



(51) International Patent Classification:

B05B 13/04 (2006.01)

DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(21) International Application Number:

PCT/US2013/043547

(22) International Filing Date:

31 May 2013 (31.05.2013)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/654,403 1 June 2012 (01.06.2012) US
61/661,684 19 June 2012 (19.06.2012) US(71) Applicant: **SURMODICS, INC.** [US/US]; 9924 West 74th Street, Eden Prairie, Minnesota 55344-3523 (US).(72) Inventors: **CHAPPA, Ralph A.**; 3509 133rd Lane Northeast, Ham Lake, Minnesota 55304 (US). **BACH, Andrew G.**; 3112 Georgia Ave South, St. Louis Park, Minnesota 55426 (US). **MACGREGOR, Mark**; 141 Belvidere Street East, St. Paul, Minnesota 55107 (US).(74) Agent: **DEFFNER, Mark E.**; 121 South 8th Street, TCF Tower, Suite 900, Minneapolis, Minnesota 55402-2481 (US).

(84) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: APPARATUS AND METHOD FOR COATING BALLOON CATHETERS

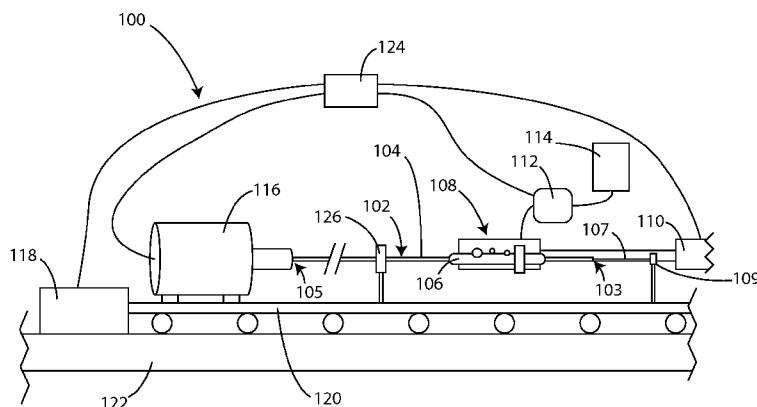


FIG. 1

(57) **Abstract:** Embodiments of the invention include apparatus and methods for coating drug eluting medical devices. In an embodiment, the invention includes a coating apparatus including a coating application unit comprising a movement restriction structure; a fluid applicator; and an air nozzle. The apparatus can further include a rotation mechanism and an axial motion mechanism, the axial motion mechanism configured to cause movement of at least one of the coating application unit and the rotation mechanism with respect to one another. Other embodiments are also included herein.

APPARATUS AND METHOD FOR COATING BALLOON CATHETERS

This application is being filed as a PCT International Patent application on May 5, 2013 in the name of SurModics, Inc., a U.S. national corporation, applicant for the designation of all countries and Ralph A. Chappa, a U.S. Citizen, and Andrew G. Bach, a U.S. Citizen, and Mark MacGregor, a U.S. Citizen, are inventors only for the designated states, and claims priority to U.S. Provisional Patent Application No. 61/654,403, filed June 1, 2012, and to U.S. Provisional Patent Application No. 61/661,684, filed June 19, 10, 2012, the contents of which are herein incorporated by reference in its entirety.

Field of the Invention

The present invention relates to apparatus and methods for coating medical devices.

Background of the Invention

Functional improvements to implantable or insertable medical devices can be achieved by coating the surface of the device. For example, a coating formed on the surface of the device can provide improved lubricity, improved biocompatibility, or drug delivery properties to the surface. In turn, this can improve movement of the device in the 20 body, extend the functional life of the device, or treat a medical condition near the site of implantation. However, various challenges exist for the design and use of coating apparatus designed to provide coatings to medical devices.

Traditional coating methods, such as dip coating, are often undesirable as they may result in flawed coatings that could compromise the function of the device or present 25 problems during use. These methods can also result in coating inaccuracies, which can be manifested in variable amounts of the coated material being deposited on the surface of the device. When a drug is included in the coating material, it is often necessary to deliver precise amounts of the agent to the surface of the device to ensure that a subject receiving the coated device receives a proper dose of the agent. It has been difficult to 30 achieve a great degree of accuracy using traditional coating methods and machines.

One type of insertable medical device is a balloon catheter. Balloon catheter constructions are well known in the art and are described in various documents, for example, U.S. Pat. Nos. 4,195,637, 5,041,089, 5,087,246, 5,318,587, 5,382,234, 5,571,089, 5,776,101, 5,807,331, 5,882,336, 6,394,995, 6,517,515, 6,623,504, 6,896,842, 5 and 7,163,523. Balloon catheters generally include four portions, the balloon, catheter shaft, guide wire, and manifold. A balloon catheter generally includes an elongated catheter shaft with an inflatable balloon attached to a distal section of the catheter shaft. At a proximal end of the catheter shaft, there is typically a manifold. At the manifold end, placement of the catheter can be facilitated using a guide wire. Guide wires are small and 10 maneuverable when inserted into an artery. Once the guide wire is moved to the target location, the catheter with balloon portion is then fed over the guide wire until the balloon reaches the target location in the vessel. The balloon is typically inserted into the arterial lumen of a patient and advanced through the lumen in an unexpanded state. The balloon is then inflated when the catheter reaches target site resulting in application of 15 mechanical force sufficient to cause vessel dilation. The balloon is typically inflated using a fluid, which is injected through an inflation port. The manifold can control the fluid introduction within shaft for expansion of the balloon. The mechanics of fluid transfer and introduction within balloons vary according to the specific design of the catheter, and are well known in the art.

20

Summary of the Invention

Embodiments of the invention include apparatus and methods for coating drug coated medical devices. In an embodiment, the invention includes a coating apparatus including a coating application unit comprising a movement restriction structure; a fluid 25 applicator; and an air nozzle. The apparatus can further include a rotation mechanism and a axial motion mechanism, the axial motion mechanism configured to cause movement of at least one of the coating application unit and the rotation mechanism with respect to one another.

In an embodiment, the invention includes a coating apparatus including a coating 30 application unit comprising a fluid applicator; a fluid distribution bar; an air nozzle; and

a rotation mechanism. The coating apparatus can further include an axial motion mechanism, the axial motion mechanism configured to cause movement of the coating application unit with respect to the rotator.

In an embodiment, the invention includes a method of coating including rotating a balloon catheter with a rotation mechanism, the balloon catheter comprising a balloon, contacting the balloon with a movement restriction structure defining a channel; applying a coating solution onto the surface of the balloon with a fluid applicator, contacting the surface of the balloon with a fluid distribution bar, blowing a stream of a gas onto the surface of the balloon, wherein the channel limits lateral movement of the balloon.

This summary is an overview of some of the teachings of the present application and is not intended to be an exclusive or exhaustive treatment of the present subject matter. Further details are found in the detailed description and appended claims. Other aspects will be apparent to persons skilled in the art upon reading and understanding the following detailed description and viewing the drawings that form a part thereof, each of which is not to be taken in a limiting sense. The scope of the present invention is defined by the appended claims and their legal equivalents.

Brief Description of the Figures

The invention may be more completely understood in connection with the following drawings, in which:

FIG. 1 is a schematic side view of a coating apparatus in accordance with various embodiments herein.

FIG. 2 is a schematic view of a coating application unit in accordance with various embodiments herein.

FIG. 3 is a schematic view of a movement restriction structure in accordance with various embodiments herein.

FIG. 4 is a schematic view of a movement restriction structure in accordance with various embodiments herein.

FIG. 5 is a schematic view of a movement restriction structure in accordance with various embodiments herein.

FIG. 6 is a schematic end view of a fluid distribution bar in conjunction with the balloon of a balloon catheter.

FIG. 7 is a schematic end view of a fluid applicator in conjunction with the balloon of a balloon catheter.

5 FIG. 8 is a schematic end view of an air nozzle in conjunction with the balloon of a balloon catheter.

FIG. 9 is a schematic view of a coating application unit in accordance with various embodiments herein.

10 FIG. 10 is a schematic view of a coating application unit in accordance with various embodiments herein.

FIG. 11 is a schematic top view of a movement restriction structure in accordance with various embodiments herein.

FIG. 12 is a schematic end view of a movement restriction structure in accordance with various embodiments herein.

