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(71) Applicant and
(72) Inventor: SCHEER, Ingo [DE/US]; 6455 La Jolla Blvd, La Jolla, CA 92037 (US).

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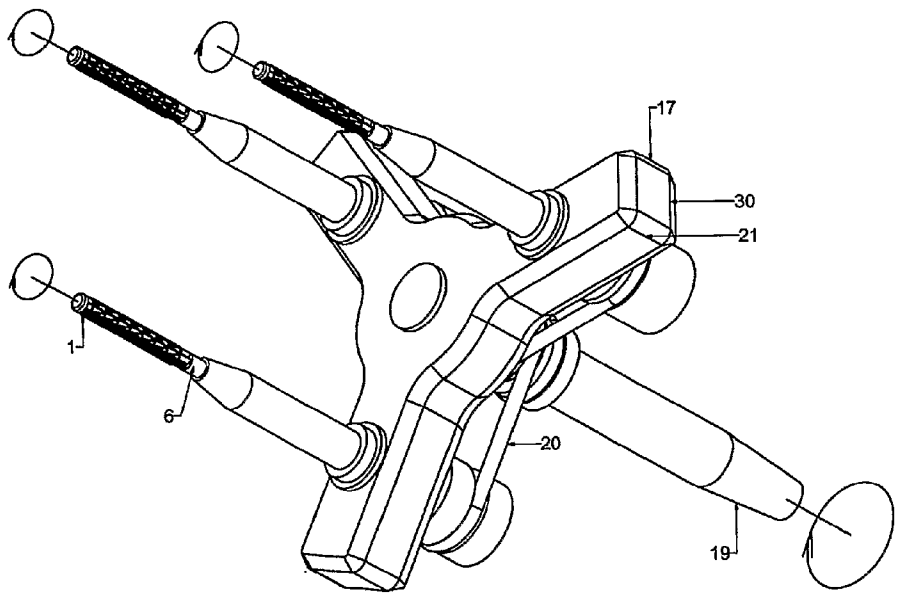
(54) Title: APPARATUS AND METHOD FOR COATING A SUBSTRATE



(57) Abstract: An apparatus and method is provided to allow higher volume production of medical devices and to minimize coating defects resulting from manual handling of medical devices by supporting multiple medical devices at the same time and performing one or more process steps automatically.

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INVENTION TITLE

Apparatus and method for coating a substrate

CROSS-REFERENCE TO RELATED APPLICATIONS

This Application relates to and claims priority from commonly owned U.S. Provisional Patent Application Serial No. 60/776522, filed on February 24, 2006, U.S. Patent Application Serial No. 11/431,366, filed on March 03, 2006 and U.S. Patent Application Serial No. 11/644,267, filed on December 23, 2006.

FEDERALLY SPONSORED RESEARCH

Not Applicable

SEQUENCE LISTING OR PROGRAM

Not Applicable

BACKGROUND OF THE INVENTION – FIELD OF INVENTION

This invention relates to an apparatus and a method of coating hollow cylindrical objects using the device. More specifically, the present invention provides an apparatus and a method of efficiently coating and securely handling one or more hollow cylindrical objects, such as stents or catheters.

BACKGROUND OF THE INVENTION

Coatings are often applied to medical implants, such as pacemakers, vascular grafts, catheters, stents, heart valves, tissues or sensors to have desired effects and increase their effectiveness. These coatings may deliver a therapeutic agent to the lumen that reduces smooth muscle tissue proliferation or restenosis and may comprise a polymer carrier. Furthermore, implants may be coated to improve surface properties such as lubriciousness, to achieve enhanced biocompatibility and to control the timing and rate of release of the therapeutic agent being delivered. Balloon delivery systems, stent grafts and expandable stents are specific examples of implants that may be coated and inserted within the body. Stents such as described in U.S. Pat. No. 4,733,665 are tiny, expandable mesh tubes supporting the inner walls of a lumen used to restore adequate blood flow to the heart and other organs.

Conventionally, coatings are applied to the stent in a number of ways including, though not limited to, dip coating, spin coating or spray coating processes. Spray coating processes generally require an apparatus for securely holding and rotating the flexible, tiny stent structure during the coating operation to allow a repeatable and homogeneous coating application.

However, holding devices known from the prior art have several drawbacks which may result in low volume production of medical devices. Conventional medical device holding fixtures are not designed to securely support multiple stents at a time, to perform different process steps automatically, and/or to apply several process steps simultaniously.

In addition, conventional holding devices often require complicated handling procedures. Damage of the coating may occur after completition of the coating process during handling and inspection. Inspection of medical devices generally requires dismounting the stent from the holding device being used during the coating process in order to mount the stent to an inspection fixture that typically contacts the outer surface of the stent. A damaged coating, on the other hand, may compromise the implant's effectiveness due to potential complications arising from an inhomogeneous distribution of the therapeutic agent at the target site.

Thus, there is a need for a system and a method for efficiently applying a high quality coating on the surface of a medical device, while minimizing the risk of damaging the coating during handling and inspection.

SUMMARY

One object is to provide a holding arrangement for securing, handling and rotating at least one medical device.

