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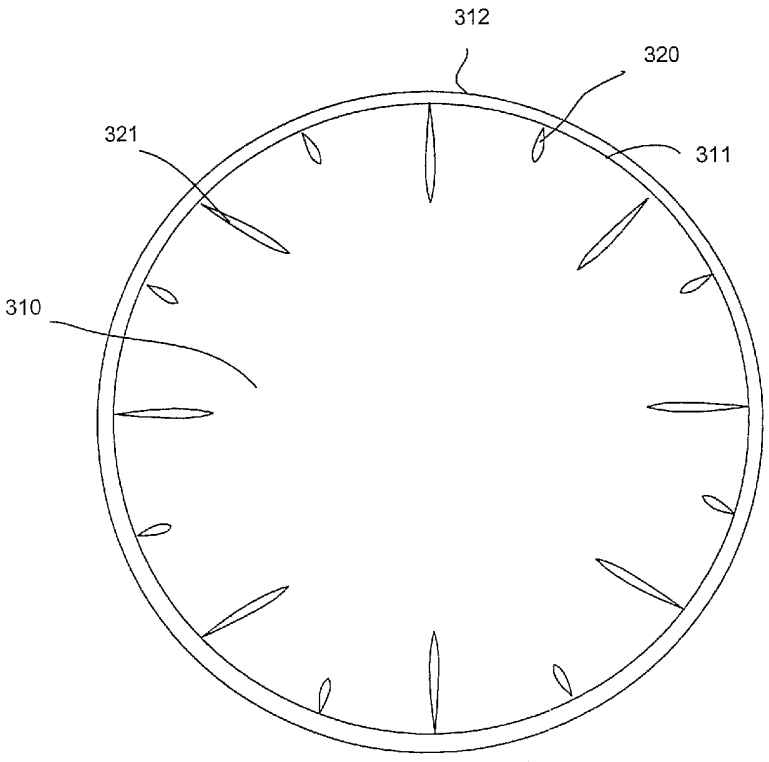
(54) Title: A CILIATED STENT-LIKE SYSTEM

(57) Abstract: A ciliated stent-like system and method of operating the same.



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A CILIATED STENT-LIKE SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is related to, claims the earliest available effective filing date(s) from (e.g., claims earliest available priority dates for other than provisional patent applications; claims benefits under 35 USC § 119(e) for provisional patent applications), and incorporates by reference in its entirety all subject matter of the following listed applications; the present application also claims the earliest available effective filing date(s) from, and also incorporates by reference in its entirety all subject matter of any and all parent, grandparent, great-grandparent, etc. applications of the following listed applications:

1. United States patent application entitled A SYSTEM FOR PERFUSION MANAGEMENT, naming Lowell L. Wood Jr. as inventor, filed 19 April 2004 and assigned USAN 10/827,576.

2. United States patent application entitled A SYSTEM WITH A SENSOR FOR PERFUSION MANAGEMENT, naming Lowell L. Wood Jr. as inventor, filed 19 April 2004 and assigned USAN 10/827,578.

3. United States patent application entitled A SYSTEM WITH A RESERVOIR FOR PERFUSION MANAGEMENT, naming Lowell L. Wood Jr. as inventor, filed 19 April 2004 and assigned USAN 10/827,572.

4. United States patent application entitled A TELESCOPING PERFUSION MANAGEMENT SYSTEM, naming Lowell L. Wood Jr. as inventor, filed 19 April 2004 and assigned USAN 10/827,390.

TECHNICAL FIELD

The present application relates, in general, to endoprosthetic devices for the treatment and/or management of disease, disorders, or conditions.

SUMMARY

In one aspect, a device includes but is not limited to: a flexible hollow portion with an outer surface and an inner surface and wherein the flexible hollow portion is sized for placement in a location in a receiver; and a plurality of movable parts coupled to the inner surface of the flexible hollow portion, the movable parts operable as a group for moving particles. In addition to the foregoing, other method aspects are described in the claims, drawings, and text forming a part of the present application.

In one aspect, a method includes but is not limited to: forming a supporting passage implantable in an animal; coupling a plurality of moving parts to the supporting passage; and sizing the supporting passage and the plurality of moving parts coupled to the supporting passage for placement in a location in the animal. In addition to the foregoing, other method aspects are described in the claims, drawings, and text forming a part of the present application.

In one aspect, a method includes but is not limited to: placing a hollow expandable device in a luminal portion of a recipient wherein the interior of the hollow

expandable device is coupled to a plurality of moving pieces; positioning the hollow expandable device in the lumen of the organ; and monitoring the hollow expandable device. In addition to the foregoing, other method aspects are described in the claims, drawings, and text forming a part of the present application.

In one or more various aspects, related systems include but are not limited to circuitry and/or programming for effecting the herein-referenced method aspects; the circuitry and/or programming can be virtually any combination of hardware, software, and/or firmware configured to effect the herein- referenced method aspects depending upon the design choices of the system designer.

In one or more various aspects, related systems include but are not limited to energy- and power-management circuitry and/or programming for effecting the herein-referenced method aspects; the circuitry and/or programming can be virtually any combination of hardware, software, and/or firmware configured to effect the herein-referenced method aspects depending upon the design choices of the system designer.

In addition to the foregoing, various other method and or system aspects are set forth and described in the text (e.g., claims and/or detailed description) and/or drawings of the present application.

The foregoing is a summary and thus contains, by necessity; simplifications, generalizations and omissions of detail; consequently, those skilled in the art will appreciate that the summary is illustrative only and is NOT intended to be in any way limiting. Other aspects, inventive features, and advantages of the devices and/or processes described herein, as defined solely by the claims, will become apparent in the non-limiting detailed description set forth herein.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a plan view of an embodiment of ciliated stent-like system 100.

Figure 2 is a plan view of various aspects of the ciliated stent-like system 100.

Figure 3 is one aspect of a cross sectional view of the ciliated stent-like system 100.

Figure 4 is one aspect of a cross sectional view of the ciliated stent-like system 100.

Figure 5 is a diagrammatic view of one aspect of the ciliary movement in the interior of the ciliated stent-like system 100.

Figure 6 is a diagrammatic view of one aspect of the ciliary movement in the interior of the ciliated stent-like system 100.

Figure 7 is an illustration of the ciliated stent-like system 100 implanted in a trachea or a bronchial tree portion 701.

The use of the same symbols in different drawings typically indicates similar or identical items.

DETAILED DESCRIPTION

The present application uses formal outline headings for clarity of presentation. However, it is to be understood that the outline headings are for presentation purposes, and that different types of subject matter may be discussed throughout the application (e.g., device(s)/structure(s) may be described under the process(es)/operations heading(s) and/or process(es)/operations may be discussed under structure(s)/process(es) headings). Hence, the use of the formal outline headings is not intended to be in any way limiting.

1. A Ciliated Stent-Like System(s) and/or Process(es).

With reference now to Figure 1, shown is a side plan view illustrative of various exemplary ciliated stent-like system(s) and/or process(es). Accordingly, the present application first describes certain specific exemplary structures of Figure 1; thereafter, the present application illustrates certain specific exemplary processes. Those having skill in the art will appreciate that the specific devices, systems and processes described herein are intended as merely illustrative of their more general counterparts.

It will also be appreciated by those skilled in the art that in one embodiment, the ciliated stent-like system includes a powered ciliated stent-like system. Furthermore, while the structure is referred to as a ciliated stent-like system, the terminology is not intended to be limiting. The term stent-like system may for example, refer stents or similar devices that may include any structure or device for providing support to an orifice, such as, for example, slender rods, threads, or catheters.

