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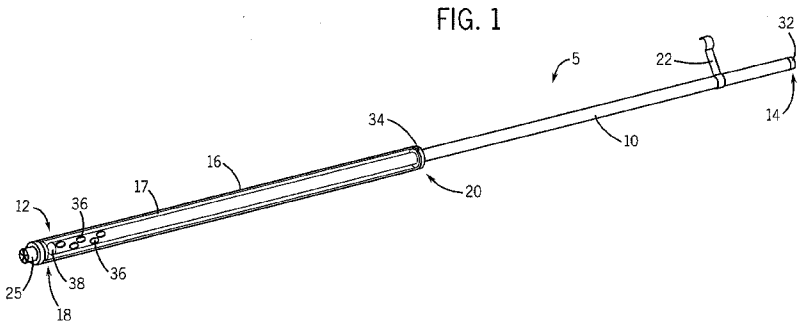
(54) Title: PRE-WETTED HYDROPHILIC INTERMITTENT CATHETER AND METHOD FOR USING THE SAME

FIG. 1



(57) Abstract: A catheter assembly (5) includes a tubular member (16) having a first end (18) and a second end (20). A catheter (10) has a first end (12) and a second end (14). At least a portion of the catheter (10) is disposed within the tubular member (16). The first end (18) of the tubular member (16) is openable by axial movement of the catheter (10). A sealing engagement (34) is provided between the tubular member (16) and the catheter (10). A method provides for removing a protective cap (30), advancing the catheter (10) through the first cap (24) and into the body, and draining the fluid from the body using the catheter (10).

PRE-WETTED HYDROPHILIC INTERMITTENT CATHETER AND METHOD FOR USING THE SAME

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The instant application is an International Application based on U.S. provisional application No. 61/227,564, filed July 22, 2009, the disclosure of which is hereby expressly incorporated by reference hereto in its entirety.

STATEMENT CONCERNING GOVERNMENT INTEREST

[0002] Not applicable.

BACKGROUND OF THE INVENTION

[0003] Catheters suitable for draining the bladder include both intermittent and indwelling catheters. Indwelling catheters include Foley catheters. Foley catheterization is typically indicated for surgical and medical patients who require, at least temporarily, assisted bladder voiding. Common indications to catheterize a patient include acute or chronic urinary retention (which can damage the kidneys), medical procedures (i.e., surgeries) that may at least temporarily limit a patient's movement, the need for accurate monitoring of input and output (such as in an ICU), benign prostatic hyperplasia, incontinence, and the effects of various surgical interventions involving the bladder and prostate.

[0004] A standard Foley catheter design includes a balloon disposed at the distal end of the catheter to anchor the catheter in the bladder. The catheter includes at least one lumen to drain urine from the bladder and at least one lumen to inflate the balloon (e.g., with sterile water). The proximal end of the Foley catheter includes at least two ports in communication with the two lumens, a first that is connected to the drainage lumen and has an interface with fittings for drainage and sampling, and a second that is connected to the inflation lumen with a valve to ensure the inflation fluid remains within the lumen and balloon once filled. The tip of a standard Foley catheter extends beyond the sides of the balloon into the bladder and includes one or more apertures or "eyes" to drain fluids and debris from the bladder. This standard design has not changed in approximately 100 years, although catheters with various additions (e.g., mechanical anchors, etc.) and improvements have been proposed and investigated.

[0005] A typical intermittent catheter differs from an indwelling catheter primarily in that the intermittent catheter does not have a retention balloon or an associated inflation lumen. Rather, the intermittent catheter is typically a single-lumen device, with a plurality of drainage eyes at the proximal end and a funnel at the distal end. Intermittent catheterization is often performed in individuals with malfunctioning urinary systems (e.g., suffering from strictures and traumas), as well as disabled individuals (e.g., para- or quadraplegics) who may be unable to voluntarily urinate. Such individuals will often self-catheterize with an intermittent catheter several times daily.

[0006] Intermittent catheters are generally catheters or tubes having a rounded, atraumatic distal tip that is inserted into the bladder of a patient. A molded funnel is typically connected to a distal end that remains outside the body of the patient or user. The distal tip may include slots or openings on the shaft to facilitate drainage of urine therefrom once the tip is positioned inside the bladder.

[0007] Pre-wetted intermittent catheters are intermittent catheters having a highly lubricious coating on an outer surface thereof, which are packaged or otherwise brought into contact with fluid in order to provide a catheter with a slippery outer surface to facilitate insertion into the patient or user.

[0008] Existing pre-wetted intermittent catheters fall into three broad categories. In a first type, the catheter is packaged in a dry environment, but it contains a lubricious coating that requires a wetting fluid in order to become hydrated. The wetting fluid is obtained from an external source by the user (e.g., sink, bottled water, etc.), and the catheter is positioned within the wetting fluid for a period of time to become hydrated. Use of this first type of intermittent catheter may prove difficult where no clean water or wetting fluid is readily available. Moreover, catheter sterility may be compromised due to the user's handling of the catheter when wetting fluid is applied.

[0009] A second type of pre-wetted intermittent catheter is also packaged in a dry environment and contains a lubricious coating. However, the wetting fluid is positioned in a pouch or container within the catheter package itself. To hydrate the catheter, the pouch or container is opened when the user is ready for insertion. Suitable examples of such catheters are disclosed in U.S. 7,087,048 (the disclosure of which is incorporated herein by reference in its entirety). As with the first type, this second type may be disadvantageous because the

catheter is exposed to the wetting fluid for a period of time to ensure hydration of the lubricious coating. The sterility of the catheter may also be compromised during insertion.

[00010] A third type of pre-wetted intermittent catheter is packaged in a wet environment. That is, the catheter is exposed to a wetting fluid within the catheter package, thus hydrating the coating. However, the user may have difficulty handling the catheter due to its slippery surface, and excessive or imprecise handling may result in contamination of the catheter by the user. This could then expose the user to a urinary tract infection.