Another object is to provide an apparatus to automatically index at least one medical device at different angular positions and to rotate and/or translate the medical device.

Yet another object is to provide a method to automatically perform several process steps upon the same medical device at different angular positions.

Still another object is to provide a method to automatically perform a process step consecutively upon multiple medical devices, which are supported by the same holding arrangement.

A further object is to provide a method to automatically perform a process step simultaneously upon multiple medical devices, which are supported by the same holding arrangement.

In one embodiment, a holding arrangement for handling, supporting and transmitting rotary motion to at least one medical device is provided. The holding arrangement comprises a frame, at least one holding device to support the medical device, and a shaft. In a first state, rotary motion is transmitted from the shaft to the holding device in order to rotate the medical device in relation to the frame, and during indexing the holding arrangement rotates around the axis of the shaft. In one or more embodiments, the medical device is a stent and the holding device is interchangeable.

In another embodiment, an apparatus for rotating at least one medical device and indexing the holding arrangement is provided. The holding device comprises at least one guide member and a detachable holding arrangement for handling, supporting and rotating one or more medical devices. The holding arrangement includes a frame and at least one holding device, which supports the medical device and can be rotated in relation to the frame. During rotation of the medical device the frame of the holding arrangement is in contact with the guide member to secure the angular position of the holding arrangement, and during change of angular position, the frame is not in contact with the guide member and the holding arrangement can freely rotate. In one or more embodiments, linear motion is applied to the holding arrangement to translate the medical device. The apparatus may further comprise at least one motion unit to move the holding arrangement. A spray source or a dispenser may also be provided to apply a coating to the medical device. The medical device which is supported by the apparatus is preferably a stent or a catheter.

In yet another embodiment, a method to support and to rotate at least one medical device and to perform an operation upon the medical device, comprises the following steps. In a first step, the medical device is mounted to a detachable holding arrangement having a frame, at least a holding device and at least a shaft. The holding device and the shaft can be rotated in relation to the frame and rotary motion is transferred from the shaft to the holding device. In a next step, the holding arrangement is secured at a first angular position and rotary motion is applied to the holding arrangement to rotate the

medical device around its longitudinal axis. Then, an operation is performed. In another step, the holding arrangement is indexed to the next angular position. Next, the holding arrangement is secured and rotary motion is induced in the holding arrangement to rotate the medical device around its longitudinal axis. Then, an operation is performed. In one or more embodiments, different operations are performed at various angular positions. Furthermore, the same operation may be performed upon multiple medical devices and an operation can be preformed at each angular position.

The operation preferably consists of applying a coating to at least one medical device.

DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, serve to explain the principles of the invention. The drawings are in simplified form and not to precise scale.

FIG. 1 is an isometric view of an holding arrangement to support and rotate multiple stents;

FIG. 2A is an isometric view of an alternative holding arrangement to support and rotate multiple stents;

FIG. 2B is an isometric view of the holding arrangement shown in Fig. 2A during indexing;

FIG. 3 is an isometric view of an holding arrangement to support and rotate several catheters;

FIG. 4 is an isometric view of a stent coating apparatus;

FIG. 5A is an isometric view of an holding arrangement to support and rotate one stent during the application of a first coating layer;

FIG. 5B is an isometric view of the holding arrangement shown in Fig. 5A during indexing; and

FIG. 5C is an isometric view of the holding arrangement shown in Fig. 5A during the application of a second coating layer.

DETAILED DESCRIPTION

To allow higher volume production of medical devices, such as stents and catheters, and to minimize coating defects resulting from manual handling, it is desirable to have an apparatus and method for supporting multiple medical devices at the same time and to perform one or more process steps automatically.

Referring now to **FIG. 1**, an isometric representation of an exemplary holding arrangement **30** to secure and to rotate up to three stents **1** is shown. The holding arrangement **30** includes frame **17**, shaft **19** to be coupled to a drive shaft (not shown) for transmission of linear and/or rotary motion and three holding devices **6** being engaged with the inner section of the stent **1**. The shaft **19** and the three holding devices **6** are bearing mounted to the frame **17**. The holding devices **6** are connected with belts **20** to the shaft **19** and rotary motion is transmitted via the shaft **19** to the holding devices **6** to rotate the stents. Guide section **21** is provided to secure the angular position of the holding arrangement using a guide or lock member (not shown) and to prevent revolving during rotation of the holding devices **6**.

The holding arrangement is furthermore designed to be used during subsequent inspection of the coated stents in various inspection setups, comprising for example guide members, a linear stage and an inspection apparatus. The stent can be rotated to inspect the coating by turning the shaft of the holding arrangement. Thus, it is not required to dismount and remount the stents for inspection purposes or to use inspection fixtures that may damage the outer surface of the stent. Coating damages during handling and inspection can therefore be prevented or minimized resulting in savings in time and cost.

