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(54) **STENT COATING METHOD AND APPARATUS**

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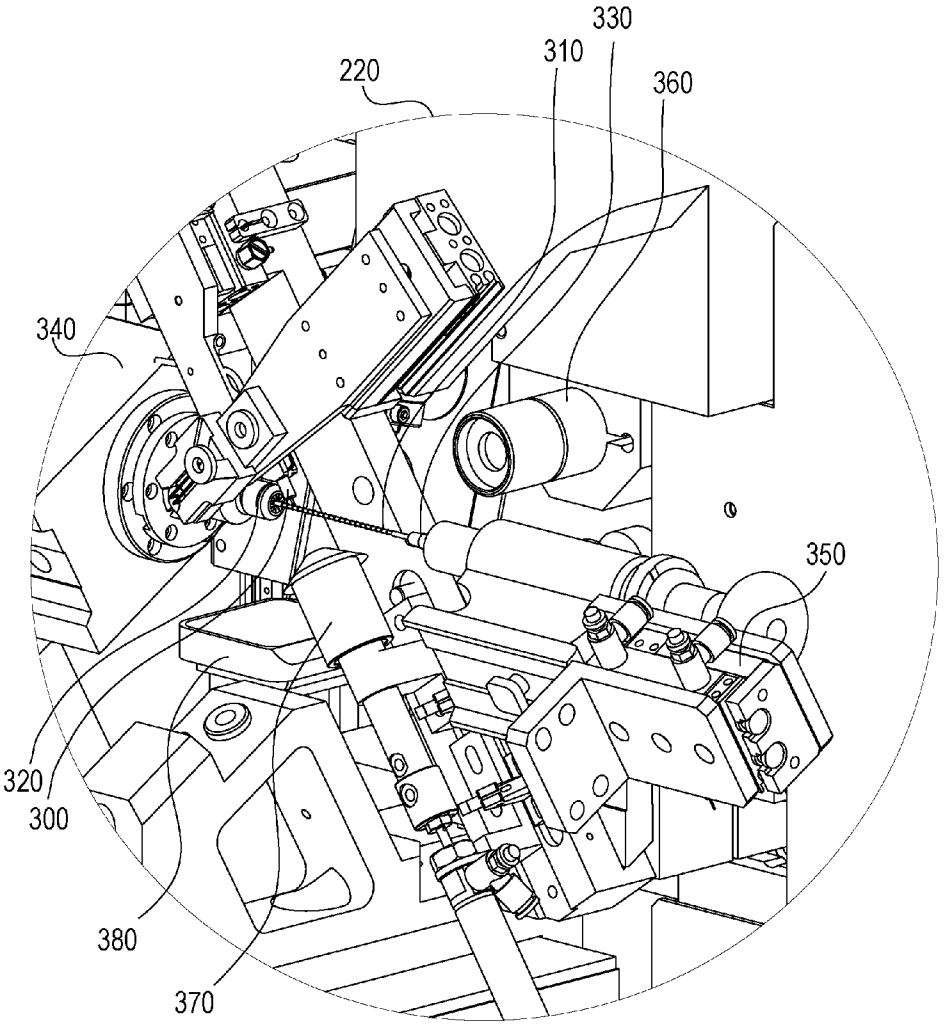
(57) **ABSTRACT**

An apparatus includes a mandrel for supporting a stent during a composition deposition process. The mandrel includes an elongated body for insertion into a longitudinal bore of a stent. The body comprises carbide.



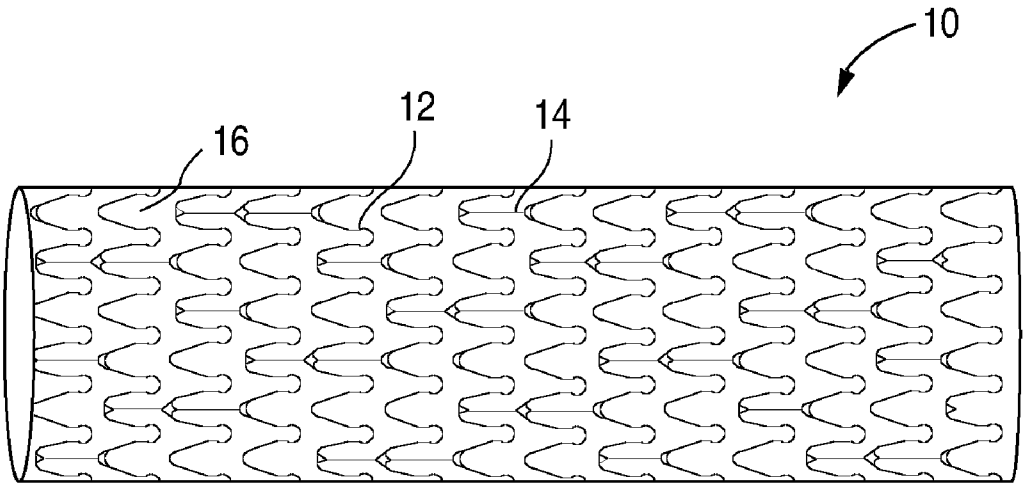


FIG. 1
(PRIOR ART)