[00011] Current intermittent catheter offerings are often ill-suited for those patients who self-catheterize in environs other than their homes (e.g., public restrooms). Discrete and compact packaging is important for such patients, in terms of privacy, being able to carry multiple intermittent catheters on the patient's person, and to facilitate discrete disposal of the used catheters. The present invention is directed to easy-to-use urinary catheter assemblies that provide for discrete transport and disposal and that eliminate or minimize some of the shortcomings of prior art devices.

SUMMARY OF THE INVENTION

[00012] In one non-limiting exemplary embodiment of the present invention, there is provided herein a urinary catheter assembly comprising a tubular member having a first end and a second end. A urinary catheter has a first end and a second end, wherein at least a portion of the urinary catheter is coaxially disposed within the tubular member. A first cap is arranged on the first end of the tubular member, wherein the first cap is openable by axial movement of the first end of the urinary catheter therethrough. A sealing member is arranged proximal to the second end of the tubular member, wherein the sealing member provides a seal between the inner diameter of the tubular member and the outer diameter of the urinary catheter.

[00013] According to another non-limiting exemplary embodiment of the present invention, there is provided herein a method for draining urine from a bladder, comprising providing a urinary catheter assembly comprising a tubular member having a first end and a second end. A urinary catheter has a first end and a second end, wherein at least a portion of the urinary catheter is coaxially disposed within the tubular member A cap is arranged on the first end of the tubular member, wherein the cap is openable by axial movement of the first end of the urinary catheter therethrough. A sealing member is arranged proximal to the

second end of the tubular member, wherein the sealing member provides a seal between the inner diameter of the tubular member and the outer diameter of the urinary catheter. A clip secures the tubular member to the urinary catheter, such that the assembly has a substantially U-shape. The method further includes disconnecting the clip from one of the tubular member and the urinary catheter, inserting at least a portion of the cap into the urethral meatus, advancing the urinary catheter through the cap and into the urethra, and draining the bladder through the urinary catheter.

[00014] The invention also provides for a catheter assembly comprising a tubular member having a first end and a second end, a catheter having a first end and a second end, at least a portion of the catheter being disposed within the tubular member, a first cap arranged on the first end of the tubular member and being openable by axial movement of the first end of the catheter, and a sealing member forming a seal between the tubular member and the catheter.

[00015] The catheter assembly may be at least one of a urinary catheter assembly and a flexible telescopic pre-wetted hydrophilic intermittent catheter. The sealing member may form and/or provide a seal between an inner diameter of the tubular member and an outer diameter of the catheter. The portion of the catheter may be generally coaxially disposed within the tubular member. The sealing member may be arranged in an area of the second end of the tubular member and may provide a seal between an inner diameter of the tubular member and an outer diameter of the catheter. The tubular member may comprise a wetting liquid contained therein. The tubular member may be substantially rigid. The tubular member may have a substantially circular cross section and/or is generally cylindrical. The catheter may comprise a hydrateable coating. The catheter may comprise a hydrophilic biocompatible coating over a surface and/or outer surface thereof. At least a portion of the first cap may be configured for insertion into an urethral meatus. The first cap may comprise at least one flexible and/or deflectable flap member.

[00016] The catheter assembly may further comprise a clip that is at least one of adapted to secure the catheter assembly in a storage or pre-use configuration, adapted to secure the catheter assembly in an a generally U-shaped configuration, and affixed to at least one of the tubular member and the catheter.

[00017] The catheter assembly may further comprise a clip configured to secure the tubular member to the catheter, such that the catheter assembly forms a substantially U-shape.

[00018] The second end of the catheter may comprise a second cap configured to seal the end thereof. The second cap may be at least one of removable, disposable, may comprise a frangible member disposed within an inner portion of the second end of the catheter, and may comprise a portion disposed about an outer diameter of the second end of the catheter. The second end of the catheter may be adapted to be coupled to a funnel. The second end of the catheter may be adapted to be coupled to a disposable fluid collection member. The second end of the catheter may be adapted to be coupled to a disposable urine collection member.

[00019] The invention also provides for a method for draining a fluid from a body using a catheter assembly as described herein, wherein the method comprises removing a protective cap, advancing the catheter through the first cap and into the body, and draining the fluid from the body using the catheter.

[00020] The fluid may be urine from a bladder. The removing may comprise removing the protective cap to expose the first cap, and the method may further comprise placing the catheter assembly into a usable configuration from a storage configuration. The draining may comprise draining the bladder through the catheter, and the method may further comprise before the advancing, inserting the first cap into a urethral meatus. The method may further comprise wetting at least a portion of the catheter with a wetting liquid disposed in the tubular member as the catheter is advanced through the tubular member. The method may further comprise during the advancing, wetting at least a portion of the catheter with a wetting liquid disposed in the tubular member as the catheter is advanced through the tubular member. The method may further comprise removing a cap from the second end of the catheter to facilitate drainage therethrough. The method may further comprise wetting a coating of at least a portion of the catheter with a wetting liquid disposed in the tubular member so as to facilitate insertion of the catheter. The method may further comprise collecting fluid drained by the catheter using a disposable collection member coupled to the second end of the catheter.

[00021] The invention also provides for a catheter assembly comprising one of at least one feature shown in the drawings and/or described in the instant application, a majority of features shown in the drawings and/or described in the instant application, any combination of plural features shown in the drawings and/or described in the instant application, and substantially all of the features shown in the drawings and/or described in the instant application.

BRIEF DESCRIPTION OF DRAWINGS OF EXEMPLARY EMBODIMENTS

[00022] FIG. 1 illustrates a perspective view of an exemplary catheter assembly.

[00023] FIG. 2 illustrates a perspective view of a stowed catheter assembly.

[00024] FIG. 3 illustrates a perspective view of an exemplary catheter assembly in an extended configuration.