FIG. 2A and **FIG. 2B** depict an alternative embodiment of an holding arrangement to support and to rotate two stents at the same time, having a securing mechanism to precisely adjust the position of the holding device and a mechanism to transmit rotary motion. The exemplary holding arrangement comprises frame **17**, sleeves **29**, two holding devices **6** to secure two stents at both ends, stop members **34** and a shaft **19** to be coupled to the drive shaft of a motion unit (not shown). In this embodiment, belts **20** are used to transmit rotary motion between the shaft and the sleeves. It is understood that other means, such as gears, may be used for the transmission of rotary motion. The holding devices **6**, that are coupled to the sleeves **29**, can be uncoupled and moved in axial direction in relation to the sleeves to engage or disengage the stents **1**. Stop members **34** are mounted to the holding devices **6** to define the axial position of the holding device in relation to the stent, so that the stent is contacted at a predetermined position. The holding devices **6** can be adjusted for various stent lengths by changing the position of the stop members **34**. Sleeves and stop members are preferably used in combination with a magnetic coupling (not shown) to facilitate positioning and securing of the holding devices. The magnetic coupling connects the stop member **34** to the sleeves **29** during engagement with the stent **1** and transmits rotary motion from the sleeves **29** via stop members **34** to the support members **6**. In a first position, the holding devices are engaged with the stents and the stop members are coupled to the

sleeves to secure the stent. In a second position, at least one stop member is uncoupled from the sleeve and the holding devices are not engaged with the stent, so that the stent can be dismounted.

Referring to **FIG. 2A**, rotary motion is induced at the shaft **19** and transmitted via belts **20**, sleeves **29**, magnetic coupling, stop members **34**, and holding devices **6** to the supported stents **1**. The angular position of the holding arrangement is secured during rotation of the stents. The guide section **21** is in contact with a guide or lock member (not shown) and prevents revolving of the holding device during rotation.

FIG. 2B shows the holding arrangement during indexing. The guide section **21** is no longer in contact with the guide or lock member (not shown) and the holding arrangement can freely rotate around the axis of shaft **19**.

For increased production output, the holding arrangement depicted in **FIG. 1** and **FIG. 2AB** can be equipped with a larger frame to support up to six stents.

When coating other tubular devices having a comparatively long length, such as catheters, the holding arrangement is preferably vertically oriented, so that the catheters can hang from the frame. **FIG. 3** is an isometric representation of an exemplary medical device holder. Each catheter **51** is supported by a holding device **6** contacting at least partially its inner section. The holding arrangement comprises a frame **17**, a shaft **19**, belts **20** and holding devices **6** being rotable in relation to the frame. The holding devices **6** are connected with belts **20** to the shaft **19** and rotary motion is transmitted via the shaft **19** to the holding devices **6** to rotate the stents. Guide section **21** is provided to secure the angular position of the holding arrangement using a guide or lock member (not shown) and to prevent revolving during rotation of the holding devices.

FIG. 4 illustrates an exemplary stent holding apparatus and setup. The compact design allows the integration of two apparatus in an isolator to coat twelve or more stents simultaneously.
Three stents **1** are supported by the holding arrangement **30** of the present invention and an atomizer **27** is provided to apply a coating composition to one stent at a time. The holding arrangement **30**, described in detail in **FIG. 1** and **FIG. 2**, is connected via coupling **23** to the drive shaft **26** of motion unit **25** and is in contact with guide member **24** to prevent unwanted indexing of the holding arrangement **30**. The frame **17** aligns the holding arrangement **30** in relation to the guide member **24** and the guide section **21** ensures precise alignment of the holding arrangement **30** in relation to the atomizer **27**. An automated coupling element **23** is preferably used to facilitate the connection between the drive shaft **26** and the shaft **19** of the holding arrangement.

During the application of the coating, rotary and linear motion is applied via drive shaft **26** to the holding arrangement **30**. Rotary motion is induced via shaft **19**, belts **20** and holding devices **6** to rotate the stents **1**. The holding arrangement **30** is moved in a linear direction relative to the atomizer **27** generating spray plume **28** and the stents **1** are rotated. The atomizer **27** is preferably aligned in relation to the stent **1**, so that the center axis of the spray plume **28** is perpendicular to the rotation axis of stent **1** and both axes are located on the same plane. When the first stent is coated, the holding arrangement **30**

is moved to the backward position **47** to disconnect the guide section **21** from guide member **24** so that the frame **17** can be freely rotated. The holding arrangement **30** indexes by 120 degrees and the coating can be applied to the next stent.

After coating all supported devices another process step may be performed, such as applying a different coating layer or performing a drying operation.

Alternatively, the holding arrangement may be dismounted to continue with the optical inspection of the coated medical devices. The holding arrangement **30** is moved to the forward position **48**, uncoupled from coupling **23** and removed from drive shaft **26** and guide member **24**.