15 FIG. 13 is a schematic front view of a movement restriction structure in accordance with various embodiments herein.

FIG. 14 is a schematic front view of a movement restriction structure in accordance with various embodiments herein.

20 FIG. 15 is a schematic end view of a movement restriction structure in accordance with various embodiments herein.

FIG. 16 is a schematic end view of a fluid applicator in accordance with various embodiments herein.

While the invention is susceptible to various modifications and alternative forms, specifics thereof have been shown by way of example and drawings, and will be 25 described in detail. It should be understood, however, that the invention is not limited to the particular embodiments described. On the contrary, the intention is to cover modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

Detailed Description of the Invention

The embodiments of the present invention described herein are not intended to be exhaustive or to limit the invention to the precise forms disclosed in the following detailed description. Rather, the embodiments are chosen and described so that others 5 skilled in the art can appreciate and understand the principles and practices of the present invention.

All publications and patents mentioned herein are hereby incorporated by reference. The publications and patents disclosed herein are provided solely for their disclosure. Nothing herein is to be construed as an admission that the inventors are not 10 entitled to antedate any publication and/or patent, including any publication and/or patent cited herein.

Embodiments herein can be used to apply visually uniform coatings, such as 15 coatings including active agents, onto medical devices, such as onto the balloons of drug coated or drug eluting balloon catheters, that have substantially uniform active agent concentrations along the length of the medical device. For example, in some embodiments, coatings can be formed with apparatus and methods wherein each section of the device that has been coated contains an amount of the active agent that is within ten percent of the average amount of active agent across all sections coated.

Referring now to FIG. 1, a schematic side view is shown of a coating apparatus 20 100 in accordance with various embodiments herein. The coating apparatus 100 is shown in conjunction with a drug coated balloon catheter 102. The drug coated balloon catheter 102 can include a catheter shaft 104 and a balloon 106. The balloon 106 can assume a deflated configuration and an inflated configuration. The drug coated balloon catheter 102 can include a distal end 103 and a proximal end 105. The drug coated balloon 25 catheter 102 can include a proximal end manifold (not shown). The coating apparatus 100 can include a coating application unit 108. The coating apparatus 100 can further include, in some embodiments, an axial motion mechanism 110 (axial with respect to the axis of rotation of the balloon catheter and thus parallel to the lengthwise axis of the balloon catheter) that can function to move one or more components of the coating 30 application unit 108. In some embodiments, axial motion can be substantially horizontal. In other embodiments, axial motion can be substantially vertical. In some embodiments,

axial motion can be somewhere in between horizontal and vertical, depending on the orientation of the lengthwise axis of the balloon catheter. However, it will be appreciated that in other embodiments, the coating application unit 108 can remain stationary.

Coating of the balloon 106 to make it drug coated can occur starting at the

5 proximal end of the balloon and proceeding to the distal end. However, in other embodiments, coating of the drug coated balloon 106 can occur starting at the distal end of the balloon and proceeding to the proximal end. In many embodiments, coating can take place with a single pass of the coating application unit 108 with respect to the balloon. However, in other embodiments, multiple passes of the coating application unit
10 with respect to the balloon can be made.

The coating apparatus 100 can further include a fluid pump 112. The fluid pump 112 can be, for example, a syringe pump. The fluid pump 112 can be in fluid communication with components of the coating application unit 108 (such as the fluid applicator) and with a fluid reservoir 114. The fluid pump 112 can operate to pump a
15 coating solution at a rate sufficient to apply about 0.5 μ l to about 10 μ l of the coating solution per millimeter of length of the balloon or other device to be coated. The coating apparatus 100 can further include a rotation mechanism 116 (or rotating balloon catheter fixture). The rotation mechanism 116 can be directly or indirectly coupled to the drug coated balloon catheter in order to rotate the drug coated balloon catheter 102 around its
20 lengthwise (major) axis (about the central lumen of the catheter). In some embodiments, the drug coated balloon catheter can be rotated at a speed of between 100 and 400 rotations per minute. In some embodiments, the drug coated balloon catheter can be rotated at a speed of between 200 and 300 rotations per minute.

In some embodiments, a guide wire 107, passing through the central lumen of the

25 catheter, can extend from the distal tip of the catheter and be inserted into a distal tip support ring 109 or guide. In this manner, the guide wire 107 can be used to support the distal tip of the balloon catheter to be coated while allowing the balloon catheter to rotate freely.

The coating apparatus 100 can further include, in some embodiments, an axial

30 motion mechanism 118 which can be configured to move the drug coated balloon catheter 102 in the direction of its lengthwise major axis. In some embodiments, axial

motion can be substantially horizontal. In other embodiments, axial motion can be substantially vertical. In some embodiments, axial motion can be somewhere in between horizontal and vertical, depending on the orientation of the lengthwise axis of the balloon catheter. In some embodiments, the axial motion mechanism 118 can be a linear actuator. In some embodiments, the axial motion mechanism 118 can include an electric motor. The coating apparatus 100 can further include a frame member 120 (in some embodiments this can also be referred to as an axial motion support rail). The frame member 120 can support other components of the coating apparatus 100 such as one or more guides 126. The frame member 120 can itself be support by a platform 122. The 10 coating apparatus 100 can further include a controller 124 that can serve to control operation of the coating apparatus 100 including, specifically, fluid pump 112, axial motion mechanism 110, rotation mechanism 116, and axial motion mechanism 118.

15 Referring now to FIG. 2, a schematic view of a coating application unit 108 in accordance with various embodiments herein is shown. The coating application unit 108 can include a movement restriction structure 202 (or wobble control structure), an air nozzle 204, a fluid distribution bar 206, and a fluid applicator 208. The movement restriction structure 202 can serve to limit the lateral motion (e.g., movement in a direction perpendicular to the lengthwise axis of the catheter) of the balloon during a coating operation.

20 The fluid applicator 208 can serve to apply a coating solution 209 to the surface of the balloon 212 on the drug coated balloon catheter. In some embodiments, the fluid applicator 208 is less than or equal to about 1 cm away from the movement restriction structure 202. In some embodiments, the air nozzle 204 is less than or equal to about 2 cm away from the fluid applicator 208. The air nozzle 204 can provide a stream of a gas 25 in order to assist in drying the coating solution after it has been applied to the balloon or other medical device.

30 The fluid distribution bar 206 can serve to promote distribution of the applied coating solution. For example, the fluid distribution bar 206 can serve to prevent pooling of the applied coating solution. In some embodiments, the fluid distribution bar 206 can be at least about 0.5 mm away from the fluid applicator and less than 2 cm away. In some

embodiments, the fluid distribution bar 206 can be at least about 0.2 cm away from the fluid applicator and less than 2 cm away.

In this embodiment, the coating application unit 108 can move, relative to the balloon 212 in the direction of arrow 230. As such, during a coating operation, the 5 movement restriction structure 202 can pass over the balloon first, followed by the fluid applicator 208, followed by the fluid distribution bar 206, with the air nozzle last. It should be emphasized, however, that this movement is relative in the sense that in some embodiments the coating application unit 108 is moving and the balloon 212 is rotating but otherwise stationary, in some embodiments the balloon 212 is rotating and moving in 10 the direction of its lengthwise axis and the coating application unit 108 is stationary, in still other embodiments both the coating application unit 108 and the balloon 212 are moving. The speed of movement of the balloon 212 relative to the coating application unit 108 can vary depending on the amount of coating solution to be applied. In some embodiments the speed can be from about 0.02 centimeters per second to about 0.2 15 centimeters per second.

It will be appreciated that based on the rotation of the drug coated balloon catheter and the movement of the balloon relative to the coating application unit that the path of the deposition of the coating onto the balloon follows a roughly helical path. It will be appreciated that the combination of the rotation speed of the drug coated balloon catheter 20 and the speed of the movement of the balloon relative to the coating application unit can influence the amount of coating solution that is deposited at any given point and the nature of the helical path. For example, the coating material can be deposited in helical layers that partially overlap one another at their edges, helical layers wherein the edge of one turn substantially meets the edge of a previous turn, and helical layers wherein there 25 are gaps in between subsequent helical turns. In some embodiments, these helical patterns can be configured so as to maximize release of the active agent. For example, in some embodiments, the apparatus can be used to coat device so as to produce helical ridges of the coating material on the balloon surface.