[00025] FIG. 4 illustrates a cut-away perspective view of an exemplary catheter assembly.

[00026] FIG. 5 illustrates a partial perspective view of an exemplary catheter assembly.

[00027] FIG. 6 illustrates another partial perspective view of an exemplary catheter assembly.

[00028] FIG. 7 is a cross-sectional view of the distal end of an exemplary catheter assembly along line 5 shown in FIG. 5.

DESCRIPTION

[00029] The following description should be read with reference to the drawings, in which like elements in different drawings are identically numbered. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. The detailed description illustrates by way of example, not by way of limitation, the principles of the invention. This description will enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations,

alternatives and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[00030] As used herein, the reference terms "proximal" and "distal" (proximal being closer than distal) refer to proximity with respect to a health care professional catheterizing a patient. For example, the region or section of the catheter apparatus that is closest to the health care professional during catheterization is referred to herein as "proximal," while a region or section of the catheter apparatus closest to the patient's bladder is referred to as "distal." In the case of a self-catheterizing patient, proximal refers to a point external to the patient's body, and distal refers to a point within the patient's body (i.e., the bladder).

[00031] The catheter assemblies as described herein are discussed in the context of a urinary catheter for insertion into a bladder for drainage of urine therefrom. The instant catheter assemblies, however, may also be used for other applications not specifically mentioned herein. As such, the instant invention is not limited to urinary catheter applications.

[00032] FIGS. 1 and 2 illustrate an exemplary urinary catheter assembly **5** in accordance with the present disclosure. FIG. 1 shows the catheter in a deployed, ready-to-use configuration and FIG. 2 shows the catheter assembled in a substantially U-shaped, stowed configuration. Urinary catheter **10** has a distal end **12**, a proximal end **14,** and a lumen **13** (FIG. 7) running longitudinally therethrough. The distal end **12** contains a plurality of aperture eyelets **36** configured to receive urine from a bladder. The number of aperture eyelets **36** may range from 1 to 10, for example, 2 to 6. According to various non-limiting embodiments, the aperture eyelets **36** are circular or ovoid in shape, and the edges thereof may be polished or rounded in order to minimize tissue trauma during insertion.

[00033] The proximal end of lumen **13** is blocked by a removable cap **32**. The cap **32** can be of any configuration suitable for blocking the flow of liquid (i.e., wetting liquid or urine) through the catheter **10** until the cap **32** is removed by the user. By way of non-limiting example, the cap **32** can be constructed of a frangible material disposed within the inner diameter of lumen **13**, which material is destructible by the user when the catheter **10** is ready for use.

[00034] According to another embodiment, the removable cap **32** is constructed from a rigid and relatively inflexible material that engages at least the inner diameter of catheter **10**.

According to various embodiments, proximal end **14** of catheter **10** comprises a funnel (not shown) which is standard on many intermittent catheters. The cap **32** may be disposed within the funnel. According to another embodiment, proximal end **14** comprises a mechanism to engage an optional urine collection chamber (not shown). By way of non-limiting example, the proximal end **14** can also contain outwardly extending hooks to pierce and secure a distal end of the chamber, or a radially extending flange configured to engage a complementary and opposed surface of the optional urine collection chamber.

[00035] The distal portion of catheter **10** is coaxially disposed in tubular member **16** having a distal end **18** and a proximal end **20**. By way of non-limiting example, the tubular member **16** can be substantially transparent or translucent. According to various embodiments, the volume or fluid space **17** disposed between catheter **10** and tubular member **16** contains a wetting liquid in a volume sufficient to wet the outer surface of at least the distal portion of catheter **10**.

[00036] With reference to FIGS. 4-7, the distal end **18** of tubular member **16** comprises a cap **24** having a portion **23** sealingly engaging the inside diameter of distal end **18** of tubular member **16**. Cap **24** additionally comprises member **25** configured for insertion into the urethral meatus. The distal surface of member **25** is illustrated in FIGS. 1-7 as being substantially flat. According to various embodiments, the member **25** can also have a generally rounded, atraumatic tip or distal surface to facilitate insertion into the urethral meatus. The distal surface of member **25** is illustrated in FIGS. 1-7 as having a plurality of flexible baffles or flaps **26,** which flaps are deflectable and releasable to form or assume an enlargeable aperture **28** when distal end **12** of catheter **10** is urged in a distal direction through cap **24** (see FIGS 5 and 6).

[00037] As shown in FIG. 2, a protective cap **30** releasably seals the distal end **18** of the tubular member **16** and the member **25**. According to various embodiments, the cap **30** may have gripping features to ease removal by the patient. A clip **22** functions to removably fasten the proximal portion of the catheter **10** to the tubular member **16**. The clip **22,** in a securing position, allows the assembly 5 to assume the configuration shown in Fig. 2. According to various embodiments, the clip **22** can be permanently attached to either the catheter **10** or the tubular member **16**, and releasably attached to the other. With reference to FIG. 1, the clip **22** can function as a handle for grasping by the self-catheterizing patient,

allowing the patient to urge catheter **10** distally through tubular member **16**. Clip **22** can be mechanically or chemically affixed to tubular member **16** and/or catheter **10**.

[00038] According to various embodiments, catheter **10** contains a biocompatible, hydrophilic coating over at least a portion of the surface thereof (suitable hydrophilic coatings being well-known in the art). A wetting liquid, such as water, saline, or any other suitable wetting liquid, is contained in the volume or fluid space **17** between the catheter **10** and the tubular member **16** to hydrate the coating during storage, shipment and just prior to use. One purpose of the wetting fluid is to maintain hydration of the lubricious coating such that upon insertion of the catheter into a user, at least an outer portion thereof is extremely slippery, facilitating insertion. According to another embodiment, the catheter assembly **5**, including catheter **10**, contains a biocompatible antimicrobial coating on at least an outer surface thereof. Suitable non-limiting examples of such lubricious and antimicrobial coatings are disclosed in U.S. Patent Nos. 4,585,666; 5,558,900; 5,077,352; 5,179,174; 6,329,488 (suitable for, e.g., polysiloxane substrates); 6,716,895; 6,949,598; and U.S. Patent Application Publication No. 2004/0116551, each of which is incorporated by reference in its entirety.