The method and apparatus to support and to rotate a medical device, and to perform several process steps automatically is illustrated by the application of different coating layers, as shown in **FIG. 5 A-C**. The coating is applied to the medical device using three spray sources **27**, which are coupled to a dedicated liquid supply (not shown). First, the medical device is mounted to the holding arrangement **30** comprising frame **17**, shaft **19**, belt **20** and holding devices **6**. The holding devices **6** and the shaft **19** can be rotated in relation to the frame **17** and rotary motion is transferred between the shaft **19** and the holding devices **6**. Next, the holding arrangement is detachably connected to a motion unit (not shown) to rotate the medical devices supported by the holding arrangement. In another step, the holding arrangement **30** is secured by a lock member **24** at a first angular position of 0 degrees and rotary motion is applied to the holding arrangement to rotate the medical device **1** around its longitudinal axis. The medical device is located in the coating area below the first coating applicator **27** generating spray plume **28** and a coating layer is applied to the medical device **1**, as shown in **FIG. 5A**. In a further step depicted in **FIG. 5B**, the holding arrangement **30** is unlocked and indexed to an angular position of 120 degrees.

As shown in **FIG. 5C**, the holding arrangement is secured at the next angular position and rotary motion is applied to the holding arrangement to rotate the medical device around its longitudinal axis. The next coating layer is applied using second coating applicator **27**. A further coating layer can be provided as described above at an angular position of 240 degrees.

Depending on the particular application, the coating sequence may be repeated or other process steps like drying can be performed.

In an alternative embodiment, the method and apparatus to support and to rotate several medical devices, and to perform at least one process step automatically upon several medical devices is illustrated by the application of a coating layer. First, the medical devices are mounted on the holding arrangement comprising a frame, holding devices and at least a shaft. The holding devices and the shaft can be rotated in relation to the frame and rotary motion is transferred between the shaft and the holding device. Next, the holding arrangement is detachably coupled to a motion unit to rotate and translate the medical devices supported by the holding arrangement. In a further step, the holding arrangement is secured at a determined angular position so that the first medical device is located in the coating area in vicinity to the first coating applicator. Rotary motion is applied to the holding arrangement to rotate the medical device around its longitudinal axis. Then, the coating is applied to the first medical device. After

application of the coating, the holding arrangement is indexed to the next angular position so that the second medical device is located in the coating area in vicinity to the second coating applicator. In another step, the coating is applied to the second medical device.

Further coating layers may be applied as described above at a variety of angular positions. Depending on the particular application, the coating sequence may be repeated or other process steps like drying can be performed. In a further embodiment, one or more process steps may be performed simultaneously for all supported devices.

STENT COATING EXAMPLE

The following method of coating one or more stents using the holding device of the present invention is being provided by way of illustration and is not intended to limit the embodiments of the present invention.

Stents (manufactured by STI, Israel) having a diameter of 3 mm and a length of 20 mm may be coated. The coating composition may include a solvent capable of dissolving the polymer at the concentration desired in the composition, a non-bioabsorbable or bioabsorbable polymer that can be dissolved in the composition, and a therapeutic substance. The composition can also include active agents, radiopaque elements, or radioactive isotopes.

The coating composition may comprise a solvent, a polymer, and a therapeutic substance. The therapeutic substance may include, but is not limited to, proteins, hormones, vitamins, antioxidants, antimetabolite agents, anti-inflammatory agents, anti-restenosis agents, anti-thrombogenic agents, antibiotics, anti-platelet agents, anti-clotting agents, chelating agents, or antibodies. Examples of suitable polymers include, but are not limited to, synthetic polymers including polyethylen (PE), poly(ethylene terephthalate), polyalkylene terepthalates such as poly(ethylene terephthalate) (PET), polycarbonates (PC), polyvinyl halides such as poly(vinyl chloride) (PVC), polyamides (PA), poly(tetrafluoroethylene) (PTFE), poly(methyl methacrylate) (PMMA), polysiloxanes, and poly(vinylidene fluoride) (PVDF); biodegradable polymers such as poly(glycolide) (PGA), poly(lactide) (PLA) and poly(anhydrides); or natural polymers including polysaccharides, cellulose and proteins such as albumin and collagen. The coating composition can also comprise active agents, radiopaque elements or radioactive isotopes. The solvent is selected based on its biocompatibility as well as the solubility of the polymer. Aqueous solvents can be used to dissolve water-soluble polymers, such as Poly(ethylene glycol) (PEG) and organic solvents may be used to dissolve hydrophobic and some hydrophilic polymers. Examples of suitable solvents include methylene chloride, ethyl acetate, ethanol, methanol, dimethyl formamide (DMF), acetone, acetonitrile, tetrahydrofuran (THF), acetic acid, dimethyle sulfoxide (DMSO), toluene, benzene, acids, butanone, water, hexane, and chloroform. For the sake of brevity, the term solvent is used to refer to any fluid dispersion medium whether a solvent of a solution or the fluid base of a suspension, as the invention is applicable in both cases.