In some embodiments, the coating application unit 108 can optionally include a 30 manifold block 210. The manifold block 210 can facilitate support of, and in some embodiments movement of, the components of the coating application unit 108. In some

embodiments, the components of the coating application unit can move together as a unit during a coating operation. However, in other embodiments the components of the coating application unit are substantially separate from one another and can move independently. In some embodiments, the components of the coating application unit are 5 all substantially stationary during a coating operation.

While the components of the coating application unit 108 are shown in FIG. 2 as being within a particular plane and disposed at approximately the same angle with respect to the balloon 212 being coated, it will be appreciated that this is not the case with all 10 embodiments herein. In some embodiments, the components of the coating application unit 108 lie in different planes with respect to the balloon 212 and/or the components of the coating application unit 108 are disposed at different angles (both with respect to the lengthwise axis of the balloon and radially) with respect to the balloon.

Referring now to FIG. 3, a schematic end view is shown of a movement 15 restriction structure 302 in accordance with various embodiments herein. The structure 302 can include a body member 306 defining a channel 304 or aperture. The body member 306 can be formed of various materials such as polymers, metals, ceramics, and the like. In a particular embodiment, the body member 306 is formed of polytetrafluoroethylene (PTFE). The channel 304 can have a diameter 308 that is sufficiently large so as to accommodate the balloon of a drug coated balloon catheter in 20 an expanded state. In the example of FIG. 3, the channel 304 is shown as being bounded in a radially continuous manner by the body member 306 (e.g., it is completely surrounded on all sides by the body member 306). However, it will be appreciated that in some embodiments the channel 304 is not bounded in a radially continuous manner by the body member 306.

25 In some embodiments the movement restriction structure can include multiple pieces that together define a channel or aperture. Referring now to FIG. 4, a movement restriction structure 402 is shown including a body member that includes a first piece 406 and a second piece 408 that together define a channel 404 or aperture. The first piece 406 and second piece 408 are joined together by a hinge 410 in this embodiment, however it 30 will be appreciated that there are many ways known to those of skill in the art by which to hold two structure pieces in association with one another.

It will be appreciated that body members of movement restriction structures can take on many different shapes. In addition, the shape of the channel defined by the body member(s) can take on many different shapes. Referring now to FIG. 5, a movement restriction structure 502 is shown including a first side piece 506 and a second side piece 508 that together define a channel 504 or aperture. In this case, the first side piece 506 and the second side piece 508 are supported by a frame member 510. However, it will be appreciated that there are many different ways of supporting the first side piece 506 and the second side piece 508. In some embodiments, one or both of the first side piece 506 and the second side piece 508 can be spring loaded such that it is biased toward sliding inward toward the other piece. In other embodiments, one or both of the first side piece 506 and the second side piece 508 can be adjustable and then fixed in position so as to create a channel 504 of a desired size.

Referring now to FIG. 6 a schematic end view of a fluid distribution bar 606 in conjunction with the balloon 618 of a drug coated balloon catheter 614 is shown. In some embodiments, the fluid distribution bar 606 can include a support structure 608 and a shaft 610. In some embodiments, the support structure 608 can be omitted. The shaft 610 can be formed of various materials such as polymers, metals, ceramics, and the like. In a particular embodiment, the shaft 610 is formed of polytetrafluoroethylene (PTFE). The shaft 610 can be of various lengths and diameters and can have various cross-sectional shapes. In some embodiments, the shaft 610 is from about 2 mm to about 15 cm and is substantially circular in cross-sectional shape. In some embodiments, the shaft is about 1/16 inch in diameter. The shaft 610 is configured to rest against the balloon 618 of the balloon catheter 614.

In yet other embodiments the fluid distribution bar 606 can include multiple rods or extensions from support structure 608. Exemplary of these embodiments can include, but are not limited to, a comb-like structure or a brush.

The balloon 618 is supported by the catheter shaft 616, but generally only at the ends of the balloon 618. Because of the limited support of the balloon 618 by the catheter shaft 616, the inherent flexibility of the balloon material and manufacturing variations, the balloon 618 may not be perfectly round. As such, when it is being rotated during a coating operation there may be variations in the distance of the outer surface of

the balloon 618 from the catheter shaft 616 of the balloon catheter 614. If unaccounted for, this could lead to circumstances where the fluid distribution bar 606 does not maintain contact with the surface of the balloon 618. As such, the shaft 610 of the fluid distribution bar 606 can be configured to maintain contact with the surface of the balloon 618. For example, the shaft 610 of the fluid distribution bar 606 can be positioned such that it exerts a small degree of pressure against the surface of the balloon 618 such that when an irregularity in the balloon is encountered the fluid distribution bar 606 can move slightly in order to maintain contact with the balloon surface. In some embodiments the shaft 610 of the fluid distribution bar 606 is flexible to accommodate movement to stay in contact with the balloon surface. In other embodiments, the fluid distribution bar 606 can be configured to pivot from where it is mounted in order to accommodate movement to stay in contact with the balloon surface.

While the shaft 610 of the fluid distribution bar 606 is shown in FIG. 6 as contacting the top of the balloon 618 and thus exerting a pressure downward in the direction of arrow 612, it will be appreciated that in other embodiments the surface of the balloon 618 can be contacted at other points along its surface, such as on the sides or on the bottom.

Referring now to FIG. 7, a schematic end view of a fluid applicator 708 in conjunction with the balloon 718 of a drug coated balloon catheter 714 is shown in accordance with an embodiment of the invention. The fluid applicator 708 can include a shaft 706 and an orifice 704. In some embodiments, the fluid applicator 708 can be a pipette. Fluid, such as a coating solution, can travel through the shaft 706 of the fluid applicator 708 in order to be deposited on the surface of the balloon 718 of the drug coated balloon catheter 714. The shaft 706 is configured to rest against the balloon 718 of the balloon catheter 714. The balloon 718 is supported by the catheter shaft 716, but generally only at the ends of the balloon 718. Because of the limited support of the balloon 718 by the catheter shaft 716, the inherent flexibility of the balloon material and manufacturing variations, the balloon 718 may not be perfectly round. As such, when it is being rotated during a coating operation there may be variations in the distance of the outer surface of the balloon 718 from the catheter shaft 716 of the balloon catheter 714. If unaccounted for, this could lead to circumstances where the fluid applicator 708 does

not maintain contact with the surface of the balloon 718. As such, the shaft 706 of the fluid applicator 708 can be configured to maintain contact with the surface of the balloon 718. For example, the shaft 706 of the fluid applicator 708 can be positioned such that it exerts a small degree of pressure against the surface of the balloon 718 such that when an 5 irregularity in the balloon 718 is encountered the fluid applicator 708 can move slightly in order to maintain contact with the balloon surface. In some embodiments the shaft 706 of the fluid applicator 708 is flexible to accommodate movement to stay in contact with the balloon surface. In other embodiments, the fluid applicator 708 can be configured to pivot from where it is mounted in order to accommodate movement to stay in contact 10 with the balloon surface. In other embodiments, the fluid applicator may not be in direct contact with the balloon surface but situated closely, for example within 1 millimeter.

While the shaft 706 of the fluid applicator 708 is shown in FIG. 7 as contacting the upper right side (approximately equivalent to an area between the 1 and 2 position of a clock face) of the balloon 718, it will be appreciated that in other embodiments the 15 surface of the balloon 718 can be contacted at other points along its surface. For example, in some embodiments, the very top of the balloon 718 can be contacted by the fluid applicator 708.

In some embodiments the fluid distribution bar 606 and the fluid applicator 708 can be configured such that the shaft 610 of the fluid distribution bar 606 contacts the 20 surface of the balloon at approximately the same point radially along the surface of the balloon as the shaft 706 of the fluid applicator 708. In some embodiments, the fluid distribution bar 606 and the fluid applicator 708 can be configured such that the shaft 610 of the fluid distribution bar 606 contacts the surface of the balloon within at least 90 degrees radially along the surface of the balloon as the shaft 706 of the fluid applicator 25 708.

Referring now to FIG. 8, a schematic end view of an air nozzle 804 in conjunction with the balloon 818 of a drug coated balloon catheter 814 is shown. The air nozzle 804 can include an orifice 806. A gas such as nitrogen, ambient air or another gas can be directed to flow out of the orifice 806 and towards the balloon 818 of the drug coated 30 balloon catheter 814. In some embodiments, the gas can be heated. For example, in some embodiments the gas can be from about 50 to about 70 degrees Celsius. While the

orifice 806 of the air nozzle 804 is shown in FIG. 8 as directing air to the top of the balloon 818, it will be appreciated that in other embodiments the air nozzle 804 and orifice 806 can be configured to direct air at other parts of the balloon 818 such as, but not limited to, the sides or the bottom.