A. Structure(s) and or Device(s)

With reference to the figures, and with reference now to Figure 1, shown is a plan view of a ciliated stent-like system 100. The ciliated stent-like system 100 is an endoprosthetic device which may be employed in a recipient, a receiver, or a host, for example, an animal. In one aspect, the ciliated stent-like system 100 may be inserted into a lumen of a vessel threading a tissue or organ or portion thereof. The surface of the ciliated stent-like system 100 may include surface modifications to attach to or to positionally contact the vessel walls of the animal. For example, the surface modifications may include bumps 101, rings, grooves, ridges, or contours, one or more of which may be power-actuated. In one aspect, the ciliated stent-like system 100 is a longitudinal or elongated device with a substantially hollow interior. The ciliated stent-like system 100 may be used as an intraluminal prosthetic device to repair, open, evacuate, replace, medicate or support a lumen in the recipient. For example, the lumen of a vessel threading a tissue or an organ may be a part of a vascular system, a

neurovascular system, a urogenital tract, a pulmonary tract, a gastrointestinal tract, or any other lumen-threaded tissue or organ or portion thereof.

With reference to the figures, and with reference now to Figure 2, depicted is a plan view of various aspects of the ciliated stent-like system 100. In one aspect, the ciliated stent-like system 100 may have an open configuration. In another aspect, the ciliated stent-like system 100 may have a flexible, compressible, or expansive configuration. The ciliated stent-like system 100 may be self-expanding, balloon expandable, dilatable or contractible under control of an embedded controller. Expansion may be achieved, for example, by including an expandable material or a specific configuration, or a combination. For example, the expandable material, includes but is not limited to, nickel-cobalt-chromium based alloys, or titanium. Furthermore, expandability can also be configured by using a coil or spring-like configuration, or via any of many types of powered devices or mechanisms.

Continuing to refer to Figure 2, in another aspect, the ciliated stent-like system 100 may have an open flexible configuration. Such a configuration would permit the ciliated stent-like system 100 to be minimized in size for insertion. On insertion at a location the ciliated stent-like system 100 may expand to provide support. The shape or type of the ciliated stent-like system 100 may depend on the location of its use. For example, the ciliated stent-like system 100 may have a helical coil shape (Figure 2A and 2B), a tubular mesh shape (Figure 2C), a bifurcated shape (Figure 2D), an irregular Y shape, or an elongated segmented shape including taper (Figure 2E). In one aspect, the ciliated stent-like system 100 may be formed from a single wire, or have an open lattice or network structure. Additional information can be found, for example, in U.S. Patent Nos. 5,395,390 and 5,234,457 both of which are hereby incorporated by reference in their entirety. In one aspect, the ciliated stent-like system 100 may include a segmented structure, for example, for promoting flexibility and closer adherence to the lumen. In another aspect, the ciliated stent-like system 100 may include one or more expandable forks or branches, for example, for enhancing the support and/or removal of occluded material. Additionally, the ciliated stent-like system 100 may include attachments,

including but not limited to, an evacuating device, a siphon, a sensor, an actuator, a device for storing materials, a device for releasing materials stored, a controller, or a device for providing telemetry solutions.

Some or all of the parts, for example, the tissue-contacting parts, of the ciliated stent-like system 100 may be formed from a biocompatible material, a shape memory material or a metal such as, for example, nickel titanium alloy, metal, silicon, plastic or polymer. Examples of polymers include but are not limited to, polyethylene, polypropylene, polyglycolic acid, polylactic acid, cellulose acetate, or cellulose nitrate. In one aspect some or all of the parts of the ciliated stent-like system 100 may be made of a biodegradable material. In another aspect, the ciliated stent-like system 100 may be coated by one or more polymers or materials which are, for example, biocompatible, organic or biodegradable.

Furthermore, the ciliated stent-like system 100 may be used to deliver an agent, for example, including but not limited to, by passive delivery or under control of an controller either internal or external to the ciliated stent-like system 100. In one aspect, when delivering the agent by passive delivery, the ciliated stent-like system 100 may be coated with one or more agents, such as, for example, including, but not limited to, a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal-contracting agent, an antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, or a peptide.

In one aspect the ciliated stent-like system 100 is sized for placement in the recipient, for example, including but not limited to, in a lumen of a blood vessel in an adult human body. In another aspect the ciliated stent-like system 100 is sized for placement, for example, in the lumen of an organ in a pediatric body. In one example, the size of the diameter of the stent may be about 1-2 cm. In another example, both of the exterior and the interior diameters of the ciliated stent-like system 100 may be uniform or may vary to accommodate dimensions of the location of insertion, placement

of functionality-conferring devices, or functionality of the ciliated stent-like system 100. In another example, the ciliated stent-like system 100 may be sized to fit within a portion of a bronchial tree, wherein the internal diameter of portions of the bronchial tree is about 0.1-10 mm. It is also within the scope of the invention, that the ciliated stent-like system 100 may be used to replace, fully or partially, the functionality of the section portion of the bronchial tree. In this example, the outer diameter of the ciliated stent-like system 100 has a diameter corresponding to about the external diameter of the portion of the bronchial tree.

With reference now to Figure 3, and with reference now to Figure 4, depicted is one aspect of a cross sectional view of the ciliated stent-like system 100. In one aspect, the ciliated stent-like system 100 may have an outer surface 312 made of a metal and coated with a polymer. The outer surface 312 may have a coefficient of friction lower or higher in comparison to an inner surface 311 promoting the adherence of the outer surface 312 of the ciliated stent-like system 100, for example, to the bounding walls of the lumen. The outer surface 312 may also include surface protuberances 101, for example, to position or adhere the ciliated stent-like system 100, for example, to the bounding walls of the lumen. The inner surface 311 may have a low coefficient of friction to promote flow of air, fluid, debris, fluidized particles, exudates, particles, mucus, or debris. The inner surface 311 may be smooth to decrease the attachment or adherence of materials, thereby decreasing occlusion. The overall coefficient of friction of the outer surface 312 need only be of a sufficient value to permit the device to be reasonably secured to and/or positioned within a region and to minimize unwanted migration. Thus, the value of the coefficient of friction, for the ciliated stent-like system 100, will vary and, in one example, depend on the location of its use, or its intended use. It is known in the art that the coefficient of friction of Teflon-coated surfaces, for example, is about 0.05, the coefficient of friction of skin is about 0.8, and that of steel is about 0.58. In one exemplary aspect, the coefficient of friction of the inner surface 311 is between 0.0001 to about 0.58, whereas the coefficient of friction for the outer surface 312 is at least about 0.0001. In other applications or other aspects, the coefficient of friction

of the inner surface 311 and the coefficient of friction for the outer surface 312 may differ from these ranges, and the ranges should not be considered limiting.

In one aspect, the ciliated stent-like system 100 has a plurality of cilia 320 and 321 arranged in the inner surface 311 of the ciliated stent-like system 100. The plurality of cilia may include one or more movable parts attached to the ciliated stent-like system 100. In one aspect, the plurality of cilia 320 and 321 may be arranged, for example, in rows, columns, or similarly-ordered groupings. The plurality of cilia 320 and 321 may fully or partially encompass the inner surface 311. In one aspect, the length, the dimensions or other configuration aspects of the cilia will depend on the intended functions of the cilia. For example, where a pulmonary ciliated stent is employed in a trachea or a bronchi, the ciliary movement may help degrade occlusions or the formation thereof. In this example, the cilia may be long, the undulatory movement of the cilia may be responsible for moving, expelling or propelling, for example, fluid, clots, occlusive material, or fluid, particles, fluidized particles, mucus, exudate or biological debris. In another aspect, the plurality of cilia 320 and 321, may be a combination of various ciliary lengths suitable for operating an undulating propelling mechanism. It will be appreciated by those skilled in the art that the plurality of cilia 320 and 321 includes, but is not limited to, cilia-like functional structures and/or cilia-like appearing structures.

