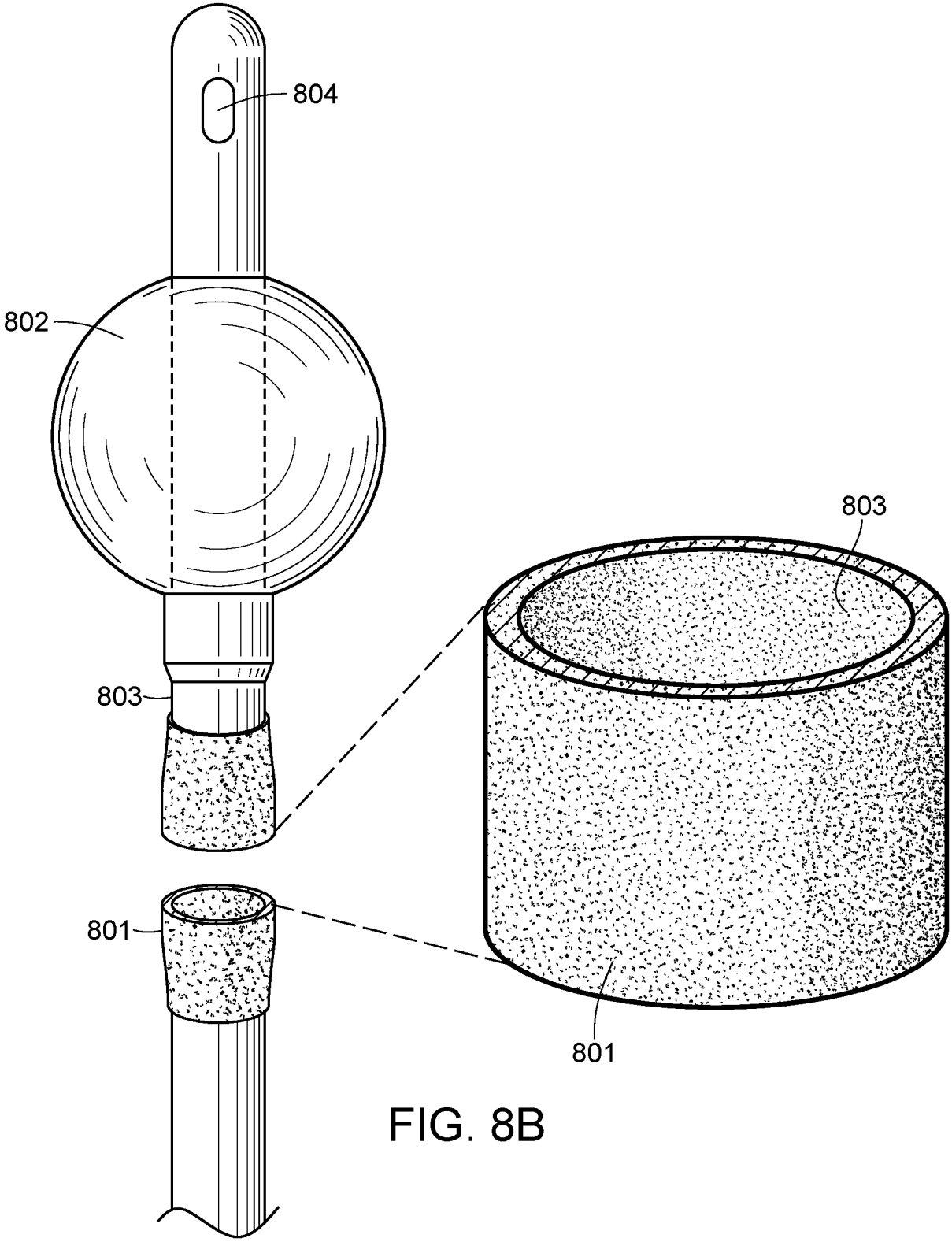

FIG. 8B

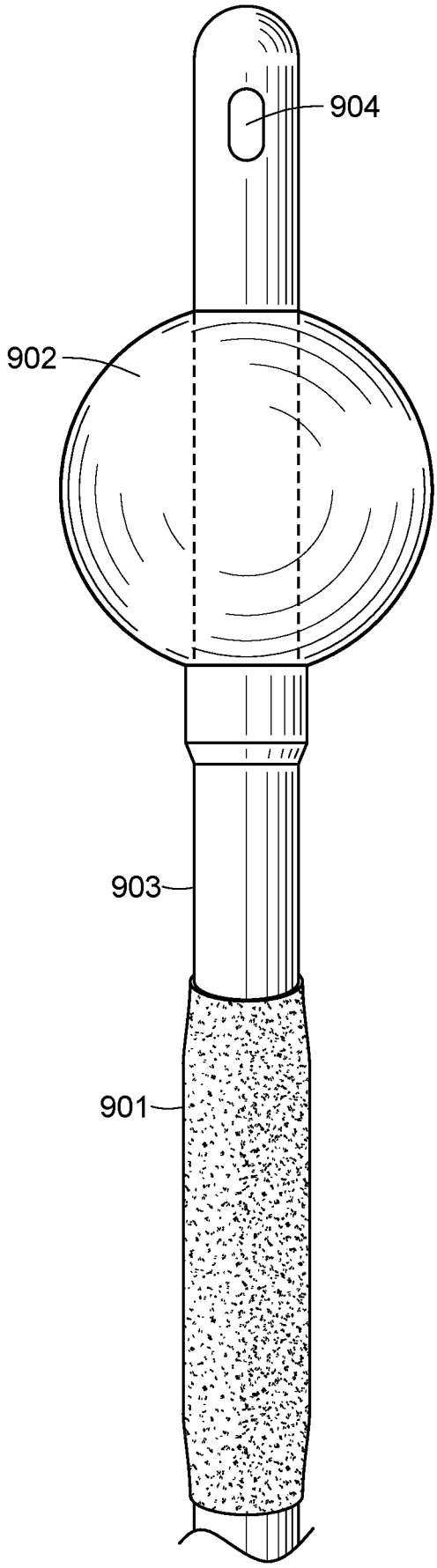

FIG. 9A

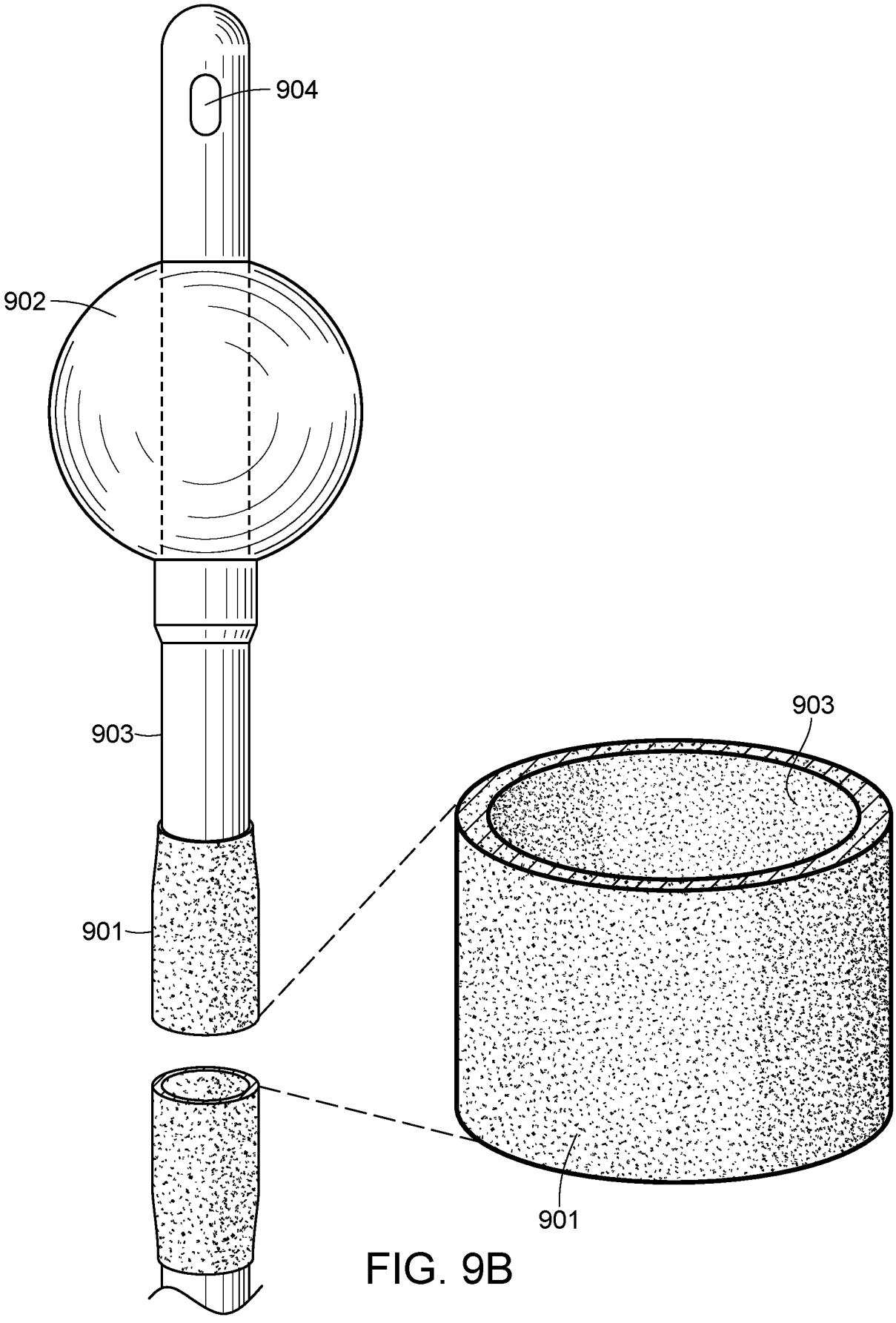

FIG. 9B

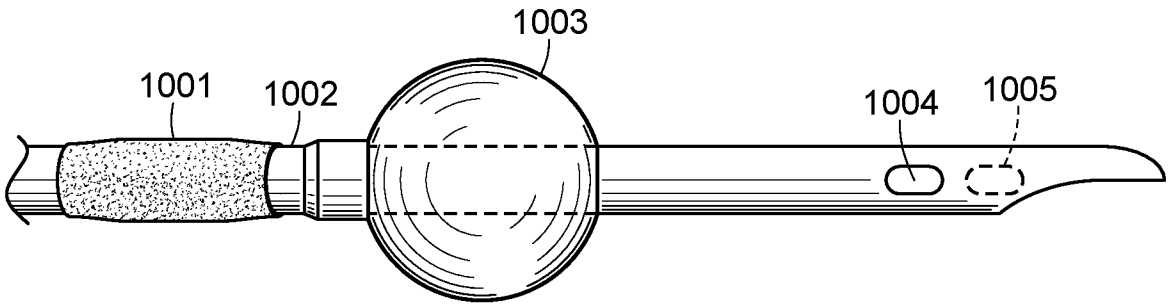

FIG. 10A

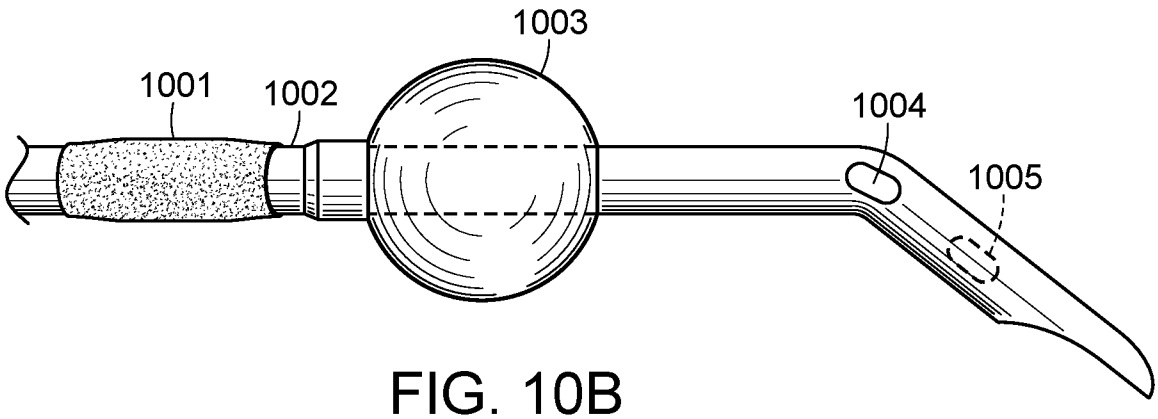

FIG. 10B

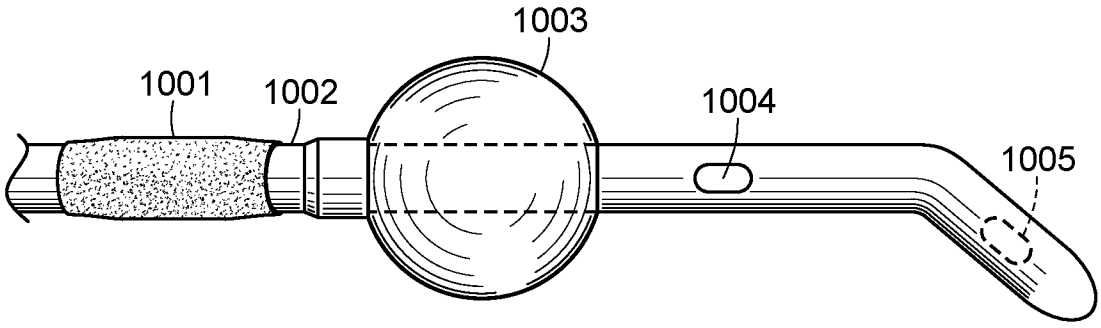

FIG. 10C