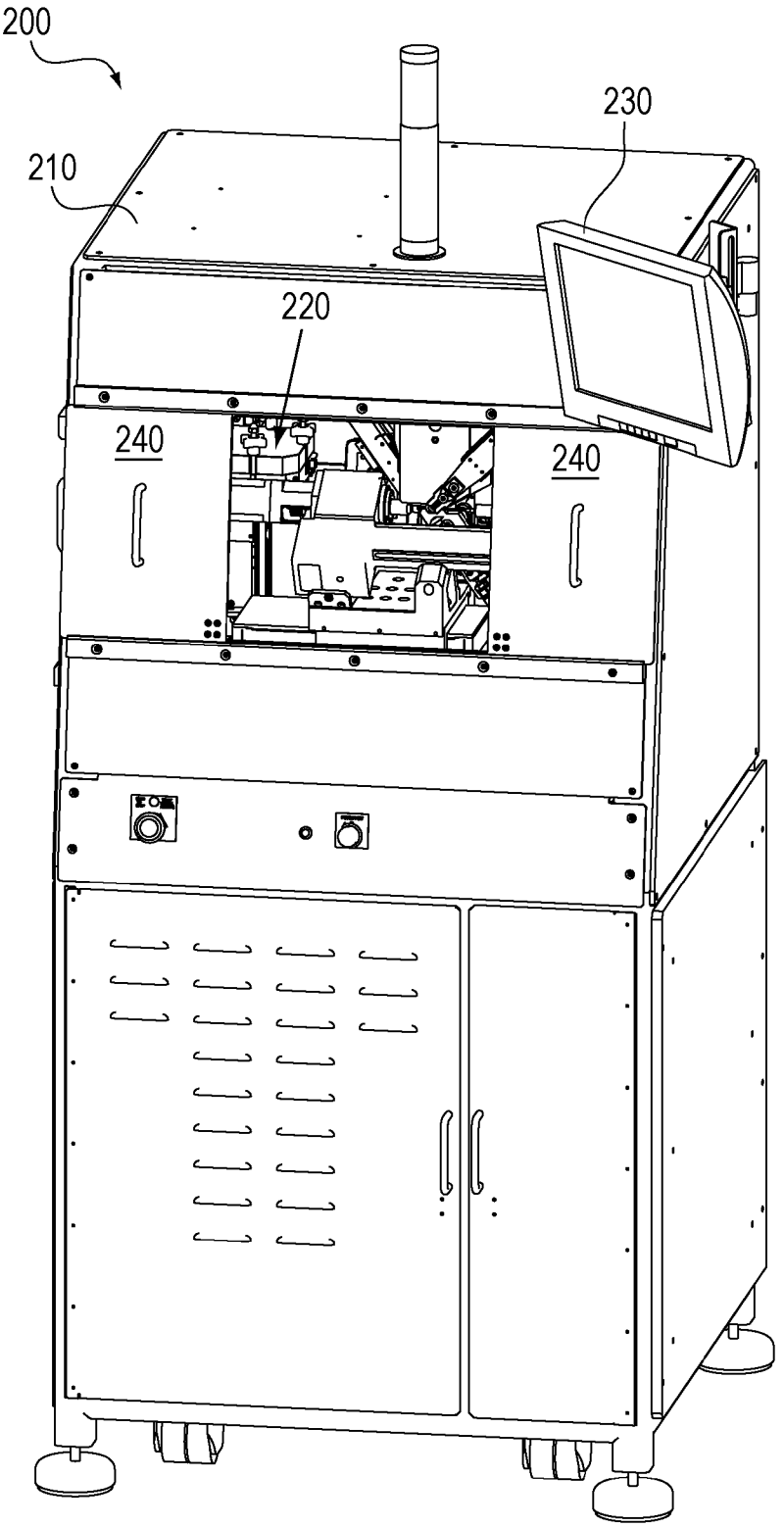


FIG. 2

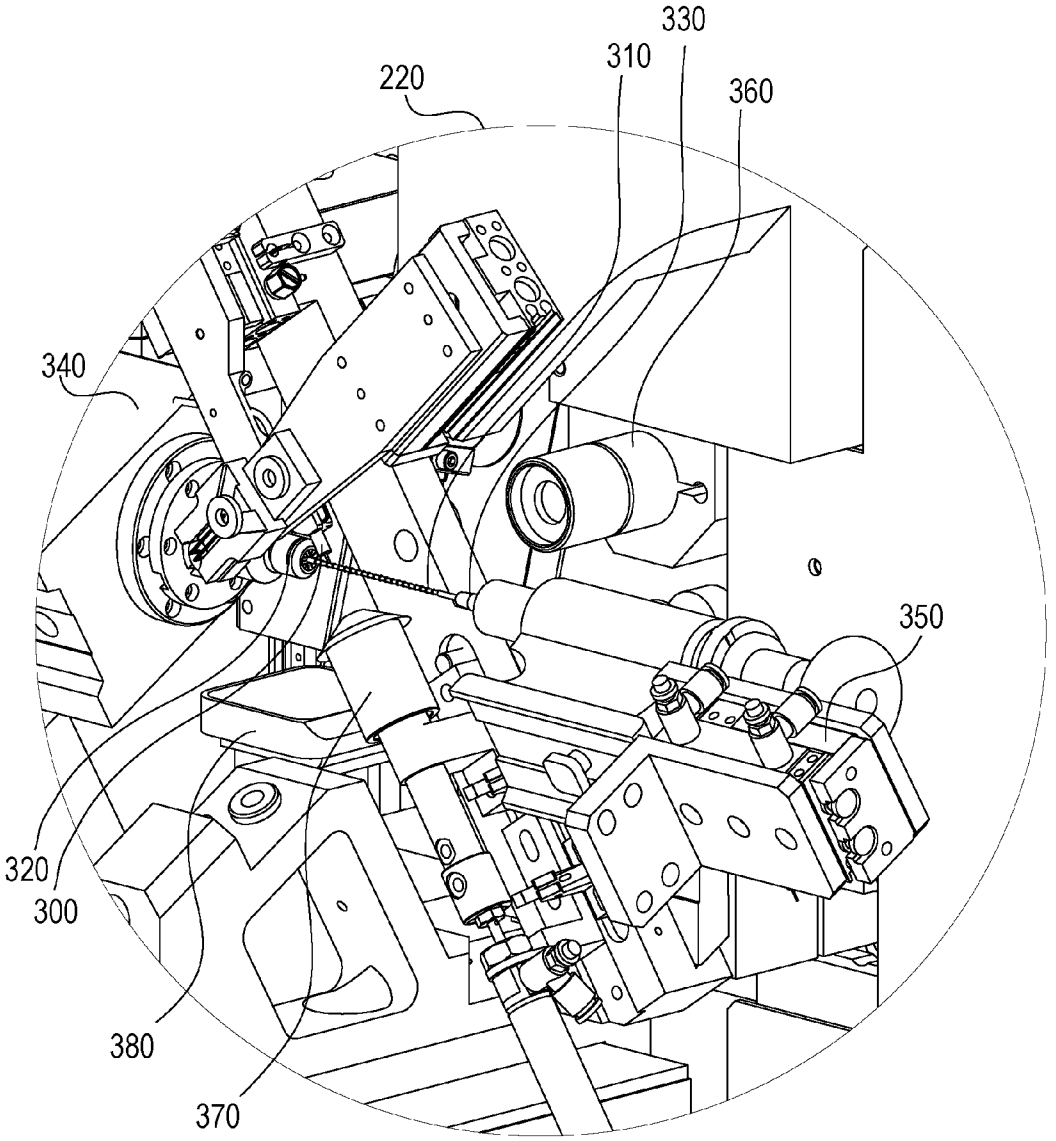


FIG. 3

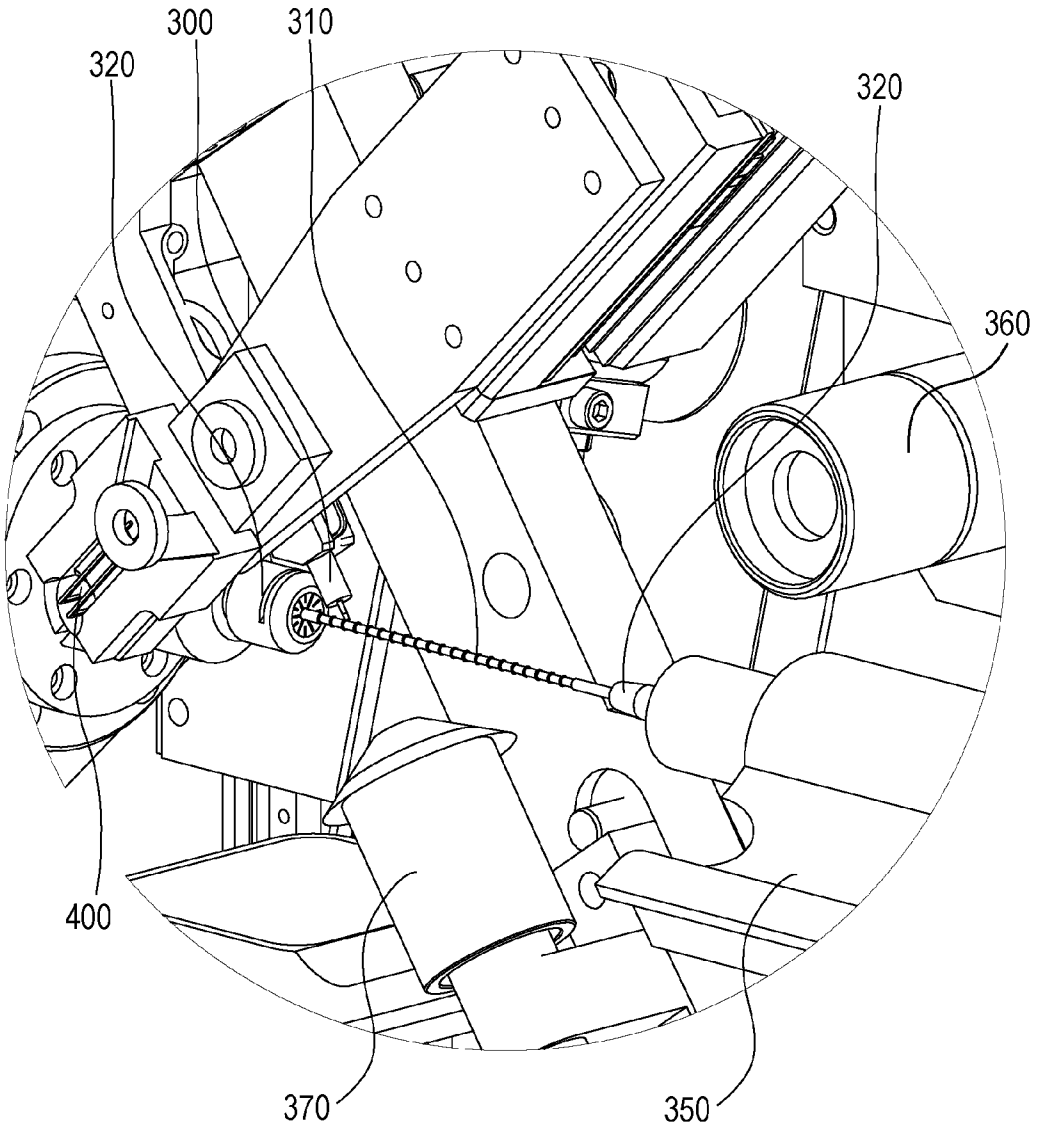


FIG. 4

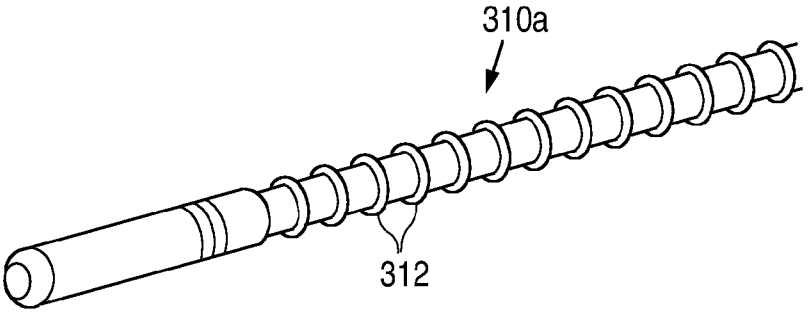


FIG. 5A

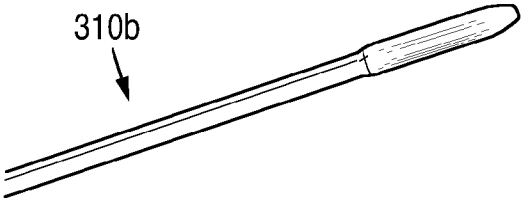


FIG. 5B

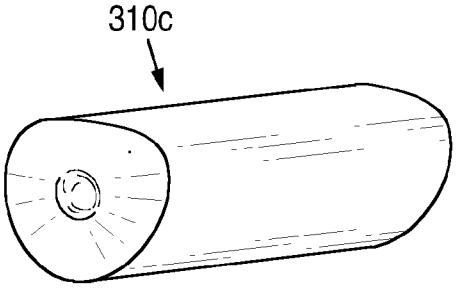


FIG. 5C

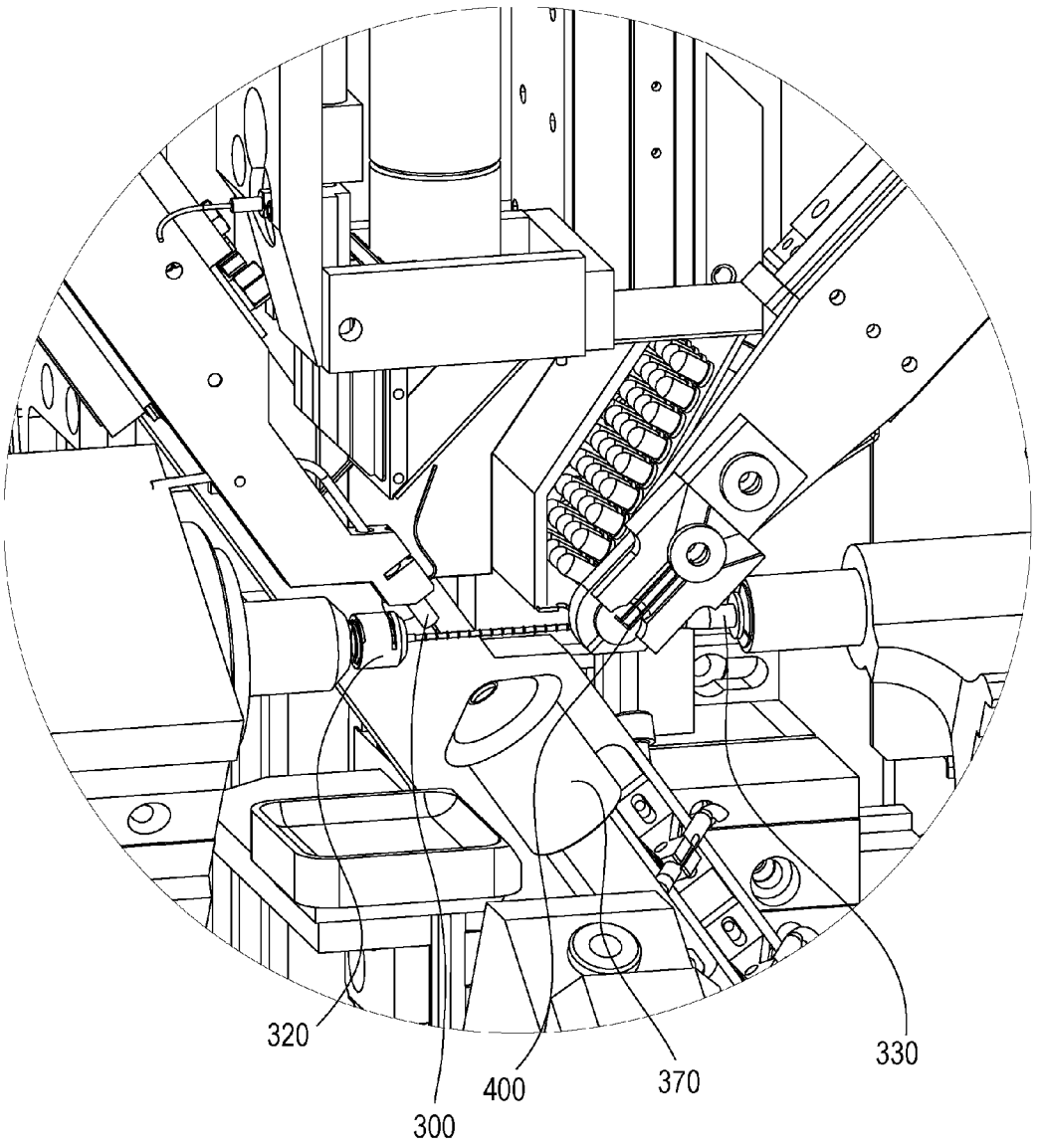


FIG. 6