5 Referring now to FIG. 9, a schematic view of a coating application unit in accordance with various embodiments herein is shown. The coating application unit 900 can include a movement restriction structure 902, a first air nozzle 914, a fluid applicator 908, and a second air nozzle 904. The first air nozzle 914 is disposed on one side of the fluid applicator 908 and the second air nozzle 904 is disposed on the other side of the 10 fluid applicator 908. In some embodiments the first air nozzle 914 can act to avoid pooling of the coating at the fluid applicator 908. In some embodiments the second air nozzle 904 can act to avoid pooling of the coating fluid at the fluid applicator 908. The fluid applicator 908 can serve to apply a coating solution 909 to the surface of the balloon on the drug coated balloon catheter. Other embodiments can include three or more air 15 nozzles.

In this embodiment, the coating application unit 900 can move, relative to the balloon 912 in the direction of arrow 930. As such, during a coating operation, the movement restriction structure 902 can pass over the balloon first. It should be emphasized, however, that this movement is relative in the sense that in some 20 embodiments the coating application unit 900 is moving and the balloon 912 is rotating but otherwise stationary, in some embodiments the balloon 912 is rotating and moving in the direction of its lengthwise axis and the coating application unit 900 is stationary, in still other embodiments both the coating application unit 900 and the balloon 912 are moving.

25 It will be appreciated that the coating solution can be applied on to the balloon in various ways including, but not limited to, spraying (including both ultrasonic spraying and conventional spraying techniques), dribbling, blade coating, contact printing, drop coating, or the like. In some embodiments, the fluid applicator can include a fluid spray nozzle. Referring now to FIG. 10, a schematic view of a coating application unit in 30 accordance with various embodiments herein is shown. The coating application unit 1000 can include a movement restriction structure 1002, an air nozzle 1004, a fluid

distribution bar 1006, and a fluid spray nozzle 1008. The fluid spray nozzle 1008 can serve to apply a coating solution 1009 to the surface of the balloon 1012 on the drug coated balloon catheter. In some embodiments there is a small gap between the fluid spray nozzle 1008 and the balloon 1012. For example, the gap can be between 1 5 millimeter and 10 centimeters. In some embodiments, multiple fluid applicators and/or spray nozzles can be used.

In this embodiment, the coating application unit 1000 can move, relative to the balloon 1012 in the direction of arrow 1030. As such, during a coating operation, the movement restriction structure 1002 can pass over the balloon first. It should be 10 emphasized, however, that this movement is relative in the sense that in some embodiments the coating application unit 1000 is moving and the balloon 1012 is rotating but otherwise stationary, in some embodiments the balloon 1012 is rotating and moving in the direction of its lengthwise axis and the coating application unit 1000 is stationary, in still other embodiments both the coating application unit 1000 and the balloon 1012 15 are moving.

FIG. 11 is a schematic top view of a movement restriction structure in accordance with various embodiments herein. The structure 1102 can include a first body member 1104 and a second body member 1106. The first and second body members 1104, 1106 can be formed of various materials such as polymers, metals, ceramics, and the like. The 20 first and second body members 1104, 1106 can function together to restrict movement of a balloon 1118 to be coated. The first and second body members 1104, 1106 can be separated from one another by a distance 1108 that is greater than or equal to the diameter of the balloon 1118. In some embodiments, the distance 1108 is approximately equal to the balloon 1118. In some embodiments, the distance 1108 is between about 3 25 millimeters and about 10 millimeters.

FIG. 12 is a schematic end view of the movement restriction structure 1102. The first body member 1104 can include a curved segment 1142 and an end 1144. The curved segment 1142 can define a portion of a channel which can surround at least a portion of the balloon 1118, thereby restricting its movement. In some embodiments, the 30 second body member 1106 can be formed similarly but with a different orientation so that together the first body member 1104 and the second body member 1106 can effectively

restrict movement of the balloon 1118. For example, the end 1146 of the second body member 1106 can be pointed upward instead of downward. FIG. 13 is a schematic front view of the movement restriction structure 1102 that shows the differing orientations of the first body member 1104 and the second body member 1106.

5 It will be appreciated that the balloon can be loaded into the movement restriction structure in various ways. For example, in some embodiments, the balloon catheter can simply be threaded through the movement restriction structure before or after being connected with other portions of the apparatus in preparation for coating. In other embodiments, the movement restriction structure itself can be manipulated in order to
10 load the balloon. For example, in some embodiments, the movement restriction structure can be rotated into an open orientation in order to accommodate loading the balloon from the side. Then, in some embodiments, the movement restriction structure can be rotated from the open orientation to a closed orientation in order to lock the balloon in place.
15 Referring now to FIG. 14, a schematic front view of the movement restriction structure 1102 is shown illustrating an open orientation. In this view, it can be seen that the first body member 1104 and the second body member 1106 are rotated approximately 90 degrees from their respective positions in FIG. 13. The balloon 1118 can be slid out from between the first and second body members 1104, 1106 when the movement restriction structure 1102 is in this orientation. In operation, then, a new balloon to be coated can be
20 slid back in between the first and second body members 1104, 1106 and then the body members can be rotated in the direction of arrows 1150 and 1152 to put the movement restriction structure 1102 into the closed position (illustrated in FIG. 13) where the balloon 1118 is locked in place. In some embodiments, the first and second body members 1104, 1106 can be rotated in either direction. The first and second body
25 members 1104, 1106 can be rotated together around a single axis or independently from one another around two separate axes.

It will be appreciated that body members of movement restrictions structures in accordance with embodiments herein can also include various other features. Referring now to FIG. 15, a schematic end view of portions of a movement restriction structure 30 1500 are shown in accordance with various embodiments herein. The movement restriction structure 1500 can include a first body member 1502. The first body member

1502 can include a curved segment 1504 and an end 1508. The curved segment 1504 can define a portion of a channel which can surround at least a portion of the balloon 1518, thereby restricting the balloon's 1518 movement, in conjunction with a second body member (not shown in this view). The first body member 1502 can also include an 5 alignment lip 1506 adjacent to the end 1508. The alignment lip 1506 can include a surface 1510 that is angled away from the channel defined by the curved segment 1504. The alignment lip 1506 can aid in positioning the balloon 1518 within the channel formed by the curved segment 1504. For example, when the first body member 1502 is rotated starting from the open position, if the balloon 1518 is slightly out of position by being too 10 close to the end 1508, the surface 1510 of the alignment lip 1506 will contact the balloon 1518 surface and cause the balloon 1518 to move into alignment with the channel.

It will be appreciated that fluid applicators can take on various configurations in accordance with embodiments herein. FIG. 16 is a schematic end view of a fluid applicator 1600 in accordance with various embodiments herein. The fluid applicator 15 1600 can include a shaft 1602 and an orifice 1608. The orifice 1608 can be located along the shaft 1602 at a position other than at the distal end 1620 of the shaft 1602. Fluid 1604, such as a coating solution, can pass from the fluid applicator 1600 through the orifice 1608 in order to be deposited on the surface of the balloon. The segment 1606 of the shaft 1602 that extends beyond where the orifice 1608 is located can be curved, in 20 some embodiments, in order to form part of a channel which can serve to maintain the position of the balloon relative to the fluid applicator 1600. In some embodiments, segment 1606 can be disposed between the orifice 1608 and the distal end 1620 of the shaft 1602.

It will be appreciated that coating solutions applied onto balloons can include 25 various components including, but not limited to, one or more active agents, carrier agents and/or solvents, polymers (including degradable or non-degradable polymers), excipients, and the like. The relative amounts of the components of the coating solution will depend on various factors including the desired amount of active agent to be applied to the balloon and the desired release rate of the active agent.

30 Embodiments herein include methods of applying coatings onto balloon catheters. In an embodiment, the method can include rotating a balloon catheter with a rotation

mechanism, the balloon catheter comprising a balloon, contacting the balloon with a movement restriction structure defining a channel, wherein the channel limits lateral movement of the balloon, applying a coating solution onto the surface of the balloon with a fluid applicator (such as through direct contact with a fluid applicator), contacting the 5 surface of the balloon with a fluid distribution bar, and blowing a stream of a gas onto the surface of the balloon. In some embodiments, the balloon catheter can be rotated at a speed of between 100 and 400 rotations per minute.