Three stents are mounted to the holding arrangement depicted in **FIG. 1**. After mounting the stents, the holding arrangement is removably connected to the motion unit of the present invention as shown in **FIG. 4** to automatically index the stents at different angular positions and to rotate and translate the stents. The first stent is located in the coating area in vicinity to the coating applicator at an angular position of 0 degrees. A pneumatic atomizer is used to disintegrate the coating composition into fine droplets. Alternatively, other types of atomizers, such as ultrasonic nozzles can also be employed for the application of the composition. The spray nozzle can disintegrate the coating solution into fine droplets at a liquid flow rate of about 0.1 to 80 ml/h and an atomizing pressure ranging from about 0.5 bar to about 1.5 bar. The nozzle is preferably operated at a liquid flow rate of 5 ml/h and at an atomizing gas flow rate of 5 l/min at an atomizing pressure of 0.8 bar. Droplets having a volumetric median diameter between 2 and 7 microns and a largest droplet diameter of less than 20 microns are produced. The atomizer may be aligned in relation to the stent being located in the coating area, such that the spray axis of the atomizer is perpendicular to the rotation axis of the stent and both axes are in the same plane. The spray nozzle is preferably adjusted to provide a distance from the nozzle tip to the outer surface of the stent of 10 to 35 mm. A syringe pump, which may be operated at a constant flow rate of approximately 5 ml/h, can be used to feed the liquid to the atomizer during the application of the coating.

Rotary motion is transmitted from the motion unit to the holding arrangement to rotate the stent around its longitudinal axis. Translational motion is transmitted to the holding arrangement to move it in a linear direction along the guide member in relation to the spray nozzle so that the first stent is exposed to the spray.

During the application of the coating solution, rotary motion is transmitted between the drive shaft of the motion unit and the holding arrangement to rotate the stent about its central longitudinal axes. The rotation speed of the stent can be from about 5 rpm to about 250 rpm. By way of example, the stent may rotate at 130 rpm. Alternatively, the stent can be translated along its central longitudinal axes. The translation speed of the stent can be from about 0.2 mm/s to 8 mm/s. When applying the coating solution, the translation speed is preferably 0.5 mm/s.

The stent can be moved along the nozzle one time to apply the coating in one pass or several times to apply the coating in several passes. Alternatively, the nozzle may be moved one time or several times along the stent length. The flow rate of the coating solution may range from about 1ml/h to 50 ml/h, and is preferably 5 ml/h.

After coating the first stent, the holding arrangement is moved to the backward position. The holding arrangement is not any more in contact with the guide member and the holding arrangement is indexed by 120 degrees to locate the next stent in the coating area.

After coating all supported stents, the holding arrangement may be detached form the coating apparatus to inspect the stents.

While the invention will be described in connection with certain embodiments, it will be understood that the invention is not limited to these embodiments. On the contrary, the invention includes

all alternatives, modifications and equivalents as may be included within the spirit and scope of the present invention. Details in the Specification and Drawings are provided to understand the inventive principles and embodiments described herein, to the extent that would be needed by one skilled in the art to implement those principles and embodiments in particular applications that are covered by the scope of the claims.

CLAIMS

1. Holding arrangement for handling, supporting and transmitting rotary motion to at least one medical device, the holding arrangement comprising a frame, at least one holding device to support the medical device and a shaft, wherein
   in a first state, rotary motion is transmitted from the shaft to the holding device in order to rotate the medical device in relation to the frame, and
   in a second state, during indexing the holding arrangement rotates around the axis of the shaft.
2. Holding arrangement according claim 1 wherein the medical device is a stent.
3. Holding arrangement according claim 1 wherein the holding device is interchangeable.
4. An apparatus for rotating at least one medical device and indexing the holding arrangement, comprising:
   at least one guide member and a detachable holding arrangement for handling, supporting and rotating of at least one medical device, the holding arrangement including a frame and at least one holding device, which supports the medical device and can be rotated in relation to the frame, wherein during rotation of the medical device the frame of the holding arrangement is in contact with the guide member to secure the angular position of the holding arrangement and during the change of the angular position the frame is not in contact with the guide member so that the holding arrangement can freely rotate.
5. The apparatus according to claim 4, wherein linear motion is applied to the holding arrangement to translate the medical device.
6. The apparatus according to claim 4, further comprising at least one motion unit to transmit motion to the holding arrangement.
7. The apparatus according to claim 4, further comprising a spray source to apply a coating to the medical device.
8. The apparatus according to claim 4, further comprising a dispenser to apply a coating to the medical device.
9. The apparatus according to claim 4, wherein the medical device is a stent.
10. The apparatus according to claim 4, wherein the medical device is a catheter.

11. Method to support and to rotate at least one medical device and to perform an operation upon at least a medical device, comprising the steps of:
mounting the medical device to a detachable holding arrangement having a frame, at least a holding device and at least a shaft, wherein the holding device and the shaft can be rotated in relation to the frame and rotary motion is transferred from the shaft to the holding device;
securing the holding arrangement at a first angular position and applying rotary motion to the holding arrangement to rotate the medical device around its longitudinal axis;
performing an operation;
indexing the holding arrangement to the next angular position by rotating the holding arrangement around the axis of the shaft;
securing the holding arrangement and applying rotary motion to the holding arrangement to rotate the medical device around its longitudinal axis; and
performing an operation.
12. The method according to claim 11, wherein different operations are performed at various angular positions.
13. The method according to claim 11, wherein the same operation is performed upon multiple medical devices.
14. The method according to claim 11, wherein an operation is preformed at each angular position.
15. The method according to claim 11, wherein the operation consists of applying a coating to at least one medical device.