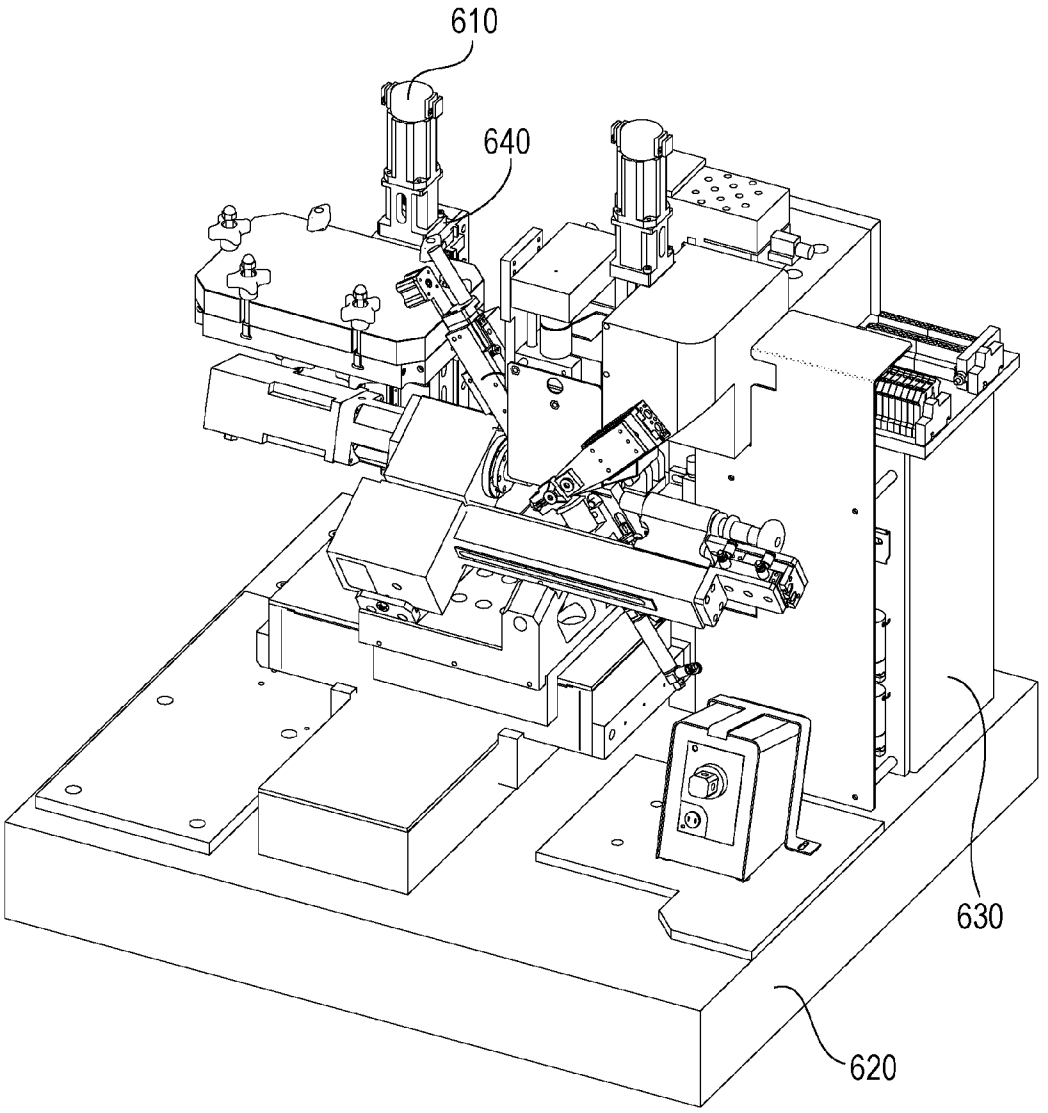


FIG. 7

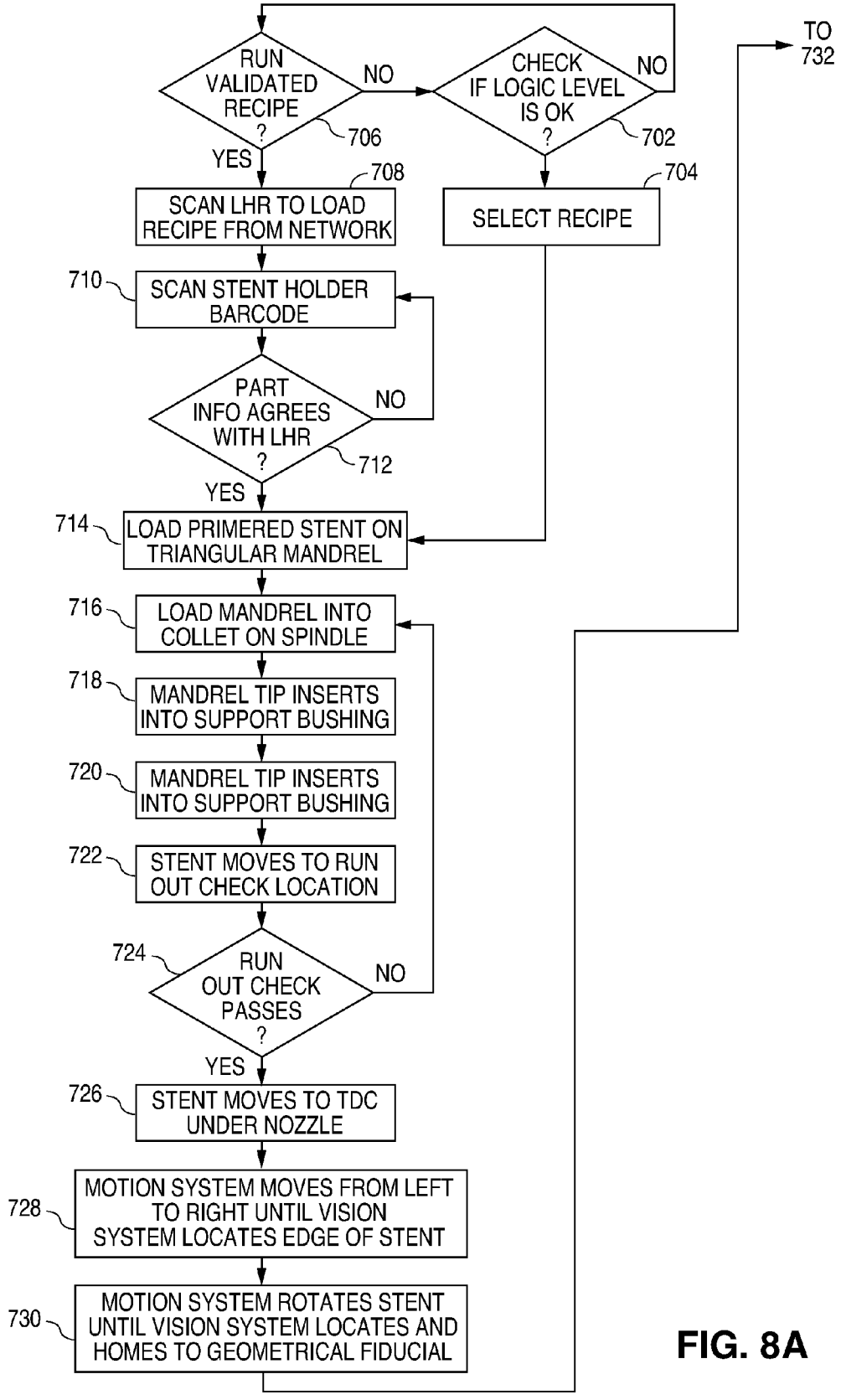

RUN VALIDATED RECIPE ?
706
NO
YES
CHECK IF LOGIC LEVEL IS OK ?
702
NO
TO 732
708
SCAN LHR TO LOAD RECIPE FROM NETWORK
704
SELECT RECIPE
710
SCAN STENT HOLDER BARCODE
PART INFO AGREES WITH LHR ?
712
NO
YES
714
LOAD PRIMERED STENT ON TRIANGULAR MANDREL
716
LOAD MANDREL INTO COLLET ON SPINDLE
718
MANDREL TIP INSERTS INTO SUPPORT BUSHING
720
MANDREL TIP INSERTS INTO SUPPORT BUSHING
722
STENT MOVES TO RUN OUT CHECK LOCATION
724
RUN OUT CHECK PASSES ?
NO
YES
726
STENT MOVES TO TDC UNDER NOZZLE
728
MOTION SYSTEM MOVES FROM LEFT TO RIGHT UNTIL VISION SYSTEM LOCATES EDGE OF STENT
730
MOTION SYSTEM ROTATES STENT UNTIL VISION SYSTEM LOCATES AND HOMES TO GEOMETRICAL FIDUCIAL