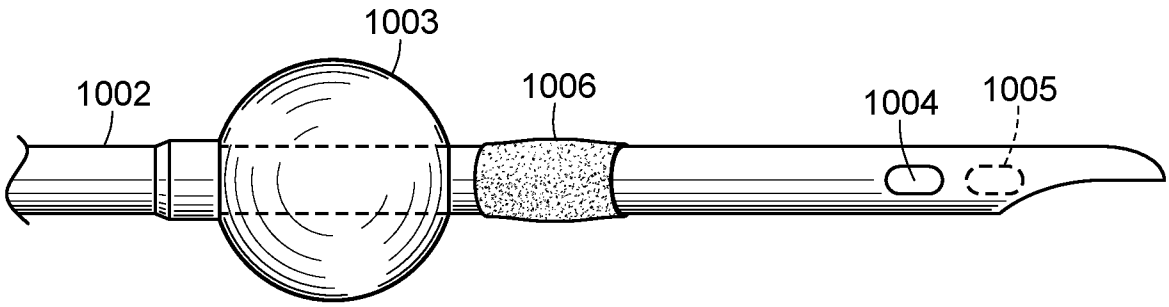

FIG. 11A

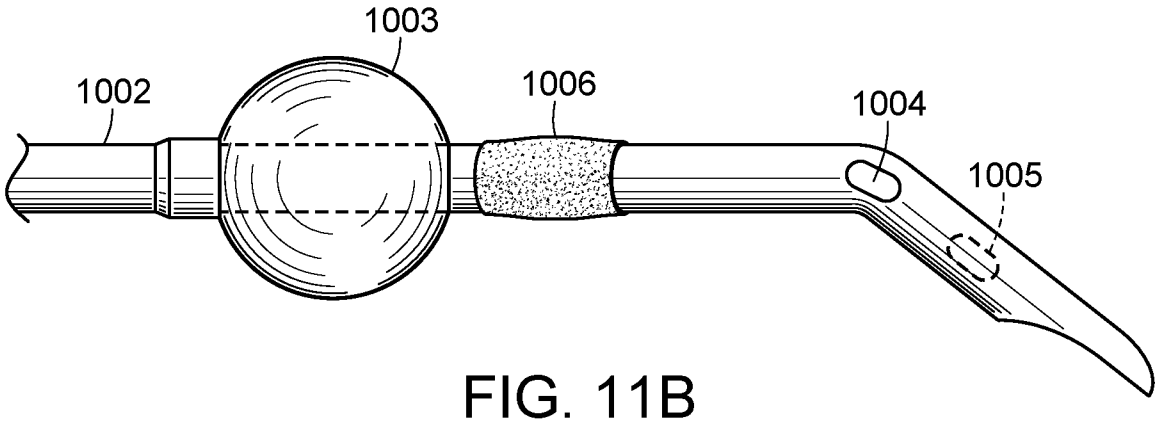

FIG. 11B

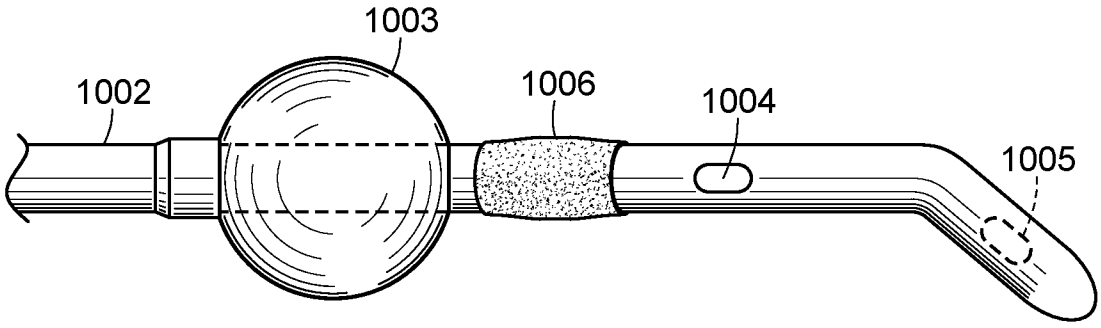

FIG. 11C

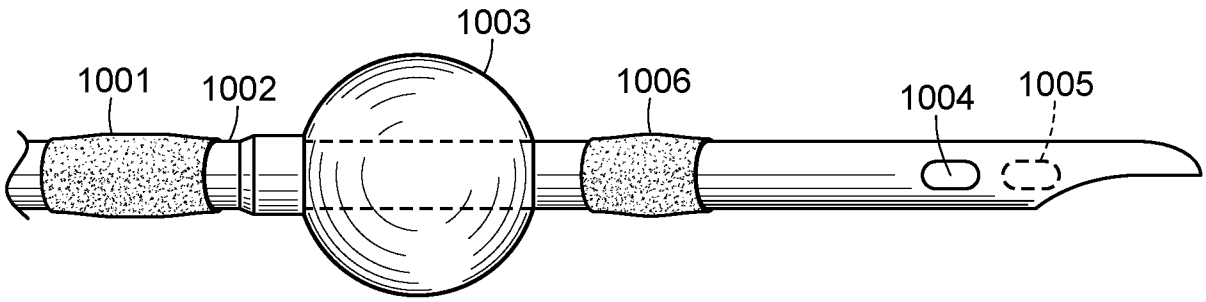

FIG. 12A

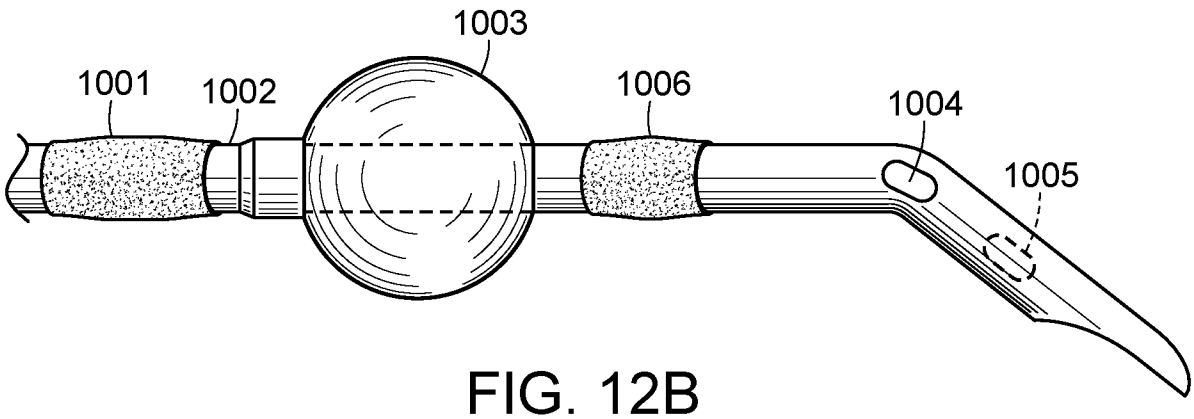

FIG. 12B

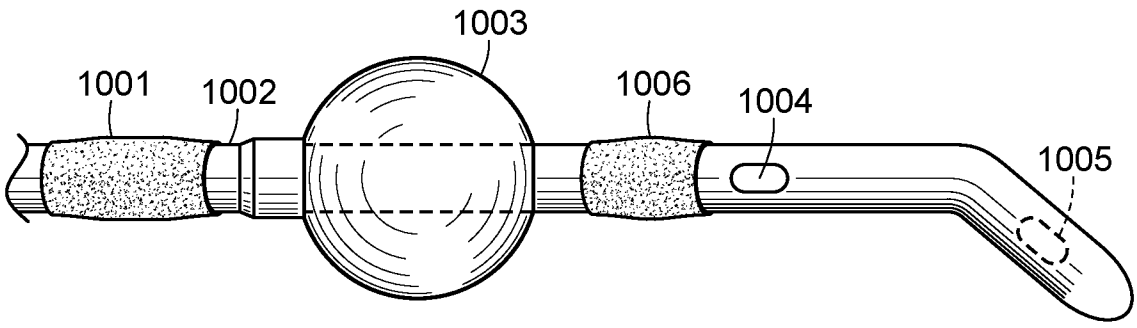

FIG. 12C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/026450

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00
ADD. A61M25/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 1 280 481 A (RENZO BEGANI) 29 December 1961 (1961-12-29)	1,2, 5-15, 29-32
Y	page 1, column 1, line 1 - page 2, column 2, line 47; figures 1,2	16-28
Y	US 2016/367747 A1 (LOSKE GUNNAR [DE]) 22 December 2016 (2016-12-22) page 1, paragraph 3 - page 10, paragraph 139; figures 1a-9b	16-28
X	US 3 981 299 A (MURRAY HARRY ELMER) 21 September 1976 (1976-09-21)	1-4, 7-15, 29-33
Y	column 1, line 3 - column 2, line 32; figures 1-6	16-28

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 October 2017	19/10/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Rolland, Philippe

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/026450

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 417 657 A (HAUER CAROLYN [US]) 23 May 1995 (1995-05-23)	1-4, 7-15, 29-33
Y	column 1, line 6 - column 7, line 61; figures 1-9	16-28

X	US 5 269 755 A (BODICKY RAYMOND O [US]) 14 December 1993 (1993-12-14)	1-4, 7-15, 29-33
Y	column 1, line 7 - column 9, line 18; figures 1-7	16-28

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/026450

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