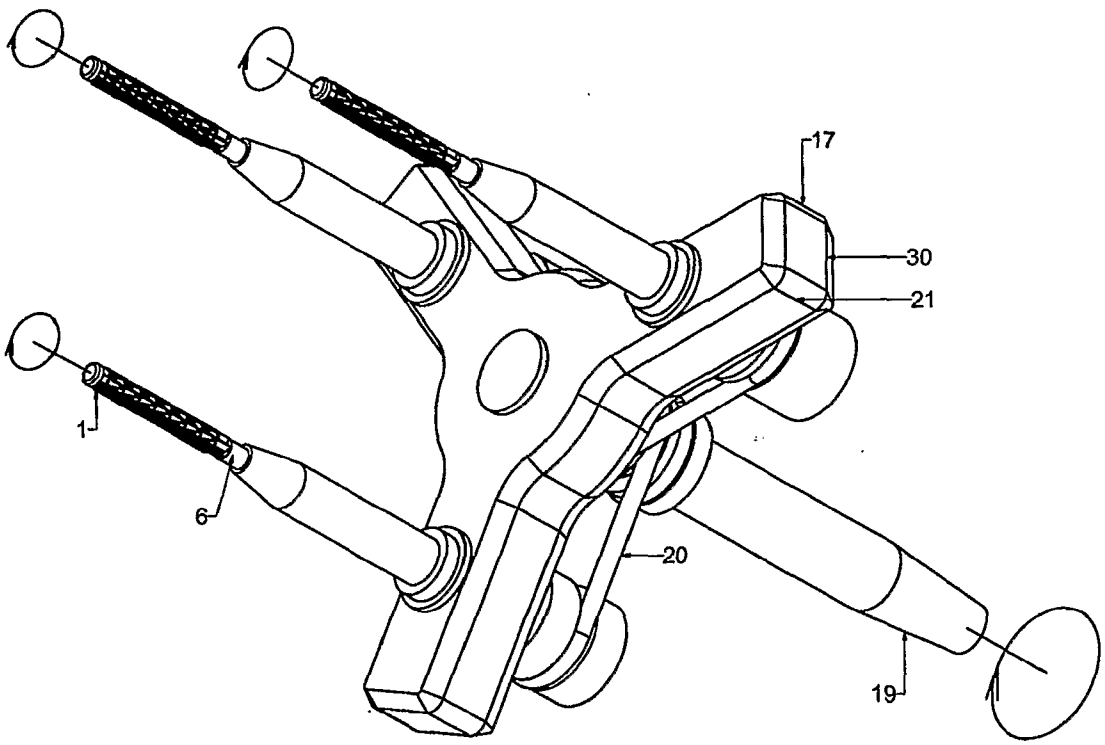

FIG. 1

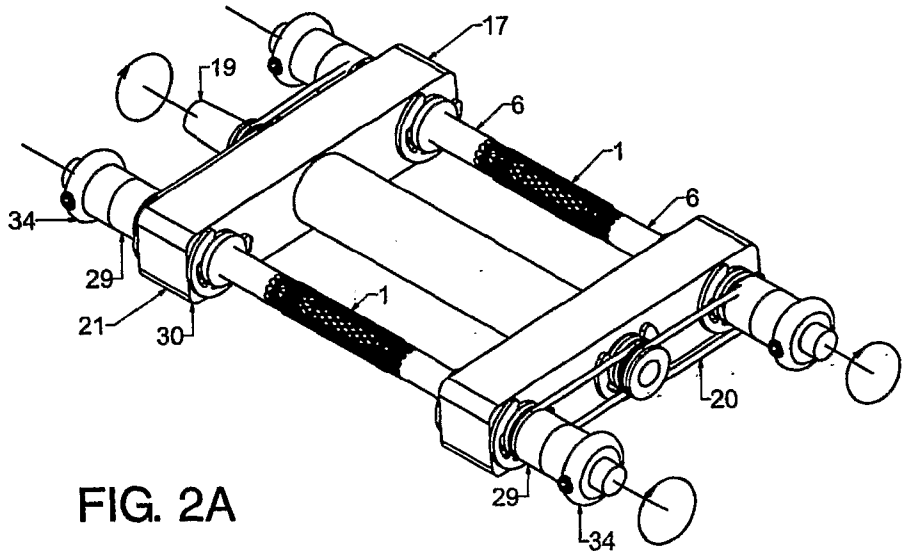

FIG. 2A

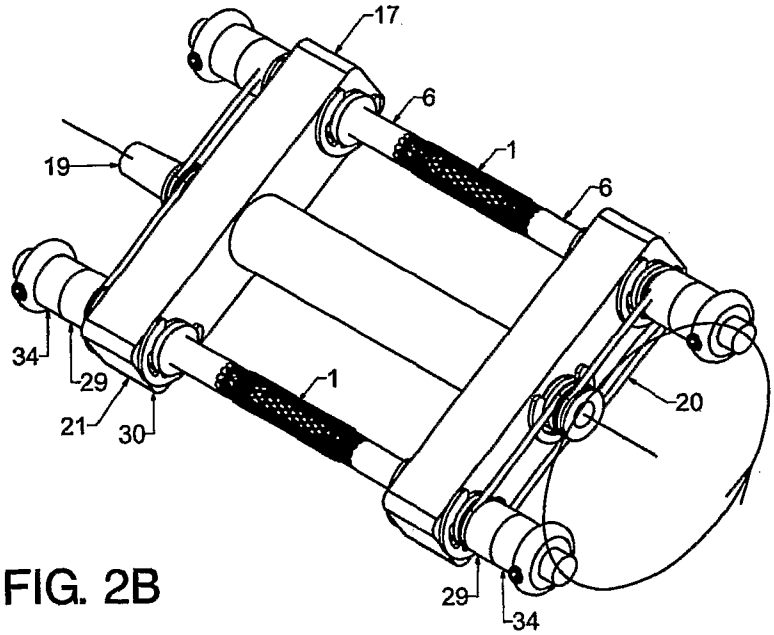