In one aspect the plurality of cilia 320 and 321 may be arranged on the inner surface 311 of the ciliated stent-like system 100. However, it is within the scope of the invention to include the plurality of cilia 320 and 321 on the outer surface 312 or on both surfaces. It is also within the scope of the invention, that the plurality of cilia 320 and 321 present on the outer surface 312 or the inner surface 311 may differ, for example, in the type of cilia, control mechanism associated with the cilia, and/or the function performed by the plurality of cilia 320 and 321. For example, the plurality of cilia 320 and 321 present on the outer surface 311 may be of a type, or have features that aid in the placement of the ciliated stent-like system 100 in a location in a recipient whereas the plurality of cilia 320 and 321 present on the inner surface 312 may be of a type or have features that perform other functions.

With reference now to Figure 5, in one aspect, the plurality of cilia 320 and 321 may include an actuator made of a self-oscillating polymer gel. Additional information may be found in an article by O. Tabata, H. Hirasawa, K, and S. Aoki "Ciliary Motion Actuator using Self-Oscillating gel." The 14th Annual International Conference On Micro ElectroMechinical Systems, pp.405-408, 2001, which is herein incorporated by reference. In another aspect, both the plurality of cilia 320 and 321 may be made of self-oscillating polymer gel. The self-oscillating polymer gel exhibits spontaneous swelling 520 and deswelling 521 and is responsible for propagating a wave motion. Ciliary movement, includes but is not limited to, up and down, undulating, wave like, pulsing, vectorial, oscillating, circular, lateral, vertical, rhythmic, or sideways movement or the like. Ciliary movement need not be limited to larger movements, but may include nanoscale-level movements.

Ciliary movement may be self-propagating or induced. For example, with regards to a pulmonary ciliated stent, induction may occur when a particle touches a cilium, or when the patient coughs, or otherwise moves or actuates his/her chest. Actuation may make use of stored energy, derived, for example, from previous motion; in the pulmonary case, for example, this motion may be that associated with inhalation and/or exhalation or with myocardial motion. The ciliated stent-like system 100 may be part of a disposable stent, for example, where the majority of the stent is composed of biodegradable or other material subject to solubilization or disintegration within the body. It will be appreciated by those skilled in the art that techniques for fabricating such cilia from self-oscillating polymer gels are well known in and are herein incorporated by reference. It will also be appreciated by those skilled in the art that techniques for favoring ciliary-driven transport in one direction along the stent relative to the other, particularly when a power source is available, are well-known and are herein incorporated by reference.

In another aspect, the plurality of cilia 310 and 321 includes one or more flexible polymeric rods. Additional information may be found in a presentation by R. L. Carroll, B. Wilde, R. M. Taylor, L. Vicci, S. Washburn, and R. Superfine, "Biomimetic Flexible

Polymer Rods- Artificial Cilia." The 70th Annual meeting of the Southeastern Section of the American Physical Society, November 6-8, 2003. Polymeric rods imitating ciliary structures are known structures. The polymeric rods may have a length about 10 microns, and a diameter of about 800 nm and would be able to propel fluid, fluidized particles, mucus, exudate or biological debris. However, polymeric rods of different dimensions are within the scope of the invention. In one example, the one or more flexible polymeric rods includes magnetic material. External oscillating magnetic fields may manipulate or actuate the flexible polymeric fields, for example, directly or by inductive coupling to an energy-store and/or power supply within the stent. It will be appreciated by those skilled in the art that such techniques and similar techniques are known, and are herein incorporated by reference.

In another aspect, the plurality of cilia 320 and 321 includes one or more MEMS micro-actuator arrays. It will be appreciated by those skilled in the art that the one or more MEMS micro-actuator arrays may be made to perform various modes of oscillatory movement and could be included in the interior of the ciliated stent-like system 100, for example, to provide a force for moving fluid, particles, fluidized particles, mucus, exudate or biological debris through the interior of the ciliated stent-like system 100. It will be appreciated by those skilled in the art that MEMS fabrication and actuation techniques are known in the art, and are herein incorporated by reference.

With reference now to the Figure 6, in one aspect, the plurality of cilia 320 and 321 are arranged, for example, in a centralized group or an array 620. Each cilium may have, for example, a modified paddle-shaped structure for efficiently moving fluid, fluidized particles, particles, mucus, exudate or biological debris.

In one aspect, the plurality of cilia 310 and 321 or the array 620 includes one or more actuator arrays, for example, MEMS actuator arrays. The MEMS actuator arrays may be coated with a thin film of a material that improves the physical, chemical, or electronic, properties of the array, for example, including, but not limited to, polyimide. The MEMS actuator arrays may promote the sensorless manipulation of small objects

using thermal and electrostatic control mechanisms. In one aspect the MEMS actuator arrays may be arranged, for example, including but not limited to, on the inner surface 311 of the ciliated stent-like system 100. The actuator arrays may be capable of providing a wide variety of movements, such as, for example, translation, rotation, centering, or orientation. Additionally, they may induce a low-level gait to the plurality of cilia 320 and 321, such as, for example, up-and-down motion, cyclical motion, or flagelatory motion resulting in the fluid, particles, fluidized particles, mucus, exudate or biological debris, being moved. In this example, the speed of the moving fluid, particles, fluidized particles, mucus, exudate or biological debris is dependant on the displacement of the actuators per cycle, the number of times the cycle is repeated per unit of time, the surface properties of the particle to be moved, the weight of the particle to be moved, the local surface tension, the local orientation relative to the direction of gravity or other acceleration field, etc. In another example, the one or more MEMS actuator arrays may be used to induce a high-level control, or a high-level gait, such as, for example, orienting and aligning fluid, particles, fluidized particles, mucus, exudate or biological debris. In this example, the one or more MEMS actuator arrays may be used to position or rotate an obstructing or blocking particle for its expulsion or removal from the lumen of a vessel. It will be appreciated by those skilled in the art that such techniques are known in the art and are herein incorporated by reference. Additional information may be found in an article by W. Suh, R. B. Darling, K. F. Böhringer, B. R. Donald, H. Baltes, G. T. A. Kovacs, "Fully Programmable MEMS Ciliary Actuator Arrays for Micromanipulation Tasks." IEEE International Conference on Robotics and Automation (ICRA), pp. 1101-1108, San Francisco, CA, April 2000, which is herein incorporated by reference.

Continuing to refer to Figure 6, in one example, the plurality of cilia 320 and 321, for example, may move in a programmed or otherwise controlled rhythm. The plurality of cilia 320 and 321 may extend to an upward extended position 621 from a middle resting position, to a downward position 623 before returning to the middle resting position. In another example the resting position of the plurality of cilia 320 and 321 may be the downward position 623. Other combinations of synchronous or non-synchronous beatings of the plurality of cilia 320 and 321 are within the scope of the

invention, including those in which one or more waves of ciliary action are made to propagate along some selected direction relative to the local axis of the stent.