FIG. 8A

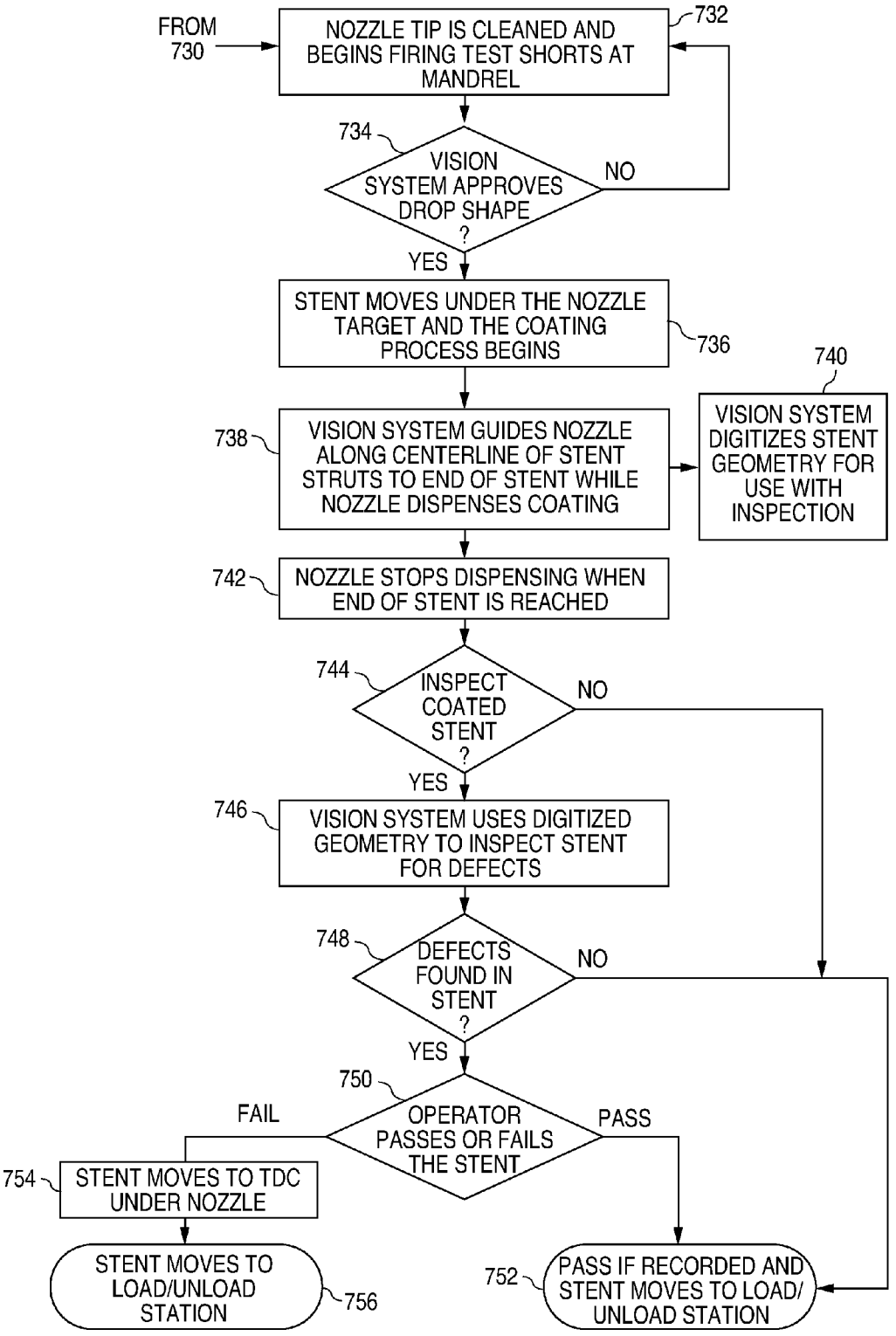

FROM 730
NOZZLE TIP IS CLEANED AND BEGINS FIRING TEST SHORTS AT MANDREL
732
734
VISION SYSTEM APPROVES DROP SHAPE ?
NO
YES
STENT MOVES UNDER THE NOZZLE TARGET AND THE COATING PROCESS BEGINS
736
740
VISION SYSTEM DIGITIZES STENT GEOMETRY FOR USE WITH INSPECTION
738
VISION SYSTEM GUIDES NOZZLE ALONG CENTERLINE OF STENT STRUTS TO END OF STENT WHILE NOZZLE DISPENSES COATING
742
NOZZLE STOPS DISPENSING WHEN END OF STENT IS REACHED
744
INSPECT COATED STENT ?
NO
YES
746
VISION SYSTEM USES DIGITIZED GEOMETRY TO INSPECT STENT FOR DEFECTS
748
DEFECTS FOUND IN STENT ?
NO
YES
750
OPERATOR PASSES OR FAILS THE STENT
FAIL
PASS
754
STENT MOVES TO TDC UNDER NOZZLE
STENT MOVES TO LOAD/UNLOAD STATION
756
752
PASS IF RECORDED AND STENT MOVES TO LOAD/ UNLOAD STATION

FIG. 8B

STENT COATING METHOD AND APPARATUS

CROSS-REFERENCE

[0001] This is a divisional of application Ser. No. 11/475,151 filed on Jun. 28, 2006.

TECHNICAL FIELD

[0002] This invention relates to a method and apparatus for coating a stent surface.

BACKGROUND

[0003] In the last several years, minimally invasive surgical procedures, such as percutaneous transluminal coronary angioplasty (PTCA), have become increasingly common. A PTCA procedure involves the insertion of a catheter into a coronary artery to position an angioplasty balloon at the site of a stenotic lesion that is at least partially blocking the coronary artery. The balloon is then inflated to compress the stenosis and to widen the lumen to allow an efficient flow of blood through the coronary artery.

[0004] Following PTCA and other stenotic treatment procedures, a significant number of patients experience restenosis or other vascular blockage problems. These problems are prone to arise at the site of the former stenosis.

[0005] In order to help avoid restenosis and other similar problems, a stent may be implanted into the vessel at the site of the former stenosis with a stent delivery catheter. Stents are described in U.S. Pat. No. 4,733,665 to Palmaz, U.S. Pat. No. 4,800,882 to Gianturco, and U.S. Pat. No. 4,886,062 to Wiktor.

[0006] FIG. **1** illustrates a conventional stent **10** formed from radially expandable struts **12** that are interconnected by connecting elements **14**. Lateral openings or gaps **16** are formed between adjacent struts **12**. The struts **12** and the connecting elements **14** define a tubular stent body having an outer, tissue-contacting (abluminal) surface and an inner (luminal) surface.

[0007] Stents can also be used to deliver drugs locally. Local delivery is often preferred over systemic delivery, particularly where high systemic doses are necessary to affect a particular site. High systemic doses of drugs often create adverse effects. For example, following angioplasty, radiotherapy and drug delivery treatments applied to the former stenosis have been found to aid in the healing process and to reduce significantly the risk of restenosis and other similar problems. One proposed method of local delivery is to coat a stent surface with one or more drugs.

[0008] There are several conventional methods for coating a stent with a drug, e.g. by dipping the stent in a coating substance containing the drug or by spraying the solution onto the stent. Dipping and spraying usually results in completely coating all stent surfaces, i.e., both luminal and abluminal surfaces. While the coating on the abluminal surface provides an advantageous direct delivery of the drug to the site of the former stenosis, the coating on the luminal surface can be washed away by the blood, which in some cases makes it therapeutically insignificant.

[0009] Moreover, the luminal surface coating often detrimentally affects stent deliverability and the coating's mechanical integrity. The luminal coating may increase the friction coefficient of the stent's surface, making withdrawal of a deflated balloon more difficult. The coating may also adhere to the balloon. Consequently, balloon deflation and withdrawal may damage the coating or remove portions of the coating from the stent, resulting in a thrombogenic stent surface and embolic debris.

[0010] The dipping and spraying methods have additional shortcomings. For example, these methods tend to cause webbing between adjacent stent struts and coating pools on the stent, making it difficult to control the amount of drug coated on the stent. Additionally, the spraying method may cause coating defects at the stent-stent-mandrel interface. Upon removal from the stent mandrel, the coating material at the interface may detach from the stent, leaving uncoated stent areas.

[0011] To overcome the above shortcomings, piezoelectric delivery systems have been developed, which deliver coating droplets to specific stent surfaces, allowing a more precise coating of the stent. However, these systems also have several drawbacks. For example, they do not consider several factors that affect droplet size (or volume). For example, the droplet size is affected by the coating substance's viscosity or density. The higher the viscosity or density, the smaller the droplet size. In addition, nozzle clogging also affects droplet size. As a result, these conventional piezoelectric delivery systems cannot precisely control the delivery rate of coating substance.

SUMMARY

[0012] The present invention provides a method and apparatus that can monitor the size (diameter or volume) of droplets generated by a piezoelectric delivery system and adjust system parameters to maintain a desired droplet size. The invention can be used also for other purposes. For example, the method and apparatus can be additionally or alternatively used to monitor and control a droplet's alignment with a stent strut, allowing a precise delivery of coating substance to a specific stent surface. Moreover, the method and apparatus can be used to monitor and control droplet velocity. Further, the method and apparatus can be used to monitor and control "drop mode" to ensure that a "single drop mode" has been achieved and there are no undesirable "satellite" droplets.

[0013] According to one aspect of the invention, a method includes the steps of ejecting a droplet of a coating substance towards a stent strut with a print head of a piezoelectric delivery system; sensing a parameter of the droplet; and determining whether the parameter of the droplet meets a requirement. The sensed droplet parameter may be droplet size, droplet velocity, the droplet's alignment with a stent strut, and/or the drop mode.

[0014] According to another aspect of the invention, an apparatus includes a piezoelectric print head, a sensor and a controller. The piezoelectric print head can eject a droplet of a coating substance. The sensor can sense a parameter of the droplet. The controller is communicatively coupled to the print head and the sensor, and can determine whether the parameter of the droplet meets a requirement.