FIG. 2B

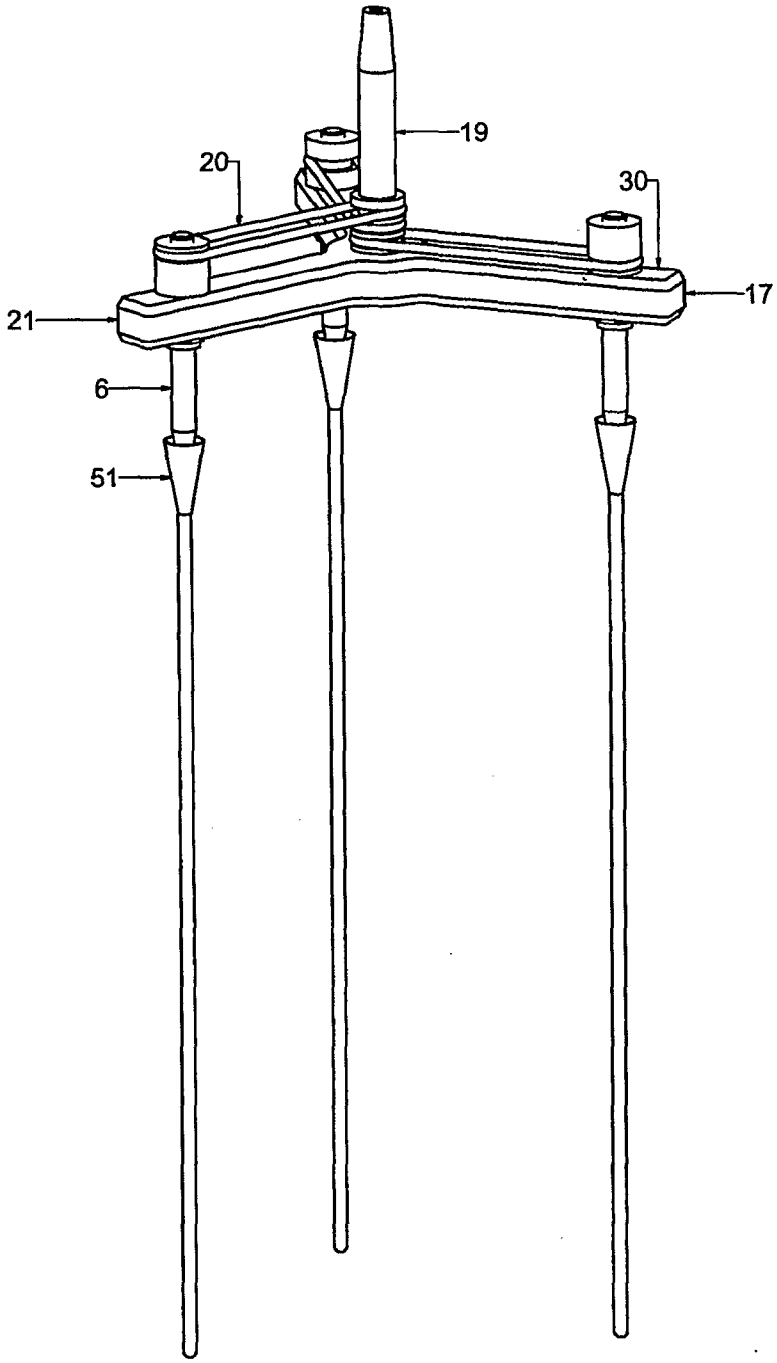

FIG. 3

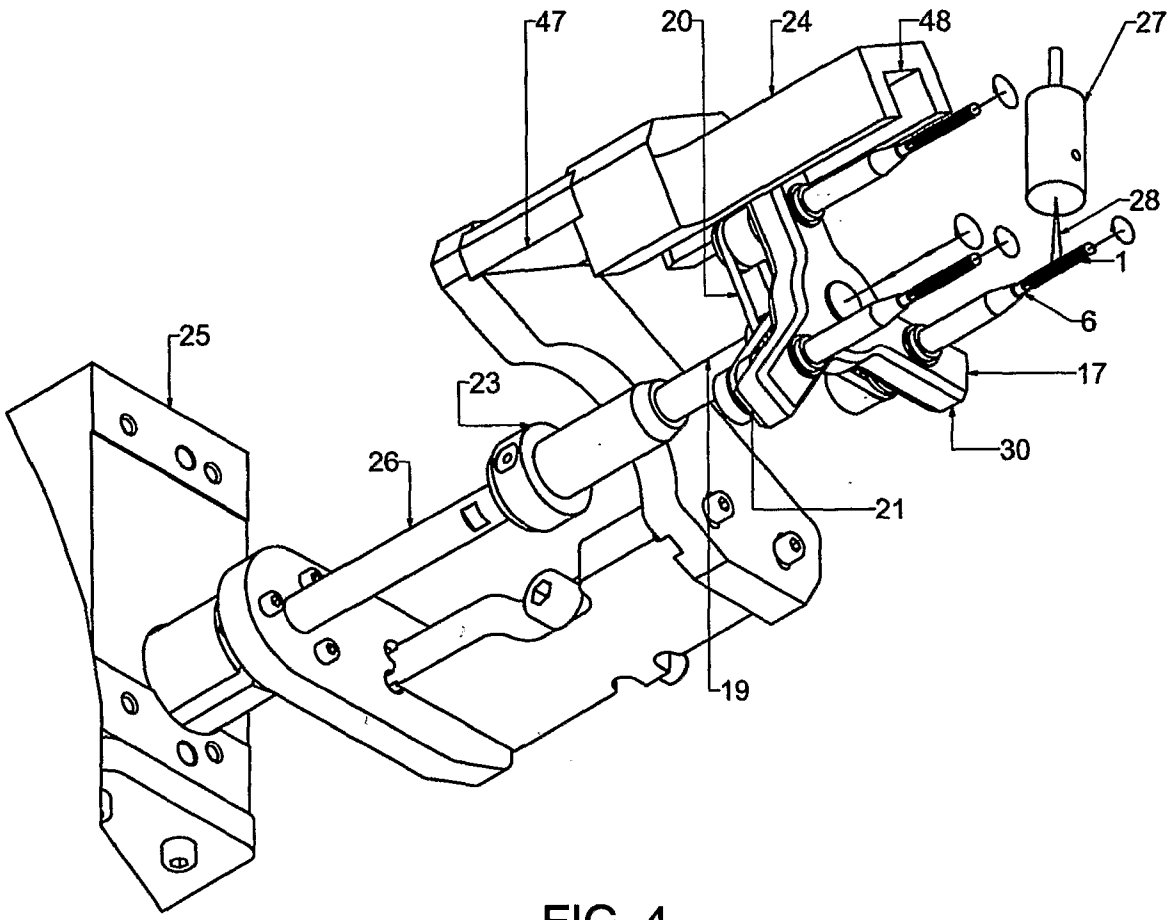

FIG. 4