In another aspect, motors may be included in the plurality of cilia 320 and 321 to provide the energy or to generate the force needed for moving fluid, particles, fluidized particles, mucus, exudate or biological debris or fluid. In one example, protein molecule-based motors, such as those employing kinesin or dynein, may be used to provide motive force for ciliary rotational or directional movement. For example, including but not limited to, the direction of the movement of the biological molecular motors, is influenced by the orientation of any tubulin present, or the matrix that the motors may use as their tracks. In one aspect, ATP hydrolysis may provide the energy for the actuation of the biological molecular motors, and ATP and ATPase may be furnished, for example, by coupling mitochondria to the biological molecular motors. In another example, the actin-myosin system may be included in the plurality of cilia 320 and 321 in order to provide the force for moving fluid, particles, fluidized particles, mucus, exudate or biological debris. It will be appreciated by those skilled in the art that such techniques are known in the art and are herein incorporated by reference. This subject is described in further detail by N. Thomas and R.A. Thornhill in the Journal of Physics D: Applied Physics 31, pages 253-266, 7 February 1998, and by Carlo Montemagno, George Bachand, Scott Stelick, and Marlene Bachand in Nanotechnology 10:225-231, 1999, both of which are herein incorporated by reference.

In another aspect, the plurality of cilia 320 and 321 includes an electro-active transducer with an electroactive polymer, which deflects in response to an electrical field. In one example, the deflection of the electroactive polymer is operable to move fluid. In another example, the deflection of the electroactive polymer is operable to move fluid, particles, fluidized particles, mucus, exudate or biological debris, such as, for example, congealed or clotted liquids. The transducer includes at least two electrodes in electrical communication with the electroactive polymer. Deflection of the electroactive polymer may produce a range of motions, including, but not limited to, one or more of a rotational, vibrational, linear, flagelatory or the like. Additional information regarding

electroactive polymers can be found in U.S. Patent Application No. 2004/0008853 which is herein incorporated by reference.

In another aspect, the plurality of cilia 320 and 321 includes, for example, electrostrictive materials, such as, piezoelectric materials, or magnetostrictive materials. These materials may be actuated by application of electric or magnetic fields, respectively, sourced, for example, by a power source internal or external to the ciliated stent-like system 100. In one aspect, the power source may be external to the ciliated stent-like system 100 but internal to the recipient. For example, including, but not limited to, acoustic energy may be sourced from either within the ciliated stent-like system 100, from elsewhere within the recipient in which the ciliated stent-like system 100 is located. In another aspect, the power source may be external to the recipient, for example, power may be supplied to the ciliated stent-like system 100 from outside of the recipient, including powering actuation of the plurality of cilia 320 and 321, either directly or indirectly. In yet another aspect, the power source may be internal to the ciliated stent-like system 100.

In another aspect, control of ciliary motion may be performed by a controller, for example, including, but not limited to, one centered on a digital microprocessor, embedded in whole or in part within the ciliated stent-like system 100 or the powered stent-like system. Such embedded controller may be interrogated or programmed with acoustic-, wired- or optical-circuitry or via wireless transmission of electrically-, magnetically- or electromagnetically-conveyed signals. Such controller may be informed by one or more sensors within the ciliated stent-like system 100 or the powered stent-like system. Such controller may, from time-to-time in a programmed manner, also direct release of one or more materials from one or more reservoirs or storage compartments located within the ciliated stent-like system 100 or the powered stent-like system, or may direct, monitor or control one or more large-scale motions of part or all of the ciliated stent-like system 100 or the powered stent-like system system 100.

Provision of energy to the power the ciliated stent-like system 100 includes, but is not limited to, including one or more primary or secondary batteries possibly embedded into, battery-recharging or direct power transfer via body-external magnetic, electric, acoustic, gross-mechanical-motion or optical fields applied for this purpose, a system generating chemical energy possibly embedded within the system. In one aspect, energy may be recharged or regenerated. For example, by external or intra-body sources, and transduction/conversion of kinetic energy deriving from action of one or more muscles of the body in which the ciliated stent-like system 100 or the powered stent-like system is embedded or implanted, for example, including but not limited to, inertial-mechanical-electrical transduction.

The ciliated stent-like system 100 or the powered stent-like system may include additional devices, integrated devices, or properties for diametrically expanding and/or contracting, as well as translating along the axis of the local lumen, any portion of the system, including all of it. These may include, but aren't limited to, mechanical devices, such as, for example, linear motors, electro- or magneto-strictive actuators, tractive devices, pneumatic actuators, peristaltic devices, etc.

The ciliated stent-like system 100 or the powered stent-like may include additional devices, integrated devices, or properties for sensing and/or quantitatively measuring to a specified accuracy one or more features or variables of its environment, for processing, storing and transmitting such information to a body-external receiver, and for receiving control or interrogation information from one or more body-external points.

The format of materials which may be stored and/or released by the ciliated stent-like system 100 includes, but is not limited to, liquids, gases, emulsions, gels, mists, sprays, dusts, powders, aerosolized or carbureted particulate matter of all types, and the composition thereof may be one or more of a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal–contracting agent, an antibiotic or antifungal or

antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, or a peptide, a contrast agent, or a pharmacological agent.

B. Operation(s) and/or Process(es)

With reference to the figures, and with reference now to Figure 7, is an illustration of the ciliated stent-like system 100 implanted in a trachea 701. In another implementation the ciliated stent-like system 100 is implanted in a bronchiole 703, or a bronchi 702 or any part of the bronchial tree. In other implementations, the ciliated stent-like system 100 is not restricted to the pulmonary system but is employed in the lumen of any vessel or organ of the recipient, for example, any vessel in an animal body.

In one implementation, the ciliated stent-like system 100 includes, but is not limited to, an external controller for manipulating the ciliated stent-like system 100 and/or the plurality of cilia 320 and 321. Manipulation of the ciliated stent-like system 100 may include, for example, expelling, moving, guiding, positioning or repositioning the ciliated stent-like system 100. In one example, the ciliated stent-like system 100 may be controlled or manipulated from a remote location by medical personnel. In another example, the ciliated stent-like system 100 may be controlled or manipulated external to the recipient. In another implementation, the external controller may include a monitoring system, and/or wireless circuitry for manipulating the ciliated stent-like system 100 0 and/or the plurality of cilia 320 and 321.

In one implementation, the ciliated stent-like system 100 includes a system or apparatus for removing or relocating biological debris of various types, such as, for example, fluid, particles, fluidized particles, mucus, exudate or biological debris. For example, the apparatus or the system may include a siphon connected to a monitor for visualizing the debris field. Observable debris may then be siphoned by positioning and operating the siphon. In one example, the siphon may be used in collaboration with the

plurality of cilia 320 and 321. In this example, the plurality of cilia 320 and 321 may be used to gather and/or expel any debris and the siphon employed to collect and/or relocate the gathered or expelled debris, for example, from within one or more locations in the pulmonary tract into the esophagus.

In one implementation, the use of the ciliated stent-like system 100 includes, but is not limited to, the treatment of pulmonary diseases, such as, for example, chronic obstructive pulmonary disease (COPD). COPD includes diseases characterized by dyspnea or disorders characterized by, such as, for example, chronic bronchitis, asthma, or emphysema. Additional information may be found in the following two articles by P.J. Barnes, "Small Airways in COPD." New England Journal of Medicine, 350:256, pages 2635-2637, July 04, 2004, and by E.R. Sutherland, R.M. Cherniack, "Management of Chronic Obstructive Pulmonary Disease, pages 2689-2697, June 24, 2004, which is herein incorporated by reference. In another implentation, the ciliated stent-like system 100 may be configured to address diseases, such as, for example, cystic fibrosis, in which under-performance of the muco-ciliary system results in the accumulation of mucus, exudates and pathogens in the lung, causing prolonged, occasionally life-threatening infections. In this example, the ciliated stent-like system 100 may be employed to help clear the air passages by expelling actively, for example, fluid, fluidized particles, mucus, exudate or biological debris, including in conjunction with release and/or dispersal of surfactants or viscosity-modulating agents, either from the ciliated stent-like system 100 or from other sources.