[0015] The sensing step may be carried out by an imaging device, such as a camera, which provides an image of the droplet. From the image, the droplet parameter can be determined. The droplet may be illuminated to provide a clear image, preferably by a strobe light.

[0016] The piezoelectric print head may be controlled to adjust the droplet parameter to meet the requirement. For example, the ejecting power of the print head may be controlled. More specifically, one or more of the pulse width,

pulse magnitude, pulse frequency, and ejection frequency of the print head may be controlled. Furthermore, the stent position or print head position may be adjusted based on the droplet parameter.

[0017] The present invention has several advantages over the prior art. For example, the present invention delivers a precisely-controlled amount of coating to a stent surface. This is accomplished by monitoring droplet parameters, such as droplet size, droplet velocity, droplet mode, and/or the droplet's alignment with the stent strut, and by controlling the piezoelectric print head to maintain the droplet parameters at desired values.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] Non-limiting and non-exhaustive embodiments of the present invention are described with reference to the following figures, wherein like reference numerals refer to like parts throughout the various views unless otherwise specified.

[0019] FIG. **1** illustrates a conventional stent;

[0020] FIG. **2** illustrates a stent coating apparatus according to an embodiment of the invention;

[0021] FIG. **3** and FIG. **4** illustrate the apparatus of FIG. **2** in further detail;

[0022] FIGS. **5***a* to **5***c* illustrate three embodiments for the stent mandrel of the apparatus of FIG. **2**;

[0023] FIG. **6** illustrates the apparatus of FIG. **2** from a different angle;

[0024] FIG. **7** illustrates the apparatus of FIG. **2** removed from a housing; and

[0025] FIGS. **8**A and **8**B show flowcharts illustrating a method of coating an abluminal stent surface.

DETAILED DESCRIPTION

[0026] The following description is provided to enable any person having ordinary skill in the art to make and use the invention, and is provided in the context of a particular application and its requirements. Various modifications to the embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments and applications without departing from the spirit and scope of the invention. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles, features and teachings disclosed herein.

[0027] FIG. **2** illustrates a stent coating apparatus **200** according to an embodiment of the present invention. The apparatus **200** includes a casing **210** holding an electromechanical stent coating mechanism **220**. The mechanism **220** can be accessed via sliding doors **240** located on a face of the casing **210**. A touchpad monitor **230** is also coupled to the casing **210** and enables an operator to enter instructions for controlling the mechanism **220**.

[0028] FIG. **3** to FIG. **7** illustrate the stent coating mechanism **220** in greater detail. The mechanism **220** may include a stent mandrel for supporting a stent **10** and a piezoelectric print head **300** for coating the stent **10**. The mandrel **310** is supported by a collet **320** at a first end and by a support **330**, such as a bearing support, at a second end. An electric motor **340** may be connected to the collet **320** to rotate the stent **10** about its longitudinal axis. A second electric motor **350** (see FIGS. **3** and **7**) may be provided for linearly moving the mandrel **310** back and forth. The print head **300** may include a transducer that converts electrical energy into acoustic (vibrational) energy in the form of acoustic pulses. The acoustic energy ejects (or dispenses) droplets of the coating substance from the print head **300** onto the stent **10**. Preferably, each acoustic pulse dispenses a single droplet from the print head **300**.

[0029] Preferably, the mandrel is manufactured with sufficient precision and has sufficient dimensional stability, so that stent movement during coating operation is precise and predictable. Precise and predictable stent movement makes a precise coating of the stent possible. For example, the mandrel preferably is straight so as to limit the total indicated run out of the stent. Further, the mandrel diameter preferably is precise so that it is slightly less than the inner diameter of the stent. If the mandrel diameter is too small, the gap between the mandrel and the stent may cause the stent to move randomly during coating. If the mandrel diameter is too large, the stent inner surface may be damaged when the stent is mounted on the mandrel.

[0030] Preferably, carbide is used as the mandrel material to provide the mandrel with precise dimensions and dimensional stability over time and temperature. Since a carbide mandrel generally does not bend (it breaks instead of bending), the dimensional stability of an intact mandrel can be ensured. Additionally, a carbide mandrel can be machined without warping; this is difficult to do with many other materials because the mandrel is relatively thin and long.

[0031] Preferably, the mandrel has a color that facilitates the imaging of a mounted stent. For example, the mandrel may have a dark color, such as black, which provides a dark background for a light-colored stent. Or the mandrel may have a light color, such as white, which provides a light background for a dark stent. This can be accomplished by using a dark or light-colored carbide. Alternatively, the mandrel may be coated with Teflon of a desired color. For example, a Teflon jacket of a desired color may be heat shrunk over the mandrel. Furthermore, a Teflon coating may provide a lubricious mandrel surface for a stent to slide on. This may facilitate the mounting of the stent on the mandrel and avoid or reduce damages to the stent inner surface.

[0032] Preferably, the contact between the inner surface of the stent and the outer surface of the mandrel is minimized or reduced. The surface contact between the stent and the mandrel may provide areas where a liquid coating substance can flow, wick, and collect as the coating substance is applied to the stent. As the solvent evaporates, the excess coating substance hardens to form excess coating at and around the contact points between the stent and the mandrel. Upon removal of the coated stent from the mandrel, the excess coating may stick to the mandrel, thereby removing some of the coating from the stent and leaving bare areas. Alternatively, the excess coating may stick to the stent, thereby leaving excess coating substance as clumps or pools on the stent.

[0033] The mandrel may be configured to minimize the surface contact between the stent and the mandrel so as to reduce areas of potential coating defects. FIG. **5***a* illustrates a mandrel **310***a* with circular protrusions **312** that are arranged along the longitudinal axis of the mandrel **310***a*. The spacing of the circular protrusions **312** matches the spacing of the stent rings. These circular protrusions **312** have line contact with the inner surface of the stent. In addition, the line contact is at the wide portion of the stent. The limited line contact at the wide portion of the stent geometry results in minimal coating defects. FIG. **5***b* illustrates a mandrel **310***b* with a

triangular cross-section, and FIG. **5***c* illustrates a mandrel **310***c* with a cross-section having three lobes, although the cross-section may have more than three lobes. Each of the two mandrels **310***b*, **310***c* shown in FIGS. **5***b* and **5***c* has line contacts with the stent. Each of the three mandrels **310***a*, **310***b*, **310***c* may have a circumscribed diameter that is slight less than the inner diameter of the stent. Preferably, the circumscribed diameter of each mandrel **310***a*, **310***b*, **310***c* is 0.005 inches to 0.010 inches less than the inner diameter of the stent.

[0034] The print head **300** preferably is aligned with a stent strut **12** or connecting element **14** and coats each individual stent strut **12** or connecting element **14**. Hereinafter, the term stent strut will also refer to connecting element for ease of discussion. The coating can be limited to just the outer surface of the strut **12**. In some cases, the sidewalls of the struts **12** between the outer and inner surfaces can be partially coated. Partial coating of the sidewalls can be incidental, such as when some coating flows from the outer surface onto the sidewalls, or intentional.

[0035] The apparatus **200** may also include an imaging device **360** that images droplets generated by the print head **300**. Preferably, the imaging device **360** is a camera, but another type of imaging device, such as a radar or an electron scanner, may be used. The apparatus **200** preferably includes a light **400**, such as a strobe light, to illuminate the droplets. The images from the imaging device **360** can be used to confirm that the print head **300** did in fact emit a droplet and that droplet parameters meet certain requirements, such as requirements on volume, velocity, mode, and alignment with a stent strut.

[0036] The apparatus **200** may further include a controller that can determine droplet parameters from the images. The methods for determining droplet parameters from images are known and will not be described herein. The controller then compares the droplet parameters with the desired values and controls the print head **300** to adjust the droplet parameters towards the desired values. For example, if the droplets are too small or their velocity is too low, the controller can increase the ejecting power of the print head **300** to increase droplet volume or velocity. The ejecting power can be increased by increasing at least one of the width and magnitude of the acoustic pulses. On the other hand, droplet diameter decreases exponentially as pulse frequency increases.

[0037] The controller may also control other parameters of the print head **300** based on the droplet parameters. For example, the controller may control the ejection frequency to achieve a constant coating rate. If the droplet volume decreases, the droplet frequency may be increased to maintain a constant coating rate. For another example, the controller may stop coating one area and start coating another area when the first area has received a desired amount of coating. Whether the first area has received the desired amount of coating can be determined from the number of droplets applied to the area and the volume of each droplet.