In some embodiments, the method can include moving the fluid applicator relative to the lengthwise axis of the drug eluting balloon catheter. In some 10 embodiments, the method can include moving the drug eluting balloon catheter along its lengthwise axis relative to the fluid applicator, fluid distribution bar, and movement restriction structure.

It should be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly 15 dictates otherwise. Thus, for example, reference to a composition containing "a compound" includes a mixture of two or more compounds. It should also be noted that the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

It should also be noted that, as used in this specification and the appended claims, 20 the phrase "configured" describes a system, apparatus, or other structure that is constructed or configured to perform a particular task or adopt a particular configuration to. The phrase "configured" can be used interchangeably with other similar phrases such as arranged and configured, constructed and arranged, constructed, manufactured and arranged, and the like.

25 All publications and patent applications in this specification are indicative of the level of ordinary skill in the art to which this invention pertains. All publications and patent applications are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated by reference.

The invention has been described with reference to various specific and preferred embodiments and techniques. However, it should be understood that many variations and modifications may be made while remaining within the spirit and scope of the invention.

The Claims Are:

1. A coating apparatus comprising:
a coating application unit comprising
a movement restriction structure;
a fluid applicator;
an air nozzle; and
a rotation mechanism; and
an axial motion mechanism, the axial motion mechanism configured to cause movement of at least one of the coating application unit and the rotation mechanism with respect to one another.
2. The coating apparatus of any of claims 1 and 3-22, wherein the coating application unit is stationary and the rotation mechanism moves
3. The coating apparatus of any of claims 1-2 and 4-22, wherein the rotation mechanism is stationary and the coating application unit moves
4. The coating apparatus of any of claims 1-3 and 5-22, wherein the rotation mechanism comprises an electric motor.
5. The coating apparatus of any of claims 1-4 and 6-22, further comprising a fluid reservoir in fluid communication with the fluid applicator;
6. The coating apparatus of any of claims 1-5 and 7-22, further comprising a fluid pump in fluid communication with the fluid reservoir and the fluid applicator.
7. The coating apparatus of any of claims 1-6 and 8-22, further comprising a controller configured to control the fluid pump and the rotation mechanism.
8. The coating apparatus of any of claims 1-7 and 9-22, the fluid applicator comprising a polymeric tube.

9. The coating apparatus of any of claims 1-8 and 10-22, the fluid applicator comprising a shaft including a curved portion and an orifice, wherein the curved portion of the shaft is disposed between the orifice and the distal end of the shaft.
10. The coating apparatus of any of claims 1-9 and 11-22, wherein the rotation mechanism is configured to rotate a drug eluting balloon catheter.
11. The coating apparatus of any of claims 1-10 and 12-22, the coating application unit further comprising a fluid distribution bar.
12. The coating apparatus of any of claims 1-11 and 13-22, wherein the movement restriction structure prevents lateral movement of the drug eluting balloon catheter as it is being rotated by the rotation mechanism.
13. The coating apparatus of any of claims 1-12 and 14-22, the movement restriction structure defining a channel surrounding the drug eluting balloon catheter.
14. The coating apparatus of any of claims 1-13 and 15-22, the movement restriction structure defining a channel having a size sufficient to surround the balloon of the drug eluting balloon catheter when the balloon is in an expanded state.
15. The coating apparatus of any of claims 1-14 and 16-22, the movement restriction structure defining a channel surrounded by the movement restriction structure in a radially continuous manner.
16. The coating apparatus of any of claims 1-15 and 17-22, the movement restriction structure defining a channel surrounded by the movement restriction structure in a radially non-continuous manner.
17. The coating apparatus of any of claims 1-16 and 18-22, the movement restriction structure comprising a first body member and a second body member, the first body member defining a first portion of a channel and the second body member defining a second portion of a channel, the first body member and second body member separated from one another by a distance of at least 3 millimeters.

18. The coating apparatus of any of claims 1-17 and 19-22, the movement restriction structure comprising a first body member and a second body member, the first body member defining a first portion of a channel and the second body member defining a second portion of a channel, the first body member and second body member configured to rotate between a closed position where a balloon is locked in place in the channel and an open position where the balloon is released.

19. The coating apparatus of any of claims 1-18 and 20-22, wherein the first body member and second body member rotate together around a single axis.

20. The coating apparatus of any of claims 1-19 and 21-22, wherein the first body member and second body member rotate independently from one another.

21. The coating apparatus of any of claims 1-20 and 22, wherein the axial motion mechanism creates horizontal motion.

22. The coating apparatus of any of claims 1-21, wherein the axial motion mechanism creates vertical motion.

23. A coating apparatus comprising:
a coating application unit comprising
a fluid applicator;
a fluid distribution bar;
an air nozzle; and
a rotation mechanism; and
an axial motion mechanism, the axial motion mechanism configured to cause movement of the coating application unit with respect to the rotator.

24. The coating apparatus of claim 23, the coating application unit further comprising a movement restriction structure.

25. A method of coating comprising:

rotating a drug eluting balloon catheter with a rotation mechanism, the drug eluting balloon catheter comprising a balloon;
contacting the balloon with a movement restriction structure defining a channel, wherein the channel limits lateral movement of the balloon;
applying a coating solution onto the surface of the balloon with a fluid applicator;
contacting the surface of the balloon with a fluid distribution bar; and
blowing a stream of a gas onto the surface of the balloon.

26. The method of any of claims 25 and 27-29, wherein the drug eluting balloon catheter is rotated at a speed of between 100 and 400 rotations per minute.

27. The method of any of claims 25-26 and 28-29, further comprising moving the fluid applicator along the lengthwise axis of the drug eluting balloon catheter.

28. The method of any of claims 25-27 and 29, further comprising moving the fluid applicator, fluid distribution bar, and movement restriction structure along the lengthwise axis of the drug eluting balloon catheter.

29. The method of any of claims 25-28, wherein applying a coating solution onto the surface of the balloon with a fluid applicator is accomplished through direct contact between the surface of the balloon with the fluid applicator.