In one implementation, the plurality of cilia 320 and 321 are programmed for moving intermittently. In another implementation, the plurality of cilia 320 and 321 may be programmed to move continuously. It will be appreciated by those skilled in the art that the movements of the plurality of cilia 320 and 321 may be adjusted depending on a number of criteria, for example, the area of use or the specifics of the task required to be performed.

C. Variation(s), and/or Implementation(s)

Those having skill in the art will recognize that the present application teaches modifications of the devices, structures, and/or processes within the spirit of the teaching herein. For example, the ciliated stent-like system 100 need not be limited to a cylindrical or tubular shape. For example, the ciliated stent-like system 100 may have a composite or multi-segmented flexible shape to provide a best fit in the use-location in the animal. In another example, the ciliated stent-like system 100 may have a substantially planar or conical shape, or may change its shape markedly as it installs within or transverses a luminal tract of a vessel within an animal. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

It will also be appreciated by those skilled in the art that the ciliated stent-like system 100 may be made of materials that render it fully or partially disposable. In one example, the outer surface 312 of the ciliated stent-like system 100 is designed to deliver an agent or perform functions to remove an obstruction, and then disintegrate. For example, the outer surface 312 of the ciliated stent-like system 100 may be coated with the agent which is made to contact the walls of the lumen. The main body of the ciliated stent-like system 100 may be designed to disintegrate or dissolve over a certain interval of time leaving the agent on/within the lumen. Alternatively, the ciliated stent-like system 100 may release one or more agents into the lumen itself, either continually or under program control. Any such agent may be replenished by reloading into a compartment or reservoir within the ciliated stent-like system 100. Other modifications of the subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

It will also be appreciated by those skilled in the art that the ciliated stent-like system 100 may include wireless or robotic attachments for controlling it from the exterior of the recipient or animal in which it is placed. Other modifications of the

subject matter herein will be appreciated by one of skill in the art in light of the teachings herein.

The foregoing described aspects depict different components contained within, or connected with, different other components. It is to be understood that such depicted architectures are merely exemplary, and that in fact many other architectures can be implemented which achieve the same functionality. In a conceptual sense, any arrangement of components to achieve the same functionality is effectively "associated" such that the desired functionality is achieved. Hence, any two components herein combined to achieve a particular functionality can be seen as "associated with" each other such that the desired functionality is achieved, irrespective of architectures or intermedial components. Likewise, any two components so associated can also be viewed as being "operably connected", or "operably coupled", to each other to achieve the desired functionality.

While particular aspects of the present subject matter described herein have been shown and described, it will be obvious to those skilled in the art that, based upon the teachings herein, changes and modifications may be made without departing from this subject matter described herein and its broader aspects and, therefore, the appended claims are to encompass within their scope all such changes and modifications as are within the true spirit and scope of this subject matter described herein. Furthermore, it is to be understood that the invention is defined solely by the appended claims. It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims (e.g., bodies of the appended claims) are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.). It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory

phrases "at least one" and "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to inventions containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an" (e.g., "a" and/or "an" should typically be interpreted to mean "at least one" or "one or more"); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation *is* explicitly recited, those skilled in the art will recognize that such recitation should typically be interpreted to mean *at least* the recited number (e.g., the bare recitation of "two recitations," without other modifiers, typically means *at least* two recitations, or *two or more* recitations), etc.

CLAIMS

1. A device, comprising:

   a flexible hollow portion with an outer surface and an inner surface and wherein the flexible hollow portion is sized for placement in a location in a receiver; and

   a plurality of movable parts coupled to the inner surface of the flexible hollow portion, the movable parts operable as a group for moving particles.

2. The device of Claim 2, wherein the flexible hollow portion further comprises:

   a substantially tubular or cylindrical structure.

3. The device of Claim 2, wherein the a substantially expandable tubular or cylindrical structure further comprises:

   at least one of a substantially expandable, or contractile structure.

4. The device of Claim 2, wherein the substantially expandable tubular or cylindrical structure flexible further comprises:

   an expandable mesh.

5. The device of Claim 2, wherein the substantially tubular or cylindrical structure further comprises:

   a plurality of expandable segments coupled to the plurality of movable parts.

6. The device of Claim 2, wherein the substantially tubular or cylindrical structure comprises:

one or more of a metal, silicon, polymer, plastic, organic, or biodegradable material.

7. The device of Claim 2, wherein the substantially tubular or cylindrical structure further comprises:

a coating of one or more of a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal–contracting agent, an antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, a peptide, polymer, or a biodegradable material.

8. The device of Claim 1, wherein the flexible hollow portion further comprises:

a shape or configuration for placement in the location.

9. The device of Claim 8, wherein the flexible hollow portion further comprises:

a shape or configuration for placement in a trachea, a bronchi, a bronchial tree, a urogenital tract, a gastrointestinal tract, a pulmonary tract, a neurovascular system, or a vascular system.

10. The device of Claim 8, wherein the flexible hollow portion further comprises:

a shape or configuration for placement for placement in a lumen threaded organ or tissue or portion thereof of the receiver.

11. The device of Claim 1, wherein the flexible hollow portion further comprises:

one or more flexible hollow portions coupled to form an operable piece configured for a location.

12. The device of Claim 1, wherein the flexible hollow portion further comprises:

one or more forks or branches.

13. The device of Claim 1, wherein the flexible hollow portion further comprises:

a substantially smooth inner surface.

14. The device of Claim 1, wherein the flexible hollow portion comprises:

an inner surface with a low coefficient of friction operable for low-impedance flow of air or fluid.

15. The device of Claim 1, wherein the flexible hollow portion comprises:

an outer surface with a surface modification operable for adhesion, adherence or positioning to the location in the receiver

16. The device of Claim 1, wherein the receiver includes:

an animal or a plant.

17. The device of Claim 13, wherein the surface modification comprises:

one or more of a groove, bump, ridge, ring or contour.

18. The device of Claim 1, wherein the plurality of movable parts further comprises:

one or more of a gel, a hydrogel, a colloid, a polymer, an oscillating polymer, an electro-active polymer, a polymer, an electro- or magneto-strictive material, a linear motor-device, or a material coated with a biologically compatible material.

19. The device of Claim 1, wherein the plurality of movable parts further comprises:

a low-level gait or motion for moving fluid, particles, fluidized particles, mucus, exudate or debris.

20. The device of Claim 1, wherein the plurality of movable parts further comprises:

a high-level gait or motion for moving fluid, particles, fluidized particles, mucus, exudate, or debris.

21. The device of Claim 1, wherein the device further comprising:

an actuator, a motor, a biomolecular motor, or a device operable for providing motion coupled to the plurality of movable parts.

22. The device of Claim 1, wherein the device further comprises:

an electric, magnetic, acoustic, optical or electromagnetic field for controlling the plurality of movable parts or the flexible hollow portion.

23. The device of Claim 1, wherein device further comprises:

an external or internal electric, magnetic, acoustic, optical or electromagnetic field for controlling the device.

24. The device of Claim 1, wherein the device comprises:

a custom size, shape, or a dimension for replacing or functionally supplementing at least a portion of a trachea, a bronchi, a bronchial tree, a urogenital tract, a gastrointestinal tract, a pulmonary tract, a neurovascular system, or a vascular system.