[00039] To get the catheter **10** ready-for-use, the clip **22** is released from at least one of catheter **10** and tubular member **16** – so as to allow the assembly **5** to assume the configuration shown in FIG. 1. The cap **32** is removed from the distal end of the catheter, and an optional urine collection chamber (not shown) is placed in fluid communication with proximal end **14** of catheter **10**. At this point, at least some volume of wetting fluid may drain from volume **17** via eyelets **36**.

[00040] As shown in FIGS. 3-6, once caps **30** and **32** are removed, member **25** is optionally inserted into the urethral meatus, and catheter **10** is urged distally through the tubular member **16** by optionally grasping and manipulating clip **22** in a distal direction. At the beginning of that motion, a distal tip **38** of catheter **10** pierces cap **24** by swaying or deflecting the baffles **26** distally. The remaining portion of catheter **10** that is inserted into the body is lubricated by the wetting liquid in volume **17** during the catheter's distal movement. Sealing member **34** (FIGS. 1, 2 and 4) provides a substantially fluid-tight seal between the outer diameter of catheter **10** and inner diameter of tubular member **16**, such that the wetting liquid does not flow or leak, or at least substantially flow or leak, proximally

along the outer surface of catheter **10**. Once the distal end **12** of catheter **10** is inserted in a urine-filled bladder, urine flows through the catheter **10** and drains from proximal end **14**.

[00041] The components of the catheter assembly **5** disclosed herein can be made from various well-known materials. For example, the portions of the assembly other than the catheter **10** can be made of polyvinyl propylene, polyvinyl chloride, polyethylene, and other types of suitable polymeric materials. The components can be molded or extruded according to well-known manufacturing techniques.

[00042] Materials commonly used to make catheter **10** include, but are not limited to natural rubber latexes (available, for example, from Guthrie, Inc., Tucson, Ariz.; Firestone, Inc., Akron, Ohio; and Centrotrade USA, Virginia Beach, Va.), silicones (available, for example, from GE Silicones, Waterford, N.Y., Wacker Silicones, Adrian, Mich.; and Dow Corning, Inc., Midland, Mich.), polyvinyl chlorides (available, for example, from Kaneka Corp., Inc., New York, N.Y.), polyurethanes (available, for example, from Bayer, Inc., Toronto, Ontario, Rohm & Haas Company, Philadelphia, Pa.; and Ortec, Inc., Greenville, S.C.), plastisols (available, for example, from G S Industries, Bassett, Va.), polyvinyl acetate, (available, for example from Acetex Corp., Vancouver, British Columbia) and methacrylate copolymers (available, for example, from Heveatex, Inc., Fall River, Mass.). Natural rubber latexes, polyurethanes, and silicones are preferred materials. Any combination of the foregoing materials may also be used in making catheters. In one embodiment, a rubberize layer that includes latex and a methacrylate is used with build up and finish layers that include latex but not methacrylate. In another embodiment, a polyurethane rubberize layer is used with latex build up and finish layers. In another embodiment, a polyvinyl acetate and latex rubberize layer is used with latex build up and finish layers. Each of the foregoing embodiments in which specific Young's Modulus values are specified may be used with any material.

[00043] The urinary catheter **10** of the present invention can be manufactured by a variety of well-known methods. For example, according to various embodiments, the catheter is manufactured by dipping. An elongated rod or "form" is dipped into a first liquid coating material to form a layer of coating material on the form. The form has the shape and dimensions of the lumen **13** of the catheter. This first coating layer forms the inner or rubberize layer of the catheter. Once the first layer has dried, the form is then dipped into a second coating material to build up an intermediate or build up layer. Multiple dips into the

second coating material may be desirable to build up an intermediate layer of appropriate thickness. The build up layer is then dried. The finish layer is applied with a subsequent dip and is dried. The catheter may be stripped from the form, and eyelets **36** may then be formed thereon. Further manufacturing steps may be found in U.S. 2004/0133156, the disclosure of which is incorporated by reference herein.

[00044] Caps **30**, **32**, and **24** may be secured to catheter **10** and tubular member **16**, respectively, by friction fit, threaded engagement (i.e., either the cap or the end section contains threads, protrusions, etc., and the other contains grooves, detents, recesses, etc. to receive the threads, protrusions, etc.), or other like securing methods known to one skilled in the art.

[00045] Different lengths, sizes (e.g., diameter, width, etc.), and configurations are possible for the catheter **10**, depending on the user's anatomy. For female users, the insertable length may range from 40 to 100 mm, for example 50 to 80 mm, such as 55 to 75 mm. For male users, the insertable length can range from 170 to 260 mm, such as 190 to 240 mm, for example 230 mm. The tip design can vary according to the needs of a user, for example, the catheters disclosed herein can be provided with a coude tip. The catheter may have a round or substantially round cross-sectional shape, an oval cross-sectional shape, or any other cross-sectional shape that may facilitate insertion into the body of a user/patient, and in particular, into the bladder of the user/patient through the urethra. According to various embodiments, the shape of the catheter can be variable along its length. The tubular member **16** can have any shape suitable to facilitate discrete storage and usage. According to various embodiments, the shape is round or substantially triangular, and/or has indentations to facilitate secure gripping by the user.

[00046] This invention has been described and specific examples of the invention have been portrayed. While the invention has been described in terms of particular variations and illustrative figures, those of ordinary skill in the art will recognize that the invention is not limited to the variations of figures described. In addition, where methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art will recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Therefore, to the extent there are variations of the invention, which are

within the spirit of the disclosure or equivalent to the inventions found in the claims, it is the intent that this patent will cover those variations as well. Finally, all publications and patent applications cited in this specification are herein incorporated by reference in their entirety as if each individual publication or patent application were specifically and individually put forth herein.