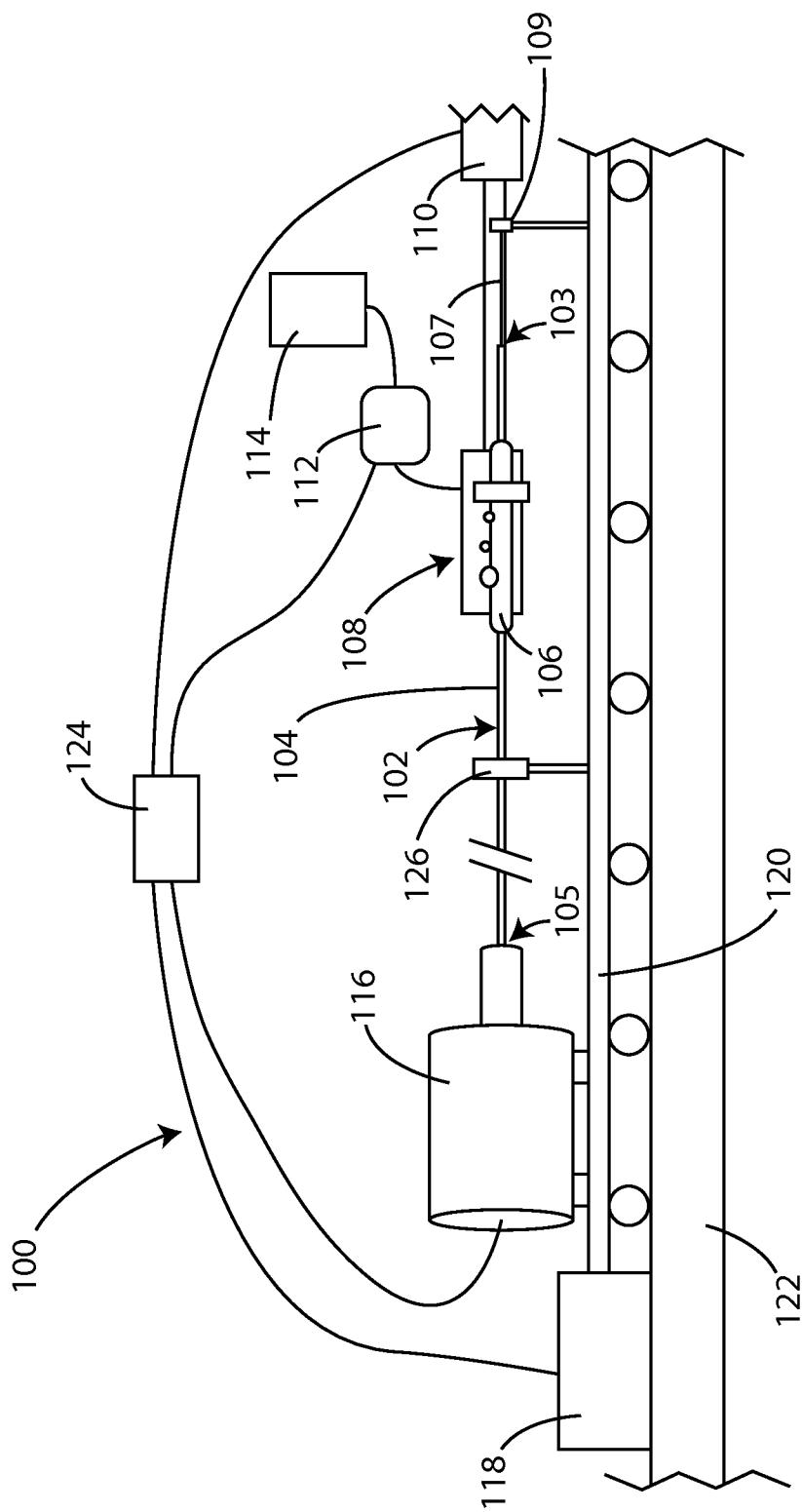


FIG. 1

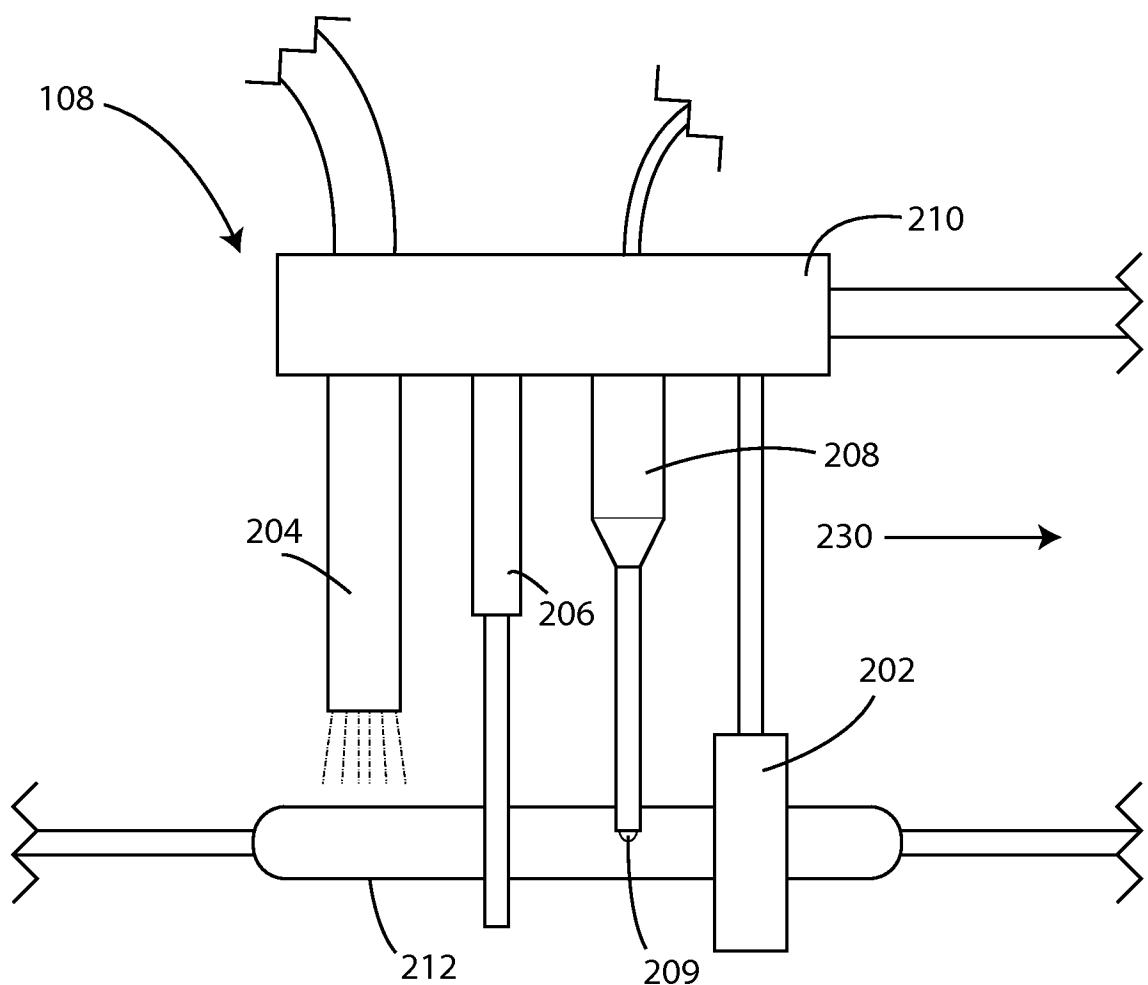


FIG. 2

3/9

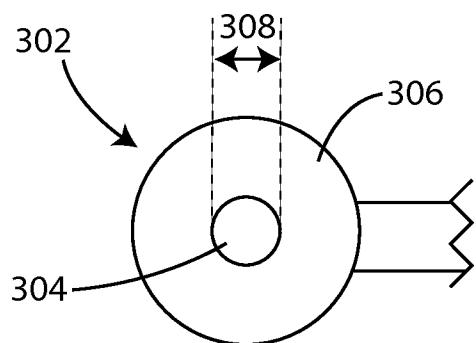


FIG. 3

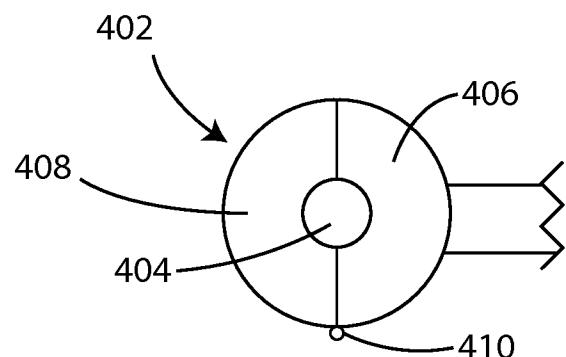


FIG. 4

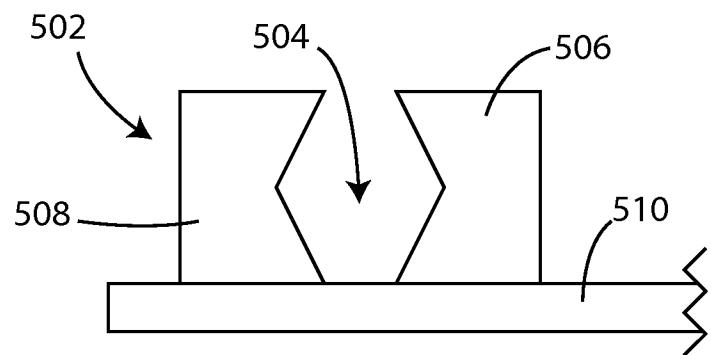
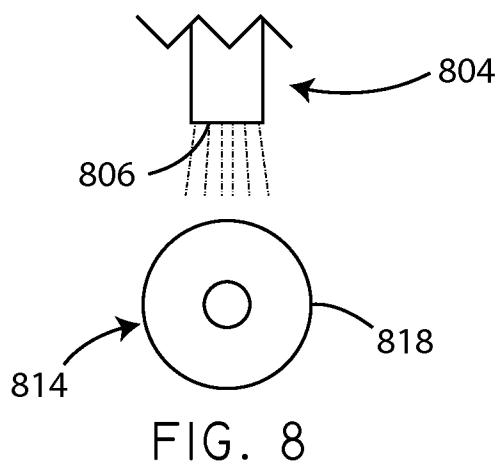
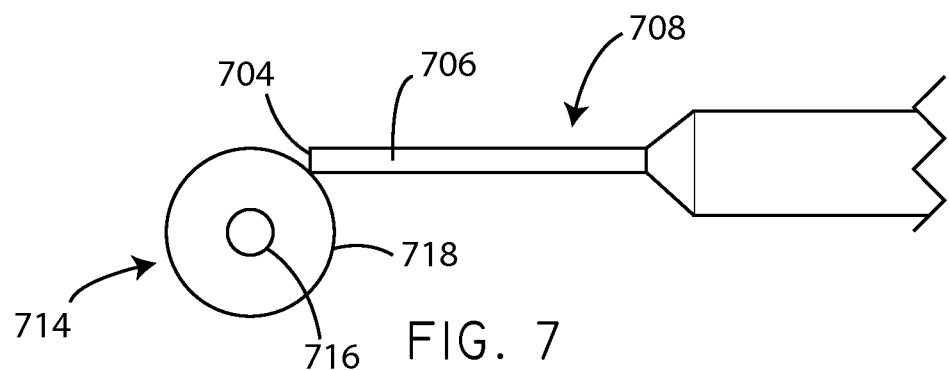
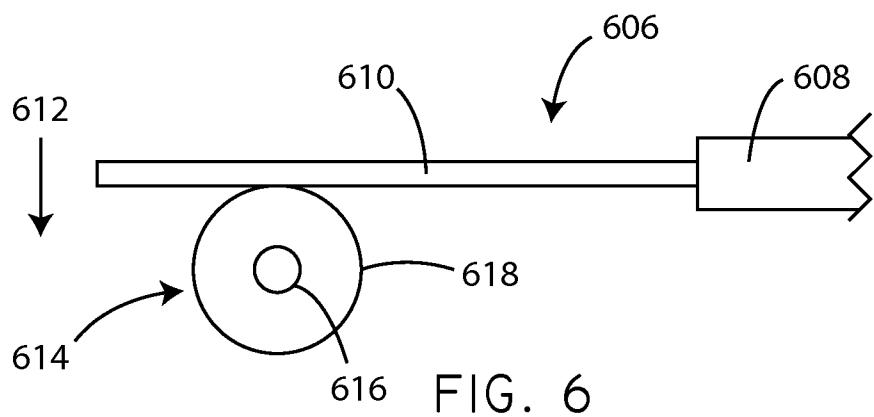