25. The device of Claim 1, wherein the device further comprises:

an external controller coupled to the device for monitoring, manipulating or controlling the device.

26. The device of Claim 1, wherein the device further comprises:

a monitor coupled to an external controller.

27. The device of Claim 1, wherein the device further comprises:

a remote control system coupled to the device for manipulating the device.

28. The device of Claim 1, wherein the device further comprises:

an evacuating device coupled to the device.

29. The device of Claim 1, wherein the device further comprises:

a mechanism for dispensing of at least one of a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal–contracting agent, an antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, a peptide, a polymer, or a biodegradable material.

30. The device of Claim 1, wherein the device further comprises:

a reservoir for storing one or more of a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal–contracting agent, an antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, a peptide, a polymer, or a biodegradable material.

31. The device of Claim 1, wherein the flexible hollow portion further comprises:

one or more movable parts coupled to the outer surface of the flexible hollow portion.

32. The device of Claim 1, wherein the device further comprises:

a mechanism for powering the device.

33. The device of Claim 32, wherein the mechanism for powering the device further comprises:

a mechanism for obtaining or storing energy.

34. A method of making a device, comprising:

forming a supporting passage implantable in a recipient;

coupling a plurality of moving parts to the supporting passage; and

sizing the supporting passage and the plurality of moving parts coupled to the supporting passage for placement in a location in the recipient.

35. The method of Claim 34, wherein the method further comprises:

coupling a plurality of moving parts to the supporting passage for moving one or more of a fluid, particle, fluidized particle, object, debris, mucus, exudate, or debris.

36. The method of Claim 34, wherein the method further comprises:

forming the supporting passage wherein at least a portion of the supporting passage is at least one of substantially flexible, compressible, or expansile.

37. The method of Claim 34, wherein the method further comprises:

forming the supporting passage including a substantially expandable tubular or cylindrical part coupled to the plurality of moving parts.

38. The method of Claim 34, wherein the method further comprises:

forming the supporting passage including an expandable mesh coupled to the plurality of moving parts.

39. The method of Claim 34, wherein the method further comprises:

forming the supporting passage coupled to the plurality of moving parts configured for placement in the location in the recipient.

40. The method of Claim 34, wherein the method further comprises:

forming a bifurcated supporting passage.

41. The method of Claim 34, wherein the method further comprises:

forming the supporting passage or plurality of moving parts with one or more of a metal, silicon, polymer, plastic, inorganic, organic, or biodegradable material.

42. The method of Claim 34, wherein the method further comprises:

coating at least a portion of the supporting passage or plurality of moving parts with a biocompatible material, polymer, biodegradable material, drug, medicinal agent, or therapeutic agent.

43. The method of Claim 34, wherein the method further comprises:

producing a smooth surface in at least a portion of the interior of the supporting passage.

44. The method of Claim 34, wherein the method further comprises:

making surface modifications in the exterior of the supporting passage operable for attaching to or positioning about the location in the animal.

45. The method of Claim 44, wherein the method further comprises:

forming surface modifications including grooves, contours, ridges, rings or bumps in the exterior of the supporting passage.

46. The method of Claim 34, wherein the method further comprises:

forming the supporting passage or the plurality of moving parts including one or more of a gel, a hydrogel, a colloid, a polymer, an oscillating polymer, an electro-active polymer, a polymer, or a material coated with a biologically-compatible material.

47. The method of Claim 34, wherein the method further comprises:

orienting the plurality of moving parts radially outward.

48. The method of Claim 34, wherein the method further comprises:

configuring the plurality of moving parts to define a low-level gait or motion.

49. The method of Claim 34, wherein the method further comprises:

configuring the plurality of moving parts to define a high-level gait or motion.

50. The method of Claim 34, wherein the method further comprises:

including in the plurality of moving parts at least one enabling an upward, downward, cyclical, rotational, aligning, translational, or horizontal movement.

51. The method of Claim 34, wherein the method further comprises:

including plurality of moving parts with an independent, sequential, or synchronous motion.

52. The method of Claim 34, wherein the method further comprises:

operably-coupling an actuator, a motor, a biomolecular motor, or a device operable for providing motion to the plurality of moving parts.

53. The method of Claim 34, wherein the method further comprises:

including an internal electric, magnetic or mechanical-stress field in the plurality of parts or in the actuator operable for controlling the motion or direction of the one or more moving parts.

54. The method of Claim 34, wherein the method further comprises:

including an electric, magnetic, acoustic, optical or electromagnetic field for controlling or directing the plurality of moving parts.

55. The method of Claim 34, wherein the method further comprises:

an external or internal electric, magnetic, acoustic, optical or electromagnetic field for controlling or directing the plurality of moving parts.

56. The method of Claim 34, wherein the method comprises:

forming the supporting passage with a custom size, shape, configuration, or dimension for placing in a trachea, a bronchi, a bronchial tree, a urogenital tract, a gastrointestinal tract, a pulmonary tract, a neurovascular system, or a vascular system.

57. The method of Claim 34, wherein the method comprises:

forming the supporting passage with a custom size, shape, configuration, or dimension for replacing or functionally supplanting at least a portion of a trachea, a bronchi, a bronchial tree, a urogenital tract, a gastrointestinal tract, a pulmonary tract, a neurovascular system, or a vascular system.

58. The method of Claim 34, wherein the method further comprises:

coupling an external control system to the plurality of moving parts or the supporting passage.

59. The method of Claim 34, wherein the method further comprises:

including an external control system for remotely operating or manipulating the device.

60. The method of Claim 34, wherein the method further comprises:

coupling a monitor to the supporting passage.

61. The method of Claim 34, wherein the method further comprises:

coupling a debris-removing, debris–displacing or debris–relocating system to the supporting passage.

62. The method of Claim 34, wherein the method further comprises:

providing a storage system for storing at least one of a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal–contracting agent, an

antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, a peptide, a polymer, or a biodegradable material.

63. The method of Claim 34, wherein the method further comprises:

coating at least a portion of the device with at least one of a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal–contracting agent, an antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, a peptide, a polymer, or a biodegradable material.

64. The method of Claim 34, wherein the method further comprises:

including a mechanism for releasing one or more of a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating a luminal–contracting agent, an antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, a peptide, a polymer, or a biodegradable material.

65. The method of Claim 34, wherein the method further comprises:

storing energy internal or external to the device.

66. The method of Claim 34, wherein the method further comprises:

providing a mechanism for obtaining power.

67. The method of Claim 34, wherein the method further comprises:

coupling the plurality of moving parts to at least one of an interior wall or an exterior wall of the supporting passage.

68. A method, comprising:

placing a hollow expandable device in a luminal portion of a recipient wherein the interior of the hollow expandable device is coupled to one or more moving pieces;

positioning the hollow expandable device in the lumen of the organ; and

monitoring the hollow expandable device.

69. The method of Claim 68, wherein the method further comprises:

adjusting, guiding, positioning, directing, or activating the hollow expandable device.

70. The method of Claim 68, wherein the method further comprises:

removing the hollow expandable device.

71. The method of Claim 68, wherein the method further comprises:

activating the one or more moving pieces coupled to the hollow expandable device to move fluid, particles, fluidized particles, mucus, exudate or debris.

72. The method of Claim 68, wherein the method comprises:

providing the size, dimensions, or custom modifications for forming the hollow expandable device.

73. The method of Claim 68, wherein the method further comprises:

applying at least one of an external electric, magnetic, acoustic, optical or electromagnetic field for removing fluid, particles, fluidized particles, mucus, exudate or debris.