CLAIMS

What is claimed:

1. A catheter assembly comprising:

a generally tubular member having a first end and a second end;

a catheter having a first end and a second end;

at least a portion of the catheter being disposed within the tubular member;

the first end of the tubular member being openable by axial movement of the catheter; and

a portion of the catheter being in sealing engagement a portion of the tubular member.

2. The catheter assembly according to Claim 1, further comprising:

a first cap arranged on the first end of the tubular member and being openable by axial movement of the first end of the catheter; and

a sealing member forming the sealing engagement between the portion of the tubular member and the catheter.

3. The catheter assembly according to Claim 2, wherein the sealing member forms a seal between an inner diameter of the tubular member and an outer diameter of the catheter.

4. The catheter assembly according to Claim 2, wherein the sealing member is arranged in an area of the second end of the tubular member and provides a seal between an inner diameter of the tubular member and an outer diameter of the catheter.

5. The catheter assembly according to Claim 2, wherein at least a portion of a first cap is configured for insertion into an urethral meatus.

6. The catheter assembly according to Claim 2, wherein the first cap comprises at least one flexible and/or deflectable flap member.

7. The catheter assembly according to Claim 1, wherein the catheter assembly is at least one of:

a urinary catheter assembly; and

a flexible telescopic pre-wetted hydrophilic intermittent catheter.

8. The catheter assembly according to Claim 1, wherein said portion of the catheter is coaxially disposed within the tubular member.

9. The catheter assembly according to Claim 1, wherein the tubular member comprises a wetting liquid contained therein.

10. The catheter assembly according to Claim 1, wherein the tubular member is substantially rigid.

11. The catheter assembly according to Claim 1, wherein the tubular member has a substantially circular cross section and/or is generally cylindrical.

12. The catheter assembly according to Claim 1, wherein the catheter comprises a hydrateable coating.

13. The catheter assembly according to Claim 1, wherein the catheter comprises a hydrophilic biocompatible coating over an outer surface thereof.

14. The catheter assembly according to Claim 1, further comprising a clip that is at least one of:

adapted to secure the catheter assembly in a storage or pre-use configuration;

adapted to secure the catheter assembly in an a generally U-shaped configuration; and

affixed to at least one of the tubular member and the catheter.

15. The catheter assembly according to Claim 1, further comprising a clip configured to secure the tubular member to the catheter, such that the catheter assembly forms a substantially U-shape.

16. The catheter assembly according to Claim 1, wherein the second end of the catheter comprises a second cap configured to seal the end thereof.

17. The catheter assembly according to Claim 16, wherein the second cap is at least one of:

removable;

disposable; and

comprises a frangible member disposed within an inner portion of the second end of the catheter; and

comprises a portion disposed about an outer diameter of the second end of the catheter.

18. The catheter assembly according to Claim 1, wherein the second end of the catheter is adapted to be coupled to a funnel.

19. The catheter assembly according to Claim 1, wherein the second end of the catheter is adapted to be coupled to a disposable fluid collection member.

20. The catheter assembly according to Claim 1, wherein the second end of the catheter is adapted to be coupled to a disposable urine collection member.

21. A method for draining a fluid from a body using a catheter assembly as described in anyone or more of claims 1-20, the method comprising:

removing a protective cap;

advancing the catheter through the first cap and into the body; and

draining the fluid from the body using the catheter.

22. The method of Claim 21, wherein the fluid is urine from a bladder.

23. The method of Claim 21, wherein the removing comprises removing the protective cap to expose the first cap, and further comprising:

placing the catheter assembly into a usable configuration from a storage configuration.

24. The method of Claim 21, wherein the draining comprises draining the bladder through the catheter, and further comprising:

before the advancing, inserting the first cap into a urethral meatus.

25. The method of Claim 21, further comprising:

wetting at least a portion of the catheter with a wetting liquid disposed in the tubular member as the catheter is advanced through the tubular member.

26. The method of Claim 21, further comprising:

during the advancing, wetting at least a portion of the catheter with a wetting liquid disposed in the tubular member as the catheter is advanced through the tubular member.

27. The method of Claim 21, further comprising removing a cap from the second end of the catheter to facilitate drainage therethrough.

28. The method of Claim 21, further comprising:

wetting a coating of at least a portion of the catheter with a wetting liquid disposed in the tubular member so as to facilitate insertion of the catheter.

29. The method of Claim 21, further comprising:

collecting fluid drained by the catheter using a disposable collection member coupled to the second end of the catheter.

30. A catheter assembly comprising:

an outer member having a first end and a second end and having an interior space adapted to contain a fluid;

a catheter having a first end and a second end and being at least partially disposed in the interior space;

the catheter being structured and arranged to move with respect to the outer member; and

a fluid arranged in the interior space and being adapted to hydrate and/or wet the catheter.

31. The catheter assembly according to Claim 30, wherein the first end of the tubular member is openable by axial movement of the catheter.

32. A catheter assembly comprising one of:

at least one feature shown in the drawings and/or described in the instant application;

a majority of features shown in the drawings and/or described in the instant application;

any combination of plural features shown in the drawings and/or described in the instant application; and

substantially all of the features shown in the drawings and/or described in the instant application.