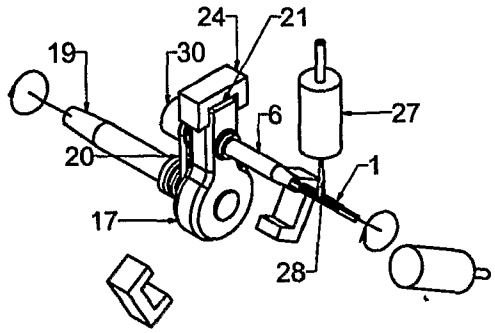

FIG. 5A

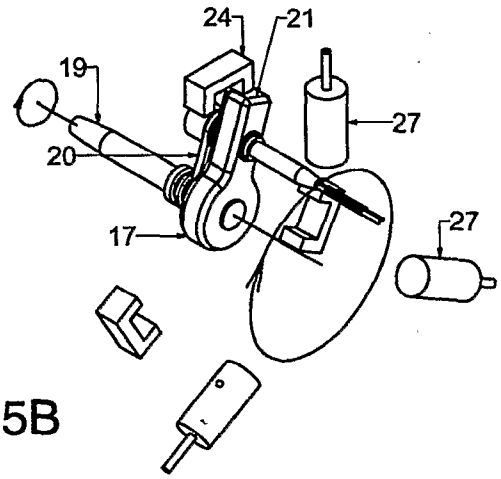

FIG. 5B

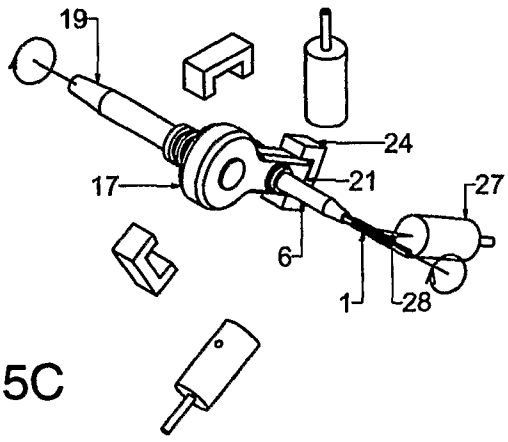

FIG. 5C