74. The method of Claim 68, wherein the method further comprises:

placing the hollow expandable device in a trachea, a bronchi, a bronchial tree, a urogenital tract, a gastrointestinal tract, a pulmonary tract, a neurovascular system, or a vascular system.

75. The method of Claim 68, wherein the method further comprises:

controlling a motion or directionality of the plurality of moving pieces.

76. The method of Claim 68, wherein the method further comprises:

adjusting the orientation of the plurality of moving pieces.

77. The method of Claim 68, wherein the method further comprises:

placing the hollow expandable device wherein the hollow expandable device has at least one fork.

78. The method of Claim 68, wherein the method further comprises:

positioning the at least one fork.

79. The method of Claim 68, wherein the method further comprises:

removing any debris.

80. The method of Claim 68, wherein the method further comprises:

monitoring the hollow expandable device remotely.

81. The method of Claim 68, wherein the method further comprises:

positioning the hollow expandable device and plurality of moving parts remotely.

82. The method of Claim 68, wherein the method further comprises:

charging the hollow expandable device.

83. The method of Claim 68, wherein the method further comprises:

delivering a drug, a medicinal agent, a therapeutic agent, a biologically active agent, a chemical, a chemical compound, a surfactant, a steroid, a luminal-dilating agent, a luminal-contracting agent, an antibiotic or antifungal or antiviral agent, a protein, a nucleic acid or a polymer comprised of one or more nucleic acids, a macromolecule, a peptide, polymer, or a biodegradable material.

Fig 1

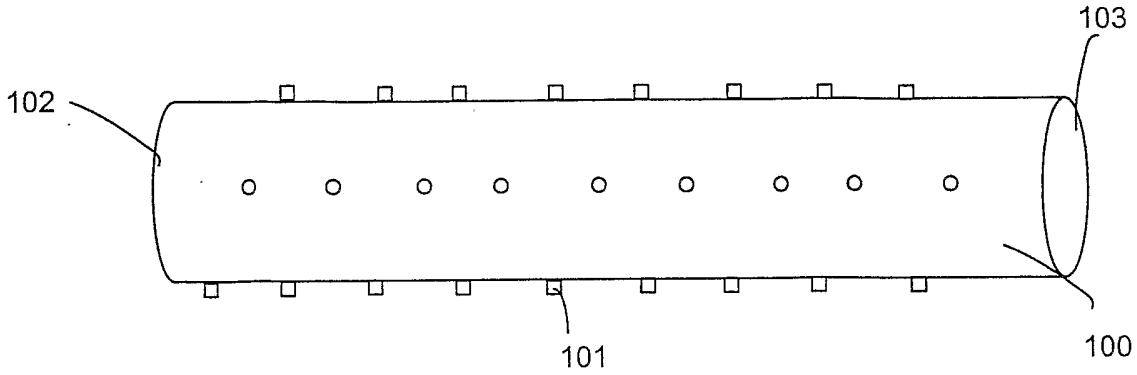
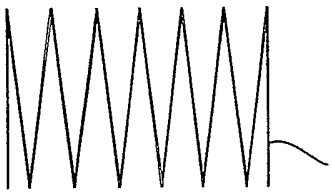


Fig 2

A



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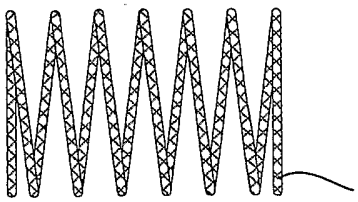

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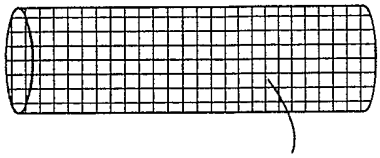

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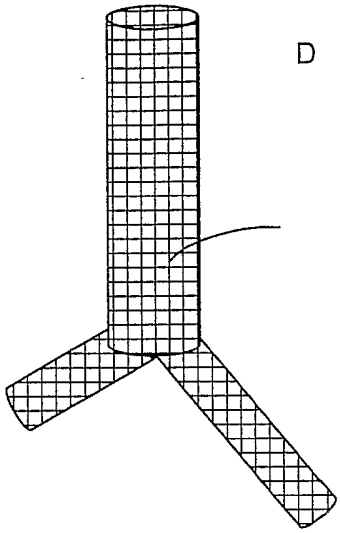