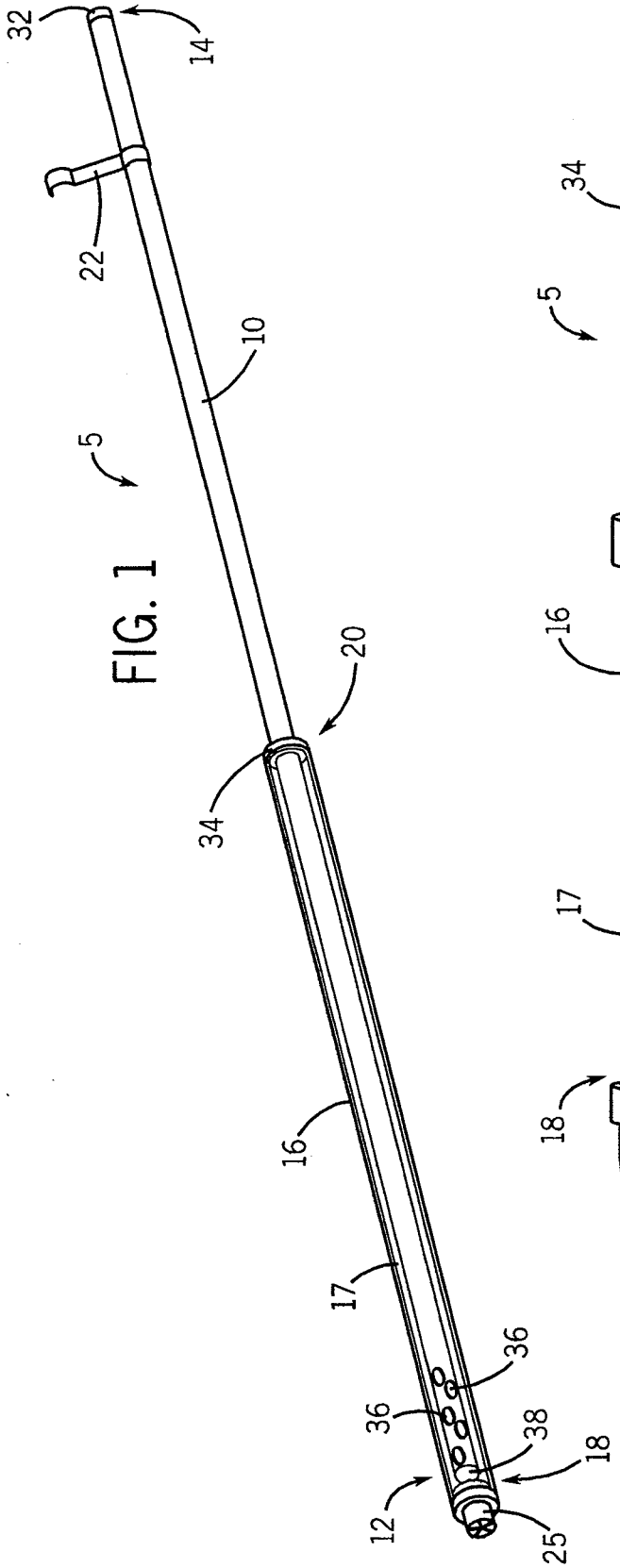

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FIG. 1

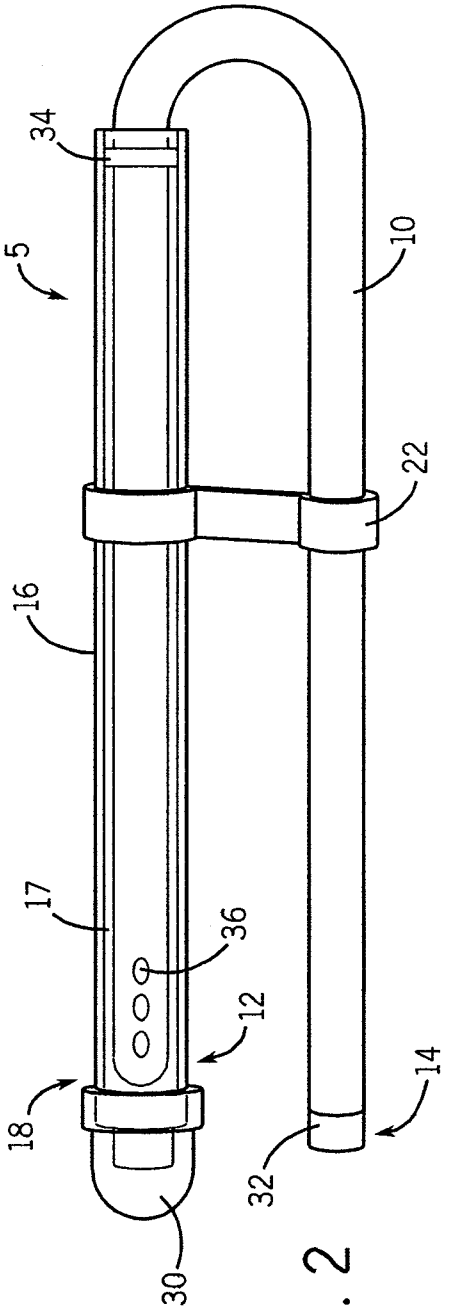
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FIG. 2