FIG. 5



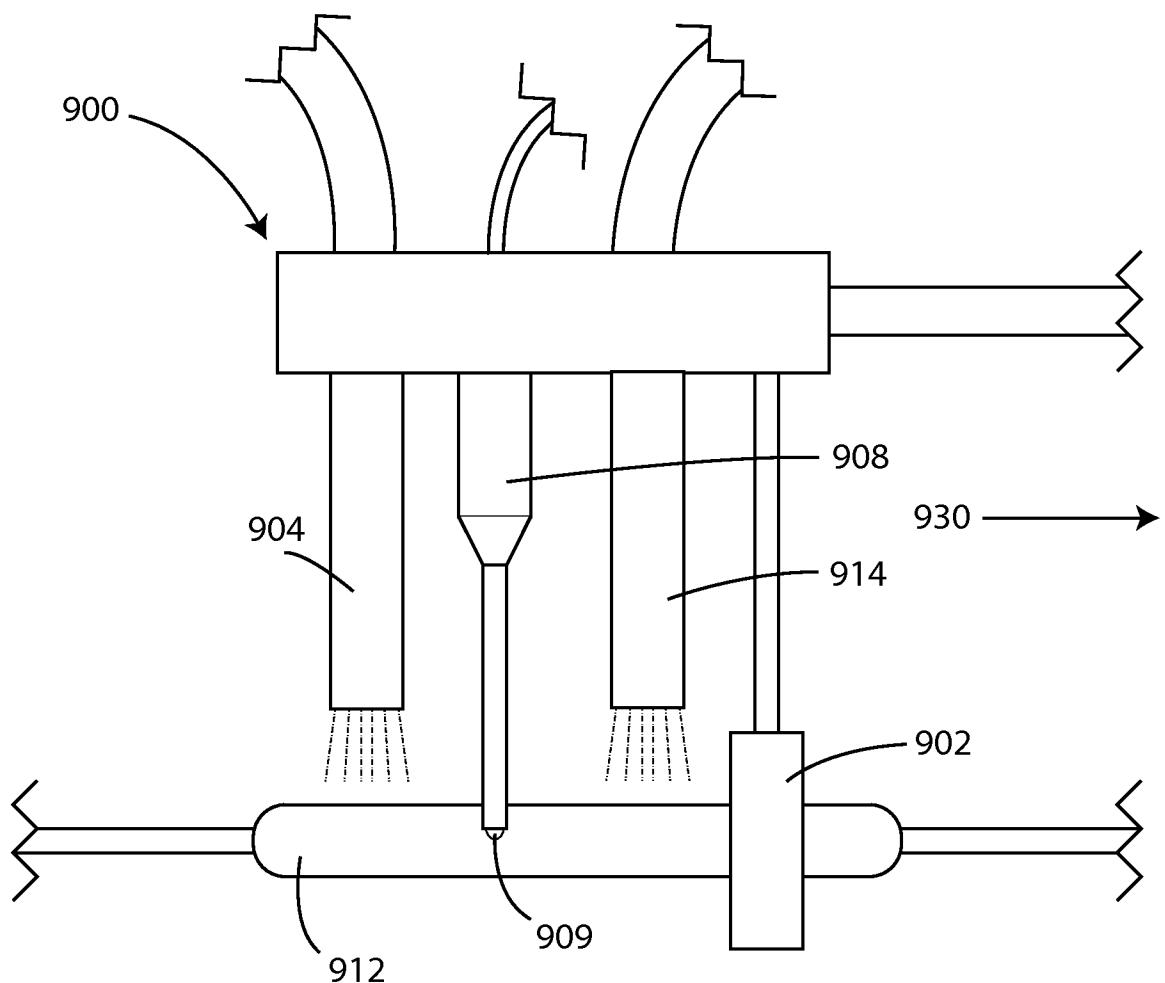


FIG. 9

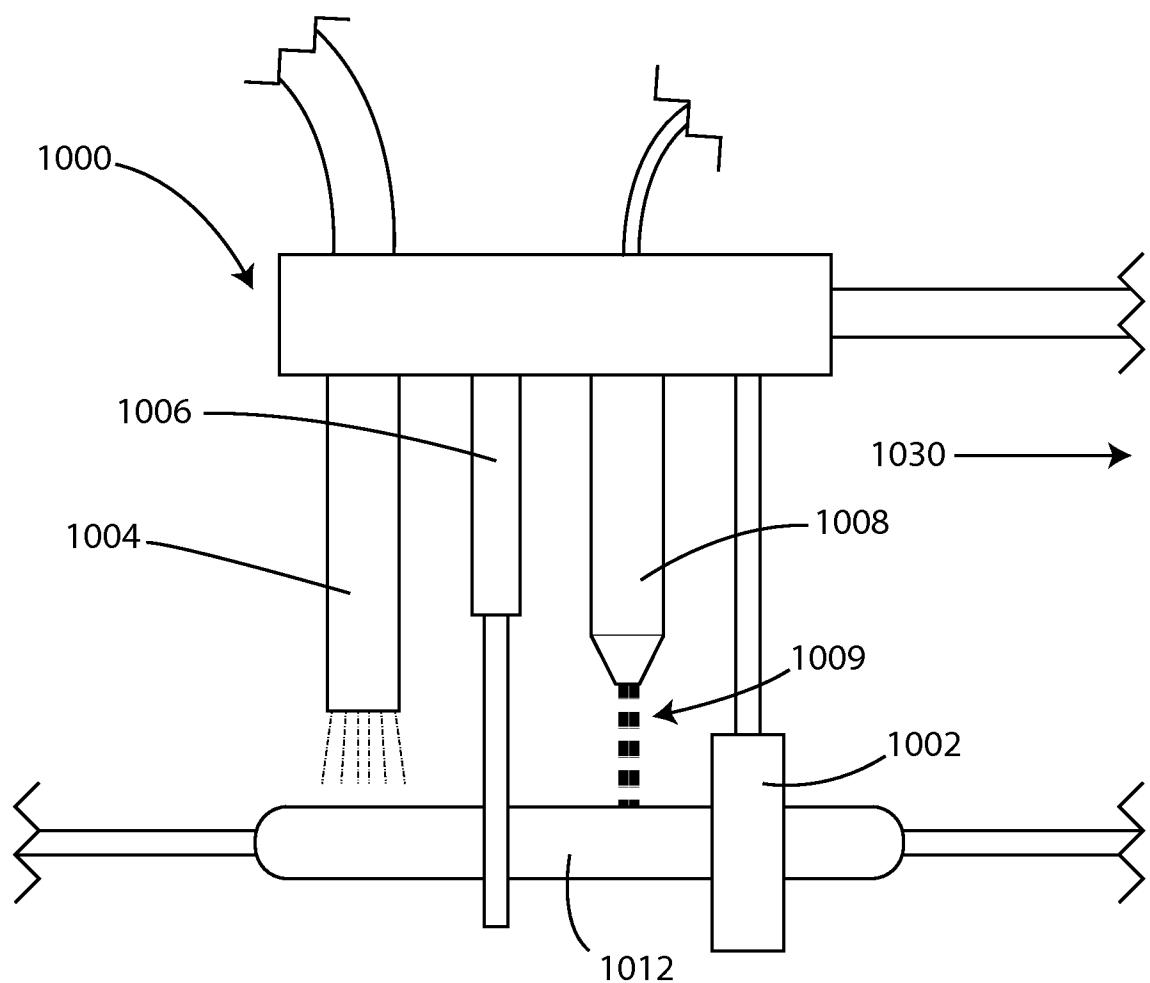


FIG. 10

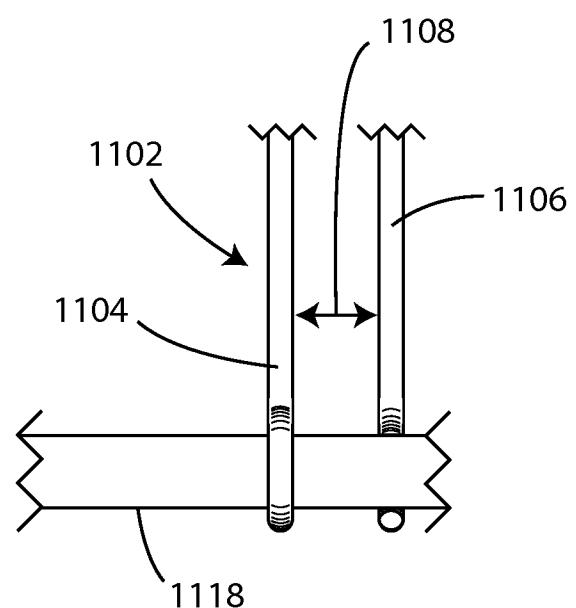


FIG. 11

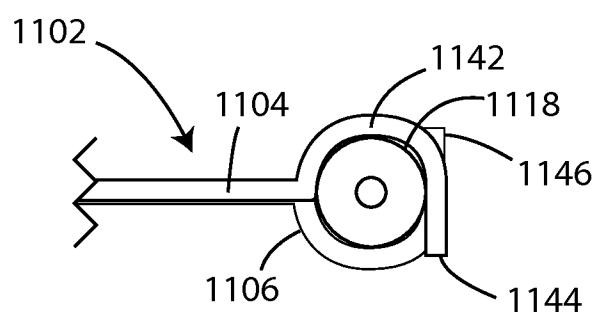


FIG. 12

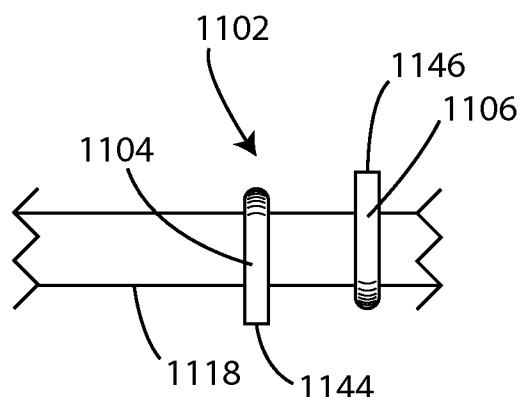


FIG. 13

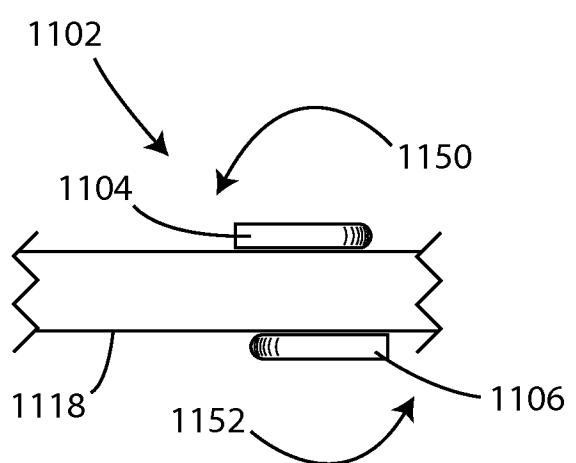
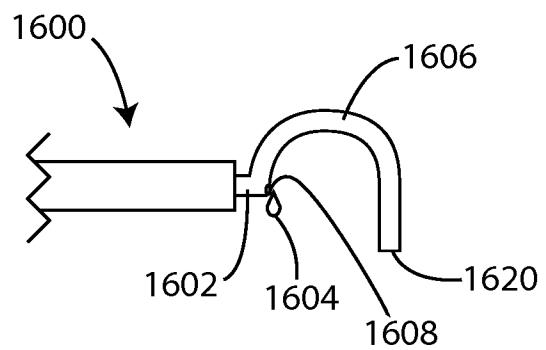
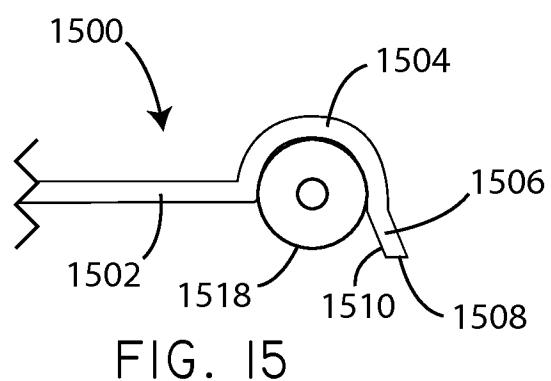


FIG. 14



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/043547

A. CLASSIFICATION OF SUBJECT MATTER
INV. B05B13/04
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M B05B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/281019 A1 (GONG, VICTORIA M. [US] ET AL) 17 November 2011 (2011-11-17) paragraph [0029] - paragraph [0051]; figures ----- WO 2010/146096 A1 (DOT GMBH [DE]; NEUMANN, HANS-GEORG [DE]; BUHRMEISTER, MISCHA [DE]) 23 December 2010 (2010-12-23) paragraph [0048] - paragraph [0070]; figures ----- US 1 281 672 A (SCHORN, ANTHONY [US]) 15 October 1918 (1918-10-15) page 2, left-hand column, line 1 - page 3, left-hand column, line 60; figures ----- -/-	1-8,10, 12,21,22 1-8, 10-12, 21-24 1,3-6,21
X		

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 September 2013	01/10/2013
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Innecken, Axel

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/043547

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/040766 A1 (CHAPPA, RALPH A. [US] ET AL) 18 February 2010 (2010-02-18) paragraph [0028] - paragraph [0069]; figures -----	1,23,25
A	WO 2010/024898 A2 (LUTONIX INC [US]; WANG, JEFFREY [US] ET AL) 4 March 2010 (2010-03-04) paragraph [0044] - paragraph [0046]; figures -----	1,23,25

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/043547

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 2011281019	A1	17-11-2011	NONE		
WO 2010146096	A1	23-12-2010	AU 2010261804 A1		12-01-2012
			CA 2765258 A1		23-12-2010
			CN 102802816 A		28-11-2012
			DE 102010030191 A1		03-03-2011
			EP 2442917 A1		25-04-2012
			JP 2012529945 A		29-11-2012
			US 2012100279 A1		26-04-2012
			WO 2010146096 A1		23-12-2010
US 1281672	A	15-10-1918	NONE		
US 2010040766	A1	18-02-2010	NONE		
WO 2010024898	A2	04-03-2010	US 2010055294 A1		04-03-2010
			US 2013209662 A1		15-08-2013
			WO 2010024898 A2		04-03-2010