E

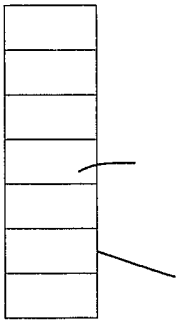


Fig 3

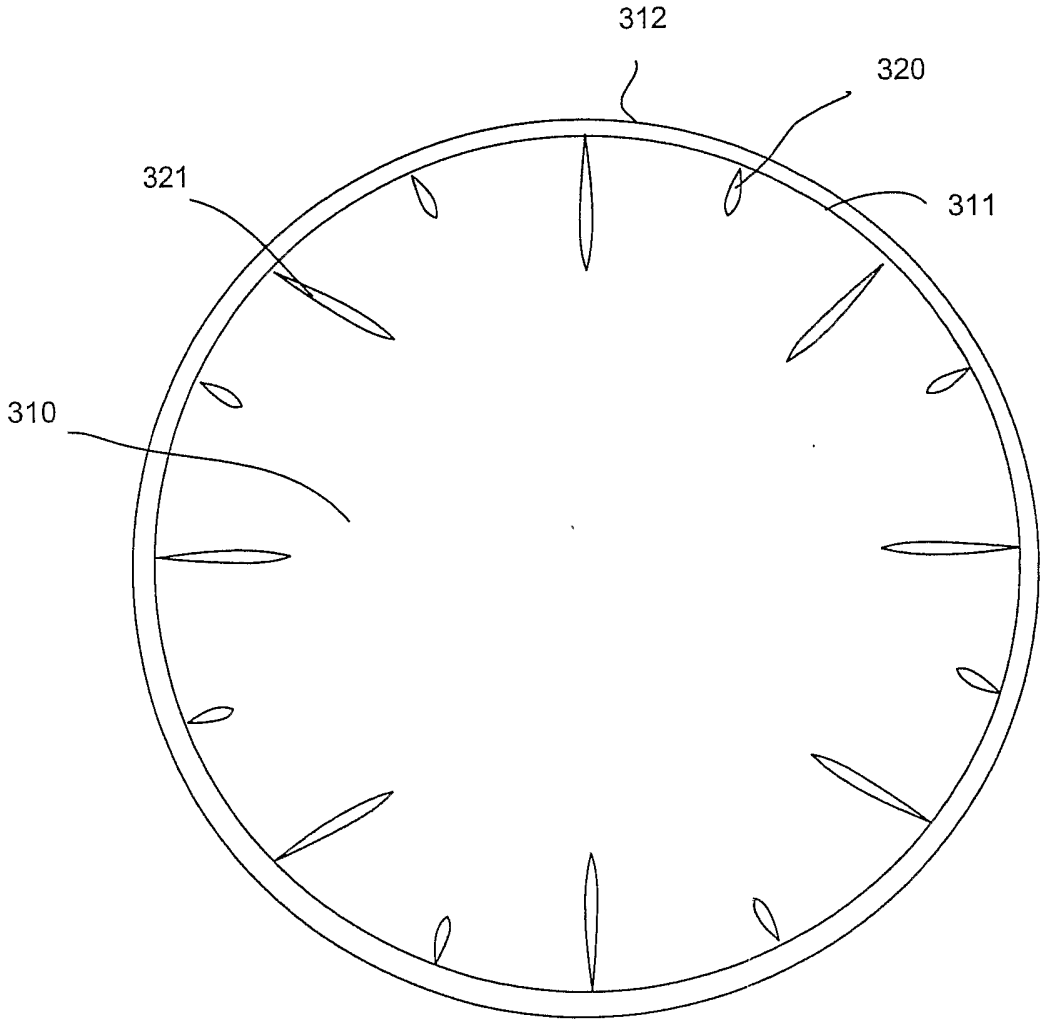


Fig 4

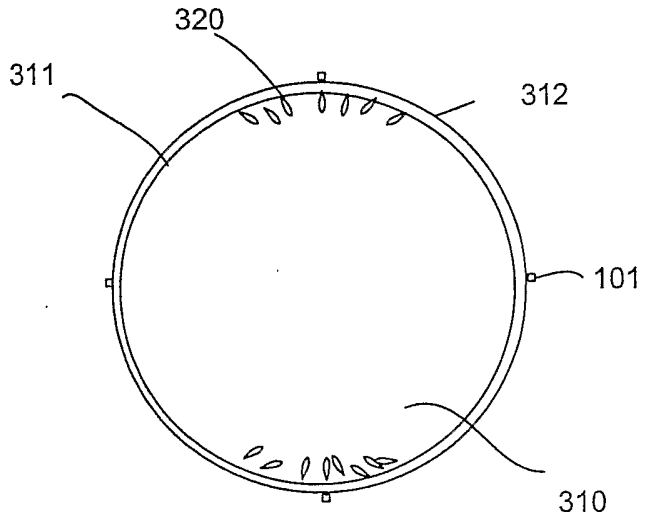
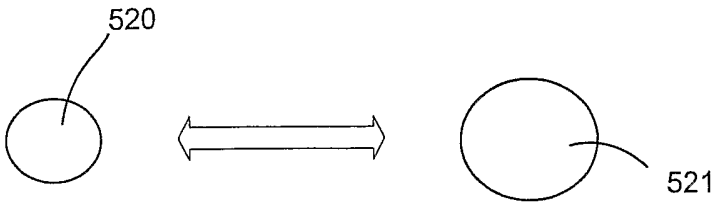


Fig 5



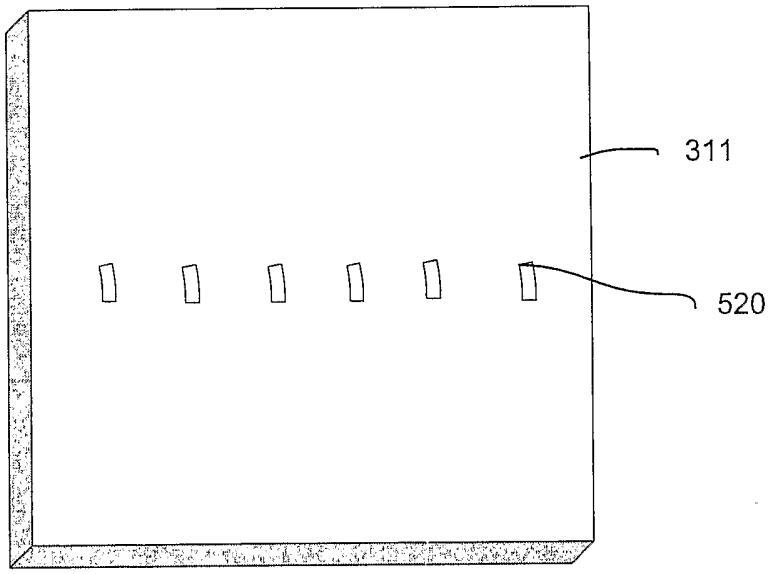


Fig 6

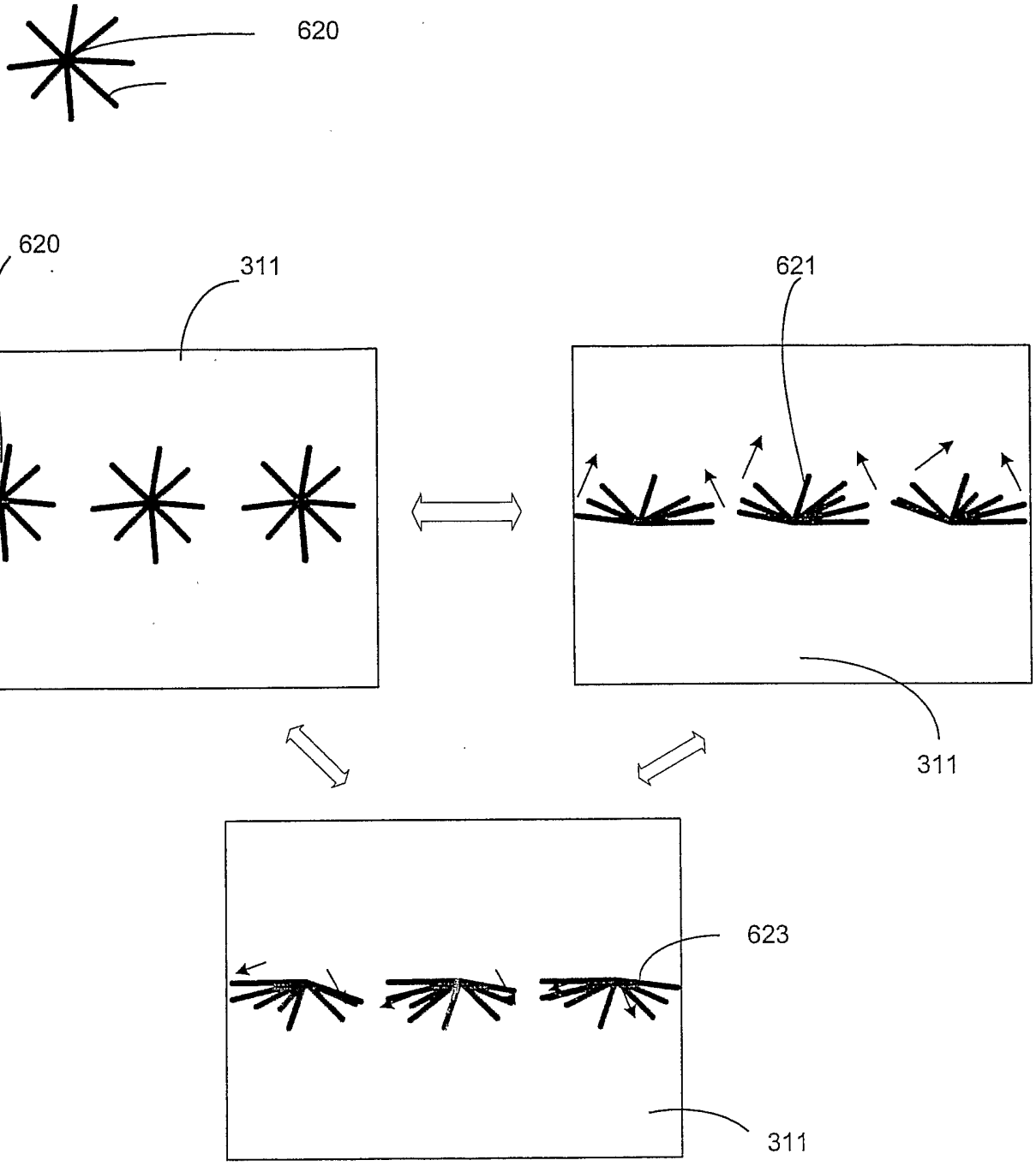


Fig 7