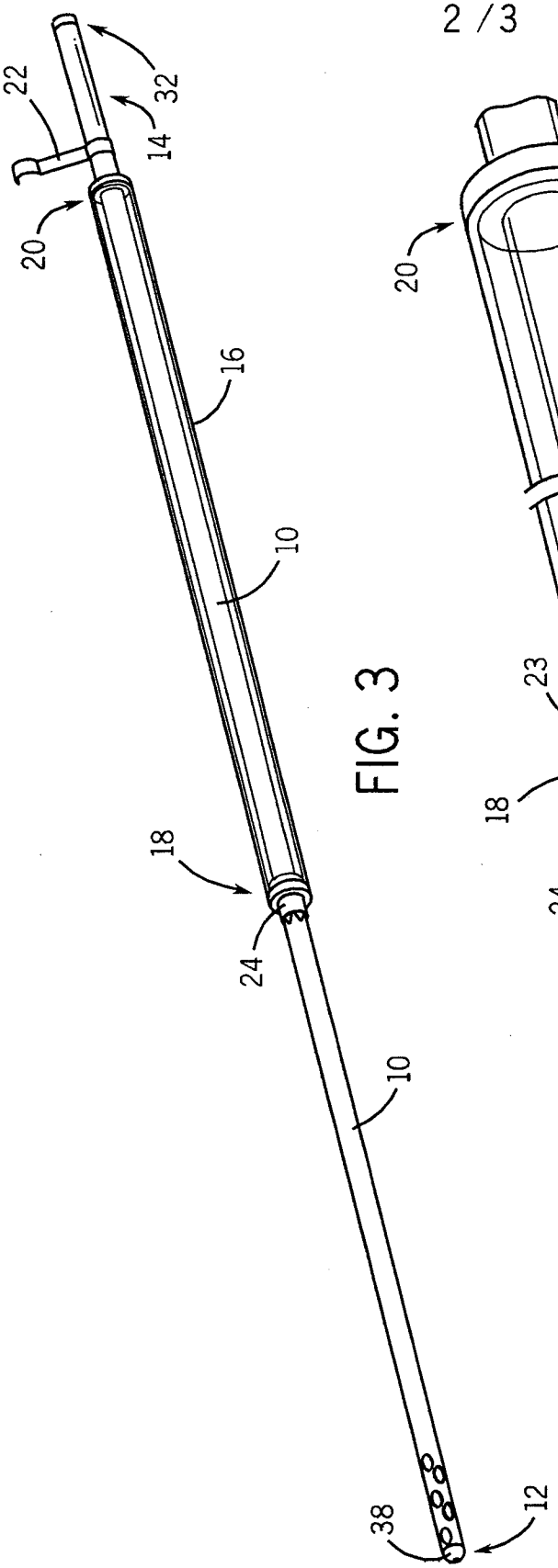
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FIG. 3

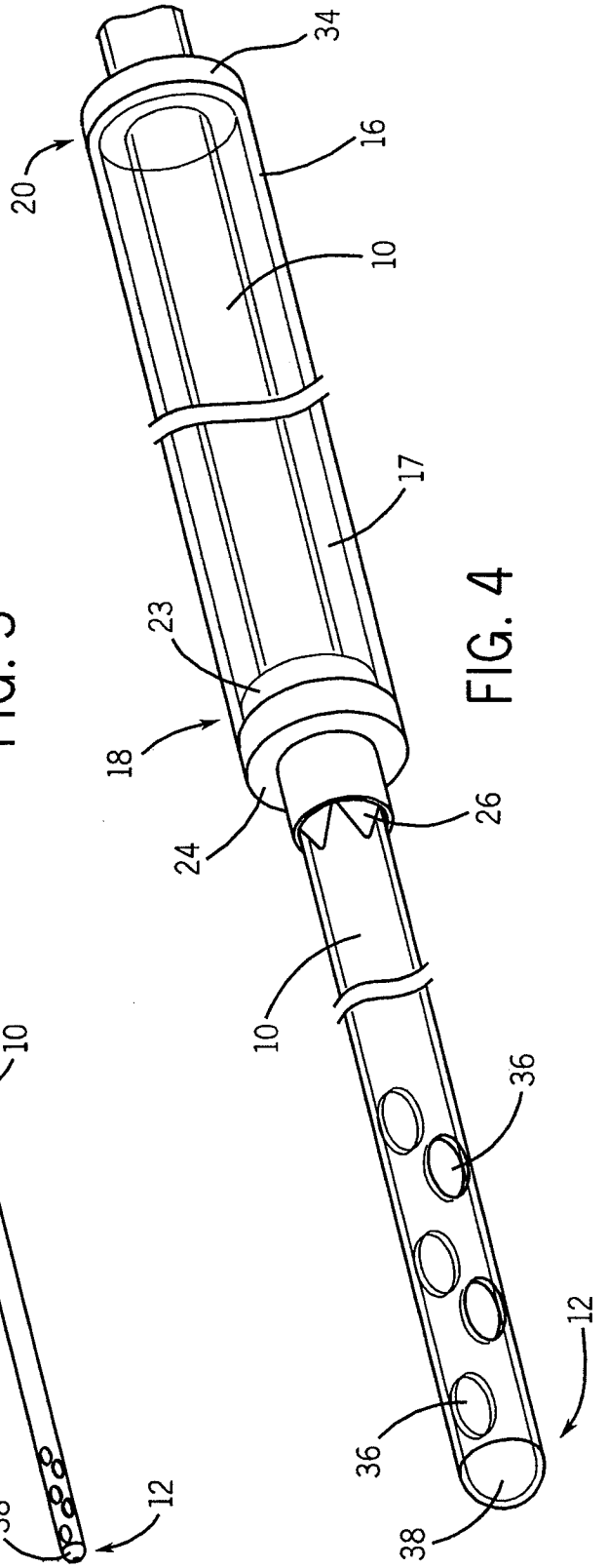
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FIG. 4