[0038] The controller may further control the parameters of the print head **300** based on parameters other than droplet parameters. For example, the controller may control the ejection frequency based on the relative velocity between the stent surface and the print head **300** to achieve a substantially constant mount of coating per unit area of stent surface. In this example, the ejection frequency decreases when the relative velocity decreases around a complicated geometry, and the ejection frequency increases when the relative velocity increases on a more linear geometry.

[0039] Preferably, the aperture of the print head **300** has a diameter of less than about 20 microns, leading to droplets with a maximum diameter of about 20 microns. Alternatively, the aperture may have a diameter of about 10 microns to about 200 microns, yielding similar-sized droplets. Droplet volume can range from about 5 picoliters to about 30 picoliters. Pulse widths can vary from about 10 μsec to about 60 μsec. Preferably, the droplet velocity is about 4 to about 6 m/s, and firing accuracy is preferably about +/− 10 um.

[0040] Another imaging device **362** (see FIG. **6**) may be used to control stent movement to keep the print head **300** aligned with the stent struts **12**. The imaging device **362** may image the surface of the stent **10**. Based on this image, the controller aligns the print head **300** with a stent strut **12** by causing the motors **340** and **350** to rotate and translate the stent **10** until alignment is achieved. The controller then causes the print head **300** to dispense coating substance. This camera **362** may also be used to align the droplet to the top-dead-center (TDC) of the stent for coating alignment. After a section of the stent has been coated, the motors **340** and **350** rotate and translate the stent **10** in relation to the print head **300** to position an uncoated section in front of the print head **300**.

[0041] The apparatus **200** may include an illumination system for illuminating the stent for run out check and/or for scanning and coating visualization. In the illustrated embodiment, the illumination system includes a backlight **380** (FIG. **3**) for illuminating the stent in silhouette for run out check and another light **382** (FIG. **6**) for illuminating the stent for scanning and coating visualization. The imaging device **362** shown in FIG. **6** images the stent under illumination and the controller ensures that the stent **10** meets quality standards before the coating process. A stent may be rejected if it is damaged or if it wobbles during rotation, indicating a bend in the stent.

[0042] After the coating of the stent abluminal surface, the stent **10** can then have the inner surface coated via electrospraying or spray coating. Without masking the outer surface of the stent **10**, both electrospraying and spray coating may yield some composition onto the outer surface and sidewalls of the stent **10**. However, the inner surface would be substantially solely coated with a single composition different from the composition used to coat the outer surface of the stent **10**. Accordingly, it will be appreciated by one of ordinary skill in the art that this embodiment enables the coating of the inner and outer surfaces of the stent **10** with different compositions. For example, the inner surface could be coated with a composition having a bio-beneficial therapeutic substance for delivery downstream of the stent **10** (e.g., an anticoagulant, such as heparin, to reduce platelet aggregation, clotting and thrombus formation) while the outer surface of the stent **10** could be coating with a composition having a therapeutic substance for local delivery to a blood vessel wall (e.g., an anti-inflammatory drug to treat vessel wall inflammation or a drug for the treatment of restenosis).

[0043] The apparatus **200** may include a tip cleaner **370** containing acetone or other cleansing agents. From time to time, such as before or after the coating of the stent **10**, the print head **300** may touch the tip cleaner **370** via movement of the print head **300** or the tip cleaner **370**. The cleaning agent helps remove coating substance that blocks the aperture of the print head **300**.

[0044] As shown in FIG. **7**, the apparatus **200** preferably includes a reservoir **610** for holding a coating substance to be applied to the stent **10**. The reservoir **610** is in fluid communication with the print head **300** and can dispense the coating substance to the print head **300** using gravity or pressure. The print head **300** generally has a small opening of 20 μm to 50 μm and therefore the coating substance does not exit the opening due to surface tension unless the transducer is activated. If the print head **300** is positioned underneath the stent **10** with the aperture pointing upwards, gravity can be used to form a negative or positive meniscus by placing the reservoir at a height above, even, or below the aperture. Further, the aperture may be coated with a low surface energy coating or any anti-wetting coating, such as TEFLON, to prevent coating from exiting the aperture except when desired. Preferably, the reservoir **610** is placed on an elevator **640**, which adjusts the vertical positioning of the elevator **640** to balance the meniscus at the print head **300**.

[0045] In an embodiment of the invention, the coating process can be continuous, i.e., the print head **300** can move along and coat the entire stent **10** without stopping, or move intermittently, i.e., coating a first section of the stent **10**, stopping, and then aligning with a second section of the stent **10**, and coating that second section. The second section may be adjacent to the first section or located a distance from the first section.

[0046] Preferably, the stent coating mechanism **220** is coupled to a granite mounting **620** and **630** beneath and behind the mechanism **220** for precision alignment component and vibration dampening. The granite mounting **620** and **630** may in turn be coupled to the casing **210**.

[0047] FIGS. **8**A and **8**B show flowcharts illustrating a method **700** of coating an abluminal stent surface. First, the operator's login level is checked (**702**). The operator's login level determines his or her level of access to the system. If the operator's login is accepted, then a recipe is selected (**704**) and a stent is loaded (**714**) on the mandrel **310**. Otherwise, the lot history record (LHR) is scanned (**708**) to determine the recipe to use. The stent holder barcode is then scanned (**710**) and it is determined (**712**) whether the part information corresponding with the barcode agrees with the LHR. If there is no match, then the scanning (**710**) is repeated. Otherwise, the stent is loaded (**714**) on the mandrel **310**. The mandrel **310** is then loaded (**716**) into the collet **320** and a recipe is initiated by pressing (**718**) a start button on the touchpad monitor **230**. The mandrel tip is then inserted (**720**) into a support bushing (e.g., the support **330**). The stent **10** is then moved (**722**) to a run-out check location for inspection, as discussed above.

[0048] If the run-out check does not pass (**724**), then the loading step (**716**) to the moving step (**722**) is repeated. Otherwise, the imaging device **362** may take an image of the stent, from which image a digitized coating path may be generated. The stent **10** is then moved (**726**) to the top dead center (TDC) under the print head **300**. The motors **340**, **350** move (**728**) from left to right until the controller locates the edge of the stent **10**. The motors **340**, **350** then rotate (**730**) the stent until the controller locates a reference point. The reference point may be a marking added to the stent or a natural feature of the stent that can be recognized by the controller. The print head is then cleaned (**732**) by being dipped in acetone and may eject (**732**) test droplets. During the test (**732**), the imaging device **360**, as discussed above, may image the test droplets and determine if the test droplets meet the requirements.

[0049] If the test droplets do not meet the requirements, then the ejection (**732**) can be repeated. Otherwise, the stent **10** moves (**736**) under the print head **300** and the coating process begins. Based on the images provided by the imaging device **360**, the controller uses the motors **340**, **350** to guide (**738**) the print head **300** along the centerline of stent struts to the end of the stent while the print head **300** dispenses the coating. The print head **300** stops dispensing (**742**) when the end of the stent **10** is reached.

[0050] As an alternative to or in addition to taking an image of the stent prior to coating to determine the coating path, the image of the stent can be taken and the coating path can be determined during coating. Also, during the coating, the imaging device **360** can image the droplets, and the controller can determine if the droplets meet the requirements. If the droplets do not meet the requirements, the controller adjusts the print head **300** as discussed above.

[0051] If the coated stent is not to be inspected (**744**), then a pass is recorded (**752**) and the stent **10** moves to a load/unload station. Otherwise, the controller inspects a digitized image of the coated stent for defects. If no defects are found (**748**), then a pass is recorded (**752**) and the stent **10** is moved (**752**) to a load/unload station. If defects are found (**748**), then the operator can pass or fail the coated stent. If passed, then the pass is recorded (**752**) and the stent moved to a load/unload station. Otherwise, the reason for failure is recorded (**754**) and the stent **10** is moved (**756**) to a load/unload station. The method **700** then ends.