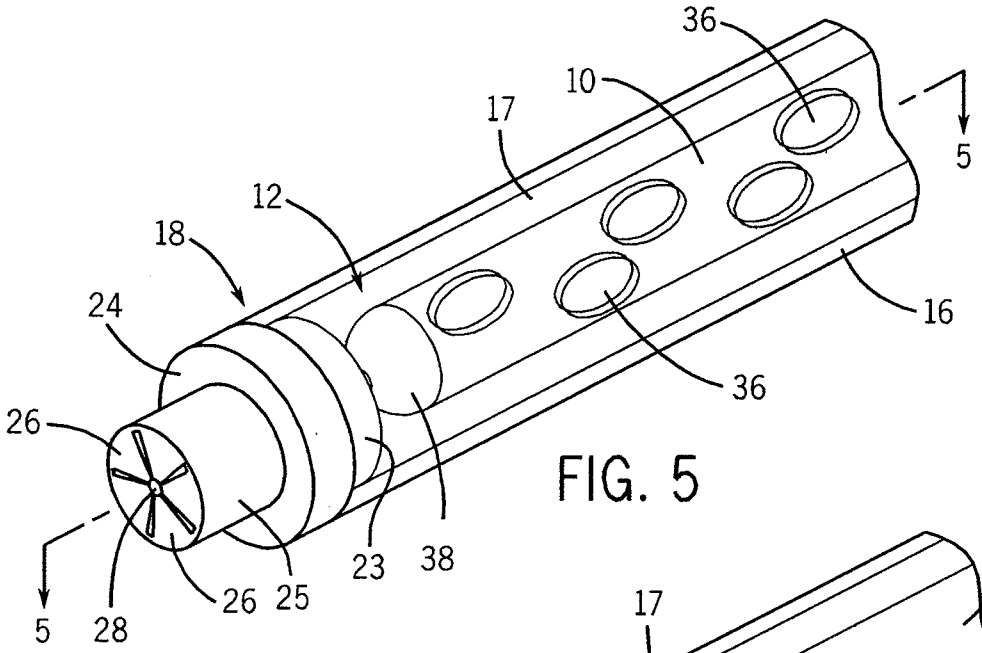

FIG. 5

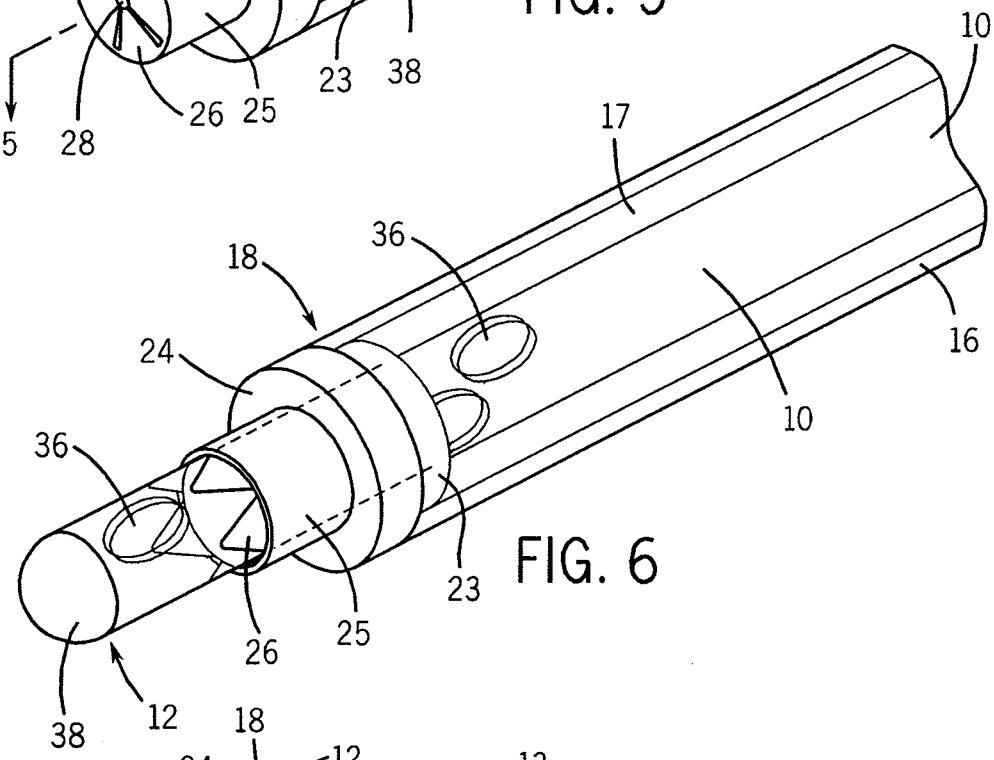

FIG. 6

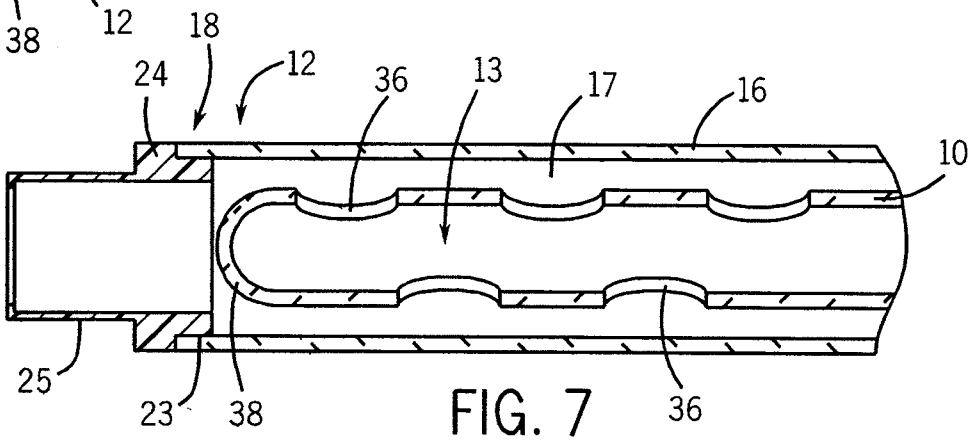

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/055354

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 27/00 (2009.01)
USPC - 604/544
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)
IPC(8) - A61M 27/00 (2009.01)
USPC - 604/19, 327, 544

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)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2007/0088330 A1 (HOUSE) 19 April 2007 (19.04.2007) entire document	30, 31 --- 1-29
Y	US 2003/0018293 A1 (TANGHOJ et al) 23 January 2003 (23.01.2003) entire document	1-29
Y	US 6,551,281 B1 (RAULERSON et al) 22 April 2003 (22.04.2003) entire document	14, 15, 23

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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
02 October 2009	14 OCT 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/055354

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 32
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claim 32 is held to be unsearchable, since the claim is an omnibus claim as it refers to the drawings and application.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.