[0052] The components of the coating substance or composition can include a solvent or a solvent system comprising multiple solvents, a polymer or a combination of polymers, a therapeutic substance or a drug or a combination of drugs. In some embodiments, the coating substance can be exclusively a polymer or a combination of polymers (e.g., for application of a primer layer or topcoat layer). In some embodiments, the coating substance can be a drug that is polymer free. Polymers can be biostable, bioabsorbable, biodegradable, or bioerodable. Biostable refers to polymers that are not biodegradable. The terms biodegradable, bioabsorbable, and bioerodable are used interchangeably and refer to polymers that are capable of being completely degraded and/or eroded when exposed to bodily fluids such as blood and can be gradually resorbed, absorbed, and/or eliminated by the body. The processes of breaking down and eventual absorption and elimination of the polymer can be caused by, for example, hydrolysis, metabolic processes, bulk or surface erosion, and the like.

[0053] Representative examples of polymers that may be used include, but are not limited to, poly(N-acetylglucosamine) (Chitin), Chitoson, poly(hydroxyvalerate), poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polyorthoester, polyanhydride, poly(glycolic acid), poly(glycolide), poly(L-lactic acid), poly(L-lactide), poly(D,L-lactic acid), poly(D,L-lactide), poly(D-lactic acid), poly(D-lactide), poly(caprolactone), poly(trimethylene carbonate), polyester amide, poly(glycolic acid-co-trimethylene carbonate), co-poly(ether-esters) (e.g. PEO/PLA), polyphosphazenes, biomolecules (such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid), polyurethanes, silicones, polyesters, polyolefins, polyisobutylene and ethylene-alphaolefin copolymers, acrylic polymers and copolymers other than polyacrylates, vinyl halide polymers and copolymers (such as polyvinyl chloride), polyvinyl ethers (such as polyvinyl methyl ether), polyvinylidene

halides (such as polyvinylidene chloride), polyacrylonitrile, polyvinyl ketones, polyvinyl aromatics (such as polystyrene), polyvinyl esters (such as polyvinyl acetate), acrylonitrile-styrene copolymers, ABS resins, polyamides (such as Nylon 66 and polycaprolactam), polycarbonates, polyoxymethylenes, polyimides, polyethers, polyurethanes, rayon, rayon-triacetate, cellulose, cellulose acetate, cellulose butyrate, cellulose acetate butyrate, cellophane, cellulose nitrate, cellulose propionate, cellulose ethers, and carboxymethyl cellulose. Representative examples of polymers that may be especially well suited for use include ethylene vinyl alcohol copolymer (commonly known by the generic name EVOH or by the trade name EVAL), poly(butyl methacrylate), poly (vinylidene fluoride-co-hexafluororpropene) (e.g., SOLEF 21508, available from Solvay Solexis PVDF, Thorofare, N.J.), polyvinylidene fluoride (otherwise known as KYNAR, available from ATOFINA Chemicals, Philadelphia, Pa.), ethylene-vinyl acetate copolymers, and polyethylene glycol.

[0054] "Solvent" is defined as a liquid substance or composition that is compatible with the polymer and/or drug and is capable of dissolving the polymer and/or drug at the concentration desired in the composition. Examples of solvents include, but are not limited to, dimethylsulfoxide, chloroform, acetone, water (buffered saline), xylene, methanol, ethanol, 1-propanol, tetrahydrofuran, 1-butanone, dimethylformamide, dimethylacetamide, cyclohexanone, ethyl acetate, methylethylketone, propylene glycol monomethylether, isopropanol, isopropanol admixed with water, N-methyl pyrrolidinone, toluene, and mixtures and combinations thereof.

[0055] The therapeutic substance or drug can include any substance capable of exerting a therapeutic or prophylactic effect. Examples of active agents include antiproliferative substances such as actinomycin D, or derivatives and analogs thereof (manufactured by Sigma-Aldrich 1001 West Saint Paul Avenue, Milwaukee, Wis. 53233; or COSMEGEN available from Merck). Synonyms of actinomycin D include dactinomycin, actinomycin IV, actinomycin I_1, actinomycin X_1, and actinomycin C_1. The bioactive agent can also fall under the genus of antineoplastic, anti-inflammatory, antiplatelet, anticoagulant, antifibrin, antithrombin, antimitotic, antibiotic, antiallergic and antioxidant substances. Examples of such antineoplastics and/or antimitotics include paclitaxel, (e.g., TAXOL® by Bristol-Myers Squibb Co., Stamford, Conn.), docetaxel (e.g., Taxotere®, from Aventis S.A., Frankfurt, Germany), methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, doxorubicin hydrochloride (e.g., Adriamycin® from Pharmacia & Upjohn, Peapack N.J.), and mitomycin (e.g., Mutamycin® from Bristol-Myers Squibb Co., Stamford, Conn.). Examples of such antiplatelets, anticoagulants, antifibrin, and antithrombins include aspirin, sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, and thrombin inhibitors such as Angiomax ä (Biogen, Inc., Cambridge, Mass.). Examples of such cytostatic or antiproliferative agents include angiopeptin, angiotensin converting enzyme inhibitors such as captopril (e.g., Capoten® and Capozide® from Bristol-Myers Squibb Co., Stamford, Conn.), cilazapril or lisinopril (e.g., Prinivil® and Prinzide® from Merck & Co., Inc., Whitehouse Station, N.J.), calcium channel blockers (such as nifedipine), colchicine, proteins, peptides, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonists, lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug, brand name Mevacor® from Merck & Co., Inc., Whitehouse Station, N.J.), monoclonal antibodies (such as those specific for Platelet-Derived Growth Factor (PDGF) receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitors, suramin, serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. An example of an antiallergic agent is permirolast potassium. Other therapeutic substances or agents which may be appropriate agents include cisplatin, insulin sensitizers, receptor tyrosine kinase inhibitors, carboplatin, alpha-interferon, genetically engineered epithelial cells, steroidal anti-inflammatory agents, non-steroidal anti-inflammatory agents, antivirals, anticancer drugs, anticoagulant agents, free radical scavengers, estradiol, antibiotics, nitric oxide donors, super oxide dismutases, super oxide dismutases mimics, 4-amino-2,2,6,6-tetramethylpiperidine-1-oxyl (4-amino-TEMPO), tacrolimus, dexamethasone, ABT-578, clobetasol, cytostatic agents, prodrugs thereof, co-drugs thereof, and a combination thereof. Other therapeutic substances or agents may include rapamycin and structural derivatives or functional analogs thereof, such as 40-O-(2-hydroxy)ethyl-rapamycin (everolimus), 40-O-(3-hydroxy) propyl-rapamycin, 40-O-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, and 40-O-tetrazole-rapamycin.

[0056] While particular embodiments of the present invention have been shown and described, it will be obvious to those skilled in the art that changes and modifications can be made without departing from this invention in its broader aspects. Therefore, the appended claims are to encompass within their scope all such changes and modifications as fall within the true spirit and scope of this invention.

1. A mandrel for supporting a stent during a composition deposition process, comprising:

an elongated body for insertion into a longitudinal bore of a stent, the body comprises carbide.

2. The mandrel of claim **1**, wherein the elongated body does not bend.

3. The mandrel of claim **1**, wherein the mandrel comprises a dark color to facilitate imaging of a light-colored stent.

4. The mandrel of claim **1**, wherein the mandrel comprises a black color to facilitate imaging of a light-colored stent.

5. The mandrel of claim **1**, wherein the mandrel comprises a light color to facilitate imaging of a dark-colored stent.

6. The mandrel of claim **1**, wherein the mandrel comprises a white color to facilitate imaging of a dark-colored stent.

7. The mandrel of claim **1**, additionally comprising a Teflon coating on the carbide body.

8. The mandrel of claim **1**, additionally comprising a Teflon jacket heat shrunk on the carbide body.

9. The mandrel of claim **1**, wherein the elongated body includes circular protrusions, each protrusion being located at a ring position of the stent.

10. A method of depositing a substance on a stent, comprising:

(a) positioning the stent on the mandrel of claim **1**;

(b) depositing a substance on the stent.

11. The method of claim **10**, additionally comprising imaging the stent or the substance being deposited, wherein the stent in light-colored and the elongated body is dark-colored or black.

12. The method of claim **10**, additionally comprising imaging the stent or the substance being deposited, wherein the stent in dark-colored and the elongated body is light-colored or white.

13. The method of claim **10**, wherein the elongated body does not bend.

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